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As confidentially submitted with the United States Securities and Exchange Commission on March 28, 2019  
as Amendment No. 2 to the confidential submission pursuant to the Jumpstart Our Business Startups Act.

Registration No. 333-

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM F-1**  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

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**CENTOGENE B.V.\***

(Exact name of Registrant as specified in its charter)

**Not Applicable**

(Translation of Registrant's name into English)

**The Netherlands**  
(State or other jurisdiction of  
incorporation or organization)

**8071**  
(Primary Standard Industrial  
Classification Code Number)

**Not Applicable**  
(I.R.S. Employer  
Identification Number)

**Am Strande 7**  
**18055 Rostock, Germany**  
**+49 (381) 80113400**

(Address, including Zip Code, and Telephone Number, including Area Code, of Registrant's Principal Executive Offices)

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**Cogency Global Inc.**  
**10 E 40th Street, 10th floor**  
**New York, New York 10016**  
**+1 (800) 221-0102**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Copies of all communications, including communications sent to agent for service, should be sent to:

**Leo Borchardt**  
**Richard D. Truesdell, Jr.**  
**Davis Polk & Wardwell LLP**  
**450 Lexington Avenue**  
**New York, NY 10017**  
**+1 (212) 450-4000**

**Paul van der Bijl**  
**NautaDutilh N.V.**  
**Beethovenstraat 400**  
**1082 PR Amsterdam**  
**The Netherlands**  
**+31 (20) 717-1000**

**Michael D. Maline**  
**Edwin M. O'Connor**  
**Goodwin Procter LLP**  
**620 Eighth Avenue**  
**New York, NY 10018**  
**+1 (212) 813-8800**

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**Approximate date of commencement of proposed sale to the public:**  
**As soon as practicable after the effective date of this registration statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act. o

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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#### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)	Amount of registration fee
Common shares, par value €0.12 per share	\$	\$

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of additional shares that the underwriters have the option to purchase.

**The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.**

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(\*) We intend to convert the legal form of our company under Dutch law from a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to a public company (*naamloze vennootschap*) and to change our name from Centogene B.V. to Centogene N.V. prior to the closing of this offering.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Prospectus (Subject to Completion) Dated \_\_\_\_\_, 2019

## Shares

CENTOGENE

**CEN TOGENE B.V.**

*to be converted into and renamed*

**CEN TOGENE N.V.**

*(incorporated in the Netherlands)*

## Common Shares

This is the initial public offering of our common shares. We are offering a total of \_\_\_\_\_ common shares, €0.12 par value per share.

We intend to apply to list our common shares on the Nasdaq Global Market under the symbol "CNTG". We are both an "emerging growth company" and a "foreign private issuer" as defined under the federal securities laws and, as such, will be subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an Emerging Growth Company" and "—Implications of Being a Foreign Private Issuer."

**Investing in our common shares involves risks. See "Risk Factors" beginning on page 11 of this prospectus.**

**Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) We refer you to "Underwriting" beginning on page 189 for additional information regarding underwriting compensation.

We have granted the underwriters the right for 30 days from the date of this prospectus to purchase up to an additional \_\_\_\_\_ common shares from us at the initial public offering price less underwriting discounts and commissions.

The underwriters expect to deliver the common shares against payment in New York, New York on \_\_\_\_\_, 2019.

**Cowen**

**Evercore ISI**

**Baird**

**BTIG**

\_\_\_\_\_, 2019

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We and the underwriters have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we may have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters have not authorized any other person to provide you with different or additional information. Neither we nor the underwriters are making an offer to sell the common shares in any jurisdiction where the offer or sale is not permitted. This offering is being made in the United States and elsewhere solely on the basis of the information contained in this prospectus. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of the common shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

**For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus or any free writing prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common shares and the distribution of this prospectus and any free writing prospectus outside the United States.**

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## ABOUT THIS PROSPECTUS

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to "Centogene" or the "Company," "we," "our," "ours," "us" or similar terms refer to (i) Centogene AG, together with its subsidiaries, prior to the completion of the exchange of all of the equity interests of Centogene AG for newly issued common shares of Centogene B.V., (ii) Centogene B.V., together with its subsidiaries, as of the completion of the exchange of all of the equity interests of Centogene AG for newly issued common shares of Centogene B.V. and (iii) Centogene N.V., together with its subsidiaries, after giving effect to the conversion of Centogene B.V. into Centogene N.V. In connection with the corporate reorganization, Centogene AG will take initial steps of its conversion into a German private limited liability company (*Gesellschaft mit beschränkter Haftung*), ("GmbH"). However, such transformation will only be completed following the consummation of the offering. See "Corporate Reorganization."

We are incorporated in the Netherlands, and a majority of our outstanding securities are owned by non-U.S. residents. Under the rules of the U.S. Securities and Exchange Commission (the "SEC"), we are currently eligible for treatment as a "foreign private issuer." As a foreign private issuer, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

## PRESENTATION OF FINANCIAL INFORMATION

We report under International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board (the "IASB"). We present our consolidated financial statements in accordance with IFRS. We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

Our financial statements included in this prospectus are presented in euro and, unless otherwise specified, all monetary amounts are in euro. All references in this prospectus to "\$," "U.S. dollars" and "dollars" means U.S. dollars and all references to "€" and "euro" mean euro, unless otherwise noted.

In this prospectus, unless otherwise indicated, some euro amounts have been translated into U.S. dollars at the rate of \$1.00 to € , the official exchange rate quoted as of , 2019 by the U.S. Federal Reserve Bank.

This prospectus contains the historical financial statements and other financial information of Centogene AG, which is expected to be acquired by Centogene B.V. prior to the closing of this offering. Centogene B.V.'s common shares are being offered hereby. Centogene B.V. is a newly incorporated holding company incorporated for the purpose of effecting the offering and has not engaged in any activities except those incidental to its formation, the corporate reorganization and the initial public offering of our common shares. Centogene B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Following the corporate reorganization, Centogene N.V. will become the holding company of Centogene AG and the historical consolidated financial statements of Centogene AG included in this prospectus will become the historical consolidated financial statements of Centogene B.V. In connection with the corporate reorganization, Centogene AG will

take initial steps of its conversion into a GmbH under German law. However, such transformation will only be completed following the consummation of the offering. See "Corporate Reorganization".

## **TRADEMARKS**

CENTOGENE™ is our main trademark. The trademarks, trade names and service marks appearing in this prospectus are property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols ® and ™, but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

## **MARKET, INDUSTRY AND OTHER DATA**

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market size estimates, is based on information from independent industry analysts, third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of such industry and market, which we believe to be reasonable. In addition, while we believe the market opportunity information included in this prospectus is generally reliable and is based on reasonable assumptions, such data involves risks and uncertainties and is subject to change based on various factors, including those discussed under the heading "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements."

## SUMMARY

*This summary highlights information contained elsewhere in this prospectus. This summary may not contain all the information that may be important to you, and we urge you to read this entire prospectus carefully, including the "Risk Factors," "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections, and our consolidated financial statements and notes to those statements included elsewhere in this prospectus, before deciding to invest in our common shares.*

### Overview

Centogene is a commercial-stage rare disease company focused on transforming clinical and genetic data into medical solutions for patients. We are focused on bringing rationality to treatment decisions and accelerating the development of new orphan drugs by using our knowledge of the global rare disease market, including epidemiological, clinical heterogeneity and innovative biomarkers. Our data repository includes epidemiologic, phenotypic and genetic information from over 380,000 patients sourced from over 110 countries thus reflecting the genetic differences in global ethnicities. We believe this represents the only platform that comprehensively analyzes multi-level data to improve the understanding of rare diseases, which can aid in the identification of patients and improve our pharmaceutical partners' ability to bring orphan drugs to the market. As of December 31, 2018, we had over 50 collaboration agreements with over 30 pharmaceutical partners and have commercialized seven biomarkers.

It typically takes an average of five to seven years for a patient with a rare disease to be diagnosed, underscoring the significant unmet need for high-quality genetic information in the rare disease space for the early identification and effective treatment of patients. Despite legislative initiatives and continued investment in rare disease drug development, significant unmet need still exists. Of the 7,000 identified rare diseases it is estimated that 80%, or 5,600, have a genetic origin and, of these hereditary rare diseases, only approximately 230 hereditary rare diseases, or 4%, have an FDA approved treatment. The introduction of new treatments and development of cost-effective drugs are constrained by a number of factors including: a lack of high-quality information regarding the clinical heterogeneity of medical symptoms, lack of comprehensive and curated medical data, difficulties in the early identification of patients, lack of biomarkers and difficulties in understanding market size and epidemiological.

We believe a detailed, global understanding of the genetic basis and the clinical phenotype of rare hereditary diseases will unlock the ability to target rare diseases and provide critical knowledge that will guide every stage of drug development. The combination of genomics, proteomics and metabolomics provides deep insights in the pathogenesis of rare hereditary diseases. The value in such a holistic diagnostics process has resulted in a shift from data generation to interpretation-based diagnostics, whereby the development of biomarkers is the central element to bring rationality to treatment decisions for rare disease patients. High-quality, standardized clinical information supporting medical interpretation is a crucial element of the diagnostic process and leads to greater knowledge of the causes and symptoms of rare diseases. We believe a combination of worldwide data and detailed access to phenotype, genotype, proteomics and metabolomics data will aid in the development of new treatments and reduce the costs associated with orphan drug development. As of December 31, 2018, we had over 881 million data points to draw upon for insight, which includes CentoMD data, clinical data, analyses performed, biochemistry data and clinical study data.

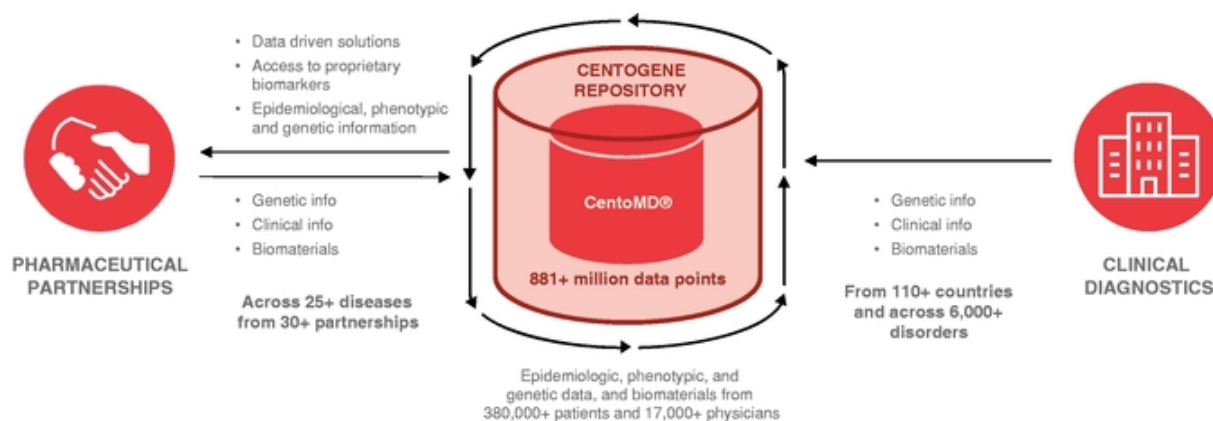
These fundamental principles were the basis of our Company's founding in 2006 by our Chief Executive Officer ("CEO") and founder, Prof. Arndt Rolfs. Our laboratory at our headquarters in

Rostock, Germany, as well as our Cambridge, Massachusetts facility, are equipped with highly advanced technologies from 13 different diagnostic platforms and, as of December 31, 2018, employed over 350 highly qualified personnel (including consultants) from over 50 nationalities. In addition to our laboratories, we have sales and administrative offices located in Rostock, Cambridge, Berlin, Boston, Vienna, Dubai and Delhi, allowing us to further expand our international footprint.

### Our Platform—An Integrated, Knowledge-Based System

We have developed a proprietary platform and system that we believe will improve methods for identifying and monitoring rare hereditary diseases and provide solutions that accelerate the development of orphan drugs. At the core of our platform is our data repository, which includes epidemiologic, phenotypic and heterogenetic data, and allows us to assemble an extensive knowledge base in rare hereditary diseases. We collect this detailed level of data in our repository through our easy-to-use CentoCard, a dried blood spot collection kit that bears the European Conformity Marking (the "CE Mark"), which captures blood samples of potential rare disease patients with a low cost of distribution. We then curate this information using a systematic and scientific approach conducted by professionals to ensure the medical validity of our data prior to feeding it into our central CentoMD database, which we believe is the world's largest curated mutation database for rare diseases. As of December 31, 2018, our CentoMD database included curated data from over 310,000 patients.

This systematic process results in information-based services that are beneficial for rare disease drug development by our biotech and pharmaceutical partners. This includes providing epidemiological insights about rare diseases, further identification of rare disease patients as well as the ability to identify new biomarkers, which can accelerate drug development by demonstrating the efficacy of the drugs, performing longitudinal monitoring and informing necessary titration for individual rare disease patients. The additional rare disease patients identified through these partnerships can fuel clinical trial enrollment which, in turn, adds more diagnostic information to our repository. This synergistic model allows us to continuously enhance our own expertise and support pharmaceutical knowledge in the rare disease field.



### Our Solutions

#### Pharmaceutical

Our pharmaceutical segment provides a variety of services to our pharmaceutical partners, including early patient recruitment and identification, epidemiological insights, biomarker discovery and patient monitoring. Our information platforms, our deep access to rare disease patients and our ability to develop proprietary technologies including biomarkers enable us to provide services to our pharmaceutical partners in all phases of the drug development process as well as



post-commercialization. Revenues in our pharmaceutical segment are generated primarily from collaboration agreements with our pharmaceutical partners, which can be structured on a fee per sample basis, milestone basis, fixed fee basis, royalty basis or a combination of these. For the year ended December 31, 2018, €17.3 million, or 42.8%, of our total revenues were derived from our pharmaceutical segment.

### ***Diagnostics***

Our clinical diagnostics segment provides targeted genetic sequencing and diagnostics services to patients through our distribution partners and clients, who are typically physicians, labs or hospitals. As of December 31, 2018, we believe we offer the broadest diagnostic testing portfolio for rare diseases, covering over 3,800 genes using over 9,000 different tests. Revenues from our diagnostics segment are typically generated by set fees per diagnostic test or per bundle of diagnostic tests under contracts with our clients. In turn, the data collected from our diagnostic services allow us to continue to grow our repository and our CentoMD database. For the year ended December 31, 2018, €23.2 million, or 57.2%, of our total revenues were derived from our diagnostics segment.

### **Strategy**

Our objective is to improve the diagnosis and treatment of rare diseases by unlocking critical knowledge that will guide every stage of drug development. To achieve this objective our strategy is to:

- § Transform the rare disease landscape by applying precision medicine techniques.
- § Bolster our leadership position as the premier source of comprehensive clinical and diagnostic information for rare hereditary diseases.
- § Accelerate the discovery and development of orphan drugs for our pharmaceutical partners.

### **Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus immediately following this prospectus summary. These risks include the following:

- § We have a history of losses and we may incur losses in the future. We may fail to generate sufficient revenue from our relationships with our clients or pharmaceutical partners to achieve and maintain profitability;
- § We may fail to maintain our current relationships with pharmaceutical companies, or enter into new relationships on a similar scale;
- § Because the identified patient populations for rare diseases are relatively small, it may be difficult to successfully identify patients for our pharmaceutical partners;
- § We are dependent on uninterrupted access to highly specialized laboratory facilities, storage facilities and equipment, and depend upon our information technology systems and a limited number of suppliers for some of our laboratory equipment;
- § The loss or transition of any member of our senior management team, in particular our current CEO, or our inability to attract and retain new talent, could adversely affect our business;
- § The knowledge and interpretation-based solutions we provide to our pharmaceutical partners may not achieve significant commercial market acceptance, and any failure to keep pace with the rapidly evolving industry in which we operate could make us obsolete;
- § We derive a large proportion of our revenues from agreements with a limited number of pharmaceutical partners and clients;
- § International expansion of our business exposes us to new and complex business, regulatory, political, operational, financial, and economic risks, and our global operations

expose us to numerous and sometimes conflicting legal and regulatory requirements, and violation of these requirements could harm our business;

- § We have failed to meet certain covenants under our syndicated loan facility, which limits our liquidity and could result in the lenders accelerating amounts we owe to them under the facility;
- § We may be unable to obtain, maintain, protect and enforce patent and other intellectual property protection for any products or solutions we develop and for our technology, or the scope of intellectual property protection obtained may not be sufficient;
- § If we are unable to protect the confidentiality of our trade secrets, know-how, and other confidential and proprietary information, our business and competitive position would be harmed; and
- § We have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return on your investment.

### **Corporate Reorganization**

We were incorporated pursuant to the laws of the Netherlands as Centogene B.V. on October 11, 2018 to become a holding company for Centogene AG. Pursuant to the terms of a corporate reorganization that will be completed prior to the closing of this offering, all of the equity interests in Centogene AG will be exchanged for newly issued common shares of Centogene B.V. and, as a result, Centogene AG will become a wholly owned subsidiary of Centogene B.V. and the current shareholders of Centogene AG will become the shareholders of Centogene B.V. Prior to the closing of this offering, we intend to convert from Centogene B.V. into Centogene N.V. In connection with the corporate reorganization, Centogene AG will take initial steps of its conversion into a GmbH under German law. However, such transformation will only be completed following the consummation of the offering. See "Corporate Reorganization."

### **Corporate Information**

Our principal executive offices are located at Am Strande 7, 18055 Rostock, Germany. Our telephone number at this address is +49 (381) 80113400. Investors should contact us for any inquiries through the address and telephone number of our principal executive office. Our principal website is [www.centogene.com](http://www.centogene.com).

We intend to make our periodic reports and other information filed with or furnished to the SEC, pursuant to Section 13(a) or 15(d) of the Exchange Act, available free of charge through our website as soon as reasonably practicable after those reports and other information are electronically filed with or furnished to the SEC. The SEC maintains a website at <http://www.sec.gov> that contains reports and other information regarding issuers that file electronically with the SEC.

Information on our website or any other website is not incorporated by reference into this prospectus and does not constitute a part of this prospectus. We have included our website address as an inactive textual reference only.

### **Implications of Being an Emerging Growth Company**

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As an emerging growth company, we may take advantage of specified reduced

disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- § the ability to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in management's discussion and analysis of financial condition and results of operations in this prospectus;
- § exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), in the assessment of our internal controls over financial reporting; and
- § to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions for up to five years or until such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer" with at least \$700 million of equity securities; (iii) the issuance, in any three-year period, by our company of more than \$1.0 billion in nonconvertible debt securities held by non-affiliates; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We may choose to take advantage of some but not all of these reduced burdens. For example, we intend to take advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F. Accordingly, the information that we provide shareholders may be different than you might obtain from other public companies.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the "Securities Act") for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

#### **Implications of Being a Foreign Private Issuer**

We are also considered a "foreign private issuer." In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, members of our management board, supervisory board and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our common shares. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of the members of our management board or supervisory board are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

We have taken advantage of certain reduced reporting and other requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies.

## THE OFFERING

Issuer	Centogene B.V., to be converted into and renamed Centogene N.V. prior to the closing of this offering.
Common shares offered	We are offering      common shares.
Underwriters' option to purchase additional common shares	We have granted the underwriters the right to purchase up to an additional      common shares from us within 30 days of the date of this prospectus.
Common shares to be outstanding after this offering	common shares (      common shares if the underwriters' option to purchase additional common shares is exercised in full).
Voting rights	Our common shares have one vote per share.
Listing	We intend to apply to list our common shares on the Nasdaq Global Market, or Nasdaq under the symbol "CNTG".
Use of proceeds	<p>We estimate that the net proceeds to us from the offering will be approximately \$      (\$      if the underwriters' option to purchase additional common shares is exercised in full).</p> <p>We currently expect to use the net proceeds from this offering for research and development in our pharmaceutical segment and for the development of our knowledge-driven information platform, as well as for working capital and other general corporate purposes. See "Use of Proceeds."</p>
Dividend policy	Under Dutch law, we may only pay dividends following the closing of the offering to the extent our shareholders' equity ( <i>eigen vermogen</i> ) exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law or by our articles of association. Subject to such restrictions, the amount of any distributions will depend on many factors, such as our results of operations, financial condition, cash requirements, prospects and other factors deemed relevant by our management board and supervisory board. We have not adopted a formal dividend policy with respect to future dividends. We may adopt such a policy in the future, in which case we intend either to place a discussion of such policy on the agenda for our annual general meetings of shareholders, consistent with the Dutch Corporate Governance Code (the "DCGC") or to disclose a deviation from the DCGC in this respect in our statutory annual report.

Lock-up agreements

We have agreed with the underwriters, subject to certain exceptions, not to offer, sell or dispose of any shares of our share capital or securities convertible into or exchangeable or exercisable for any shares of our share capital during the 180-day period following the date of this prospectus. Members of our management board, our supervisory board and our executive officers, as well as certain of our existing shareholders, have agreed to substantially similar lock-up provisions, subject to certain exceptions.

Risk factors

See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should consider before deciding to invest in our common shares.

Unless otherwise indicated, all information contained in this prospectus also reflects and assumes:

- § the completion, prior to the closing of this offering, of our corporate reorganization, as further described under the section titled "Corporate Reorganization";
- § an initial public offering price of \$            per common share, which is the midpoint of the price range set forth on the cover page of this prospectus; and
- § no exercise of the option granted to the underwriters to purchase up to            additional common shares in connection with the offering.

## SUMMARY FINANCIAL INFORMATION

The following summary consolidated statement of financial position as of December 31, 2018, and the consolidated statement of comprehensive loss for the years ended December 31, 2016, 2017 and 2018 of Centogene AG are derived from the consolidated financial statements included elsewhere in this prospectus, which have been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft ("Ernst & Young").

We maintain our books and records in euros, and we prepare our financial statements under IFRS as issued by the IASB.

Centogene B.V. is a newly formed holding company formed for the purpose of effecting the offering and has not engaged in any activities except those incidental to its formation, the corporate reorganization and the initial public offering of our common shares. Centogene B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Accordingly, summary financial information for Centogene B.V. is not presented. Centogene AG's financial statements, including the notes thereto, are included elsewhere in this prospectus. See "Corporate Reorganization."

This financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, including the notes thereto included elsewhere in this prospectus.

	For the Years Ended		
	December 31,		
	2016	2017	2018
	(€ in thousands)		
<b>Consolidated statement of comprehensive loss:</b>			
Revenue	27,669	31,689	40,478
Cost of sales	<u>12,856</u>	<u>14,939</u>	<u>19,941</u>
<b>Gross profit</b>	<u>14,813</u>	<u>16,750</u>	<u>20,537</u>
Research and development expenses	5,885	6,396	6,300
General administrative expenses	8,888	9,498	18,610
Selling expenses	5,364	5,897	7,474
Other operating income	1,295	1,043	2,306
Other operating expenses	908	457	1,065
<b>Operating loss</b>	<u>(4,937)</u>	<u>(4,455)</u>	<u>(10,606)</u>
Interest and similar income	26	14	33
Interest and similar expense	856	1,021	1,075
<b>Finance costs, net</b>	<u>(830)</u>	<u>(1,007)</u>	<u>(1,042)</u>
Loss before taxes	<u>(5,767)</u>	<u>(5,462)</u>	<u>(11,648)</u>
Income tax (benefits)/expenses	<u>(408)</u>	<u>14</u>	<u>(310)</u>
<b>Loss for the period</b>	<u>(5,359)</u>	<u>(5,476)</u>	<u>(11,338)</u>
Other comprehensive income/(loss)	9	10	(8)
<b>Total comprehensive loss for the period</b>	<u>(5,350)</u>	<u>(5,466)</u>	<u>(11,346)</u>

As of December 31, 2018	
Actual	Pro Forma As Adjusted <sup>(1)(2)</sup>
(€ in thousands) (unaudited)	
<b>Consolidated statement of financial position:</b>	
Cash and cash equivalents	9,222
Total assets	76,674
Total liabilities	50,150
Total equity	26,524

- (1) Pro forma as adjusted to give effect to the corporate reorganization and the issuance and sale of common shares in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per common share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, assuming no exercise of the underwriters' option to purchase additional common shares. The as adjusted information presented above is illustrative only and will vary based on the actual public offering price, the actual number of common shares offered by us and the other terms of the offering determined at pricing.
- (2) Each \$1.00 increase (decrease) in the assumed initial public offering price per common share would increase (decrease) our as adjusted cash and cash equivalents, total assets and total equity by approximately € \_\_\_\_\_, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares offered by us at the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, total assets and total equity by approximately € \_\_\_\_\_. U.S. dollar amounts have been translated into euros at a rate of USD \_\_\_\_\_ to €1.00, the exchange rate quoted as of \_\_\_\_\_, 2019 by the U.S. Federal Reserve. This as adjusted information is illustrative only and will vary based on the actual initial public offering price, the actual number of common shares offered by us and other terms of the offering determined at pricing.



## RISK FACTORS

*You should carefully consider the following risks and all of the other information set forth in this prospectus before deciding to invest in our common shares. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer. In such case, the trading price of our common shares could decline, and you may lose all or part of your investment.*

### **Certain Factors Relating to Our Business and Strategy**

***We may fail to generate sufficient revenue from our relationships with our clients or pharmaceutical partners to achieve and maintain profitability.***

We believe our commercial success is dependent upon our ability to successfully market and sell our products and solutions to clients and pharmaceutical partners, to continue to sell our suite of diagnostic tests, to continue to expand our current relationships and to develop new relationships with pharmaceutical partners. The demand for our existing services may decrease or may not continue at historical rates for a number of reasons, including, among others, the development by competitors of new products or solutions that we are not able to commercialize, and increased competition from companies that offer similar products and solutions. In addition to reducing our revenue, if our pharmaceutical partners or clients decide to decrease or discontinue their partnerships or relationships with us, and their use of our knowledge and interpretation-based solutions, this may reduce our access to research and patient data that facilitates the incorporation of newly developed information about rare diseases into our data repository. Our business model and strategy depend on the continued input of new data into our repository, and any such reduction in access to research and patient data could affect our ability to offer the same quality and scope of solutions to our pharmaceutical partners and other clients, which could adversely affect our business, prospects, financial condition and results of operations.

We are currently not profitable. Even if we succeed in increasing adoption of our existing solutions by pharmaceutical partners or tests by our clients or pharmaceutical partners, we may fail to generate sufficient revenue to achieve and maintain profitability.

***We may fail to maintain our current relationships with pharmaceutical companies, or enter into new relationships on a similar scale.***

Our success in the future depends in part on our ability to maintain relationships and to enter into new relationships with pharmaceutical partners. Partnerships are complex and time-consuming to negotiate and document. Whether we reach a definitive agreement for a partnership will depend on a number of factors, including, among other things, upon our partners' assessment of our industry knowledge, data repository, logistical resources and expertise, the terms and conditions of the proposed partnership, and our partners' evaluation of the potential value added from our rare disease knowledge and insights. If we are unable to do so, we may have to curtail our research on a particular rare disease or increase our expenditures and undertake research and development activities at our own expense. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have may resulted in a reduced number of potential future partners.

Our ability to maintain our current relationships with our pharmaceutical partners, or enter into new relationships, can be difficult due to several factors, including that:

- § our products and solutions are focused towards facilitating the development of rare disease treatments which limits our market to pharmaceutical partners active in the rare disease space;

- § orphan drug development is complex, expensive and time-consuming due to limited identified patient populations and limited industry knowledge of rare diseases;
- § our pharmaceutical partners may decide to decrease or discontinue their use of our rare disease information platform due to circumstances outside of our control, including changes in their research and development plans, whether they can obtain positive data or regulatory approval in clinical trials or successfully commercialize a treatment, changes in the regulatory environment, or utilization of internal testing resources or genetic tests performed by other parties, among others;
- § internal and external constraints may be placed on potential pharmaceutical partners that can limit the number and type of relationships with companies like us they can consider and consummate; and
- § our pharmaceutical partners may be dissatisfied with our products or solutions or that we may fail to deliver expected benefits from our products or solutions.

Additionally, some of our pharmaceutical partners have contracted with us to provide testing for large numbers of samples or to focus our research on a particular rare disease, which could restrict our ability to perform tests for other clients or pharmaceutical partners or limit our ability to expand our data repository outside of a specified patient population or rare disease. If we fail to maintain our current relationships with our pharmaceutical partners, or enter into new partnerships, our business could suffer.

***Because the identified patient populations for rare diseases are relatively small, it may be difficult to successfully identify patients for our pharmaceutical partners.***

Our inability to identify a sufficient number of patients for our partners' clinical trials could result in significant delays and could require our partners to abandon one or more clinical trials altogether. Enrollment delays in our partners' clinical trials may result in increased development costs for our partners' drug candidates, which would cause the value of the solutions which we offer to our pharmaceutical partners to decline. If we are unable to identify patients with a specified driver of disease or applicable genomic alteration, this could compromise our ability to add value to our partners' clinical trials by accelerating clinical development and regulatory timelines. In addition, our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our partners' existing treatments or drug candidates, are based on our internal estimates derived from data in our repository. These estimates may prove to be incorrect, and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our partners' drug candidates or patients may be difficult to identify and access, all of which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***We may fail to generate sufficient volumes of data from our diagnostic tests for inclusion in our data repository.***

Our business model assumes that we will be able to continue to generate significant diagnostic test volume in order to maintain the generation of data that feeds into our data repository, which is necessary for the development of new products and solutions for our pharmaceutical partners and clients. We may not succeed in continuing to drive clinical adoption of our tests to achieve sufficient volumes. Inasmuch as detailed genetic data from our tests have only recently become available at relatively affordable prices, the pace and degree of clinical acceptance of the utility of such testing is uncertain. Specifically, it is uncertain how much genetic data will be accepted as necessary or useful, as well as how detailed that data should be, particularly since medical practitioners may have become accustomed to genetic testing that is specific to one or a few genes. To generate demand

for our tests, we will need to continue to make our diagnostics clients, as well as physicians and key opinion leaders, aware of the benefits of our tests, including the price, the breadth of our testing options, and the benefits of having additional genetic data available from which to make treatment decisions. In addition, physicians in other areas of medicine may not adopt genetic testing for certain rare diseases as readily as it has been adopted for some more well-known rare diseases and our efforts to sell our tests to physicians outside of a set number of rare diseases may not be successful. A lack of or delay in increased clinical acceptance of our diagnostic tests would negatively impact sales and market acceptance of our tests and limit our ability to expand on the scope and quality of knowledge and interpretation-based solutions offered to our pharmaceutical partners, which could in turn impact our revenue growth and potential profitability.

In addition, genetic testing is still relatively expensive and many potential pharmaceutical partners and clients may be sensitive to pricing concerns. Potential pharmaceutical partners or clients may not adopt our tests if adequate reimbursement is unavailable, or if we are not able to maintain low prices in the future relative to our competitors. If we are not able to generate demand for our tests at sufficient volume, or if it takes significantly more time to generate this demand than we anticipate, our business, prospects, financial condition and results of operations could be materially harmed.

***We derive a large proportion of our revenues from agreements with a limited number of pharmaceutical partners and clients.***

We have historically earned a large proportion of our revenue from a limited number of pharmaceutical partners and diagnostic testing clients. In the year ended December 31, 2018, our top five pharmaceutical partners accounted for 39.0% of our revenues. The loss of, or material reduction in, revenues from any one of our major pharmaceutical partners or clients could materially reduce our total revenues, harm our reputation in the industry and/or reduce our ability to accurately predict our revenue, net income and cash flow. The loss of, or material reduction, in revenue from any one of our major pharmaceutical partners or clients could also adversely affect our gross profit and utilization as we seek to redeploy resources previously dedicated to that partner. We cannot assure you that revenue from our major pharmaceutical partners or clients will not be significantly reduced in the future. We also may not be able to maintain our relationships with our major pharmaceutical partners or clients on existing or on continued favorable terms and our major pharmaceutical partners or clients may not renew their agreements with us, in which case our business, financial condition and results of operations would be adversely affected.

In particular, during the year ended December 31, 2018, our collaboration with Shire International GmbH ("Shire") represented 27.3% of our total revenues. We expect that our collaboration with Shire will continue to account for a material portion of our revenue in 2019. The revenue attributable to Shire may fluctuate in the future, which could have an adverse effect on our financial condition and results of operations. In addition, changes in the terms of our agreements with Shire, or a modification or termination of our relationship with Shire, could result in delays in the receipt of revenue by us, or a temporary or permanent loss of revenue to us. In addition, certain pharmaceutical companies, including those with which we currently have agreements, may choose not to do business with us or may seek out other partners for genetic rare disease information due to our strategic collaboration with Shire, particularly if they are actual or potential competitors with Shire. If we are unable to continue to grow our business with other pharmaceutical companies, our business and results of operations would be adversely affected.

Our client concentration may also subject us to perceived or actual leverage that our pharmaceutical partners or clients may have, given their relative size and importance to us. If our

pharmaceutical partners or clients seek to negotiate their agreements on terms less favorable to us and we accept such unfavorable terms, this may have a material adverse effect on our business, financial condition and results of operations. Accordingly, unless and until we diversify and expand our client base, our future success will significantly depend upon the timing and volume of business from our largest pharmaceutical partners and clients and the financial and operational success of these pharmaceutical partners and clients.

***We may face restrictions or delays in the receipt of patient samples to our laboratories for genetic testing.***

Our business depends on our ability to quickly and reliably receive samples from physicians. Our CentoCard product is typically sent from locations worldwide to our laboratory in Rostock, Germany. Disruptions in delivery, whether due to factors beyond our control such as natural disasters, terrorist threats, political instability, governmental policies, failures by physicians to properly label or package the samples, failure by postage services, labor disruptions, bad weather or other factors could adversely affect the receipt by us of samples or specimen integrity and could impact our ability to process samples in a timely manner and to provide our services to our clients and pharmaceutical partners. In particular, there is a general trend in certain countries, for example in China and certain countries in South America, where policies have been introduced that restrict the processing of genetic testing outside the country in which the patient is located. This could disrupt the transportation of samples to our testing facilities in Germany from such countries, and could adversely impact our current business operations or prevent us from expanding into certain new regions.

In addition, the majority of our samples are delivered to us via regular postal services worldwide. If such services are disrupted, or if we are unable to continue to obtain expedited delivery services or specialized delivery services for certain products, such as our prenatal algorithmic test, on commercially reasonable terms, our operating results may be adversely affected.

***We may become subject to substantial product liability or professional liability claims that could exceed our resources.***

The marketing, sale and use of our products and solutions could lead to the filing of product liability claims if someone were to allege that our products and solutions identified inaccurate or incomplete information regarding the genomic alterations of the rare disease indication analyzed, reported inaccurate or incomplete information concerning the available treatments for a certain type of rare disease or otherwise failed to perform as designed. For example, we have been subject to a claim from a client that our prenatal diagnostic test conducted at their request failed to identify a specific mutation present in a patient. See "Business—Legal Proceedings." We may also be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

Our service and professional liability insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation or cause current clients or pharmaceutical partners to terminate existing agreements and potential clients or pharmaceutical partners to seek other partners, any of which could impact our results of operations.

***If the validity of a consent from a patient was challenged, we could be forced to stop using certain of our resources, which would impede our rare disease information development efforts.***

We provide diagnostic testing services to patients of our pharmaceutical partners and diagnostics clients worldwide. We also provide products and solutions, including biomarker development and testing, to our pharmaceutical partners. Such products and solutions involve the aggregation of data obtained from patients in our existing data repository and data obtained from new tests conducted both on patients whose samples remain in our biobank or new patients from whom we collect samples.

To a large extent, we also rely upon our pharmaceutical partners, our clients and, in some cases, third-party laboratories to collect the subject's informed consent and comply with applicable local laws and international regulations. Although we maintain policies and procedures designed to monitor the collection of consents by both ourselves and such third parties, we or third parties may not obtain the required consents in a timely manner, or at all. In addition, consents that we have obtained or will obtain may not meet the existing or future standards required by relevant governmental authorities.

The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of consent and the status of genetic material under a large number of different legal systems. In some jurisdictions, tissue samples that contain a person's DNA might irrevocably qualify as personal data, as in theory such samples can never be completely anonymized. Legitimate interests of the donor might cause a "revival" of his or her personal rights in the future and limit our rights of utilization. The subject's consent obtained in any particular country could be withdrawn or challenged in the future, and those consents could prove invalid, unlawful, or otherwise inadequate for our purposes. Furthermore, we may face disputes with patients should their data be used in a manner which they did not expect or if the consent was recorded incorrectly or obtained fraudulently. Any findings against us, or our pharmaceutical partners, clients or distributors, could deny us access to or force us to stop using certain of our clinical data or samples, which would impede our genetic information solution development efforts. We could become involved in legal challenges, which could consume our management and financial resources.

***If access to our highly specialized laboratory facilities, storage facilities or equipment is interrupted or damaged, our business could be negatively impacted.***

Our diagnostic testing products and pharmaceutical solutions are rendered at our laboratory facilities. We currently run all of our diagnostic testing at our laboratory in Rostock, Germany. We also commenced operations at our laboratory in Cambridge, Massachusetts in August 2018. If one or more of our laboratories, and particularly our facility in Rostock, become inoperable or some or all of our key equipment ceases to function even for a short period of time, we may be unable to perform our genetic tests or develop solutions in a timely manner or at all, which may result in the loss of clients and pharmaceutical partners or harm to our reputation, and we may be unable to regain those clients and pharmaceutical partners or repair our reputation in the future. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, flood, power loss, communications or internet failure or interruption, or terrorism, which may render it difficult or impossible for us to operate our genetic rare disease information platform for some period of time.

In particular, the biomaterials that are stored in our biobank are located in our Rostock facility. Should the biomaterials that we store there be damaged or destroyed, we would lose part or all of

our existing biomaterials and as a result we would not be able to retest this material for future research and development uses.

Furthermore, our facilities and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild any of our facilities or license or transfer our proprietary technology to a third party, particularly in light of the licensure and accreditation requirements and specific equipment needed for laboratories like ours. Even in the unlikely event we are able to find a third party with such qualifications to enable us to perform our genetic tests or develop our solutions, we may be unable to negotiate commercially reasonable terms with such third parties. Any interruption of our laboratory operations could harm relationships with our clients and pharmaceutical partners or regulatory authorities, which could adversely affect our ability to generate revenue or maintain compliance with regulatory standards.

While we carry insurance for damage to our property and laboratory and the disruption of our business, such insurance may not cover all of the risks associated with damage to our property or laboratory or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses, may be challenged by insurers underwriting the coverage, and may not continue to be available to us on acceptable terms, if at all.

***We depend upon our information technology systems, and any failure of these systems could harm our business.***

We depend on information technology and telecommunications systems for significant elements of our operations, including our repository, our CentoMD database, our CentoPortal client-facing platform, our laboratory information management system and our client relationship management system. We have installed a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial controls and reporting, contract management and other infrastructure operations. These information technology systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities. In addition, our system is backed up by two offsite data centers that offer a disaster recovery system for our database in separate locations near Frankfurt. Any technical problems that may arise in connection with third-party data center hosting facilities could result in interruptions in our service.

Our information technology systems are vulnerable to damage from a variety of sources, including network failures, malicious human acts, and natural disasters. Our business will also be harmed if our laboratory partners and potential laboratory partners believe our service is unreliable. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, malicious computer software (malware), and similar disruptive problems. Failures or significant downtime of our information technology systems, or those used by our third-party service providers, could prevent us from conducting our comprehensive genomic analyses, preparing and providing reports and data to partners and physicians, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities, and managing the administrative aspects of our business. Additionally, to the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur significant liability. Any disruption or loss of information technology or telecommunications

systems on which critical aspects of our operations depend could have an adverse effect on our business.

***We rely on a limited number of suppliers or, in some cases, a sole supplier, for some of our laboratory equipment and may not be able to find replacements or immediately transition to alternative suppliers.***

We believe that there are only a few equipment manufacturers that are currently capable of supplying and servicing the sequencing equipment necessary for our laboratory operations. Therefore, we may not be able to obtain acceptable substitute equipment from another supplier on the same basis or at all. Even if we are able to obtain acceptable substitutes from replacement suppliers, their use could require us to significantly alter our laboratory operations. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing or maintaining the proper function of this laboratory equipment. Any such interruption could negatively impact research and development and launches of new products or solutions, and significantly affect our business, financial condition, results of operations, and reputation.

We rely on a key supplier, Illumina, for certain sequencing equipment used for our processes. We also rely on a sole supplier for our CentoCard, which is our main sample collection method for our diagnostic tests.

Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, would likely affect the performance specifications of our laboratory operations, and would require that we revalidate our existing assays. There can be no assurance that we would be able to secure alternative equipment, reagents, and other materials, and bring such equipment, reagents, and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, there can be no assurance that replacement diagnostic sequencing equipment would be available or would meet our quality control and performance requirements for our laboratory operations. If we should encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and reagents we require for our assays, our business, financial condition, results of operations, and reputation could be adversely affected.

***The loss or transition of any member of our senior management team, in particular our CEO, or our inability to attract and retain new talent, could adversely affect our business.***

Our success depends on the skills, experience, and performance of key members of our senior management team, and in particular our CEO, Prof. Arndt Rolfs. The individual and collective efforts of these employees will be important as we continue to develop our rare disease genetic information platform and additional products and solutions, and as we expand our commercial activities. The loss or incapacity of existing members of our senior management team could adversely affect our operations if we experience difficulties in hiring qualified successors.

The complexity inherent in integrating a new key member of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership transitions can be inherently difficult to manage and may cause uncertainty or a disruption to our business or may increase the likelihood of turnover of other key officers and employees. Specifically, a leadership transition in the commercial team may cause uncertainty about or a disruption to our commercial organization, which may impact our ability to achieve sales and revenue targets.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses globally. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting, or retaining qualified sales people. Recruitment and retention difficulties can limit our ability to support our research and development and sales programs.

***International expansion of our business exposes us to new and complex business, regulatory, political, operational, financial, and economic risks.***

Our business strategy incorporates plans for significant expansion in the countries in which we currently operate and internationally. Doing business internationally involves a number of risks, including:

- § multiple, conflicting, and changing laws and regulations such as data protection laws, privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements (including requirements related to patient consent, testing of genetic material and reporting the results of such testing) and other governmental approvals, permits, and licenses, or government delays in issuing such approvals, permits, and licenses;
- § failure to obtain regulatory approvals for the manufacture and sale of our products and use of our products and solutions in various countries;
- § transition and management of our former distribution relationships in various countries;
- § potentially relevant third-party intellectual property rights;
- § difficulties in staffing and managing foreign operations;
- § complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property rights;
- § logistics and regulations associated with preparing, shipping, importing and exporting tissue and blood samples, including infrastructure conditions, transportation delays, and customs;
- § limits in our ability to penetrate new geographical regions due to competition;
- § logistical issues or increases in costs of transporting tests and samples since our diagnostic tests are conducted centrally in Germany;
- § financial risks, such as the impact of local and regional financial crises on demand and payment for our products and solutions, and exposure to foreign currency exchange rate fluctuations;
- § risks associated with operations in countries which have experienced, or are currently experiencing, high rates of inflation which increase our costs, inhibit economic growth and could lead to reduced demand for our products and solutions;
- § natural disasters, political, and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and
- § regulatory and compliance risks that relate to maintaining accurate information and control over sales and distribution activities that may fall within the purview of the United States Foreign Corrupt Practices Act (the "FCPA") or comparable foreign regulations, including its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. The difference in regulations under the laws of the countries in which we may expand and the laws of the countries in which we currently operate may be significant and, in order to comply with such new laws, we may have to implement global changes to our products and solutions or business practices. Such changes may result in



additional expense to us and either reduce or delay development of our products and solutions, commercialization of our biomarkers and other solutions or expansion of our data repository and biobank. In addition, any failure to comply with applicable legal and regulatory obligations could affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our activities in these countries.

Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

***Implementation of partnership agreements with our pharmaceutical partners may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of client relationships and diversion of management's attention.***

The negotiation of our existing partnership agreements, as well as any new partnership agreements that we enter into, take up significant management time and resources. Moreover, in part due to the complex nature of our partnership agreements which typically provide for research and development collaboration as well as utilization of our genetic patient screening processes, we may need to expend capital and dedicate manpower to meeting the requirements of our pharmaceutical partners. Any partnership agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations with other third parties, or to otherwise provide products and solutions in connection with a particular rare disease indication. As a result of these and other factors, our partnership agreements may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of client relationships and diversion of management's attention.

Many of these factors will be outside of our control, and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially impact our business, financial condition and results of operations. As a result, we cannot assure you that our relationship with any pharmaceutical partner will result in the realization of the anticipated benefits.

***If our products and solutions do not perform as expected, we may fail to achieve or maintain sales of our products and solutions.***

Our success depends on the market's confidence that we can provide accurate diagnostic testing products and reliable, high-quality rare disease information solutions. Our partnerships with our pharmaceutical partners and clients are typically designed to provide results in respect of a particular rare disease, and our preliminary assessments or knowledge about such disease may necessarily be limited by the amount of information currently available. As a result, the work we undertake on behalf of our pharmaceutical partners and clients may not yield the results that our pharmaceutical partners and clients expect or anticipate. We believe that our pharmaceutical partners and clients are likely to be particularly sensitive to solution and testing service defects and errors, including if our products or services fail to detect genomic alterations with high accuracy from clinical specimens or if we fail to accurately develop a biomarker.

Moreover, we may fail to maintain the accuracy and reproducibility we have demonstrated to date with our genetic testing services, particularly for clinical samples, as our test volume increases. The sequencing process yields that we achieve depend on the design and operation of our sequencing process, which uses a number of complex and sophisticated biochemical, informatics, optical, and mechanical processes, many of which are highly sensitive to external factors. An operational or technological failure in one of these complex processes or fluctuations in external variables may result in sequencing processing yields that are lower than we anticipate or that vary between sequencing runs. In addition, we are regularly evaluating and refining our sequencing process. These refinements may initially result in unanticipated issues that further reduce our sequencing process yields or increase the variability of our sequencing process yields. Errors, including if our products or solutions fail to detect genomic variants with high accuracy, or mistakes, including if we fail to or incompletely or incorrectly identify the significance of gene variants, could have a significant adverse impact on our business.

Hundreds of genes can be implicated in some disorders, and overlapping networks of genes and symptoms can be implicated in multiple conditions. As a result, a substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop an appropriate patient report. As a result, we may make errors in our interpretation of testing results, which could impair the results of our tests and (as such results are typically stored in our CentoMD database) adversely impact the quality of our overall knowledge base. The failure of our products or solutions to perform as expected would significantly impair our operating results and our reputation. We may also be subject to legal claims arising from, or loss of business as a result of, any defects or errors in our products and solutions.

***We may fail to manage our future growth effectively, which could make it difficult to execute our business strategy.***

We anticipate growth in our business operations. This future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, and sales force management. We may fail to maintain the quality or expected turnaround times of our products and services, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures.

We also plan to expand our laboratory and technical operations as our business grows. In August 2018, we opened a new facility in Cambridge, Massachusetts, in the United States and recently expanded our clinical studies team to support our U.S. operations. This or other future expansion strategies and any future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales force management. We may not be able to maintain the quality or expected turnaround times of our testing services or satisfy client demand as our business grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and managerial controls, as well as our reporting systems and procedures, and to obtain appropriate regulatory approvals and meet regulatory standards applicable for the operation of our business.

***The development of new products and solutions is a complex process, and we may be unable to successfully commercialize new products or solutions on a timely basis or at all.***

New diagnostic test products and our interpretation-based solutions, including our biomarkers, take time to develop and commercialize. We may fail to develop and commercialize new diagnostic tests or solutions on a timely basis. Moreover, there can be no assurance that our products or solutions will be capable of meeting the needs of our clients and pharmaceutical partners, or that we

will be able to commercialize them at all. Before we can commercialize any new products or solutions, we need to expend significant funds in order to:

- § conduct substantial research and development, including validation studies and potentially patient scope analyses;
- § further develop our laboratory processes or equipment;
- § allocate laboratory space for new solutions or further scale our infrastructure to accommodate research and development or new equipment;
- § in the case of products or solutions for which we are seeking regulatory or marketing approval, such as biomarkers, pursue such regulatory approval.

The development of new products and solutions involves risk, and development efforts may fail for many reasons, including the failure of any product or solution to perform as expected, a lack of validation or reference data, failure to demonstrate utility of a test or solution, or, in the case of solutions for which we are seeking or have received the Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), German Federal Institute for Medicinal Products and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*), or comparable agencies' approval, the inability to obtain such approval or the loss of such approval. In particular, our biomarker development and patent processes are subject to review by regulatory agencies and governing bodies. We cannot predict whether or when we will successfully complete development of each biomarker and if we will receive patent protection on any biomarkers that we develop.

As we develop new products and solutions, we will have to make significant investments in development, marketing, and selling resources. Any failure to develop or deliver adequate products or solutions to our clients and pharmaceutical partners on a timely basis or at all could significantly affect our business, financial condition, results of operations, and reputation.

***We have limited experience in marketing and selling our products and solutions and we may fail to expand our direct sales and marketing force to adequately address our pharmaceutical partners' and clients' needs.***

We have limited experience in marketing and selling our products and solutions to pharmaceutical partners, and currently rely on our CEO and our Chief Business Officer ("CBO") along with a small sales force to sell our products and solutions. We may not be able to market, sell, or distribute our existing products and solutions or other services we may develop effectively enough to support our planned growth.

Our future sales and further business growth will depend in large part on our ability to develop, and expand, our sales force and to increase the scope of our marketing efforts, particularly in the United States. Our target market of pharmaceutical partners and clients is a diverse market with particular, individualized needs. As a result, we believe it is necessary to develop a sales force that includes sales representatives with specific rare disease technical backgrounds. We will also need to attract and develop marketing personnel with industry expertise. Competition for such employees is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales and marketing force, which could negatively impact sales and market acceptance of our products or solutions and limit our revenue growth and potential profitability. Our expected future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, and integrate additional employees. Our future financial performance will depend in part on our ability to manage this potential future growth effectively, without compromising quality.

If we believe a significant market opportunity for our products or solutions exists in a particular jurisdiction in which we do not have direct access through one of our existing offices, from time to time we may enlist distribution partners and local laboratories to assist with sales, distribution, and client support. We may not be successful in finding, attracting, and retaining distribution partners or laboratories, or we may not be able to enter into such arrangements on favorable terms. Sales practices utilized by our distribution partners that are locally acceptable may not comply with sales practices standards required under German, Dutch, United States or other laws that apply to us, which could create additional compliance risk. If these additional sales and marketing efforts are not successful, we may not achieve significant market acceptance for our solutions in these markets, which could harm our business.

***The knowledge and interpretation-based solutions we provide to our pharmaceutical partners may not achieve significant commercial market acceptance.***

Our knowledge and interpretation-based solutions may not gain significant acceptance in the orphan drug development market and, therefore, may not generate substantial revenue or profits for us. Our ability to achieve increased commercial market acceptance for our existing knowledge and interpretation-based solutions will depend on several factors, including:

- § our ability to convince the medical and pharmaceutical community of the clinical utility of our solutions and their potential advantages over existing and new solutions;
- § the willingness of our pharmaceutical partners, as well as their physicians and patients, to utilize our solutions; and
- § the agreement by commercial third-party payors and government payors to reimburse any treatments provided by our pharmaceutical partners, the scope and amount of which will affect a partners' willingness or ability to pay for our solutions and will influence physicians' decisions to recommend our solutions.

We believe that the successful completion of clinical trials by partners that use our solutions, publication of scientific and medical results based on the information gained from our repository in peer-reviewed journals, and presentations at leading conferences are critical to the broad adoption of our solutions. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving our solutions sufficiently novel or worthy of publication.

The failure to be listed in physician guidelines or the failure of our solutions to produce favorable results for our partners or to be published in peer-reviewed journals could limit the adoption of our solutions. Failure to achieve widespread market acceptance of our solutions would materially harm our business, financial condition, and results of operations.

***Failure to keep pace with the rapidly evolving industry in which we operate could make us obsolete.***

Our business relies on commercial activities in the rare disease genetic testing and diagnosis field. In recent years, there have been numerous advances in methods used to analyze very large amounts of genomic information and the role of genetics and gene variants in rare diseases and treatments, including through the development of biomarkers. Our industry has and will continue to be characterized by rapid technological change, increasingly larger amounts of data, frequent new testing service introductions and evolving industry standards. Our future success will also depend on our ability to keep pace with the evolving needs of our clients and pharmaceutical partners on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. Our current products and solutions could become obsolete unless we continually update our offerings to reflect new scientific knowledge about genes and

genetic variations and their role in rare diseases and treatments. If we fail to anticipate or respond adequately to technological developments, demand for our products and solutions will not grow and may decline, and our business, revenue, financial condition and operating results could suffer materially.

Moreover, many companies in this market are offering, or may soon offer, products and solutions that compete with our products and solutions, in some cases at a lower cost than ours. We cannot assure you that research and discoveries by other companies will not render our existing or potential products and solutions uneconomical or result in tests superior to our existing tests and those we may develop. We also cannot assure you that any of our existing products and solutions, or those that we develop in the future, will be preferred by our clients, pharmaceutical partners, physicians or other payors to any existing or newly developed technologies or tests. If we fail to maintain competitive test products, our business, prospects, financial condition and results of operations could be adversely affected.

***We may fail to successfully respond to increasing demand for our products and solutions.***

As our sales volume grows, we will need to continue to increase our infrastructure for sample intake, customer service, billing and general process improvements, expand our internal quality assurance program, and extend our platform to support comprehensive genomic analyses at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our products and solutions. Portions of our process cannot be fully automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take a long time to procure, set up, and validate, and increase our software and computing capacity to meet increased demand.

We may fail to successfully implement any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements and we may have inadequate space in our laboratory facilities to accommodate such required expansion.

As additional products and solutions are commercialized, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult or impossible for us to meet market expectations for our products and solutions, and could damage our reputation and the prospects for our business.

***We may fail to obtain favorable pricing for our products and solutions and to meet our profitability expectations.***

If we are not able to obtain favorable pricing for our products and solutions to enable us to meet our profitability expectations, our revenues and profitability could materially suffer. The rates we are able to charge for our products and solutions are affected by a number of factors, including:

- § general economic and political conditions in the countries in which we operate;
- § the competitive environment in our industry, as described below;
- § our clients' and pharmaceutical partners' cost sensitivities;
- § our ability to accurately estimate, attain and sustain revenues and royalties, margins and cash flows over the full partnership period for our solutions, which includes our ability to estimate the impact of inflation and foreign exchange on our margins over long-term contracts; and

§ procurement practices of our pharmaceutical partners and clients and their use of third-party advisors.

The competitive environment in our industry affects our ability to obtain favorable pricing in a number of ways, all of which could have a material negative impact on our results of operations. The less we are able to clearly convey the value of our products and solutions or differentiate our products and solutions, the more risk we have that they will be seen as commodities, with price being the driving factor in selecting us as a partner. Competitors may be willing, at times, to price contracts or products lower than we do in an effort to enter the market or increase market share. Further, if competitors develop and implement methodologies that yield greater efficiency or efficacy, they may be able to offer products and solutions similar to ours at lower prices.

***Ethical, legal and social concerns related to the use of genomic information could reduce demand for our genetic rare disease knowledge and interpretation-based products and solutions.***

Genomic testing, like that conducted for our pharmaceutical partners and clients using our genetic rare disease information platform, has raised ethical, legal and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use genomic tests even if permissible.

Ethical and social concerns may also influence United States and foreign patent offices and courts with regard to patent protection for technology relevant to our business. These and other ethical, legal and social concerns may limit market acceptance of our products and solutions or reduce the potential markets for products and solutions enabled by our genetic rare disease information platform, either of which could have an adverse effect on our business, financial condition, or results of operations.

***We may expend our limited resources to pursue biomarker development for a particular rare disease and fail to capitalize on rare diseases for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus on research programs and biomarker development that we identify for rare diseases in collaboration with our pharmaceutical partners, or based on our assessment of the market needs. As a result, we may forego or delay pursuit of opportunities with other orphan drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and biomarker development for specific diseases may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements.

***If we fail to compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability.***

While personalized genomic diagnostics is a relatively new area of science, we face competition from companies that offer tests or have conducted research to profile genes and gene expression in various rare diseases. Our principal competition comes from diagnostic companies that offer

diagnostic tests that capture genetic, phenotypic and epidemiological data, as well as laboratories and academic research centers. Many hospitals and academic medical centers may also seek to perform the type of genetic testing and knowledge and interpretation-based solutions we offer at their own facilities or using their own research capabilities.

Some of our present and potential competitors may have substantially greater financial, marketing, technical or manufacturing resources than we do. Our competitors may also be able to respond more quickly to new technologies or processes and changes in client demands. They may also be able to devote greater resources towards the development, promotion and sale of their products or solutions for pharmaceutical partners than we can. As competition in our market increases, we may also be subject to increased litigation risk, including in connection with patents as well as our marketing practices and other promotional activities. In addition, our current and potential competitors may make strategic acquisitions or establish cooperative relationships among themselves or with third parties that increase their ability to address the needs of our physicians or partners. If we fail to compete successfully against current or future competitors, our business will be harmed.

Because our genetic testing and knowledge and interpretation-based solutions and products, in particular our CentoMD database, have limited patent protection, new and existing companies worldwide could seek to develop genetic tests or similar products and solutions that compete with ours. These competitors could have technological, financial, and market access advantages that are not currently available to us and they could develop and commercialize competing products and solutions faster than we are able to do so. Increased competition, including price competition, could have a material adverse impact on our net revenues and profitability.

***If our pharmaceutical partners experience any of a number of possible unforeseen events in connection with their clinical trials, our ability to commercialize future solutions or improvements to existing solutions could be delayed or prevented.***

Our pharmaceutical partners may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent their ability to continue or conduct further clinical trials or obtain regulatory approval of or commercialize future orphan drugs. Unforeseen events that could delay or prevent our pharmaceutical partners' ability to conduct or support clinical trials, obtain regulatory approval of or commercialize future orphan drugs include:

- § regulatory authorities or ethical review boards, including IRBs, may not authorize the commencement of a clinical trial or may not accept clinical trial protocols;
- § clinical trials may produce negative or inconclusive results, and our pharmaceutical partners may decide, or regulatory authorities may require them to, to abandon development programs;
- § the number of patients, or amount of data, required for clinical trials may be larger than we or our pharmaceutical partners anticipate, or patient enrollment in clinical trials may be slower than we or our pharmaceutical partners anticipate or patients may drop out of these clinical trials at a higher rate than we or our pharmaceutical partners anticipate;
- § failure to conduct our clinical trials in accordance with applicable regulatory requirements of the FDA and of the regulatory authorities responsible for oversight of the conduct of clinical trials in other countries;
- § inability to add develop companion diagnostic tests for a particular rare disease or to add companion diagnostic claims to existing tests, and/or obtain regulatory approval to market any such test on a timely basis or at all;
- § clinical trials of our pharmaceutical partners for which we are developing companion diagnostic tests may suggest or demonstrate that our partners' treatments are not as efficacious and/or as safe as other similar treatments or that our companion diagnostic test is not essential to determine which patients would benefit from these treatments; and

- § our pharmaceutical partners may decide, or regulatory authorities or institutional review boards may require them, to suspend or terminate clinical research for various reasons, including cost, adequate end market size, available data or noncompliance with regulatory requirements.

If our pharmaceutical partners choose not to conduct clinical trials for treatments in the rare disease space due to the above factors or otherwise, they may have less need of our products and solutions and may therefore choose not to partner with us. Our ability to continually expand on our existing data repository depends on our ability to maintain partnerships with our pharmaceutical clients. Should our partners delay or cancel their ongoing existing trials or choose not to begin new trials for treatments in the rare disease industry, our ability to commercialize future solutions or improvements to existing solutions could be delayed or prevented.

***Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial partners, including our distributors in our diagnostics business and pharmaceutical partners in our pharmaceutical business. Misconduct by these parties could include intentional failures to comply with the regulations of applicable regulatory authorities (including the FDA and the EMA), comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, bribery, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, client incentive programs, and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees and conduct a background check before entering into any new contracts with third party distributors, but it is not always possible to identify and deter employee or third party misconduct, and our code of conduct, due diligence and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these actions or investigations.

***We may lose the support of key thought leaders and fail to establish our products and solutions as a standard of care for patients with rare diseases, which may limit our revenue growth and ability to achieve future profitability.***

We have established relationships with leading rare disease thought leaders at premier institutions and rare disease networks. If we suffer harm to our reputation, whether due to actions outside of our control or otherwise, our relationships with these persons may suffer which could adversely impact our business, including our key pharmaceutical partnerships and diagnostic client relationships. Moreover, if these key thought leaders determine that our CentoMD platform, our existing products or solutions or other new products or solutions that we develop are not useful to



our partners' development of treatments for rare diseases, that alternative technologies are more effective, or if they elect to use internally developed products or solutions, we could encounter significant difficulty validating our testing platform, driving adoption, or establishing our genetic knowledge and interpretation-based solutions and tests as a standard of care, which would limit our revenue growth and our ability to achieve profitability.

***Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.***

In the ordinary course of our business, we collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property, and proprietary business information owned or controlled by us or physicians, pharmaceutical partners and other clients. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. We also communicate, and facilitate the exchange of, sensitive patient data to and between ourselves and physicians of the patients for whom we conduct diagnostic tests through an online client-facing portal, CentoPortal. These applications and related data encompass a wide variety of business-critical information including legally protected health information, personally identifiable information, research and development information, commercial information, and business and financial information. We face a number of key risks related to the protection of this information, including: unauthorized access risk; inappropriate or unauthorized disclosure risk; inappropriate modification risk; and the risk of our being unable to adequately monitor our controls.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy. Our information technology and infrastructure, and that of our third-party disaster recovery back-up providers, may be vulnerable to attacks by hackers or malicious software or breached due to personnel error, unauthorized access, malfeasance, or other disruptions. Any such breach or interruption could compromise the security or integrity of our networks, and the information stored there could be accessed by unauthorized parties, publicly or incorrectly disclosed, corrupted, lost, or stolen. Any such access, disclosure, corruption, other loss, or theft of information could result in governmental investigations, class action legal claims or proceedings, liability under laws that protect the privacy of personal information, such as but not limited to the Health Insurance Portability and Accountability Act ("HIPAA"), and regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, applications such as our online client-facing portals are currently accessible through public web portals and may, in the future, be accessible through dedicated mobile applications, and there is no guarantee we can absolutely protect our online portals or our mobile applications from breach. Unauthorized access to, or loss or dissemination of, the data embedded in or transferred via these applications could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill our pharmaceutical or other partners, provide client assistance solutions, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and solutions and other pharmaceutical partner and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

We are a "covered entity" as defined under HIPAA, and the United States Office of Civil Rights may impose penalties on a covered entity for a failure to comply with a requirement of HIPAA. Penalties will vary significantly depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity's

failure to comply was due to willful neglect. As of October 11, 2018, these penalties included civil monetary penalties of \$114 to \$57,051 per violation, up to an annual cap of \$1,711,533. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and imprisonment up to one year. The criminal penalties increase to \$100,000 and up to five years' imprisonment if the wrongful conduct involves false pretenses, and to \$250,000 and up to 10 years' imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm. The United States Department of Justice (the "DOJ") is responsible for criminal prosecutions under HIPAA. Furthermore, in the event of a breach as defined by HIPAA, the covered entity has specific reporting requirements under HIPAA regulations. In the event of a significant breach, the reporting requirements could include notification to the general public.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, Europe, and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Our operations or business practices may not comply with these regulations in each country, and complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

***We may be adversely affected by volatile, negative or uncertain economic, political or social conditions and the effects of these conditions on our pharmaceutical partners' and diagnostics clients' businesses and levels of business activity.***

Global economic conditions affect our pharmaceutical partners' and diagnostic clients' businesses and the markets they serve, and volatile, negative or uncertain economic conditions may have an adverse effect on our revenue growth and profitability. Volatile, negative or uncertain economic conditions in our significant markets, in particular in our North America, Middle East or European regions, where we generated 44.7%, 30.6% and 16.9% of our total revenues for the year ended December 31, 2018, respectively, could undermine business confidence, both in those markets and other markets, and cause our pharmaceutical partners or clients to reduce or defer their spending on new technologies or initiatives or terminate existing contracts, which would negatively affect our business. Growth in the markets we serve could be at a slow rate, or could stagnate, for an extended period of time. Differing economic conditions and patterns of economic growth and contraction in the geographical regions in which we operate and the industries we serve may affect demand for our products and solutions. Weakening in these markets as a result of high government deficits, credit downgrades or otherwise could have a material adverse effect on our results of operations. Ongoing economic volatility and uncertainty affects our business in a number of other ways, including making it more difficult to accurately forecast partner demand beyond the short term and effectively build our revenue and resource plans, particularly given the iterative nature of the negotiation of new contracts with our pharmaceutical partners. This could result, for example, in us not having the level of appropriate personnel where they are needed, and could have a significant negative impact on our results of operations.

Moreover, acts of terrorist violence, political unrest, armed regional and international hostilities and international responses to these hostilities, natural disasters, global health risks or pandemics or the threat of or perceived potential for these events could have a negative impact on us. These events could adversely affect our pharmaceutical partners' levels of business activity and precipitate

sudden significant changes in regional and global economic conditions and cycles. These events also pose significant risks to our people and to physical facilities and operations around the world, whether the facilities are ours or those of our distributors, pharmaceutical partners or physicians that utilize our diagnostic testing services. By disrupting communications and travel and increasing the difficulty of obtaining and retaining highly skilled and qualified personnel, these events could make it difficult or impossible for us to deliver products and solutions to our clients and pharmaceutical partners. Extended disruptions of electricity, other public utilities or network services at our facilities, as well as system failures at, or security breaches in, our facilities or systems, could also adversely affect our ability to serve our clients and pharmaceutical partners. We might be unable to protect our people, facilities and systems against all such occurrences. We generally do not have insurance for losses and interruptions caused by terrorist attacks, conflicts and wars. If these disruptions prevent us from effectively serving our clients and pharmaceutical partners, our results of operations could be adversely affected.

***We are subject to significant foreign currency exchange controls in certain countries in which we operate.***

We are in some countries, and could become elsewhere, subject to strict restrictions on the movement of cash and the exchange of foreign currencies, which limits our ability to use this cash across our global operations. We also face risks related to the collection of payments due to us from our major pharmaceutical partners or clients that are located in certain geographical regions with foreign currency or international monetary controls. This risk could increase as we continue our geographic expansion. In particular, for the year ended December 31, 2018, we derived 30.6% of our total revenues from our Middle East region. Certain Middle East economies have adopted or been subject to international restrictions on the ability to transfer funds out of the country and convert local currencies into euros. This may increase our costs and limit our ability to convert local currency into euros and transfer funds out of certain countries. Any shortages or restrictions may impede our ability to convert these currencies into euros and to transfer funds, including for the payment of dividends or interest or principal on our outstanding debt.

***We may acquire assets or other businesses that could negatively affect our operating results, dilute our shareholders' ownership or increase our debt.***

In addition to organic growth, we may pursue growth through the acquisition of assets or other businesses that may enable us to enhance our technologies and capabilities, expand our geographic market, add experienced management personnel or add new or improve our existing products and solutions. We also may pursue strategic alliances and joint ventures that leverage our technical platform and industry knowledge to expand our products and solutions. Negotiating these transactions and the formation of strategic alliances or joint ventures can be time-consuming and expensive, and may be subject to third-party approvals as well as approvals from governmental authorities, which are beyond our control. In addition, some third parties may choose not to enter into partnership or collaboration agreements with us because of our existing relationships with other pharmaceutical partners. Consequently, we may not be able to complete any contemplated transactions on favorable terms or at all, and we can make no assurance that such transactions, once undertaken and announced, will close.

An acquisition or investment may result in unforeseen operating difficulties and expenditures, including in integrating businesses, products and solutions, personnel, operations, and financial, accounting and other controls and systems, and retaining key employees, with the assumption of unknown liabilities or known liabilities that prove greater than anticipated, and in retaining the clients of any acquired business. Any such difficulties could disrupt our ongoing operations or require management resources that we would otherwise focus on developing our existing business. Future

acquisitions could result in the use of our available cash and marketable securities, potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities, or impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition. As a result, we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture. These challenges related to acquisitions or investments could adversely affect our business, results of operations, and financial condition.

## **Certain Factors Relating to Our Industry**

### **Regulatory Risks**

***Our global operations expose us to numerous and sometimes conflicting legal and regulatory requirements, and violation of these requirements could harm our business.***

We are subject to numerous, and sometimes conflicting, legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anticorruption, import/export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti-competition, data privacy and labor relations. This includes in emerging markets where legal systems may be less developed or familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly, time-consuming and requires significant resources. Violations of one or more of these regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our supervisory board or officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our clients or pharmaceutical partners also could result in liability for significant monetary damages, fines and/or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and allegations by our clients or pharmaceutical partners that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, products and solutions, pricing, reimbursement and marketing of our products and solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. The imposition of new laws or regulations, including potential trade barriers, may increase our operating costs, impose restrictions on our operations or require us to spend additional funds to gain compliance with the new rules, if possible, which could have an adverse impact on our financial condition.

***Current and future legislation, in particular legislation related to orphan drugs, may impact overall investment and activity in the rare disease space or our ability to obtain regulatory approvals.***

In the United States, the European Union, its member states and some other foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system. These changes could affect our ability to sell profitably any products for which we require approvals. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare.

Specifically, regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs.

Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the European Union, the European Commission grants orphan drug designation after receiving the opinion of the EMA's Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). In addition, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug. In the European Union, orphan drug designation entitles a party to financial incentives, such as reduction of fees or fee waivers, and a ten-year market exclusivity once the drug is on the market.

These legislative initiatives have led to an increase in investment and activity in the rare disease drug development space. If these and other legislative initiatives were to change to become less favorable to orphan drug developers and researchers, it could harm our business, results of operations and financial condition.

***We may fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business and become subject to severe financial and other consequences.***

Our laboratory in the United States is subject to the Clinical Laboratory Improvement Amendments of 1998 ("CLIA"), a United States federal law that regulates all clinical diagnostic laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality control, quality assurance, and inspections. Our laboratory facilities located in Rostock, Germany and Cambridge, Massachusetts, United States each have a current certificate of accreditation under CLIA to conduct all genetic and biochemical analyses offered through our accreditation by the College of American Pathologists ("CAP"). To renew these certificates, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced inspections of our clinical laboratories at any time.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. Most CLIA deficiencies are not classified as "condition-level" deficiencies, and there are no adverse effects upon the laboratory operations as long as the deficiencies are corrected. Remediation of these deficiencies are routine matters, with corrections occurring within several hours or weeks. More serious CLIA deficiencies could rise to the level of "condition-level" deficiencies, and CMS has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA certified laboratory by any owners or operators of the deficient laboratory. There is an administrative hearing procedure that can be pursued by the laboratory in the event of

imposition of such sanctions, during which the sanctions are stayed, but the process can take a number of years to complete. If we were to lose our CLIA certification or CAP accreditation, we would not be able to operate our clinical laboratories and perform our genetic tests, which would result in material harm to our business and results of operations.

We are also required to maintain a license for our Cambridge laboratory facility to perform testing in Massachusetts. Massachusetts laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control over and above that required by CLIA. We are also licensed to perform testing in our Cambridge laboratory facility by the states of California, Pennsylvania and Maryland. We are in the process of obtaining a New York State license to perform testing and deliver the related test report for specimens originating from New York.

We are also subject to HIPAA, under which the Department of Health and Human Services established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions; certain of our services, including our online client-facing portals for reporting and research, are subject to these standards and requirements. Amendments to HIPAA under the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), and related regulatory amendments, which strengthen and expand HIPAA privacy and security standards, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification.

We furnish to pharmaceutical partners genomic information that has been de-identified in accordance with HIPAA and relevant international health information privacy regulations. The laws of certain states and countries may require specific consent from the individual either to retain or utilize certain genetic information for research or other purposes even if such information has been de-identified, or may require that we obtain a waiver of such consent from an ethical or privacy review board. Even where we furnish to pharmaceutical partners and academic researchers genomic information that has been de-identified in accordance with applicable laws and regulations, pharmaceutical partners or academic researchers may use technology or other methods to link that de-identified genomic information to the patient from whom it was obtained in contravention of one or more applicable laws and regulations. Similarly, as we expand our decision support applications and offerings, we may encounter greater regulatory risk, such as compliance with HIPAA and other regulations governing the use of protected health information and the promotion of FDA-approved drugs. A finding that we have failed to comply with any such laws and any remedial activities required to ensure compliance with such laws could cause us to incur substantial costs, to be subject to unfavorable publicity or public opinion, to change our business practices, or to limit the retention or use of genetic information in a manner that, individually or collectively, could be adverse to our business.

In the European Union, various regulations apply to genetic testing and the use of genomic information. In Germany, the Genetic Diagnosis Act (*Gendiagnostikgesetz*) (the "GenDG") and guidelines and written opinions on novel genetic screenings developed by the Commission on Genetic Testing, an interdisciplinary independent commission established in 2009 in accordance with the GenDG, apply to such testing. The GenDG prohibits us from communicating results of genetic tests directly to a patient located within Germany. Instead, the results may only be provided to a physician who is a qualified genetic counsellor under applicable rules.

In addition to CLIA, HIPAA and the GenDG, our operations are subject to other extensive federal, state, local, and foreign laws and regulations, all of which are subject to change. Our failure

to comply with any such laws and regulations could lead to civil or criminal penalties, exclusion from participation in government healthcare programs, or prohibitions or restrictions on our ability to conduct commercial activities. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies allege that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties.

***We may fail to comply with evolving European and other privacy laws.***

In Europe, Directive 95/46/EC of the European Parliament and of the Council of October 24, 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, (the "Directive"), and Directive 2002/58/EC of the European Parliament and of the Council of July 12, 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (as amended by Directive 2009/136/EC) (the "e-Privacy Directive"), have required European Union ("EU") member states to implement data protection laws to meet strict privacy requirements. Violations of these requirements can result in administrative measures, including fines, or criminal sanctions. The e-Privacy Directive will likely be replaced in time by a new e-Privacy Regulation which may impose additional obligations and risk for our business.

Beginning on May 25, 2018, the Directive was replaced by Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the "GDPR"). The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area (the "EEA"), including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the European Union. Also, in the field of handling genetic and health data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.



We must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multinational clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

***We could be adversely affected by violations of worldwide anti-bribery laws, including the U.S. Foreign Corrupt Practices Act.***

We are subject to a variety of anti-bribery and anti-corruption laws in the jurisdictions in which we operate. In particular, we are subject to Germany's Anti-Bribery Act of 2015 (*Gesetz zur Bekämpfung der Korruption*), which implements EU anti-corruption laws and the European legislation and the Criminal Law Convention on Corruption of the Council of Europe into German law, and the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-United States government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery.

We use third-party collaborators, strategic partners, law firms and other representatives for patent registration and other purposes in a variety of countries, including those that are known to present a high corruption risk. We also use third-party distributors worldwide as part of our diagnostics business. Our reliance on third parties to sell our products and solutions internationally demands a high degree of vigilance because we can be held liable for the corrupt or other illegal activities of these third-party collaborators, or their or our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. In addition, although we have implemented policies and procedures to ensure compliance with anti-corruption and related laws and maintain a code of conduct, there can be no assurance that all of our employees, representatives, contractors, partners, or agents will comply with these laws at all times. Other United States companies in the medical device and pharmaceutical fields have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals.

These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws, any changes in these laws, or the interpretation thereof. Non-compliance with these and other relevant laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and debarment from contracting with certain governments or other persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas or



investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations, and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Enforcement actions and sanctions could further harm our business, results of operations, and financial condition.

***Transactions involving Iran or other countries or parties that are targets of U.S. or other economic sanctions could expose us to certain risks and may lead some potential customers and investors to avoid doing business with us or investing in our securities.***

U.S. law generally prohibits U.S. persons, and in some cases non-U.S. entities owned or controlled by U.S. persons, from doing business with countries, territories, individuals and entities that are the target of sanctions administered by the U.S. Department of the Treasury's Office of Foreign Assets Control, including Iran. Other countries also maintain certain economic sanctions targeting certain countries, territories and parties. The United States has also implemented certain sanctions targeting non-U.S. persons for activities conducted outside the United States "secondary sanctions" that involve specific sanctions targets or certain activities, including, among other things, certain transactions related to Iran. Further, certain countries maintain and enforce export controls regulating trade in items that originate in, incorporate content from, or are produced on the basis of technology developed in such country "export controls".

Centogene AG, which is not a U.S. person and is not owned or controlled by U.S. persons, has contracts with several laboratories and one distributor in Iran through which it provides diagnostic tests to patients in Iran, primarily non-invasive prenatal testing ("NIPT") for pregnant women. To our knowledge, neither we nor our distributor have entered into any arrangements with or sold any products to persons included on the Specially Designated Nationals and Blocked Persons List maintained by the U.S. Department of the Treasury's Office of Foreign Asset Control. During the years ended December 31, 2016, 2017 and 2018, revenues from Iran amounted to €139 thousand, €300 thousand and €2,950 thousand, respectively. In the year ended December 31, 2018, revenues were higher than in prior periods because of a new contract with the distributor under which the volume of NIPT tests performed increased. Our assets receivable from or attributable to our contacts in Iran for these periods amounted to €67 thousand, €77 thousand and €1,351 thousand, respectively. We had no liabilities due from or attributable to our contacts in Iran for these periods. Centogene believes that its business with Iranian parties is conducted in compliance with all applicable sanctions and export controls and that such activities, which involve providing genetic testing services to patients, are not sanctionable under U.S. secondary sanctions targeting Iran. However, U.S. sanctions are subject to change and if we were then determined to have engaged in activities targeted by certain U.S. sanctions, we could be exposed to the possible imposition of sanctions on us. We may also face reputational damage due to our sales to Iran. The above circumstances could have an adverse effect on our business or results of operations.

***We may fail to adhere to regulations of promotional claims and activities regarding our products and solutions.***

Once a patient has been identified and diagnosed through our diagnostics testing, we provide each patient's physician with a diagnostic report. If a positive diagnosis is confirmed, we provide the physician with information on relevant treatment options, although the physician is responsible for ultimately making clinically relevant decisions for the treatment of his or her patient.

In the United States, the FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drugs and devices. In particular, a device may not be

promoted for uses or indications beyond those contained in the device's approved labeling, or "off-label" uses. If the FDA determines that we have promoted our products for off-label use, it could request that we modify those promotional materials or take regulatory or enforcement actions, including the issuance of an untitled letter, warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities may take action if they consider our promotional or training materials to constitute promotion of an unapproved use. If not successfully defended, enforcement actions related to off-label promotion could result in significant fines or penalties. The U.S. government has levied large civil and criminal fines against companies for alleged improper promotion and has entered into corporate integrity agreements and deferred prosecution agreements with companies that engaged in off-label promotion. The FDA has also requested that such companies enter into consent decrees and has taken other enforcement action. If the DOJ or FDA determines that we have engaged in off-label promotion in our test reports, we may be subject to civil or criminal fines. Although our policy is to refrain from statements that could be considered off-label promotion of third parties, the regulatory standards regarding off-label promotion are ambiguous, and the FDA or another regulatory agency could conclude that we have engaged in off-label promotion.

In addition to promoting our devices in a manner consistent with their approved indications, we must have adequate substantiation for the claims we make for our products or solutions. If any of our claims are determined to be false, misleading or deceptive, our products or solutions could be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act (the "FDC Act") or to violate the Federal Trade Commission Act. We could also face lawsuits from our competitors under the Lanham Act, alleging that our marketing materials are false or misleading. Such lawsuits, whether with or without merit, are typically time-consuming, costly to defend, and could harm our reputation.

Federal and state legislation regulate interactions between medical device manufacturers and healthcare professionals. We are subject to federal and state laws targeting fraud and abuse in healthcare, including anti-kickback laws, false claims laws, and other laws constraining or otherwise related to financial arrangements manufacturers may enter into with healthcare professionals. For example, the Physician Payments Sunshine Act requires device manufacturers to report and disclose payments or other transfers of value made to physicians and teaching hospitals. Violations of these laws can result in criminal or civil sanctions, including fines, imprisonment, and exclusion from government reimbursement programs, all of which could materially harm our business.

In addition, incentives exist under applicable laws that encourage competitors, employees, and physicians to report violations of law governing promotional activities for pharmaceutical products and solutions. These incentives could lead to so-called whistleblower lawsuits as part of which such persons seek to collect a portion of monies allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products and solutions beyond labeled claims. These incentives could also lead to lawsuits that claim we have mischaracterized a competitor's service in the marketplace and, as a result, we could be sued for alleged damages to our competitors. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such lawsuits may also result in related shareholder lawsuits, which may also be costly to defend.

***Changes in the way that the FDA and the European Union regulate laboratory developed tests, manufactured, validated, and performed by laboratories like ours could result in additional expense in offering our current and any future products and solutions or even possibly delay or suspend development, manufacture, or commercialization of such products and solutions.***

The FDA does not currently regulate most laboratory developed tests ("LDTs"). We believe that the tests we currently offer meet the definition of LDTs, as they have been designed, developed and validated for use in a single CLIA-certified laboratory. If our tests are qualified as LDTs, they are currently not subject to FDA regulation as medical devices. Since the early 1990s, the FDA has taken the position that, although LDTs are medical devices, it would exercise enforcement discretion by not requiring compliance with the FDC Act, or its regulations for LDTs. That remains the guidance of the FDA today. However, the FDA has taken certain actions in the past that, if renewed by the FDA, could result in a new regulatory approach for LDTs. In October 2014, the FDA published two draft guidance documents that, if finalized, would implement a regulatory approach for most LDTs. The draft guidance documents proposed to impose a risk-based, phased-in approach for LDTs similar to the existing framework for in vitro diagnostic devices. In January 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining an updated possible approach to regulation of LDTs. Although the discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents, it proposes a risk-based framework that would require most LDTs to comply with most of the FDA's regulatory requirements for medical devices. In March 2017, a discussion draft of the Diagnostic Accuracy and Innovation Act ("DAIA") was circulated, which, if enacted, would implement a regulatory scheme for all diagnostic tests, including both in vitro diagnostic devices and LDTs. Under DAIA, CMS would have jurisdiction over laboratory operations under an amended CLIA, and the FDA would regulate the design, development and validation of diagnostic tests under an amended FDC Act. We cannot predict whether this bill or any other any other legislative proposal will be enacted into law or the impact such new legal requirements would have on our business. We also cannot predict whether the FDA will take action to regulate LDTs or what approach the FDA will seek to take.

In addition, in November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational use only. Among other things, the guidance states that the FDA continues to be concerned about distribution of research- or investigational-use only products intended for clinical diagnostic use. The guidance states that the FDA will assess whether a manufacturer of such research- or investigational-use only products intends that its products be used for clinical diagnostic purposes by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support such as assistance performing clinical validation, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research- or investigational-use only, the device could be deemed misbranded and adulterated within the meaning of the FDC Act. If the FDA were to undertake enforcement actions, some of our suppliers may cease selling research-use only ("RUO") products to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

In the European Union LDTs are similarly exempt from the regulations that govern medical devices and in-vitro diagnostics ("IVDs") under certain conditions. The European Union and German legislation on in-vitro diagnostic medical devices ("IVD-MDD") applies. According to the recitals of the Council Directive 98/79/EC on IVD-MDD, reagents which are produced within "health-institution laboratories" for use in that environment and which are not subject to commercial transactions are not covered by the Directive. However, the legal framework for applying the exemption clauses for

LDTs is not entirely clear as the IVD-MDD lacks an explicit definition and there is no related case law. On May 25, 2022, when the new Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in-vitro diagnostic medical devices (IVD-MDR) comes into force, diagnostic tests manufactured "on an industrial scale" will thereafter qualify as IVDs and will need a conformity assessment. If we were not able to qualify for an exemption, we would be subject to regulation in the European Union. We also cannot predict whether the EU will amend or implement new laws which may impact our current operations.

***For tests that are subject to FDA or EU regulation, we may not be able to obtain timely approvals for our tests or for modifications to our tests, which could delay or prevent us from commercializing our tests and harm our business.***

The diagnostic tests we currently offer might meet the definition of LDTs, as they have been designed, developed and validated for use in a single CLIA-certified laboratory. If our tests are LDTs, they are currently not subject to FDA or EU regulation as an in-vitro-diagnostic. In May 2022 when the new IVD Regulation 2017/746/EU comes into force in the European Union, a qualification of our diagnostic tests as IVD-MDs becomes more likely as the manufacture of diagnostic tests "on an industrial scale" will not qualify as LDTs. If the FDA or EU takes action to finalize and implement a regulatory system for LDTs, or if legislation is enacted that subjects LDTs to FDA regulation, we would need to comply with the FDA regulatory requirements for our LDTs. If the FDA takes action to regulate LDTs as devices, we believe that our LDTs would likely be regulated as Class II devices.

If services that are currently marketed as LDTs become subject to FDA requirements for in-vitro-diagnostics or are qualified as being subject to the European Union regulations on in vitro diagnostic medical devices, including requirements for premarket clearance or approval, we may not be able to obtain such clearance or approvals on a timely basis, or at all. Our business could be negatively impacted if we are required to stop selling genetic rare disease knowledge and interpretation-based products and solutions pending their clearance or approval, or the launch of any new products and solutions that we develop could be delayed. Likewise, for tests that are regulated as medical devices, we may not be able to obtain clearance or approval of new devices or modifications to marketed devices on a timely basis, or at all, which could delay or prevent us from commercializing our tests and harm our business.

Class II medical devices must obtain FDA clearance of a premarket notification, or 510(k), prior to marketing, unless the FDA has exempted the device from this requirement. Under the 510(k) process, we must demonstrate that our test is substantially equivalent in technological characteristics and intended use to a legally marketed predicate device. The FDA's review and clearance of a 510(k) usually takes from four to twelve months, but it can take longer. Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or, if the modified device is not substantially equivalent, possibly a de novo classification request or a premarket approval application ("PMA").

If we are unable to identify an appropriate predicate that is substantially equivalent to our device, we would be required to submit a PMA application or a de novo reclassification request, because devices that have not been classified are automatically categorized as Class III. Under the de novo process, we may request that the FDA classify a new low or moderate risk device that lacks an appropriate predicate as a Class I or Class II device. The de novo process typically requires the development of clinical data and usually takes between six to twelve months from the time of submission of the de novo application, but it can take longer.

***For tests that are subject to FDA or EU regulation, if we do not comply with FDA or EMA regulatory requirements, we may be subject to enforcement action, with severe consequences for our business.***

After approval, devices subject to FDA or EMA regulation are required to comply with post-market requirements. Among the requirements, we and our suppliers must comply with the FDA's Quality System Regulations ("QSRs"), which set forth requirements for the design and manufacture of devices, including the methods and documentation for the design, control testing, quality assurance, labeling, packaging, storage, and shipping of our devices. Our limited experience in complying with these requirements may lead to operational challenges as we increase the scale of our QSR-compliant operations in the United States and develop and refine our policies and procedures for evaluating and mitigating issues we encounter with our processes. Further, if there are any modifications made to the manufacturing of our PMA-approved marketed solutions, a PMA supplement may be required to be submitted to, and approved by, the FDA before the modified device may be marketed.

Other post-market requirements include the reporting of adverse events and malfunctions of which we become aware within the prescribed time frame to the FDA, post-approval studies, establishment registration and device listing, and restrictions on advertising and promotion. We may fail to meet these requirements, which could subject our business to further regulatory risks and costs.

The FDA enforces the post-market requirements of the FDC Act through announced and unannounced inspections. Failure to comply with applicable regulatory requirements could require us to expend time and resources to respond to the FDA's observations and to implement corrective and preventive actions, as appropriate. If we cannot resolve such issues to the satisfaction of the FDA, we may be subject to enforcement actions, including untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future solutions, operating restrictions, a partial suspension, or a total shutdown of service. Any such enforcement action would have a material adverse effect on our business, financial condition, and results of operations.

***In the future, we may fail to achieve coverage or adequate reimbursement for our products and solutions by commercial third-party payors or government payors.***

As we expand our operations globally, and in particular to the United States, sales of our existing and any future products and solutions we develop, in particular our diagnostic testing services, in the future may depend upon the availability of adequate reimbursement from third-party payors. These third-party payors include government healthcare programs and/or statutory health insurance schemes in various markets, such as Medicare and Medicaid in the United States and statutory health funds in Germany (the "GKV"), managed care providers, accountable care organizations, private health insurers, and other organizations. We believe that obtaining a positive Medicare Local Coverage Determination, or National Coverage Determination and a favorable Medicare reimbursement rate, and obtaining the agreement of established commercial third-party payors to provide coverage and adequate payment, for each of our existing diagnostic testing services, and any future products and solutions we develop, will be an important element in achieving material commercial success in the United States. Physicians may not order our products and solutions unless commercial third-party payors and government payors authorize coverage and pay for all, or a substantial portion, of the rates established for our products and solutions.

Commercial third-party payors and government payors internationally increasingly attempt to contain healthcare costs by lowering reimbursement rates, limiting coverage of diagnostic test

services, and creating conditions of reimbursement, such as requiring participation in clinical evidence development involving research studies and the collection of physician decision impact and patient outcomes data. As a result of these cost-containment trends, commercial third-party payors and government payors that currently provide, or in the future may provide, reimbursement for one or more of our services may propose and/or actually reduce, suspend, revoke, or discontinue payments or coverage at any time. Payors may also create conditions for coverage or may contract with third-party vendors to manage laboratory benefits, in both cases creating administrative hurdles for ordering physicians and patients that may make our products and solutions more difficult to sell. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims is likely to vary from period to period.

There is significant uncertainty surrounding whether the use of diagnostic tests that incorporate new technology will be eligible for coverage by commercial third-party payors and government payors or, if eligible for coverage, what the reimbursement rates will be for these services. In Germany, the majority of patients are insured via the GKV. The benefit catalogue defining which services in medical care are reimbursed by the GKV is specified by the directives of the Federal Joint Committee as the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. The fact that a diagnostic test has been approved for reimbursement in the past, has received approval from the FDA or EMA, or has obtained coverage for any particular rare disease indication or in any particular jurisdiction, does not guarantee that such diagnostic service will remain covered and/or reimbursed or that similar or additional diagnostic tests and/or related rare disease types will be covered and/or reimbursed in the future.

As a result, if adequate third-party coverage and reimbursement are unavailable, we may not be able to maintain volume and price levels sufficient to realize an appropriate return on investment in our diagnostic testing services or to advance our research and development solutions for our pharmaceutical partners.

We cannot predict what future healthcare initiatives will be introduced or implemented in the jurisdictions in which we operate, or how any future legislation or regulation may affect us. Any taxes imposed by legislation, as well as changes to the reimbursement amounts paid by payors for our existing and future products and solutions, could have a material adverse effect on our business, financial condition and results of operations.

### **Intellectual Property Risks Related to Our Business**

***If we are unable to obtain and maintain patent and other intellectual property protection for any products or solutions we develop and for our technology, or if the scope of intellectual property protection obtained is not sufficient, our competitors could develop and commercialize products and solutions similar or identical to ours, and our ability to successfully commercialize any products or solutions we may develop may be adversely affected.***

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries for our biomarkers and other products and solutions. Patent law relating to the scope of claims in the fields in which we operate is complex and uncertain, so we cannot make any assurances that we will be able to obtain or maintain patent or other intellectual property rights, or that the patent and other intellectual property rights we may obtain will be valuable, provide an effective barrier to competitors or otherwise provide competitive advantages. In particular, our Lyso-Gb3 biomarker, which we use to support the

diagnosis of Fabry disease, is not protected by any patents or included in any pending patent applications, and its successful commercialization by one of our competitors or by other third parties could materially harm our business or results of operations. If we are unable to obtain or maintain patent or other intellectual property protection with respect to our proprietary products and solutions, our business, financial condition, results of operations, and prospects could be materially harmed.

The scope of patent protection outside of the United States is uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The patent position of companies in our industry generally is unsettled, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our products or solutions or which effectively prevent others from commercializing competitive products and solutions.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold may be challenged, narrowed, circumvented, or invalidated by third parties. In particular, for more information regarding U.S. patent law decisions that negatively impact the patentability of biomarkers, diagnostic products and diagnostic methods, and the validity of granted U.S. patents covering such subject matter, see "—Developments in patent law could have a negative impact on our business" below. Consequently, we do not know whether any of our biomarkers or other products and solutions will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products and solutions in a non-infringing manner. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.



***If we are unable to protect the confidentiality of our trade secrets, know-how, and other confidential and proprietary information, our business and competitive position would be harmed.***

In addition to seeking patent protection for our products and solutions, we also rely upon trade secret protection and non-disclosure agreements and invention assignment agreements with our employees, consultants and other third parties to protect our unpatented know-how, technology, and other confidential or proprietary information. For example, significant elements of our proprietary platform and some of our tests, including aspects of sample preparation, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets and know-how that are not publicly disclosed. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not provide adequate protection for our proprietary information; for example, in the case of misappropriation of intellectual rights by an employee, consultant, or other third party with authorized access.

Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable non-disclosure agreements and invention assignment agreements with our employees, consultants and other third parties who have had access to our trade secrets or other proprietary information. Our security and contractual measures may not prevent an employee, consultant, or other third party from misappropriating our trade secrets and providing them to a competitor, and any recourse we take against such misconduct, including litigation, may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated intellectual property can be difficult, expensive, and time-consuming, and the outcome is unpredictable. Due to variation in the degree of protection afforded to intellectual property of this nature under the laws and regulations applicable to different international markets where our services are sold, our ability to pursue and obtain an adequate remedy may depend significantly on the jurisdiction in which the misconduct takes place and our ability to enforce a favorable judgment against the offending party in a jurisdiction in which such party has substantial assets. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our competitive position could be harmed.

***Patents covering our products or solutions could be found invalid or unenforceable if challenged.***

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Others have filed, and in the future are likely to file, patent applications that are similar or identical to ours. To determine the priority of inventions, demonstrate that we did not derive our invention from another individual or entity, or defend third-party challenges to the validity or enforceability of our patent rights, we may have to participate in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings at the U.S. Patent and Trademark Office (the "USPTO") or similar offices in Europe or other jurisdictions. For example, we are aware of an opposition proceeding filed in the European Patent Office ("EPO") by Sanofi against EP Patent No. 2 718 725 B1 (the "'725 Patent"), a European patent that we own relating to our biomarker for Gaucher disease. The EPO opposition proceeding challenges the patentability of the '725 Patent in its entirety. We cannot predict the outcome of the opposition proceeding and any party may appeal the opposition decision to the Boards of Appeal at the EPO. If we are unsuccessful in defending this opposition, the '725 Patent may be revoked or maintained in amended form, in whole or in part, which could limit our ability to stop others from using or



commercializing similar or identical products and solutions to ours, or limit the duration of the patent protection of our products and solutions. For more information regarding this proceeding, see "Business—Legal Proceedings." Sanofi or other third parties may file future oppositions or other challenges, in Europe or other jurisdictions, against other patents that we own. An adverse determination in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our products or solutions and compete directly with us, without payment to us, or result in our inability to commercialize our products or solutions without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity, or in patents being cancelled, narrowed, amended, invalidated, revoked or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and solutions, or limit the duration of the patent protection of our products and solutions. Such proceedings could also result in substantial costs in legal fees and require significant time from our management and employees, even if the eventual outcome is favorable to us. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our products or solutions, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. Such challenges could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer sufficiently cover our products and solutions. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or solutions. Such a loss of patent protection would materially harm our business, prospects, financial condition and results of operations.

***Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products and solutions or impact our share price.***

Our commercial success depends upon our ability to develop and commercialize products and solutions and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. We could become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any products or solutions we may develop, including interference proceedings, post-grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions, such as oppositions before the EPO. Third parties may assert infringement and other claims against us based on existing patents or patents that may be granted in the future, regardless of their merit, and we may assert infringement and other claims

against third parties. As we continue to commercialize our genetic rare disease information solutions (including our biomarkers), launch new solutions and enter new markets, we expect that competitors will claim that our products or solutions infringe or otherwise violate their intellectual property rights, including as part of business strategies designed to impede our successful commercialization and entry into new markets. Third parties may have obtained, and may in the future obtain, patents under which such third parties may claim that the use of our technologies constitutes patent infringement. Third parties have in the past asserted and may in the future assert that we are employing their proprietary technology without authorization, and we occasionally receive letters from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Depending upon the circumstances, we may elect to remove a particular biomarker from one of our products or solutions.

Even if we believe that third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products or solutions we may develop. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one, requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue commercializing our products or solutions. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing, royalty and other payments. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize, and sell our products and solutions, and could result in the award of substantial damages against us. In the event of a successful claim of infringement, misappropriation or other intellectual property violation against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from developing, commercializing and selling certain products or solutions. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. We also could incur substantial costs and divert the attention of our management and other employees in participating in litigation or proceedings of this nature, and an adverse ruling or perception of an adverse ruling in

could have a material adverse impact on our cash position and share price. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees and various other governmental fees associated with patents and patent applications due in several stages over the lifetime of patents and patent applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forego patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. In such an event, potential competitors might be able to enter the market with similar or identical products and solutions. If we fail to obtain, maintain, protect or enforce our intellectual property rights successfully, our competitive position could suffer. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

***Our rights to develop and commercialize our technology, products and solutions may in the future be subject, in part, to the terms and conditions of licenses granted to us by others.***

In connection with the development of new products and solutions we may license intellectual property from third parties in the future, or may deem it necessary to do so in order to commercialize our products or solutions. We may be unable to obtain these licenses at a reasonable cost, or at all. We could, therefore, incur substantial costs related to royalty payments or other payments for licenses obtained from third parties. We may also be unable to obtain exclusive rights to use such intellectual property or technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our products and solutions in the future and, as a result, we may not be able to prevent competitors from developing and commercializing competitive products or solutions. Moreover, we could encounter delays in introducing new products or solutions while we attempt to develop alternative products and solutions, and the defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing our products and solutions, which would materially affect our ability to grow.

Our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and solutions covered by such agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors might have the freedom to market competing products and solutions identical or similar to ours. Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- § the scope of rights granted under the license agreement and other interpretation-related issues;
- § the extent to which our products and solutions infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- § the sublicensing of patent and other rights under our collaborative development relationships;

- § our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- § the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- § the priority of invention of patented technology.

In addition, agreements under which we license intellectual property or technology from third parties could be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Moreover, if disputes over intellectual property or technology that we have licensed prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, defending our position could materially harm our business, prospects, financial condition and results of operations.

***Developments in patent law could have a negative impact on our business.***

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. From time to time, the United States Supreme Court (the "Supreme Court"), other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and any such changes could have a negative impact on our business. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act"), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in our industry are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. For example, diagnostic method claims and "gene patents" were considered in two landmark Supreme Court cases, *Mayo Collaborative v. Prometheus Laboratories* ("Prometheus"), and *Association for Molecular Pathology v. Myriad Genetics* ("Myriad"). In Prometheus, a case involving patent claims over a medical testing method directed to optimizing the amount of drug administered to a specific patient, Prometheus' claims failed to incorporate sufficient inventive content above and beyond merely describing underlying natural correlations to allow the claimed processes to qualify as patent-eligible processes that apply natural laws. In Myriad, a case brought by multiple plaintiffs challenging the validity of patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2, the court held that isolated genomic DNA that exists in nature, such as

the DNA constituting the BRCA1 and BRCA2 genes, is not patentable subject matter, but that cDNA, which is an artificial construct created from RNA transcripts of genes, may be patent eligible. The Federal Circuit has begun to apply the holdings in *Prometheus* and *Myriad*. In 2015, the Federal Circuit, in *Ariosa v. Sequenom*, applying *Prometheus*, found claims to a prenatal diagnostic method that relied on a natural product to be patent ineligible, and clarified that the absence of preemption of a natural phenomenon was not sufficient to demonstrate patent eligibility.

In response to the Supreme Court decisions in *Prometheus*, *Myriad*, and *Alice Corporation Pty. Ltd. v. CLS Bank International* ("Alice Corp."), and others, the USPTO has updated the Manual of Patent Examination Procedure to provide guidance to USPTO personnel in determining the eligibility of patent claims reciting judicially recognized exceptions to patentable subject matter, including laws of nature, natural phenomena, or abstract ideas, for patent eligibility. The USPTO guidance indicates that claims reciting a judicial exception to patent-eligible subject matter must amount to significantly more than the judicial exception itself in order to be patent-eligible subject matter. We cannot assure you that our efforts to seek patent protection for our products and solutions will not be negatively impacted by this interim guidance issued by the USPTO, the decisions described above, rulings in other cases, or changes in guidance or procedures issued by the USPTO.

We cannot fully predict what impact the Supreme Court's decisions in *Prometheus*, *Myriad*, *Alice Corp.*, and other decisions may have on our ability or the ability of companies or other entities to obtain or enforce patents relating to DNA, genes, or genomic-related discoveries in the future. Despite the USPTO's interim guidance and Federal Circuit cases described above, the contours of when claims reciting laws of nature, natural phenomena, or abstract ideas may meet the patent eligibility requirements are not clear and may take years to develop via interpretation at the USPTO and in the courts. There are many previously issued patents claiming nucleic acids and diagnostic methods based on natural correlations that issued before the recent Supreme Court decisions discussed, and although many of these patents may be invalid under the standards set forth in the Supreme Court's recent decisions, until successfully challenged, these patents are presumed valid and enforceable, and certain third parties could allege that we infringe, or request that we obtain a license to, these patents. Whether based on patents issued prior to or after these Supreme Court decisions, we might have to defend ourselves against claims of patent infringement, or choose to license rights, if available, under patents claiming such methods. In particular, although the Supreme Court has held in *Myriad* that isolated genomic DNA is not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other classes of gene-related patent claims, and we could have to defend ourselves against these claims by asserting non-infringement and/or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter in question if we are unable to obtain a license on reasonable terms or at all. Such outcomes could materially affect our ability to offer our products and solutions and have a material adverse impact on our business. Even if we are able to obtain a license or successfully defend against claims of patent infringement, the cost and distraction associated with the defense or settlement of these claims could have a material adverse impact on our business. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

***We may not be able to enforce our intellectual property rights throughout the world.***

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. Accordingly, we may face an increased risk in these

jurisdictions that unauthorized parties may attempt to copy or otherwise obtain or use our patented technology, trademarks, formulations or other intellectual property. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of Germany or the United States. Specifically, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents or other intellectual property rights and to prevent third parties from selling or importing products made using our inventions in and to the United States, Germany or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent or other protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in Germany or the United States. These products may compete with our products and solutions, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Additionally, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties or limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Monitoring infringement and misappropriation of intellectual property can be difficult and expensive, and we may not be able to detect every instance of infringement or misappropriation of our proprietary rights. Even if we do detect infringement or misappropriation of our proprietary rights, proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs, divert the efforts and attention of our employees and management from other aspects of our business, put our patents at risk of being invalidated or construed narrowly or provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop. In addition, changes in the law and legal decisions by courts in Germany, the United States and other jurisdictions may affect our ability to obtain adequate protection for our products and solutions and to enforce our intellectual property rights. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

***Third parties may assert ownership or commercial rights to inventions we develop.***

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. For example, we rely on certain third parties to provide us with tissue samples and biological materials that we use to conduct our genomic analyses. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims that our agreements with employees, contractors, or consultants obligating them to

assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

***Most of our employees and inventions are subject to German law.***

Most of our personnel, including our directors, work in Germany and are subject to German employment law. Inventions which may be the subject of a patent or of protection as a utility model are subject to the provisions of the German Act on Employees' Inventions (*Gesetz über Arbeitnehmererfindungen*) (the "German Inventions Act"), which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes may occur between us and our current or past employees pertaining to the sufficiency of compensation paid by us, allocation of rights to inventions under this act or alleged non-adherence to the provisions of this act, any of which may be costly to resolve and take up our management's time and efforts whether we prevail or fail in such dispute. In addition, under the German Inventions Act, certain employees retain rights to patents they invented or co-invented and disclosed to us prior to October 1, 2009. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents, such co-owners may be able to license their rights to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners to enforce any such patents against third parties, and such cooperation may not be provided to us. While we believe that all of our other current and past German employee inventors have subsequently assigned to us their interest in inventions they invented or co-invented, there can be no assurance that all such assignments are fully effective and we may be required under German law to compensate such employees for the use of the inventions and intellectual property rights related thereto. If we are required to pay compensation or face other disputes under the German Inventions Act, our results of operations could be adversely affected.

If any of our current or past employees obtain or retain ownership of any inventions or related intellectual property rights that we believe we own, we may lose valuable intellectual property rights and be required to obtain and maintain licenses from such employees to such inventions or intellectual property rights, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain a license to any such employee's interest in such inventions or intellectual property rights, we may need to cease the development, manufacture, and commercialization of one or more of the products and solutions we may develop. In addition, any loss of exclusivity of our intellectual property rights could limit our ability to stop others from using or commercializing similar or identical products and solutions. Any of the foregoing events could materially harm our business, prospects, financial condition and results of operations.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

Many of our employees and consultants are currently or were previously employed at universities or other diagnostic or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a current or former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.



In addition, while it is our policy to require our employees and consultants who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could materially harm our business, prospects, financial condition and results of operations.

***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- § others may be able to make products or solutions that are similar to any products or solutions we develop or commercialize or utilize similar technology but that are not covered by the claims of our patents or patents that we might own or license in the future;
- § we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may own or license in the future;
- § we might not have been the first to file patent applications covering certain of our inventions;
- § others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- § it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- § our issued patents may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- § our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products or solutions for sale in our major commercial markets;
- § we may not develop additional proprietary technologies that are patentable;
- § the patents of others may harm our business; and
- § we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could materially harm our business, prospects, financial condition and results of operations.

**Risks Relating to Our Financial Condition and Capital Requirements**

***We have a history of losses and we may incur losses in the future.***

We have historically incurred losses, including total comprehensive losses of €11,346 thousand in 2018, €5,466 thousand in 2017 and €5,350 thousand in 2016. We expect our losses to continue as a result of ongoing research and development expenses and increased selling and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and shareholders' equity. Because of the numerous risks and uncertainties associated with our research, development, and efforts to commercialize our solutions, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.



***Covenant restrictions under debt agreements limit our ability to operate our business.***

Our debt agreements contain covenants that restrict our ability to, among other things, use the funds for specified purposes, incur additional indebtedness, pay dividends or engage in certain business activities. In particular, our syndicated loan facility stipulates that Prof. Arndt Rolfs must remain our major shareholder and our CEO until May 31, 2019. In addition, our secured loan facilities and municipal loans require us to maintain specified financial ratios and tests, which may require that we or they take action to reduce debt or to act in a manner contrary to our business objectives. Events beyond our control, including changes in general business and economic conditions, may affect our ability to meet those financial ratios and tests. We may not meet those ratios and tests, and our lenders may not waive any failure to meet those ratios and tests.

A breach of any of these covenants or restrictions, or failure to maintain these ratios, would result in an event of default under the relevant debt facility, and any such event of default or resulting acceleration under such debt facility could negatively affect our financial condition or result in an event of default under other debt agreements. If we are not able to repay the loans, this may lead to the commencement of foreclosure or other enforcement actions against any of our assets securing such debt. Even if the bank would waive a covenant breach, we may be subject to an increase of interest rates or margins, respectively, as well as the payment of a waiver fine. Furthermore, the covenants as well as the breach of the covenants may impose restrictions on the way we can operate and may limit our ability to finance our future operations and capital needs and our ability to pursue business activities that may be in our interests.

***We have failed to meet certain covenants under our syndicated loan facility, which limits our liquidity and could result in the lenders accelerating amounts we owe to them under the facility.***

At December 31, 2018, we had €15,757 thousand of loans outstanding under our syndicated loan facility including bank overdrafts of €1,915 thousand. We did not satisfy certain financial covenants under this facility during the years ended December 31, 2016, December 31, 2017 and December 31, 2018. To respond to and resolve our covenant non-compliance, as discussed under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments," we obtained waivers from the various lenders under this facility for the years ended December 31, 2016 and December 31, 2017. The waivers impose various conditions on us, including an increase in the applicable interest rate for tranches A2, B, C and D and payment of certain waiver fees. On April 6, 2018, the net-debt ratio financial covenant requirement was again waived for the period from December 31, 2017 to December 31, 2018, with an incremental increase in the applicable interest rate for tranches A2, B, C and D.

We are otherwise in compliance with the syndicated loan facility as of the date of this prospectus and we have obtained a further waiver of certain covenants of the facility for the year ending December 31, 2019. This waiver applies to (i) the financial covenants of the facility and (ii) a covenant that requires our CEO, Prof. Arndt Rolfs, to remain the principal shareholder of Centogene AG, which we expect to no longer be in compliance with following this offering. However, we may not be able to secure a waiver or amendment for any future period we may not be able to otherwise refinance our debt going forward on terms acceptable to us, or at all. As a result, we may not be able to meet our obligations under the syndicated loan facility and the lenders would have the right to further raise the applicable interest rates or to cause the amounts outstanding under the facility to become due and payable by terminating the agreement. If we were unable to pay such amounts, the lenders could recover amounts owed to them by foreclosing against the collateral pledged to them, which would have a material adverse effect on our financial position. The syndicated loan facility is secured by a land charge in the amount of €19,910 thousand, a cash

pledge in the amount of €1,500 thousand and assignments of certain laboratory equipment and trade and other receivables.

***We may need to raise additional capital to fund our existing operations, develop our genetic information platform, commercialize new products and solutions and expand our operations.***

If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products or solutions as a result of other risks described herein, we may seek to sell common or preferred equity or convertible debt securities, enter into another credit facility or another form of third-party funding, or seek other debt financing.

Our ongoing efforts to expand our business will require substantial cash resources. We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to:

- § increase our sales and marketing efforts to drive market adoption of our products and solutions and address competitive developments;
- § fund development and marketing efforts of any future products and solutions;
- § further expand our laboratory operations;
- § expand our technologies into other types of diseases;
- § obtain, maintain, protect and enforce existing or new intellectual property rights;
- § acquire, license or invest in technologies, including information technologies;
- § acquire or invest in complementary businesses or assets; and
- § finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- § our ability to achieve revenue growth;
- § the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- § our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products and solutions;
- § our rate of progress in, and cost of research and development activities associated with, products and solutions in research and early development;
- § the effect of competing technological and market developments;
- § costs related to international expansion; and
- § the potential cost of and delays in research and development as a result of any regulatory oversight applicable to our products and solutions.

If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common shares. The terms of debt securities issued or borrowings pursuant to a credit or similar agreement could impose significant restrictions on our operations. Such financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends. If additional funds are raised by issuing equity securities, existing shareholders may suffer significant dilution. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or solutions, or grant licenses on terms that are not favorable to us.

Additional equity or debt financing might not be available on reasonable terms or at all. Because of our potential long-term capital requirements, we may access the public or private equity or debt markets whenever conditions are favorable, even if we do not have an immediate need for additional

capital at that time. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us. Lastly, if we are unable to obtain the requisite amount of financing needed to fund our planned operations, it could have a material adverse effect on our business and financial position.

***We may be required to refund grants and subsidies.***

We have received various grants and subsidies to fund our research and development programs from various funding organizations. However, the Company continues to engage in efforts to secure further grants and subsidies for the next development steps of its product candidates. In the year ended December 31, 2018, we have received a total of €3,042 thousand in grants for our activities. Some of these grants and subsidies provide for certain requirements in respect of the utilization of proceeds generated as a result of the publicly sponsored projects. For example, we received grants from the European Regional Development Fund in order to fund our Rostock facility, which grants are limited in purpose to development and innovation in the state of Mecklenburg-Western Pomerania, Germany. Other grants which we obtain may impose restrictions on our operations, and if we are in noncompliance with the restrictions and conditions of any grant or subsidy program, a partly or complete repayment cannot be excluded. This may also apply to grants and subsidies we may apply for in the future. If we are required to refund grants or subsidies, this could have a material adverse effect on our liquidity and cash flow position and may negatively affect our business, prospects and financial conditions.

***We will incur significant costs as a result of operating as a public company and our management will need to devote substantial time to public company compliance programs.***

As a public company, we incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and the Nasdaq Global Market ("Nasdaq"). The SEC and other regulatory authorities have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance- and executive compensation-related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, and the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations, and as a result of the new corporate governance- and executive compensation-related rules, regulations, and guidelines prompted by the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

To comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to

be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in the periodic reports we file with the SEC under Section 404 of the Sarbanes-Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common shares could decline.

We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting. This assessment needs to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting or if we are unable to complete our evaluation, testing, and any required remediation in a timely fashion, we will be unable to assert that our internal control over financial reporting is effective.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company" as defined in the JOBS Act. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on the price of our common shares.

***Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.***

To the extent that we choose or need to raise additional capital through the sale of common shares or securities convertible or exchangeable into common shares, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common shareholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or drug candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when

needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

***Our results of operations could be materially adversely affected by fluctuations in foreign currency exchange rates.***

Although we report our results of operations in euro, not all of our net revenues are denominated in the euro. Unfavorable fluctuations in foreign currency exchange rates could have a material adverse effect on our results of operations.

Because our consolidated financial statements are presented in euro, we must translate revenues, expenses and income, as well as assets and liabilities, into euros at exchange rates in effect during or at the end of each reporting period. Therefore, changes in the value of the euro against other currencies will affect our net revenues, operating income and the value of balance-sheet items originally denominated in other currencies. These changes cause our growth in consolidated earnings stated in euro to be higher or lower than our growth in local currency when compared against other periods.

As we continue to leverage our global delivery model, more of our expenses are incurred in currencies other than those in which we bill for the related services. An increase in the value of certain currencies against the euro could increase costs for delivery of services at off-shore sites by increasing labor and other costs that are denominated in local currency. There can be no assurance that our contractual provisions will offset their impact, or that our currency hedging activities, which are designed to partially offset this impact, will be successful. In addition, our currency hedging activities are themselves subject to risk. These include risks related to counterparty performance under hedging contracts and risks related to currency fluctuations. We also face risks that extreme economic conditions, political instability or hostilities or disasters of the type described below could impact our underlying exposures, perhaps eliminating them. Such an event could lead to losses being recognized on the currency hedges then in place, not offset by anticipated changes in the underlying hedge exposure.

**Certain Factors Relating to Our Common Shares and the Offering**

***There is no existing market for our common shares, and we do not know whether one will develop to provide you with adequate liquidity. If our share price fluctuates after this offering, you could lose a significant part of your investment.***

Prior to this offering, there has not been a public market for our common shares. If an active trading market does not develop, you may have difficulty selling any of our common shares that you buy. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on Nasdaq, or otherwise or how liquid that market might become. The initial public offering price for the common shares will be determined by negotiations between us and the underwriters and may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell our common shares at prices equal to or greater than the price paid by you in this offering. In addition to the risks described above, the market price of our common shares may be influenced by many factors, some of which are beyond our control, including:

- § the failure of financial analysts to cover our common shares after this offering or changes in financial estimates by analysts;
- § actual or anticipated variations in our operating results;

- § changes in financial estimates by financial analysts, or any failure by us to meet or exceed any of these estimates, or changes in the recommendations of any financial analysts that elect to follow our common shares or the shares of our competitors;
- § announcements by us or our competitors of significant contracts or acquisitions;
- § future sales of our shares; and
- § investor perceptions of us and the industries in which we operate.

In addition, the stock market in general has experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors may materially harm the market price of our common shares, regardless of our operating performance. In the past, following periods of volatility in the market price of certain companies' securities, securities class action litigation has been instituted against these companies. This litigation, if instituted against us, could adversely affect our financial condition or results of operations.

***Sales of substantial amounts of our common shares in the public market, or the perception that these sales may occur, could cause the market price of our common shares to decline.***

Sales of substantial amounts of our common shares in the public market, or the perception that these sales may occur, could cause the market price of our common shares to decline. This could also impair our ability to raise additional capital through the sale of our equity securities. Under our articles of association as they will read upon the closing of this offering, we are authorized to issue up to \_\_\_\_\_ common shares, of which \_\_\_\_\_ common shares will be outstanding following this offering. We, our management board members, supervisory board members and certain of our shareholders have agreed with the underwriters, subject to certain exceptions, not to offer, sell, or dispose of any shares of our share capital or securities convertible into or exchangeable or exercisable for any shares of our share capital during the 180-day period following the date of this prospectus. See "Underwriting." If, after the end of such lock-up agreements, these shareholders sell substantial amounts of common shares in the public market, or the market perceives that such sales may occur, the market price of our common shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected. We also intend to enter into a registration rights agreement upon consummation of this offering pursuant to which we will agree under certain circumstances to file a registration statement to register the resale of the common shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such common shares. In addition, upon consummation of this offering, we intend to cease any new grants under our existing equity incentive plans and to adopt a new omnibus equity incentive plan under which we would have the discretion to grant a broad range of equity-based awards to eligible participants. We intend to register all common shares that we may issue under this equity compensation plan. Once we register these common shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. If a large number of our common shares or securities convertible into our common shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common shares and impede our ability to raise future capital. We cannot predict the size of future issuances of our shares or the effect, if any, that future sales and issuances of shares would have on the market price of our common shares.

***We have broad discretion in the use of the net proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return on your investment.***

Although we currently intend to use the net proceeds from this offering in the manner described in the section titled "Use of proceeds" in this prospectus, our management will have broad discretion

in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common shares. For example, we intend to use the net proceeds from this offering for research and development in our pharmaceutical segment and for the development of our knowledge-driven information platform, as well as for working capital and other general corporate purposes. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering. The failure by our management to apply these funds effectively could result in financial losses that could harm our business, cause the price of our common shares to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***Transformation into a public company may increase our costs and disrupt the regular operations of our business.***

This offering will have a significant transformative effect on us. Our business historically has operated as a privately owned company, and we expect to incur significant additional legal, accounting, reporting and other expenses as a result of having publicly traded common shares. We will also incur costs which we have not incurred previously, including, but not limited to, costs and expenses for managing directors' and supervisory directors' fees, increased directors and officers insurance, investor relations, and various other costs of a public company.

We also anticipate that we will incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. We expect these rules and regulations to increase our legal and financial compliance costs and make some management and corporate governance activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." These rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. This could have an adverse impact on our ability to retain, recruit and bring on a qualified management board and a qualified independent supervisory board. We expect that the additional costs we will incur as a public company, including costs associated with corporate governance requirements, will be considerable relative to our costs as a private company.

The additional demands associated with being a public company may disrupt regular operations of our business by diverting the attention of some of our senior management team away from revenue producing activities to management and administrative oversight, adversely affecting our ability to attract and complete business opportunities and increasing the difficulty in both retaining professionals and managing and growing our businesses. Any of these effects could harm our business, financial condition and results of operations.

Furthermore, after the date we are no longer an emerging growth company, our independent registered public accounting firm will only be required to attest to the effectiveness of our internal control over financial reporting depending on our market capitalization. Even if our management concludes that our internal controls over financial reporting are effective, our independent registered public accounting firm may still decline to attest to our management's assessment or may issue a report that is qualified if it is not satisfied with our controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, in connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for

compliance with the requirements of Section 404. Failure to comply with Section 404 could subject us to regulatory scrutiny and sanctions, impair our ability to raise revenue, cause investors to lose confidence in the accuracy and completeness of our financial reports and negatively affect our share price.

***We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common shares less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." For example, for as long as we are an "emerging growth company" under the recently enacted JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years. See "Prospectus Summary—Implications of Being an Emerging Growth Company." We cannot predict if investors will find our common shares less attractive because we will rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

***We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.***

We will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (ii) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.



***We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.***

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. If in the future we are not a foreign private issuer as of the last day of the second fiscal quarter in any fiscal year, we would be required to comply with all of the periodic disclosure, current reporting requirements and proxy solicitation rules of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our directors and executive officers may not be United States citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we were to lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the costs we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified directors.

***As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we follow certain home country governance practices rather than the corporate governance requirements of the Nasdaq.***

We will be a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq we will rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires, among other things, an issuer to have a compensation committee that consists entirely of independent directors, Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations, and Nasdaq Listing Rule 5605(b)(2), which requires an issuer to have a majority of independent directors on its board. We will also rely on the phase-in rules of the SEC and Nasdaq with respect to the independence of our audit committee. These rules require that a majority of our directors must be independent and all members of our audit committee must meet the independence standard for audit committee members within one year of the effectiveness of the registration statement of which this prospectus forms a part. In addition, we have opted out of shareholder approval requirements, as included in the Nasdaq Listing Rules, for the issuance of securities in connection with certain events such as the acquisition of shares or assets of another company, the establishment of or

amendments to equity-based compensation plans for employees, a change of control of the Company and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. For an overview of our corporate governance principles, see "Description of Share Capital and Articles of Association." Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

***If we fail to implement effective internal controls over financial reporting, such failure could result in material misstatements in our financial statements, cause investors to lose confidence in our reported financial and other public information and have a negative effect on the trading price of our common shares.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Section 404 of the Sarbanes-Oxley Act of 2002 requires management of public companies to develop and implement internal controls over financial reporting and evaluate the effectiveness thereof. If we fail to design and operate effective internal controls, it could result in material misstatements in our financial statements, impair our ability to raise revenue, result in the loss of investor confidence in the reliability of our financial statements and subject us to regulatory scrutiny and sanctions, which in turn could harm the market value of our common shares.

We will be required to disclose changes made in our internal controls and procedures and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years after this offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

***We have identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate our material weakness or if we fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to report our financial results accurately or to prevent fraud.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Section 404 of the Sarbanes-Oxley Act of 2002 requires management of public companies to develop and implement internal controls over financial reporting and evaluate the effectiveness thereof. A material weakness is a deficiency or a combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of our unaudited interim condensed consolidated financial statements as of and for the nine month period ended September 30, 2018, we identified a material weakness in our internal controls as of December 31, 2017, related to the lack of effective review controls over closing entries in our financial statement close process. The material weakness was not fully remediated as of December 31, 2018. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Internal control over financial reporting."

In response to such material weakness, management hired appropriate accounting and financial professionals with the experience and knowledge necessary to review the accounting and internal control processes and procedures to address the material weakness identified. In addition, further internal control procedures were implemented to improve the financial reporting process and additional trainings are planned for our accounting and financial reporting personnel. If we are unable to successfully remediate our identified material weakness, if we discover additional material weaknesses or if we otherwise are unable to report our financial statements accurately or in a timely manner, we would be required to continue disclosing such material weaknesses in future filings with the SEC, which could adversely affect our business, investor confidence in our company and the market price of our common shares and could subject us to litigation or regulatory enforcement actions. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the market value of our common shares.

We will be required to disclose changes made in our internal controls and procedures and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

***Insiders will continue to have substantial control over us after this offering and could limit your ability to influence the outcome of key transactions, including a change of control.***

Our principal shareholders, directors and executive officers and entities affiliated with them will own approximately % of the outstanding common shares after this offering. As a result, these shareholders, if acting together, would be able to influence or control matters requiring approval by our general meeting of shareholders, including the election of managing directors and supervisory directors, changes to our articles of association and the approval of mergers or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. The concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our shareholders of an opportunity to receive a premium for their common shares as part of a sale of our company and might ultimately affect the market price of our common shares.

***We do not anticipate paying any cash dividends in the foreseeable future.***

We currently intend to retain our future earnings, if any, for the foreseeable future, to repay indebtedness and to fund the development and growth of our business. We do not intend to pay any dividends to holders of our common shares. As a result, capital appreciation in the price of our common shares, if any, will be your only source of gain on an investment in our common shares.

***If we do pay dividends, we may need to withhold tax on such dividends payable to holders of our shares in both Germany and the Netherlands.***

As an entity incorporated under Dutch law, but with its place of effective management in Germany (and not in the Netherlands), our dividends are generally subject to German dividend withholding tax and not Dutch dividend withholding tax. Dutch dividend withholding tax is required to be withheld from dividends if and when paid to Dutch resident holders of our shares (and non-Dutch resident holders of our shares that have a permanent establishment in the Netherlands to which their shareholding is attributable). As a result, upon a payment of dividends, we will be required to identify our shareholders in order to assess whether there are Dutch residents (or non-Dutch residents with a permanent establishment to which the shares are attributable) in respect of which Dutch dividend tax has to be withheld. Such identification may not always be possible in practice. We may approach Dutch Revenue prior to a payment of dividends to apply for a tax ruling confirming that no withholding of any Dutch dividend tax is applicable at all (as the dividend withholding tax can generally be credited against a Dutch resident shareholder's income tax anyway). The outcome of tax ruling requests is uncertain. Should we not obtain the tax ruling, if a favorable tax ruling cannot be obtained and if the identity of our shareholders cannot be determined, withholding of both German and Dutch dividend tax may occur, upon a payment of dividends.

***New investors in our common shares will experience immediate and substantial book value dilution after this offering.***

The initial public offering price of our common shares will be substantially higher than the pro forma net tangible book value per share of the outstanding common shares immediately after the offering. Based on an assumed initial public offering price of \$ \_\_\_\_\_ per share (the midpoint of the price range set forth on the cover of this prospectus) and our net tangible book value as of December 31, 2018, if you purchase our common shares in this offering you will pay more for your shares than the amounts paid by our existing shareholders for their shares and you will suffer immediate dilution of \$ \_\_\_\_\_ per share in pro forma net tangible book value. As a result of this dilution, investors purchasing shares in this offering may receive significantly less than the full purchase price that they paid for the shares purchased in this offering in the event of a liquidation.

We also have approximately \_\_\_\_\_ outstanding share options to purchase common shares with exercise prices that are below the assumed initial public offering price of the common shares. To the extent that these options are exercised, there will be further dilution.

***Shareholders may not be able to exercise preemptive rights and, as a result, may experience substantial dilution upon future issuances of common shares***

In the event of an issuance of common shares, subject to certain exceptions, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder. These preemptive rights may be restricted or excluded by a resolution of the general meeting of shareholders or by another corporate body designated by the general meeting of shareholders. Prior to the closing of this offering, our management board, subject to approval of our supervisory board, will be authorized, for a period of five years to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time and to limit or exclude preemptive rights in connection therewith. This could cause existing shareholders to experience substantial dilution of their interest in us.

***If equity and industry research analysts publish negative evaluations of or downgrade our common shares, the price of our common shares could decline.***

The trading market for our common shares relies in part on the research and reports that equity and industry research analysts publish about us or our business. We do not control these analysts. If one or more of the analysts covering our business downgrade their evaluations of our common shares, the price of our common shares could decline. If one or more of these analysts cease to cover our common shares, we could lose visibility in the market for our common shares, which in turn could cause our common shares price to decline.

***We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us.***

Since incorporation we intend to have, on a continuous basis, our place of effective management in Germany. We will therefore be a tax resident of Germany under German national tax law. By reason of our incorporation under Dutch law, we are also deemed tax resident in the Netherlands under Dutch tax law. However, based on our current management structure and current tax laws of the United States, Germany and the Netherlands, as well as applicable income tax treaties, and current interpretations thereof, we should be tax resident solely in Germany for the purposes of the convention between the Federal Republic of Germany and the Netherlands for the avoidance of double taxation with respect to taxes on income of 2012. However, we may become subject to limited income tax liability in other countries with regard to the income generated in the respective other country, for example, due to the existence of a permanent establishment or a permanent representative.

The applicable tax laws or interpretations thereof may change. Furthermore, whether we have our place of effective management in Germany and are as such tax resident in Germany is largely a question of fact and degree based on all the circumstances, rather than a question of law, which facts and degree may also change. Changes to applicable laws or interpretations thereof and changes to applicable facts and circumstances (for example, a change of board members or the place where board meetings take place), may result in us becoming a tax resident of a jurisdiction other than Germany. As a consequence, our overall effective income tax rate and income tax expense could materially increase, which could have a material adverse effect on our business, results of operations, financial condition and prospects, which could cause our share price and trading volume to decline. However, if there is a double tax treaty between Germany and the respective other country, the double taxation of income may be avoided. Thus, the detrimental tax effects should be mitigated by the application of the respective double tax treaty.

***Our ability to use our net operating loss carryforwards and other tax attributes may be limited.***

Our ability to utilize our net operating losses ("NOLs") is currently limited, and may be limited further, under Section 8c of the German Corporation Income Tax Act (*Körperschaftsteuergesetz*, the "KStG") and Section 10a of the German Trade Tax Act (*Gewerbesteuer*, the "GewStG"). These limitations apply if a qualified ownership change, as defined by Section 8c KStG, occurs and no exemption is applicable.

Generally, a qualified ownership change occurs if more than 25% of the share capital or the voting rights are directly or indirectly transferred to a shareholder or a group of shareholders within a period of five years. A qualified ownership change may also occur in case of a transaction comparable to a transfer of shares or voting rights or in case of an increase in capital leading to a respective change in the shareholding. In the case of such a qualified ownership change tax loss

carryforwards, consisting of the NOLs in the same percentage as the ownership change, cannot be utilized. If the percentage of the aforementioned ownership change/change in voting rights exceeds 50%, tax loss carryforwards expire in full. To the extent that the tax loss carryforwards exceed hidden reserves (*stille Reserven*) taxable in Germany, they may be further utilized despite a qualified ownership change. In case of a qualified ownership change within a group, tax loss carryforwards will be preserved if certain conditions are satisfied.

According to a decision of the German Federal Constitutional Court dated 29 March 2017, the present Section 8c para. 1 sentence 1 KStG is not in line with the German constitution. Thus, the legislator deleted Section 8c para. 1 sentence 1 KStG with retroactive effect for the period from January 1, 2008 until December 31, 2015. The respective tax bill was adopted by the parliament on November 8 and 23, 2018. However, Section 8c para. 1 sentence 1 KStG in the form as of January 1, 2015 will remain applicable. Furthermore, another appeal has been filed by the fiscal court of Hamburg dated August 29, 2017 with regard to Section 8c, paragraph 1, sentence 2 KStG—that is, the forfeiture of all tax loss carryforwards in case more than 50% of shares/voting rights will be assigned to a new shareholder. The appeal is still pending. It is unclear when the Federal Constitutional Court will decide this case. According to statements in German legal literature, there are good reasons to believe that the Federal Constitutional Court may come to the conclusion that Section 8, paragraph 1, sentence 2 KStG is not in line with the German constitution.

As of December 31, 2018, we had unrecognized NOL carryforwards for German tax purposes of €21,278 thousand available. Future changes in share ownership may also trigger an ownership change and, consequently, a Section 8c KStG or a Section 10a GewStG limitation. Any limitation may result in the expiration of a portion or the complete tax operating loss carryforwards before they can be utilized. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to reduce German income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

***Although we do not believe that we were a "passive foreign investment company," or a PFIC, for U.S. federal income tax purposes in 2018, we may be a PFIC in 2019 or one or more future taxable years. If we are a PFIC in 2019 or any future taxable year, U.S. shareholders may be subject to adverse U.S. federal income tax consequences.***

Under the Internal Revenue Code of 1986, as amended (the "Code"), we will be a PFIC for any taxable year in which, after the application of certain look-through rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of passive income or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. Passive income includes, among other things, dividends, interest, certain non-active rents and royalties, and capital gains. Based on our current operations, income, assets and certain estimates and projections, including as to the relative values of our assets and the treatment of our grants received as gross income that is not passive income, we do not believe that we were a PFIC for our 2018 taxable year. However, there can be no assurance that the Internal Revenue Service (the "IRS") will agree with our conclusion. In addition, whether we will be a PFIC in 2019 or any future taxable year is uncertain because, among other things, (i) we currently own, and will own after the closing of this offering, a substantial amount of passive assets, including cash, (ii) the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may vary substantially over time, (iii) the treatment of grants as income for U.S. federal income tax purposes is unclear, and (iv) the composition of our income may vary substantially over time. Accordingly, there can be no assurance that we will not be a PFIC for any taxable year.

If we are a PFIC for any taxable year during which a U.S. investor holds common shares, we would continue to be treated as a PFIC with respect to that U.S. investor for all succeeding years during which the U.S. investor holds common shares, even if we ceased to meet the threshold requirements for PFIC status, unless certain exceptions apply. Such a U.S. investor may be subject to adverse U.S. federal income tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements. We do not intend to provide the information that would enable investors to make a qualified electing fund election (a "QEF Election") that could mitigate the adverse U.S. federal income tax consequences should we be classified as a PFIC.

For further discussion, see "Taxation—Material U.S. Federal Income Tax Considerations for U.S. Holders."

***Upon the closing of this offering, we will be a Dutch public company with limited liability. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions and may not protect investors in a similar fashion afforded by incorporation in a U.S. jurisdiction.***

Upon the closing of this offering, we will be a public company with limited liability (*naamloze vennootschap*) organized under the laws of the Netherlands. Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in the Netherlands. A further summary of applicable Dutch company law is contained in this prospectus under "Description of Share Capital and Articles of Association." However, there can be no assurance that Dutch law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of investors.

The rights of shareholders and the responsibilities of managing directors and supervisory directors may be different from the rights and obligations of shareholders and board members in companies governed by the laws of U.S. jurisdictions. In the performance of their duties, our managing directors and supervisory directors are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder.

For more information, we have provided summaries of relevant Dutch corporation law and of our articles of association under "Description of Share Capital and Articles of Association."

***Provisions of our articles of association or Dutch corporate law might deter acquisition bids for us that might be considered favorable and prevent, delay or frustrate any attempt to replace or remove the members of our management board or supervisory board.***

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. In this respect, certain provisions of our articles of association may make it more difficult for a third party to acquire control of us or effect a change in our management board and supervisory board. These include:

- § a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination prepared by our supervisory board which can only be overruled by a two-thirds majority of votes cast representing more than 50% of our issued share capital;



- § a provision that our managing directors and supervisory directors may only be dismissed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the dismissal is proposed by the supervisory board in which case a simple majority of the votes would be sufficient); and
- § a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our supervisory board.

***We are not obligated to, and do not, comply with all best practice provisions of the Dutch Corporate Governance Code.***

Upon the closing of this offering, we will be subject to the DCGC. The DCGC contains both principles and best practice provisions that regulate relations between the management board, the supervisory board and the shareholders. The DCGC is based on a "comply or explain" principle. Accordingly, companies are required to disclose in their annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If they do not comply with those provisions (for example, because of a conflicting Nasdaq requirement), the company is required to give the reasons for such non-compliance. The DCGC applies to Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. We do not comply with all best practice provisions of the DCGC. For further information, see "Description of Share Capital and Articles of Association." This may affect your rights as a shareholder and you may not have the same level of protection as a shareholder in a Dutch company that fully complies with the DCGC.

***Claims of U.S. civil liabilities may not be enforceable against us.***

We are incorporated under the laws of the Netherlands, and our headquarters is located in Germany. Substantially all of our assets are located outside the United States. The majority of our management board and supervisory board reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

There is currently no treaty between the United States and the Netherlands for the mutual recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the U.S. federal securities laws, would not be enforceable in the Netherlands unless the underlying claim is relitigated before a Dutch court of competent jurisdiction. Under current practice, however, a Dutch court will generally, subject to compliance with certain procedural requirements, grant the same judgment without a review of the merits of the underlying claim if such judgment (i) is a final judgment and has been rendered by a court which has established its jurisdiction vis-à-vis the relevant Dutch companies or Dutch company, as the case may be, on the basis of internationally accepted grounds of jurisdiction, (ii) has not been rendered in violation of principles of proper procedure (*behoorlijke rechtspleging*), (iii) is not contrary to the public policy of the Netherlands, and (iv) is not incompatible with (a) a prior judgment of a Netherlands court rendered in a dispute between the same parties, or (b) a prior judgment of a foreign court rendered in a dispute between the same parties, concerning the same subject matter and based on the same cause of action, provided that such prior judgment is capable of being recognized in the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of



U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure.

The United States and Germany currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, in civil and commercial matters. Consequently, a final judgment for payment or declaratory judgments given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Germany. German courts may deny the recognition and enforcement of a judgment rendered by a U.S. court if they consider the U.S. court not to be competent or the decision to be in violation of German public policy principles. For example, judgments awarding punitive damages are generally not enforceable in Germany. A German court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

In addition, actions brought in a German court against us, our directors, our senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. In particular, German courts generally do not award punitive damages. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. German procedural law does not provide for pre-trial discovery of documents, nor does Germany support pre-trial discovery of documents under the 1970 Hague Evidence Convention. Proceedings in Germany would have to be conducted in the German language and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our directors, our senior management and the experts named in this prospectus.

Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce against us or directors, executive officers or certain experts named herein who are residents of or possessing assets in the Netherlands, Germany, or other countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains statements that constitute forward-looking statements. All statements other than present and historical facts and conditions contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this prospectus, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section entitled "Risk Factors" in this prospectus. These risks and uncertainties include factors relating to:

- § our ability to effectively manage our future growth and to execute our business strategy;
- § our ability to generate sufficient revenue from our relationships with our pharmaceutical partners and clients, and to otherwise maintain our current relationships, or enter into new relationships, with pharmaceutical partners and clients;
- § our expectations for our products and solutions achieving commercial market acceptance, and our ability to keep pace with the rapidly evolving industry in which we operate;
- § our assumptions regarding market size in the rare disease industry and our growth potential;
- § our pharmaceutical partners' and clients' need for rare disease information products and solutions and any perceived advantage of our products over those of our competitors;
- § our ability to manage our international expansion, including our exposure to new and complex business, regulatory, political, operational, financial, and economic risks, and numerous and conflicting legal and regulatory requirements;
- § our continued reliance on our senior management team, in particular our CEO, and other qualified personnel and our ability to retain such personnel;
- § our ability to obtain, maintain, protect and enforce sufficient patent and other intellectual property protection for any products or solutions we develop and for our technology;
- § the ongoing protection of our trade secrets, know-how, and other confidential and proprietary information;
- § our ability to remediate our material weakness on internal control over financial reporting;
- § general economic, political, demographic and business conditions in North America, the Middle East, Europe and other regions in which we operate;
- § changes in government and industry regulation and tax matters;
- § other factors that may affect our financial condition, liquidity and results of operations; and
- § other risk factors discussed under "Risk Factors."

You should refer to the section of this prospectus titled "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any

forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the issuance and sale of \_\_\_\_\_ common shares in this offering will be approximately \$ \_\_\_\_\_ million (or \$ \_\_\_\_\_ million if the underwriters exercise in full their option to purchase additional shares), assuming an initial public offering price of \$ \_\_\_\_\_ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from this offering as follows:

- § approximately \$ \_\_\_\_\_ million for research and development under our pharmaceutical segment, including the development of biomarkers, as well as for growth of our partnership opportunities through sales and marketing investments;
- § approximately \$ \_\_\_\_\_ million for the development of our knowledge-driven information platform, including investments in new information technology, artificial intelligence and other software solutions that improve our processes and enhance our data documentation, and for the development of solutions driving precision medicine based treatments; and
- § the remainder for working capital and other general corporate purposes.

This expected use of the net proceeds from the offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of the offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development efforts and the expansion of our suite of solutions, as well as any collaborations that we may enter into with new or existing pharmaceutical partners and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from the offering.

Pending our use of the net proceeds from the offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase (decrease) the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$ \_\_\_\_\_ million, assuming the assumed initial public offering price remains the same. The actual net proceeds payable to us will adjust based on the actual number of common shares sold by us, the actual public offering price and other terms of the offering determined at pricing.

## DIVIDENDS AND DIVIDEND POLICY

Under Dutch law, we may only pay dividends following the closing of the offering to the extent our shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law or by our articles of association. Subject to such restrictions, the amount of any distributions will depend on many factors, such as our results of operations, financial condition, cash requirements, prospects and other factors deemed relevant by our management board and supervisory board. We have not adopted a formal dividend policy with respect to future dividends. We may adopt such a policy in the future, in which case we intend either to place a discussion of such policy on the agenda for our annual general meetings of shareholders, consistent with the DCGC, or to disclose a deviation from the DCGC in this respect in our statutory annual report.

## CORPORATE REORGANIZATION

### Introduction

Centogene B.V. is a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) that was incorporated for the purpose of making this offering. Upon the incorporation of Centogene B.V., Prof. Arndt Rolfs, our CEO, became the sole director and the sole shareholder of Centogene B.V., holding one common share in the capital of Centogene B.V., the nominal value of which (in the amount of €0.12) has not been paid up. Centogene B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. As part of the corporate reorganization, all of the interests in Centogene AG will be exchanged for new common shares of Centogene B.V. to be issued to the existing security holders of Centogene AG in the course of such exchange, and as a result, Centogene AG will become a wholly owned subsidiary of Centogene B.V., while the current shareholders of Centogene AG will become the shareholders of Centogene B.V. In connection with such exchange, the common share in Centogene B.V. held by Prof. Rolfs will be cancelled (*ingetrokken*). Subsequently, Centogene B.V. will convert into a Dutch public company (*naamloze vennootschap*) and change its name to Centogene N.V. Therefore, investors in this offering will only acquire, and this prospectus only describes the offering of, common shares of Centogene N.V. We refer to the reorganization described above as our "corporate reorganization."

In connection with the corporate reorganization, Centogene AG will take initial steps of its conversion into a GmbH under German law. However, such transformation will only be completed following the consummation of the offering.

The corporate reorganization will take place in several steps, as described below.

### Exchange of Centogene AG Securities for Centogene B.V. Common Shares

Immediately following the pricing of this offering, the existing shareholders of Centogene AG will each become a party to a separate notarial deed of issue under Dutch law, the existing shareholders will (i) subscribe for new common shares in Centogene B.V. and (ii) agree to transfer their respective shares (both common and preferred) in Centogene AG to Centogene B.V. as a contribution in kind on the aforementioned common shares in Centogene B.V. The actual amount of common shares in Centogene B.V. which the holders of common shares in Centogene AG on the one hand and the holders of preferred shares in Centogene AG on the other hand may subscribe for, will be calculated pursuant to and consistent with the liquidation preference arrangement included in the Shareholders Agreement (as defined in "Certain Relationships and Related Party Transactions—Investment and Shareholders Agreement). Immediately thereafter, the existing shareholders of Centogene AG will effect such transfer of their respective shares (both common and preferred) in Centogene AG to Centogene B.V. in accordance with German law. As a result thereof, Centogene B.V. will become the sole shareholder of Centogene AG.

### Shares of Centogene B.V. to be Outstanding After the Corporate Reorganization

Preferred shares of Centogene AG will be exchanged for common shares of Centogene B.V. on a -to- basis as provided for in each notarial deed of issue.

Common shares of Centogene AG will be exchanged for common shares of Centogene B.V. on a -to- basis as provided for in each notarial deed of issue

Upon completion of this share exchange (and prior to the closing of this offering), the current shareholders of Centogene AG will hold an aggregate of \_\_\_\_\_ common shares of Centogene B.V.

### **Conversion of Centogene B.V. into Centogene N.V.**

As part of the corporate reorganization, the legal form of Centogene B.V. will be converted from a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to a Dutch public company (*naamloze vennootschap*), and the articles of association of Centogene N.V. will become effective. Such final step will take place by means of the execution of a notarial deed of conversion and amendment, which will take place prior to the listing of our common shares on Nasdaq. This deed of conversion and amendment shall be executed following the delivery of a Dutch auditor's statement confirming that, on a day within five months prior to the conversion, our shareholders' equity was at least equal to the paid-up part of our issued share capital as set forth in the deed of conversion and amendment. The conversion will result in a name change from Centogene B.V. to Centogene N.V. Our articles of association, as they will read upon the closing of this offering, are further described in the section "Description of Share Capital and Articles of Association" and are filed (as an English translation of the official Dutch version) as an exhibit to the registration statement of which this prospectus forms a part.

## CAPITALIZATION

The table below sets forth our capitalization (defined as long-term debt and shareholders' equity) as of December 31, 2018 derived from our unaudited interim condensed consolidated financial statements prepared in accordance with IFRS:

- § on an actual basis;
- § on a pro forma basis to give effect to our corporate reorganization; and
- § on a pro forma as adjusted basis to give further effect to the issuance and sale of common shares in this offering, assuming an initial public offering price of \$ per common share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

This table should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Corporate Reorganization," "Certain Relationships and Related Party Transactions" and the consolidated financial statements and notes thereto appearing elsewhere in this prospectus.

	December 31, 2018	
	Actual	Pro Forma (€ in thousands) (unaudited)
		Pro Forma As Adjusted <sup>(1)</sup>
Cash and cash equivalents	9,222	
<b>Liabilities</b>		
Non-current loans	12,915	
Current loans	3,702	
<b>Total debt</b>	<b>16,617</b>	
<b>Equity</b>		
Issued capital	322	
Capital reserve	46,923	
Retained earnings and other reserves	(19,964)	
Non-controlling interests	(757)	
<b>Total shareholders' equity</b>	<b>26,524</b>	
<b>Total capitalization</b>	<b>43,141</b>	

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately \$ million, assuming the assumed initial public offering price remains the same. The actual net proceeds payable to us will adjust based on the actual number of common shares sold by us, the actual public offering price and other terms of the offering determined at pricing.



## DILUTION

If you invest in our common shares in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share and the as adjusted net tangible book value per common share after this offering.

At December 31, 2018, we had a pro forma net tangible book value of \$                      million (€                      million), corresponding to a pro forma net tangible book value of \$                      per common share (€                      per common share). Pro forma net tangible book value represents the amount of our total assets less our total liabilities, excluding intangible assets, divided by                      , the number of common shares issued and outstanding, after giving effect to the corporate reorganization.

After giving further effect to the sale of the                      common shares offered by us in the offering, and considering an offering price of \$                      per common share (€                      per common share), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value estimated at December 31, 2018 would have been \$                      (€                      ), representing \$                      per common share (€                      per common share). This represents an immediate increase in pro forma net tangible book value of \$                      per common share (€                      per common share) to existing shareholders and an immediate dilution in net tangible book value of \$                      per common share (€                      per common share) to new investors purchasing common shares in this offering. Dilution for this purpose represents the difference between the price per common shares paid by these purchasers and net tangible book value per common share immediately after the completion of the offering.

The following table illustrates this dilution to new investors purchasing common shares in the offering.

	\$	€
Assumed initial public offering price per common share	_____	_____
Pro forma net tangible book value per common share at December 31, 2018 after giving effect to the corporate reorganization	_____	_____
Increase in net tangible book value per common share attributable to new investors	_____	_____
Pro forma as adjusted net tangible book value per common share at December 31, 2018 after giving effect to the corporate reorganization and the offering	_____	_____
Dilution per common share to new investors	_____	_____
Percentage of dilution per common share to new investors	_____	_____

Each \$1.00 increase (decrease) in the offering price per common share, respectively, would increase (decrease) the pro forma as adjusted net tangible book value after this offering by \$                      per common share (€                      per common share) and the dilution to new investors purchasing common shares in the offering by \$                      per common share (€                      per common share). Each increase (decrease) of 1.0 million in the number of shares we are offering would increase (decrease) the pro forma as adjusted net tangible book value after this offering by \$                      per common share (€                      per common share) and the dilution to new investors purchasing common shares in the offering by \$                      per common share (€                      per common share).

If the underwriters were to fully exercise their option to purchase additional shares, the pro forma as adjusted net tangible book value per common share after the offering would be \$                      per common share (€                      per common share), and the dilution per common share to new investors would be \$                      per common share (€                      per common share), in each case at the initial public offering price of \$                      per common share (€                      per common share).

## SELECTED FINANCIAL INFORMATION

The following selected consolidated statement of financial position as of December 31, 2017 and 2018, and the consolidated statement of comprehensive loss for the years ended December 31, 2016, 2017 and 2018 of Centogene AG are derived from the consolidated financial statements included elsewhere in this prospectus, which have been audited by Ernst & Young. The following selected consolidated statement of financial position as of December 31, 2016, is derived from consolidated financial statements not included in this prospectus but previously filed with the SEC on Form F-1.

We maintain our books and records in euros, and we prepare our financial statements under IFRS as issued by the IASB.

Centogene B.V. is a newly formed holding company formed for the purpose of effecting the offering and has not engaged in any activities except those incidental to its formation, the corporate reorganization and the initial public offering of our common shares. Centogene B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Accordingly, summary financial information for Centogene B.V. is not presented. Centogene AG's financial statements, including the notes thereto, are included elsewhere in this prospectus.

This financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, including the notes thereto, included elsewhere in this prospectus.

	For the Years Ended		
	December 31,		
	2016	2017	2018
	(€ in thousands)		
<b>Consolidated statement of comprehensive loss:</b>			
Revenue	27,669	31,689	40,478
Cost of sales	12,856	14,939	19,941
<b>Gross profit</b>	<b>14,813</b>	<b>16,750</b>	<b>20,537</b>
Research and development expenses	5,885	6,396	6,300
General administrative expenses	8,888	9,498	18,610
Selling expenses	5,364	5,897	7,474
Other operating income	1,295	1,043	2,306
Other operating expenses	908	457	1,065
<b>Operating loss</b>	<b>(4,937)</b>	<b>(4,455)</b>	<b>(10,606)</b>
Interest and similar income	26	14	33
Interest and similar expenses	856	1,021	1,075
<b>Finance costs, net</b>	<b>(830)</b>	<b>(1,007)</b>	<b>(1,042)</b>
Loss before taxes	(5,767)	(5,462)	(11,648)
Income tax (benefits)/expenses	(408)	14	(310)
<b>Loss for the period</b>	<b>(5,359)</b>	<b>(5,476)</b>	<b>(11,338)</b>
Other comprehensive income/(loss)	9	10	(8)
<b>Total comprehensive loss for the period</b>	<b>(5,350)</b>	<b>(5,466)</b>	<b>(11,346)</b>
Loss per share—Basic and diluted	(25)	(22)	(40)

	For the Years Ended		
	December 31,		
	2016	2017	2018
	(€ in thousands)		
<b>Consolidated statement of financial position:</b>			
Cash and cash equivalents	965	3,157	9,222
Total assets	36,208	55,486	76,674
Total current liabilities	23,890	23,808	24,283
Total non-current liabilities	9,583	15,324	25,867
Total equity	2,735	16,354	26,524

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read in conjunction with Centogene AG's audited consolidated financial statements as of December 31, 2017 and 2018 and for the years ended December 31, 2016, 2017 and 2018 and the notes thereto, included elsewhere in this prospectus, as well as the information presented under "Selected Financial Information." The following discussion is based on our financial information prepared in accordance with IFRS as issued by the IASB, which may differ in material respects from generally accepted accounting principles in the United States and other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "Risk Factors" and elsewhere in this prospectus.*

*On October 11, 2018, Centogene B.V. was incorporated under the laws of the Netherlands to become the holding company for Centogene AG in connection with this offering pursuant to the corporate reorganization. Please see "Corporate Reorganization." Centogene B.V. has not engaged in any activities except those incidental to its formation, the corporate reorganization and the initial public offering of our common shares. Centogene B.V. has no assets, liabilities or contingent liabilities and will have no assets, liabilities or contingent liabilities until the completion of our corporate reorganization. Accordingly, financial information for Centogene B.V. and a discussion and analysis of its results of operations and financial condition for the period of its operations prior to the corporate reorganization would not be meaningful and are not presented. Following the corporate reorganization, Centogene N.V. will become the holding company of Centogene AG and the historical consolidated financial statements of Centogene AG included in this Registration Statement will become part of the historical consolidated financial statements of Centogene N.V.*

### Overview

Centogene is a commercial-stage rare disease company focused on transforming clinical and genetic data into medical solutions for patients. We are focused on bringing rationality to treatment decisions and accelerating the development of new orphan drugs by using our knowledge of the global rare disease market including epidemiological, clinical heterogeneity and innovative biomarkers.

We have developed a proprietary platform and system based on our data repository, which includes epidemiologic, phenotypic and genetic data from over 380,000 patients sourced from over 110 countries thus reflecting the genetic differences in global ethnicities. We believe this represents the only platform that comprehensively analyzes multi-level data to improve the understanding of rare hereditary diseases, which can aid in the identification of patients and improve our pharmaceutical partners' ability to bring orphan drugs to the market.

We have identified two reportable segments:

- § **Pharmaceutical.** Our pharmaceutical solutions provide a variety of services to our pharmaceutical partners, including early patient recruitment and identification, epidemiological insights, biomarker discovery and patient monitoring. Our information platforms, deep access to rare disease patients and ability to develop proprietary technologies and biomarkers enable us to provide services to our pharmaceutical partners in all phases of the drug development process as well as post-commercialization. Revenues from our pharmaceutical segment are generated primarily from collaboration agreements

with our pharmaceutical partners. As of December 31, 2018, we had over 50 collaboration agreements with over 30 pharmaceutical partners and have commercialized seven biomarkers.

§ **Diagnostics.** Our diagnostics segment provides targeted genetic sequencing and diagnostics services to our clients worldwide, who are typically physicians, laboratories or hospitals, either directly or through distributors. We offer the broadest diagnostic testing portfolio for rare diseases, covering over 3,800 genes using over 9,000 different tests. In turn, the data collected from our diagnostics services allow us to continue to grow our repository and our CentoMD database.

Our business has recently seen notable expansion. In the year ended December 31, 2018, we received over 105,000 test requests, representing an approximate 27% increase as compared to approximately 83,000 test requests received during the year ended December 31, 2017.

Our revenue for the year ended December 31, 2018 was €40,478 thousand, an increase of €8,789 thousand, or 27.7%, from €31,689 thousand for the year ended December 31, 2017. Revenue for the year ended December 31, 2017 increased by €4,020 thousand, or 14.5%, from €27,669 thousand for the year ended December 31, 2016. Our pharmaceutical and diagnostics segments contributed 42.8% and 57.2%, respectively, of our total revenues for the year ended December 31, 2018, as compared to 44.0% and 56.0%, respectively, of our total revenues for the year ended December 31, 2017, and 44.6% and 55.4%, respectively, of our total revenues for the year ended December 31, 2016.

Since the inception of our business, our research and development has been substantially devoted to our biomarkers and interpretation-based solutions. For the year ended December 31, 2018, we have incurred research and development expenses of €6,300 thousand, a decrease of €96 thousand, or 1.5%, from €6,396 thousand for the year ended December 31, 2017. Our research and development expenses for the year ended December 31, 2017 increased by €511 thousand, or 8.7%, from €5,885 thousand for the year ended December 31, 2016.

Our loss before taxes for the year ended December 31, 2018 was €11,648 thousand, an increase of €6,186 thousand, or 113.3%, from €5,462 thousand for the year ended December 31, 2017. The loss before taxes for the year ended December 31, 2017 decreased by €305 thousand, or 5.3%, from €5,767 thousand for the year ended December 31, 2016. Our loss before taxes for the year ended December 31, 2018 included stock based compensation expenses of €5,521 thousand, as compared to €894 thousand for the year ended December 31, 2017, and €964 thousand for the year ended December 31, 2016.

## Financial Operations Overview

### Revenue

Our revenue is principally derived from the provision of pharmaceutical solutions and diagnostic tests enabled by our knowledge and interpretation-based platform.

We expect our revenue to increase over time as we continue to expand our commercial efforts internationally with a focus on further growth in our pharmaceutical segment. As a result, we expect revenue from the pharmaceutical segment to increase as a proportion of total revenue over time. We expect revenue from our diagnostics segment to grow in absolute terms but decrease as a percentage of revenue as we focus on growth in our pharmaceutical segment.

Changes in revenue mix between our pharmaceutical and diagnostics segments can impact our results period over period. We typically incur lower costs for the provision of solutions in our pharmaceutical segment and therefore generate higher returns from our pharmaceutical segment contracts than from our diagnostics segment contracts. As a result, we anticipate our gross profit as a percentage of revenues to improve in the future.

### *Pharmaceutical*

We generate revenue in our pharmaceutical segment from the solutions we provide to our pharmaceutical partners to accelerate their development of treatments for rare hereditary diseases. Our biomarkers can be used not only in effective identification of rare disease patients, but also used to demonstrate the efficacy of the drugs, perform longitudinal monitoring and titrate the dosage needed of individual rare disease patients. Our partnership agreements are structured on a fee per sample basis, milestone basis, fixed fee basis, royalty basis or a combination of these. We recognize our revenue from the rendering of solutions to our pharmaceutical partners as such service is performed, or upon the achievement of certain milestones if applicable to the partnership agreement.

The timing of entry into new contracts with our pharmaceutical partners can be difficult to predict. Accordingly, we can experience different revenue patterns quarter-to-quarter and year-over-year due to the satisfaction of performance obligations involving significant upfront and milestone fees due from our pharmaceutical partners. We recognize revenue for upfront fees at a point in time when the right to use the intellectual property is transferred to the customer, while revenue for milestone payments is recognized over time using an input method based on the work rendered by us, or at a point in time when the applicable provisions for over-time recognition per IFRS 15 are not present (e.g., the sale of CentoCards). For the year ended December 31, 2018, we entered into two collaboration agreements with Evotec International GmbH ("Evotec") and Denali Therapeutics Inc. ("Denali"). Under the terms of these collaboration agreements, we received upfront payments totaling €4,000 thousand in relation to the licensing by Evotec and Denali of certain of our intellectual property. We expect such fluctuations will grow as we expand our pharmaceutical segment.

### *Diagnostics*

We generate revenue in our diagnostics segment primarily from targeted genetic sequencing and diagnostics services, such as whole exome sequencing ("WES") and whole genome sequencing ("WGS"). For the year ended December 31, 2018, our total diagnostic segment revenues were split amongst our primary testing products as follows: 34.7% WES, 20.9% panel sequencing, 19.3% single gene testing, 14.3% non-invasive pre-natal testing ("NIPT"), 10.5% WGS and 0.3% biochemistry. We provide these services in over 110 countries either directly or through third party distributors. Revenues are based on a negotiated price per test or on the basis of agreements to provide certain testing volumes over defined periods. Revenue from the rendering of clinical diagnostic services (e.g., sequencing or interpretation) is recognized over time by reference to the percentage of completion of the service on the reporting date, assessed on the basis of the work rendered. We strategically focus on countries around the globe where the prevalence of rare hereditary diseases is high or the availability of national genetic testing and interpretation is to some extent limited and therefore the complete reimbursement or partial payment by the government for our services is more likely. The major markets for our diagnostics business currently include the Middle East and North Africa region, Scandinavia, parts of Central and Eastern Europe, Latin America, Canada and parts of Asia. In most of our markets, our diagnostics tests are billable directly to the party submitting the request for a test to us and we have less than 1% bad debts written off since the inception of our business.

### ***Cost of Sales and Operating Expenses***

Our cost of sales and our operating expenses support all of the products and services that we provide to our customers and, as a result, are presented in an aggregate total for both business segments. We allocate certain overhead expenses, such as rent, utilities and depreciation to cost of sales and operating expense categories based on headcount and facility usage. As a result, overhead expense allocation is reflected in cost of sales and each operating expense category.

#### *Cost of Sales*

Cost of sales consists of cost of consumables, supplies and other direct costs such as personnel expenses, depreciation of laboratory equipment, amortization of biomarkers, repair and maintenance costs, shipping costs and certain allocated overhead expenses.

We expect these costs in absolute terms will increase as we grow our revenue but decrease as a percentage of revenue over time as our pharmaceutical segment revenue increases and as we continue to implement operational efficiencies. During the year ended December 31, 2018, our cost of sales represented 49.3% of our total revenue, as compared to 47.1% for the year ended December 31, 2017, and 46.5% for the year ended December 31, 2016.

#### *Research and Development Expenses*

Our research and development expenses consist primarily of costs incurred for the development of new products and solutions, in particular our biomarkers, and the development of our IT driven and interpretation-based solutions, including our CentoMD database. In the three fiscal years ended December 31, 2018, we spent €27,839 thousand on research and development, of which €9,258 thousand was capitalized as intangible assets.

Expenses for research activities are recognized through profit or loss in the period in which they are incurred, unless they reach the development stage and prove to be technically and commercially feasible, upon which the expenses are capitalized. With respect to biomarkers, expenses are capitalized when the target validation process is completed and commercialization is probable. With respect to IT driven solutions, expenses are capitalized upon the completion of our internal validation test. Before such dates, any development costs are recognized in profit or loss.

Research and development which we conduct pursuant to our pharmaceutical partnership agreements is typically limited to a specified rare disease. As a result, our research and development expenses may vary substantially from period to period based on the timing of our research and development activities or our pharmaceutical partners, including due to the entry into, renegotiation of or termination of our partnership agreements. Our research and development expenses may also be impacted by changes in regulatory requirements and healthcare policies globally, particularly in respect of the validation and patent application processes that we conduct for our biomarkers.

During the year ended December 31, 2018, our research and development expenses represented 15.6% of our total revenue, as compared to 20.2% for the year ended December 31, 2017, and 21.3% for the year ended December 31, 2016. We expect that our overall research and development expenses will increase in absolute terms as we continue to innovate our information platform, develop additional products and solutions and expand our data management resources.

#### *General Administrative Expenses*

Our general administrative expenses include costs for our personnel, premises, IT operations, accounting and finance, legal and human resources functions. These expenses consist principally of

salaries, bonuses, employee benefits, travel, and stock-based compensation, as well as professional services fees such as consulting, audit, tax and legal fees and general corporate costs and allocated overhead expenses. We account for all general administrative expenses as incurred.

During the year ended December 31, 2018, our general administrative expenses represented 46.0% of our total revenue, as compared to 30.0% for the year ended December 31, 2017, and 32.1% for the year ended December 31, 2016. The increase in general administrative expenses for the year ended December 31, 2018 was primarily attributable to an increase in stock-based compensation expenses compared to the year ended December 31, 2017, as well as expenses incurred for the preparation of the Offering to which this prospectus relates. As a result of our continued international growth, including the expansion of our laboratory in Rostock, Germany and the opening of our new laboratory in Cambridge, Massachusetts in October 2018, we expect our general administrative costs to increase relative to prior periods. We also expect that our general administrative expenses will increase due to the costs of operating as a public company, such as additional legal, accounting, corporate governance and investor relations expenses, and higher directors' and officers' insurance premiums.

#### *Selling Expenses*

Our selling expenses consist of costs from our sales organization, which includes our direct sales force and sales management, client services, distributor relations, marketing and business development personnel. These expenses primarily include salaries, commissions, bonuses, employee benefits and travel, as well as marketing and educational activities and allocated overhead expenses. We expense all sales and marketing costs as incurred.

During the year ended December 31, 2018, selling expenses accounted for 18.5% of our total revenue, as compared to 18.6% for the year ended December 31, 2017, and 19.4% for the year ended December 31, 2016. We expect that our selling expenses will continue to grow as we continue to increase our business footprint and expand our business development efforts in our pharmaceutical segment.

#### *Other Operating Income / (Expenses)*

Other operating income primarily includes government grants and exchange rate gains. Our other operating expenses include currency losses, recognized impairments on trade receivables and loss on the sale of property, plant and equipment, among others.

Government grants contain performance-based grants to subsidize research, development and innovation in the state of Mecklenburg-Western Pomerania from funds granted by the European Regional Development Fund. Furthermore, government grants contain the release of deferred income from investment related grants. Government grants that compensate for our research and development expenses are recognized directly in profit or loss, while grants relating to an asset are initially recognized as deferred income and subsequently released to profit or loss on a systematic basis over the useful life of the asset. We received different government grants in the state of Mecklenburg-Western Pomerania from funds granted by the European Regional Development Fund to subsidize our research, development and innovation. In addition, during the year ended December 31, 2018, we received investment-related government grants of €3.0 million that we used for the purchase of certain items of property, plant and equipment, including the development of our facilities in Rostock, as compared to €6.8 million for the year ended December 31, 2017 and €2.8 million for the year ended December 31, 2016. This amount was included in other liabilities and will be recognized in other operating income throughout the useful life of the facilities. The government grants which we receive can fluctuate from period to period.



**Results of Operations****Year Ended December 31, 2017 Compared to Year Ended December 31, 2018**

	For the Years Ended December 31,	
	2017	2018
	(€ in thousands)	
<b>Consolidated statement of comprehensive loss:</b>		
Revenue	31,689	40,478
Cost of sales	14,939	19,941
<b>Gross profit</b>	<b>16,750</b>	<b>20,537</b>
Research and development expenses	6,396	6,300
General administrative expenses	9,498	18,610
Selling expenses	5,897	7,474
Other operating income	1,043	2,306
Other operating expenses	457	1,065
<b>Operating loss</b>	<b>(4,455)</b>	<b>(10,606)</b>
Interest and similar income	14	33
Interest and similar expenses	1,021	1,075
<b>Finance costs, net</b>	<b>(1,007)</b>	<b>(1,042)</b>
Loss before taxes	(5,462)	(11,648)
Income tax expenses/(benefits)	14	(310)
<b>Loss for the period</b>	<b>(5,476)</b>	<b>(11,338)</b>
Other comprehensive income/(loss)	10	(8)
<b>Total comprehensive loss for the period</b>	<b>(5,466)</b>	<b>(11,346)</b>

*Revenue*

Revenue increased by €8,789 thousand, or 27.7%, to €40,478 thousand for the year ended December 31, 2018 from €31,689 thousand for the year ended December 31, 2017, principally due to improvement in performance by both pharmaceutical and diagnostics businesses, with new partnerships and clients gained during the period.

The breakdown of our revenue by segment was as follows:

	For the Years Ended December 31,	
	2017	2018
	(€ in thousands)	
<b>Revenue by segment:</b>		
Pharmaceutical	13,931	17,307
Diagnostics	17,758	23,171
<b>Total Revenue</b>	<b>31,689</b>	<b>40,478</b>

Revenues from our pharmaceutical segment were €17,307 thousand for the year ended December 31, 2018, an increase of €3,376 thousand, or 24.2%, from €13,931 for the year ended December 31, 2017. This increase was primarily attributable to new pharmaceutical partnerships. As

of December 31, 2018, we had collaborations with over 30 pharmaceutical partners, as compared to 19 pharmaceutical partners as of December 31, 2017. During the year ended December 31, 2018, the Company entered into two major collaborations, one with Evotec and the other with Denali. Under the terms of these collaborations, upfront payments totaling €4,000 thousand were received related to certain of the Company's intellectual property. These upfront fees were recognized as revenues during the period as they represented the transaction price to be allocated to the grant of licences, which are distinct and allow for use of such intellectual property for an unlimited period or for the time specified in the agreements. During the year ended December 31, 2018, revenues from one pharmaceutical partner represented 27.3% of the Group's total revenues, as compared to 38.1% for the year ended December 31, 2017.

Revenues from our diagnostics segment were €23,171 thousand for the year ended December 31, 2018, an increase of €5,413 thousand, or 30.5%, from €17,758 thousand for the year ended December 31, 2017. The total number of test orders received in the diagnostics segment for the year ended December 31, 2018 was approximately 48,000 tests, an increase of approximately 84.9% as compared to approximately 26,000 test orders received for the year ended December 31, 2017. The increases in both revenues and number of tests were primarily attributable to strong growth in sales of our NIPT diagnostic test products, a product that was launched in July 2017. Within the diagnostics segment, revenue from sales of NIPT products was €3,288 thousand for the year ended December 31, 2018, an increase of €3,155 thousand from €133 thousand for the year ended December 31, 2017. The sales growth was primarily driven by both a change in our unit pricing strategy for NIPT products and a new contract for the product which was entered into in June 2018. The growth in the volume of sales of such product was the main contributor to the 30.5% increase in diagnostics segment revenue across the periods, partially offset by a decrease in the average price of NIPT products. The total number of NIPT test orders received for the year ended December 31, 2018 was nearly 15,800, an increase of approximately 15,350 orders as compared to nearly 450 orders for the year ended December 31, 2017. In our other diagnostic product categories, changes in price had a minimal impact on diagnostics segment revenue.

The breakdown of our revenue from both of our segments, in the aggregate, by geographical region was as follows:

	For the Years Ended December 31,	
	2017	2018
<b>Revenue by geographical region:</b>		
Europe	5,676	6,850
<i>Of which: Germany</i>	—	1,061
Middle East	8,846	12,401
<i>of which: Saudi Arabia</i>	4,926	5,475
North America	14,897	18,113
<i>of which: United States</i>	13,482	17,296
Latin America	1,474	2,185
Asia Pacific	796	929
<b>Total Revenue</b>	<b>31,689</b>	<b>40,478</b>

In cases where our pharmaceutical partners are developing a new rare disease treatment, we generally anticipate that the final approved treatment will be made available globally. As a result, we allocate the revenues of our pharmaceutical segment by geographical region by reference to the

location where each pharmaceutical partner mainly operates, which is based on the region from which most of their revenues are generated. The allocation of revenues in our diagnostics segment is based on the location of each customer. Our North America region contributed €18,113 thousand to revenue for the year ended December 31, 2018, an increase of €3,216 thousand, or 21.6%, from €14,897 thousand for the year ended December 31, 2017, primarily driven by revenues from our pharmaceutical business, including revenues from the Denali collaboration. Revenues from the North America region represented 44.7% of our total revenues for the year ended December 31, 2018 as compared to 47.0% for the year ended December 31, 2017.

Our Middle East region contributed €12,401 thousand to revenue for the year ended December 31, 2018, an increase of €3,555 thousand, or 40.2%, from €8,846 thousand for the year ended December 31, 2017. This revenue growth was primarily attributable to an increase in sales of NIPT tests during the period based on a fixed fee contract.

Our Europe region contributed €6,850 thousand to revenue for the year ended December 31, 2018, an increase of €1,174 thousand, or 20.7%, from €5,676 thousand for the year ended December 31, 2017, primarily driven by an increase in the number of clients within our diagnostics segment and revenues from our pharmaceutical business, including revenues from the Evotec collaboration.

#### *Cost of Sales*

Cost of sales increased by €5,002 thousand, or 33.5%, to €19,941 thousand for the year ended December 31, 2018, from €14,939 thousand for the year ended December 31, 2017. This increase was primarily attributable to an increase in the volume of test requests processed, of which the largest contributor was consumables and direct personnel costs attributed to the diagnostics segment. Cost of sales increased at a lower rate as compared to the volume of test requests for the year ended December 31, 2018, when compared to the year ended December 31, 2017, because the increase in the volume of test requests was primarily driven by an increase in sales of NIPT products, for which the consumables costs in absolute amount is relatively lower than other diagnostics products. Certain stock-based compensation of €646 thousand related to options granted to production staff also contributed to the increase.

#### *Gross Profit*

As a result of these and other factors, our gross profit increased by €3,787 thousand, or 22.6%, to €20,537 thousand for the year ended December 31, 2018, from €16,750 thousand for the year ended December 31, 2017.

#### *Research and Development Expenses*

Research and development expenses remained largely unchanged, at €6,300 thousand for the year ended December 31, 2018, from €6,396 thousand for the year ended December 31, 2017. This represents IT-related expenses and research that does not qualify for capitalization and includes consumable costs, software and hardware costs, personnel costs, consultation and legal expenses and depreciation of equipment.

#### *General Administrative Expenses*

General administrative expenses increased by €9,112 thousand, or 95.9%, to €18,610 thousand for the year ended December 31, 2018, from €9,498 thousand for the year ended December 31, 2017, principally due to an increase in general expenses, such as IT-related costs, as a result of the expansion of the business. The general administrative expenses included stock-based compensation

expenses of €4,875 thousand for the year ended December 31, 2018, an increase of €3,981 thousand as compared to €894 thousand for the year ended December 31, 2017.

#### *Selling Expenses*

Selling expenses increased by €1,577 thousand, or 26.7%, to €7,474 thousand for the year ended December 31, 2018, from €5,897 thousand for the year ended December 31, 2017, principally due to the expansion of our business development team for the pharmaceutical segment, as well as additional marketing expenses.

#### *Other Operating Income / (Expenses)*

Other operating income increased by €1,263 thousand, or 121.1%, to €2,306 thousand or the year ended December 31, 2018, from €1,043 thousand for the year ended December 31, 2017, principally due to an increase in recognition of grant income.

Other operating expenses increased by €608 thousand, or 133.0%, to €1,065 thousand for the year ended December 31, 2018, from €457 thousand for the year ended December 31, 2017, principally due to the recognition of impairment losses on trade and other receivables in line with IFRS 9, a new accounting standard effective from January 1, 2018, resulting from an increased aging in our trade and other receivables due from customers in the Middle East region in our Diagnostics segment.

#### *Interest and Similar Income / (Expenses)*

Interest and similar income increased by €19 thousand to €33 thousand for the year ended December 31, 2018, from €14 thousand for the year ended December 31, 2017.

Interest and similar expenses increased by €54 thousand, or 5.3%, to €1,075 thousand for the year ended December 31, 2018, from €1,021 thousand for the year ended December 31, 2017, mainly relating to the interest expenses from loans relating to the development of our new laboratory in Rostock.

#### *Loss Before Taxes for the Year*

As a result of the factors described above, our loss before taxes for the year ended December 31, 2018 was €11,648 thousand, an increase of €6,186 thousand, or 113.3%, from €5,462 thousand for the year ended December 31, 2017.

#### *Segment Adjusted EBITDA*

We evaluate segment performance based on segment results and measure it with reference to Adjusted EBITDA, which we define as operating loss presented in the consolidated statements of comprehensive loss, adjusted for corporate expenses, depreciation and amortization as well as share-based payment expenses. Our Segment Adjusted EBITDA was as follows:

	For the Years Ended December 31,	
	2017	2018
<b>Segment Adjusted EBITDA:</b>		
Pharmaceutical	10,870	13,641
Diagnostics	2,552	2,285

Adjusted EBITDA from our pharmaceutical segment was €13,641 thousand for the year ended December 31, 2018, an increase of €2,771 thousand, or 25.5%, from €10,870 thousand for the year ended December 31, 2017. This increase was primarily attributable an increase in revenues during the year.

Adjusted EBITDA from our diagnostics segment was €2,285 thousand for the year ended December 31, 2018, an decrease of €267 thousand, or 10.5%, from €2,552 thousand for the year ended December 31, 2017. The decrease was primarily attributable to the increase in cost of sales in 2018, as a result of increase in direct personnel costs and consumable costs.

#### Year Ended December 31, 2016 Compared to Year Ended December 31, 2017

	For the Years Ended December 31,	
	2016	2017
	(€ in thousands)	
<b>Consolidated statement of comprehensive loss:</b>		
Revenue	27,669	31,689
Cost of sales	12,856	14,939
<b>Gross profit</b>	<b>14,813</b>	<b>16,750</b>
Research and development expenses	5,885	6,396
General administrative expenses	8,888	9,498
Selling expenses	5,364	5,897
Other operating income	1,295	1,043
Other operating expenses	908	457
<b>Operating loss</b>	<b>(4,937)</b>	<b>(4,455)</b>
Interest and similar income	26	14
Interest and similar expenses	856	1,021
<b>Finance costs, net</b>	<b>(830)</b>	<b>(1,007)</b>
Loss before taxes	(5,767)	(5,462)
Income tax (benefits)/expenses	(408)	14
<b>Loss for the period</b>	<b>(5,359)</b>	<b>(5,476)</b>
Other comprehensive income	9	10
<b>Total comprehensive loss for the period</b>	<b>(5,350)</b>	<b>(5,466)</b>

#### Revenue

Revenue increased by €4,020 thousand, or 14.5%, to €31,689 thousand for the year ended December 31, 2017 from €27,669 thousand for the year ended December 31, 2016, principally due to new pharmaceutical partnerships as well as further expansion in our diagnostics business.

The breakdown of our revenue by segment was as follows:

	For the Years Ended December 31,	
	2016	2017
	(€ in thousands)	
<b>Revenue by segment:</b>		
Pharmaceutical	12,348	13,931
Diagnostics	15,321	17,758
<b>Total Revenue</b>	<b>27,669</b>	<b>31,689</b>

Revenues from our pharmaceutical segment were €13,931 thousand for the year ended December 31, 2017, an increase of €1,583 thousand, or 12.8%, from €12,348 thousand for the year ended December 31, 2016. This increase was primarily attributable to four new pharmaceutical partnerships. During the year ended December 31, 2017, we had collaborations with 19 pharmaceutical partners in all phases of the drug development process as well as post-commercialization, as compared to 15 partners during the year ended December 31, 2016. During the year ended December 31, 2017, revenues from one pharmaceutical partner represented 38.1% of the Group's total revenues, flat compared to the prior year.

Revenues from our diagnostics segment were €17,758 thousand for the year ended December 31, 2017, an increase of €2,437 thousand, or 15.9%, from €15,321 thousand for the year ended December 31, 2016. The total number of test orders received from the diagnostics segment for the year ended December 31, 2017 was for over 26,000 tests, which represented an increase of 25% as compared to approximately 21,000 test orders received for the year ended December 31, 2016. The increases in both revenues and number of tests were primarily attributable to strong growth in sales of our WES and WGS diagnostic test products in 2017. During the year ended December 31, 2017, revenues from sales of WES and WGS tests contributed 40% and 12% of the revenues in our diagnostics segment, respectively (as compared to 36% and 6% during the year ended December 31, 2016, respectively). The total number of WGS and WES test orders received for the year ended December 31, 2017 was nearly 11,500, an increase of 27.7% as compared to year ended December 31, 2016.

The breakdown of our revenue from both of our segments, in the aggregate, by geographical region was as follows:

	For the Years Ended	
	December 31,	
	2016	2017
	(€ in thousands)	
<b>Revenue by geographical region:</b>		
Europe	5,281	5,676
Middle East	7,014	8,846
<i>of which: Saudi Arabia</i>	3,728	4,926
North America	14,033	14,897
<i>of which: United States</i>	12,158	13,482
Latin America	747	1,474
Asia Pacific	594	796
<b>Total Revenue</b>	<b>27,669</b>	<b>31,689</b>

Our North America region contributed €14,897 thousand to revenue for the year ended December 31, 2017, an increase of €864 thousand, or 6.2%, from €14,033 thousand for the year ended December 31, 2016. Revenues from the North America region represented 47.0% of our total revenues for the year ended December 31, 2017 as compared to 50.7% for the year ended December 31, 2016, primarily driven by revenues from our pharmaceutical segment.

Our Middle East region contributed €8,846 thousand to revenue for the year ended December 31, 2017, an increase of €1,832 thousand, or 26.1%, from €7,014 thousand for the year ended December 31, 2016. This revenue growth was primarily attributable to an increase in number of clients within our diagnostics segment.

Our Europe region contributed €5,676 thousand to revenue for the year ended December 31, 2017, an increase of €395 thousand, or 7.5%, from €5,281 thousand for the year ended December 31, 2016, primarily driven by an increase in the number of clients within our diagnostics segment.

#### *Cost of Sales*

Cost of sales increased by €2,083 thousand, or 16.2%, to €14,939 thousand for the year ended December 31, 2017, from €12,856 thousand for the year ended December 31, 2016, largely in line with the increase in test orders received and revenues. This increase was primarily attributable to an increase in the cost of consumables for our diagnostic business, in particular as more WGS and WES tests were received. In addition, depreciation expense increased due to the purchase of new sequencing equipment at the end of 2016.

#### *Gross Profit*

As a result of these and other factors, our gross profit grew by €1,937 thousand, or 13.1%, to €16,750 thousand for the year ended December 31, 2017, from €14,813 thousand for the year ended December 31, 2016.

#### *Research and Development Expenses*

Research and development expenses increased by €511 thousand, or 8.7%, to €6,396 thousand for the year ended December 31, 2017, from €5,885 thousand for the year ended December 31, 2016, principally due to an increase in IT-related expenses and other research which does not qualify for capitalization. This includes costs, personnel costs, consultation and legal expenses and depreciation of equipment.

#### *General Administrative Expenses*

General administrative expenses increased by €610 thousand, or 6.9%, to €9,498 thousand for the year ended December 31, 2017, from €8,888 thousand for the year ended December 31, 2016, principally due to an increase in general expenses in line with the expansion of the business, offset by the decrease in stock-based compensation of €70 thousand to €894 thousand for the year ended December 31, 2017 from €964 thousand for the year ended December 31, 2016.

#### *Selling Expenses*

Selling expenses increased by €533 thousand, or 9.9%, to €5,897 thousand for the year ended December 31, 2017, from €5,364 thousand for the year ended December 31, 2016, principally due to the expansion of our sales team and additional marketing efforts, including an increase in personnel attendance at conferences and exhibitions.

#### *Other Operating Income / (Expenses)*

Other operating income decreased by €252 thousand, or 19.5%, to €1,043 thousand for the year ended December 31, 2017, from €1,295 thousand for the year ended December 31, 2016, principally due to a reduction in income related to government grants.

Other operating expenses decreased by €451 thousand, or 49.7%, to €457 thousand for the year ended December 31, 2017, from €908 thousand for the year ended December 31, 2016, principally due to an impairment of trade receivables recognized in 2016.

#### *Interest and Similar Income / (Expenses)*

Interest and similar income decreased by €12 thousand, or 46.2%, to €14 thousand for the year ended December 31, 2017, from €26 thousand for the year ended December 31, 2016.

Interest and similar expenses increased by €165 thousand, or 19.3%, to €1,021 thousand for the year ended December 31, 2017, from €856 thousand for the year ended December 31, 2016, principally due to an increase in interest expenses from loans relating to the development of our new laboratory in Rostock, Germany in 2017.

#### *Loss Before Taxes for the Year*

As a result of the factors described above, our loss before taxes for the year ended December 31, 2017 was €5,462 thousand, a decrease of €305 thousand, or 5.3%, from €5,767 thousand for the year ended December 31, 2016.

#### *Segment Adjusted EBITDA*

Our Segment Adjusted EBITDA was as follows:

	For the Ended Years December 31,	
	2016	2017
<b>Segment Adjusted EBITDA:</b>		
Pharmaceutical	10,865	10,870
Diagnostics	(122)	2,552

Adjusted EBITDA from our pharmaceutical segment was €10,870 thousand for the year ended December 31, 2017, a slight increase of €5 thousand from €10,865 thousand for the year ended December 31, 2016. This increase was primarily attributable to an increase in revenue as described above, offset by an increase in personnel costs for production and business development.

Adjusted EBITDA from our diagnostics segment was €2,552 thousand for the year ended December 31, 2017, an increase of €2,674 thousand from negative €122 thousand for the year ended December 31, 2016. This increase was primarily attributable to an increase in revenues due to strong growth in sales of our WES and WGS diagnostic test products in 2017.

## **Liquidity and Capital Resources**

### **Overview**

Our cash requirements are principally for working capital and capital expenditures, including expansions and improvements to our laboratory facilities, technology infrastructure and research and development activities. In fiscal year 2019 and beyond, we anticipate that our capital expenditures will increase from prior periods as we continue to increase our research and development efforts. Historically, our main source of liquidity has been our secured loans, municipal loans and government funding of research programs, proceeds from our shareholders and the private financings in 2017 and 2018.

Our financial condition and liquidity is and will continue to be influenced by a variety of factors, including our ability to continue to generate cash flows from our operations, our capital expenditure requirements and changes in exchange rates which will impact our generation of cash flows from operations when measured in euros.

Our known material liquidity needs for periods beyond the next twelve months are described below in "Contractual Obligations and Commitments." We believe cash generated from our operations, cash equivalents and financial instruments, together with government funding of research programs will be sufficient to fund our operations for at least 12 months.



**Comparative Cash Flows****Comparison of the Year Ended December 31, 2017 and 2018**

The following table sets forth our cash flows for the periods indicated:

	For the Years Ended December 31,	
	2017	2018
	(€ in thousands)	
<b>Consolidated statement of cash flows:</b>		
Cash flow used in operating activities	(4,336)	(4,577)
Cash flow used in investing activities	(11,154)	(8,694)
Cash flow provided by financing activities	17,682	19,336
<b>Net increase in cash and cash equivalents</b>	<b>2,192</b>	<b>6,065</b>
Cash and cash equivalents at the beginning of the period	965	3,157
<b>Cash and cash equivalents at the end of the period</b>	<b>3,157</b>	<b>9,222</b>

*Operating Activities*

Our cash flow used in operating activities primarily relates to changes in the components of our working capital, including cash received from our pharmaceutical partners and diagnostics clients, and payment made to our suppliers.

For the year ended December 31, 2018, cash used in operating activities was €4,577 thousand, an increase of €241 thousand as compared to €4,336 thousand for the year ended December 31, 2017. This change was principally due to an increase in trade receivables from our diagnostics clients.

*Investing Activities*

Our cash flow used in investing activities for the year ended December 31, 2018 consists of investments in intangible assets, and plant, property and equipment, grants received for investments in property, plant and equipment and cash used in disposals of property, plant and equipment. These include investments in the development of new facilities, including our new headquarters in Rostock, Germany, our new facility in Cambridge, Massachusetts, the purchase of laboratory equipment, and the development of new biomarkers and interpretation-based solution products development such as our CentoPortal online platform and CentoMD database.

For the year ended December 31, 2018, cash flow used in investing activities was €8,694 thousand, a decrease of €2,460 thousand as compared to €11,154 thousand for the year ended December 31, 2017. This change was principally due to decrease in investment in property, plant and equipment as the development of our new headquarters in Rostock, Germany was completed in early 2018.

*Financing Activities*

Our cash flow provided by financing activities for the year ended December 31, 2018 consists of proceeds we received from our shareholders and investors through private financing, along with cash obtained from secured bank loans which contributed to the construction of our new facility in Rostock.

For the year ended December 31, 2018, cash generated from financing activities was €19,336 thousand, an increase of €1,654 thousand as compared to €17,682 thousand for the year ended December 31, 2017. In 2017, we received €5,000 thousand from one of our shareholders through a private financing, as well as €15,000 thousand from a consortium of investors through an external private financing. In 2018, an additional €20,000 thousand was received from certain of the investors that comprised the external private financing group in 2017 (see "Certain Relationships and Related Party Transactions—Investment and Shareholders Agreement").

### Comparison of the Year Ended December 31, 2016 and 2017

The following table sets forth our cash flows for the periods indicated:

	For the Years Ended December 31,	
	2016	2017
	(€ in thousands)	
<b>Consolidated statement of cash flows:</b>		
Cash flow provided by/(used in) operating activities	1,390	(4,336)
Cash flow used in investing activities	(8,687)	(11,154)
Cash flow provided by financing activities	7,867	17,682
<b>Net increase in cash and cash equivalents</b>	<b>570</b>	<b>2,192</b>
Cash and cash equivalents at the beginning of the period	395	965
<b>Cash and cash equivalents at the end of the period</b>	<b>965</b>	<b>3,157</b>

#### *Operating Activities*

Our cash flow used in operating activities primarily relates to changes in the components of our working capital, including cash received from our pharmaceutical partners and diagnostics clients, and payment made to our suppliers.

For the year ended December 31, 2017, cash used in operating activities was €4,336 thousand, an increase in outflow of €5,726 thousand as compared to cash provided by operating activities of €1,390 thousand for the year ended December 31, 2016. This change was principally due to the difference in timing between the receipt of revenues in our diagnostics business and the payment of our suppliers. Our payment terms with our diagnostics clients typically range from 30 to 90 days and may extend to 120 days in some circumstances, particularly for our clients in the Middle East region. However, because our typical payment terms for our suppliers range from 30 to 60 days, the timing differences result in short term capital requirements to finance our operations.

#### *Investing Activities*

Our cash flow used in investing activities consists of investments in the development of new facilities, including our new facility in Rostock, Germany, the purchase of laboratory equipment, research and development of new biomarkers, interpretation-based solution products development and IT improvements such as our CentoPortal online platform and CentoMD database, as well as other research and development activities.

For the year ended December 31, 2017, cash used in investing activities was €11,154 thousand, an increase of €2,467 thousand as compared to €8,687 thousand for the year ended December 31, 2016. The increase was principally a result of an increase in investment in our new facility in Rostock in 2017, which is partially subsidized by government grants, with the remaining investment financed by long-term bank loans.

### Financing Activities

Our cash flow generated from financing activities consists of the proceeds we received from our shareholders through a private financing in January 2017, along with cash obtained from secured bank loans which contributed to the construction of our new facility in Rostock. In addition, we completed an additional private financing in June 2017.

For the year ended December 31, 2017, cash generated from financing activities was €17,682 thousand, an increase of €9,815 thousand as compared to €7,867 thousand for the year ended December 31, 2016. This increase was principally as a result of cash received from the private financing of €15,000 thousand, partially offset by the repayment of our bank overdraft and a loan repayment of €8,749 thousand in 2017.

### Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

### Contractual Obligations and Commitments

The table below presents the residual contractual terms of the financial liabilities on the reporting date, including estimated interest payments. The figures are undiscounted gross amounts, including estimated interest payments and interest on undrawn loan funds, but without showing the impact of offsetting.

The following table presents information relating to our contractual obligations (including estimated interest payments) as of December 31, 2018:

	Payments due by Period				
	Total	Less than 1 year	Between 1 and 3 years	Between 3 and 5 years	More than 5 years
	(€ in thousands)				
Secured bank loans <sup>(1)</sup>	15,985	2,201	3,975	1,833	7,976
Bank overdraft	1,915	1,915	—	—	—
Finance lease liabilities	3,234	1,435	1,799	—	—
Municipal loans <sup>(2)</sup>	1,273	—	—	—	1,273
Trade payables	5,429	5,429	—	—	—
Operating leases	252	197	55	—	—
	28,088	11,177	5,829	1,833	9,249

- (1) Secured bank loans and bank overdraft represent part of our Syndicated Loan Facility (defined below). The Syndicated Loan Facility includes financial covenants which stipulate that the Company must meet certain quarterly equity ratio and net debt ratio targets, as well as revenue and EBITDA performance targets, that are reset annually. During the years ended December 31, 2016 and 2017, such covenants were not met by us. In 2018 and 2019, we obtained formal written waivers for non-compliance with such covenants.
- (2) The municipal loans with MBMV (as defined below) are guaranteed by our shareholders. See "—Municipal Loans" below.

Secured bank loans are the most significant financing instruments for us and are used for the purpose of financing the development of our laboratory in Rostock. As of December 31, 2018, we had secured bank loans outstanding under our Syndicated Loan Facility in an aggregate principal

amount of €15,757 thousand, including bank overdrafts of €1,915 thousand under the Tranche D Loan (defined below). Our material loan agreements are summarized as below:

#### *Syndicated Loan Facility*

On August 4, 2015, we entered into a loan agreement (as amended or supplemented to date, the "Syndicated Loan Facility") with certain German commercial banks. The Syndicated Loan Facility consists of four tranches. As of December 31, 2018, €13,842 thousand was outstanding under tranches A and B, as compared to €13,836 thousand as of December 31, 2017. As of December 31, 2018 and 2017, there were no balances outstanding under tranche C and such overdraft facility expired on June 30, 2018. €1,915 thousand in bank overdrafts was outstanding under Tranche D as of December 31, 2018 (December 31, 2017: None utilized).

The Syndicated Loan Facility consists of:

- § a Tranche A loan in an aggregate principal amount of €12,000 thousand, which is subdivided into a Tranche A1 loan and a Tranche A2 loan that are scheduled to mature on June 30, 2030 (the "Tranche A Loans"), and bear interest at a fixed rate of 2.5% per annum until June 30, 2025, thereafter to be amended in consideration of the development of the capital markets as well as of our financial situation and the value of the collateral;
- § a Tranche B loan in an aggregate principal amount of €5,410 thousand that is scheduled to mature on December 30, 2022 (the "Tranche B Loan") and bears interest at a floating rate of EURIBOR plus a margin of 2.95% per annum;
- § a Tranche C loan in an aggregate principal amount of up to €2,500 thousand as overdraft facility that matured and was fully repaid on June 30, 2018 (the "Tranche C Loan") and bore interest at a floating rate of 6.25% per annum (adjusted in line with the respective Deutsche Bundesbank reference interest rate). The Company repaid all outstanding amounts under the Tranche C Loan in June 2018; and
- § a Tranche D loan with an aggregate principal amount of up to €2,500 thousand as overdraft facility (the "Tranche D Loan") and bears interest at EURIBOR plus a margin of 3.5% per annum. Pursuant to a cash pledge that we entered into in January 2018 with the lenders under the Tranche D loan, as at December 31, 2018, we had pledged €1,500 thousand in cash in connection with amounts outstanding thereunder.

The Tranche A Loans were granted to finance the development of our laboratory in Rostock. This includes financing the acquisition of land, construction of the building and purchase of laboratory equipment. The Tranche B Loan is used to purchase laboratory equipment on a pro rata basis. In addition, it serves to refinance rental purchases for short-term investments in laboratory equipment and IT equipment. The Tranche C Loan is used for advance and interim financing of investment grants. The Tranche D Loan serves us as a working capital line and for the repayment of certain facilities with Commerzbank AG in an aggregate amount of €2,500 thousand.

The Syndicated Loan Facility is secured by a land charge in the amount of €19,910 thousand, and additionally by assignments of certain laboratory equipment, by global assignments of our trade and other receivables and by pledge of a bank account with OstseeSparkasse Rostock.

The Syndicated Loan Facility contains certain financial covenants and other provisions which impose restrictions on the way we operate our business. In particular, the Syndicated Loan Facility provides that we may not (i) assume further indebtedness or grant security interests or any guarantees above certain amounts, (ii) dispose or acquire further assets exceeding certain limits or (iii) pay dividends if in breach of certain financial covenants. In addition, our CEO, Prof. Arndt Rolfs, must remain our major shareholder and CEO until May 31, 2019. He has committed himself by a separate agreement not to sell more than 10% of his shares in our company prior to such date.

The Syndicated Loan Facility also includes financial covenants which stipulate that we must meet certain quarterly equity ratio and net debt ratio targets, as well as revenue and EBITDA performance targets that are reset annually. The equity ratio and the net debt ratio are calculated quarterly on the basis of the Group's consolidated quarterly reports. During the years ended December 31, 2016 and 2017, these covenants of the Syndicated Loan Facility were not met by us. Subsequent to each relevant year end, we obtained formal written waivers for the breach of such covenants. We obtained such waivers from the various lenders under this facility for years ended December 31, 2016, December 31, 2017 and December 31, 2018. We have also obtained a further waiver of certain covenants of the facility for the year ending December 31, 2019. See "Risk Factors—We have been in default under our syndicated loan facility, which limits our liquidity and could result in the lenders accelerating amounts we owe to them under the facility."

#### *Revolving Credit Agreements*

We have entered into two further secured bank overdraft agreements totaling €1,500 thousand which we use to finance our day-to-day business operations. Neither of these facilities was utilized as of December 31, 2018 and 2017.

- § Our €1,000 thousand revolving credit agreement has an initial floating interest rate of 3.85% (adjusted on EURIBOR) when utilized as an overdraft facility. It is partially secured by separate guarantees provided by a German development bank in an amount up to €210,000 (guarantee fee of 1.25% per annum) and, in an amount of €100,000 each, by our CEO Prof. Arndt Rolfs, and Christoph Ehlers. In case there is a change in our shareholder structure, the lender is entitled to request further collateral from us.
- § Our €500 thousand revolving credit agreement has an initial floating interest rate of 4.5% per annum, an up-front fee of 0.25% per annum and is secured by two guarantees of up to €250 thousand. Prof. Arndt Rolfs and Christoph Ehlers are guarantors pursuant to the revolving credit agreement. In case there is a change in our shareholder structure, the lender is entitled to terminate the revolving credit agreement if we are unable to agree with the lender on the continuation of the loan under amended terms.

#### *Municipal Loans*

We entered into four financings, structured as silent participation agreements, with Mittelständische Beteiligungsgesellschaft Mecklenburg-Vorpommern mbH ("MBMV") (the "Municipal Loans"), pursuant to which MBMV participates in the Company as a silent partner on the following material terms:

The silent partnership agreement dated May 18, 2011 (the "Municipal Loan 1") provides for a cash contribution of €500 thousand which matures on December 31, 2021. MBMV is entitled to a fee consisting of an annual non-profit-related remuneration of 8.25% of the contribution per annum and an annual share in our profits of 1.5% of the investment value. If a two year loss is reported, the annual non-profit-related remuneration is increased by 0.75% of the contribution per annum. MBMV is entitled to terminate the Municipal Loan 1 if we do not comply with the contractual obligations under the agreement, including if the contribution is not used in accordance with its designated purposes. If the Municipal Loan 1 is terminated early, we will pay a surcharge fee to MBMV. Arndt Rolfs and Christoph Ehlers (each in the amount of €500 thousand) guarantee our obligations under the Municipal Loan 1 under separate agreements with MBMV. In addition, Bürgschaftsbank Mecklenburg-Vorpommern GmbH provided a guarantee to MBMV for the repayment of up to 80% of its contribution and up to 80% of the fees in accordance with a separate guarantee agreement.

The silent partnership agreement dated March 20, 2013 (the "Municipal Loan 2") provides a cash contribution of €360 thousand which matures on December 30, 2022. MBMV is entitled to a fee consisting of an annual non-profit related remuneration of 8.0% of the contribution per annum and

an annual share in our profits of 1.5% of the investment value. If a two year loss is reported, the annual non-profit related remuneration is increased by 0.75% of the contribution per annum. The Municipal Loan 2 contains a covenant to maintain an equity ratio of 20% calculated on a consolidated basis. If this agreed ratio is not achieved, the annual non-profit-related remuneration will be increased by 1.5% per annum. MBMV is entitled to terminate the Municipal Loan 2 if we do not comply with the contractual obligations under the agreement, including if the contribution is not used in accordance with its designated purposes. If the Municipal Loan 2 is terminated early, we will pay a surcharge fee to MBMV. Arndt Rolfs and Christoph Ehlers (each in the amount of €150 thousand) as well as Hans-Bodo Hartmann, Michael Schlenk and Stefan Maeser (each in the amount of €50 thousand) guarantee our obligations under the Municipal Loan 2 under separate agreements with MBMV. In addition, provided a guarantee to MBMV for the repayment of up to 80% of its contribution and up to 80% of the fees in accordance with a separate guarantee agreement.

The silent partnership agreement dated August 5, 2015 (the "Municipal Loan 3") between us, certain of our shareholders and MBMV provided for a cash contribution of €140 thousand which would have matured on May 30, 2021. MBMV was entitled to a fee consisting of an annual non-profit-related remuneration of 6.5% of the contribution per annum and an annual share in our profits of 50% but not exceeding 1.5% of the investment value. On April 25, 2018, we and MBMV agreed to terminate the Municipal Loan 3. We repaid the outstanding amount of the contribution in full on June 29, 2018.

The silent partnership agreement dated July 8, 2016 (the "Municipal Loan 4") between us, certain shareholders and MBMV provided for a cash contribution of €1,000 thousand which would have matured on December 31, 2023. MBMV was entitled to a fee consisting of an annual non-profit-related remuneration of 7.49% of the contribution per annum and an annual share in our profits of 50%, capped at 2.0% of the investment value. On April 25, 2018, we and MBMV agreed to terminate the Municipal Loan 4. We repaid the outstanding amount of the contribution in full on June 29, 2018.

## **Our Partnership Agreements**

### ***Shire***

We have entered into a strategic collaboration with Shire International GmbH ("Shire"), pursuant to a global master services agreement originally entered into in January 2015, as subsequently amended, a supply agreement with Shire Pharmaceuticals Ireland Ltd. originally entered into in December 2013, as subsequently amended, and two research agreements with Shire and the University of Rostock Albrecht-Kossel Institute for Neuroregeneration (the "University of Rostock"), respectively, each as described below.

#### *Global Master Services Agreement*

Under the global master services agreement with Shire, we provide diagnostic services to Shire and its affiliates. Shire makes an annual flat-fee payment to us for performance of an unlimited number of diagnostic tests for Morbus Fabry, Morbus Gaucher, Morbus Hunter, MPS1, MPS2, MPS3, MPS4, MPS6 and MPS7. Tests for some of these diseases are eligible for incremental payments from Shire upon meeting a minimum quantity threshold.

#### *Supply Agreement*

Under the supply agreement with Shire, we develop, manufacture and supply customized CentoCards and kits for use in approximately 50 countries as requested by Shire. These kits are language-specific and include a filter-card with requested patient/clinician information, self-addressed and labeled envelopes, barcode/tracking stickers, an informed consent form and instructions.

Payments are calculated at fixed and variable rates, including fixed rates per newly designed language-specific kits and related storage and quality control fees. Kits are then billed at variable rates based on volumes, with minimum order requirements. We granted Shire and its affiliates a non-exclusive license to use any intellectual property in our existing kits or these custom-developed kits as necessary to distribute and provide the kits pursuant to the agreement.

#### *Research Agreement*

We entered into a statement of work for collaborative research with Shire, the University of Rostock and one of our employees dated June 2015 for a research project studying Lyso-Gb1 as a long-term prognostic biomarker in Gaucher disease. This research agreement is governed by the terms of our master services agreement with Shire. Under the agreement, Shire will provide funding for the research project.

#### *Project Services Agreement*

We have also entered into a project services agreement with Shire dated March 2018 for a collaborative research project on hereditary angioedema ("HAE") dried-blood-spot-based diagnostic testing screening. All charges under the agreement are to be paid by Shire. We and Shire granted each other the limited right to use each other's data and intellectual property for the sole purpose of performing research under the agreement. Any subsequent research results and inventions are to be co-owned by us and Shire, and Shire has the exclusive right, for six months after our delivery of a research report, to negotiate with us to purchase ownership of or a license to our rights in any research results or inventions on commercially reasonable terms.

#### **Evotec**

In July 2018, we entered into a drug discovery collaboration agreement with Evotec in the field of lysosomal storage disorders. Under this agreement we agreed to license to Evotec diagnostic biomarkers and deliver patient primary cells for up to 10 mutually selected indications. The agreement entitles Evotec to use any patient cells provided by us and our biomarker know-how for research, development and commercialization purposes. Evotec is permitted under the agreement to use (or transfer to third parties for such use) the patient primary cells and biomarker know-how for research, development and commercialization purposes on its own behalf or, with respect to the patient primary cells only, on behalf of third parties. We have granted Evotec exclusivity of the patient primary cells for a maximum of two years after delivery of the patient primary cells and biomarker know-how materials for each selected indication for drug discovery.

Each party will own any intellectual property developed pursuant to the collaboration that relates solely to its own pre-existing intellectual property. We will own any intellectual property related to blood-derived diagnostic biomarkers, and Evotec owns any other intellectual property developed as a result of the collaboration. We granted to Evotec and its affiliates a worldwide, non-exclusive, royalty-free right and license to access and use CentoMD and the developed biomarker intellectual property for any discovery, research and development purposes for the 10 selected indications and to develop and commercialize compounds or products derived from the use of CentoMD or the developed biomarker intellectual property. This license is only transferrable or sublicenseable to Evotec's affiliates.

In consideration for the licenses granted and the assets transferred, Evotec paid us a one-time signing fee for the transfer of knowledge and technology, with additional payments depending on the achievement of pre-specified milestones. In the event that, following delivery of patient primary cells for the selected rare diseases, Evotec enters into a strategic transaction with a third party with respect to compounds or products derived from or incorporating the patient cells and related cell

lines supplied by us, we are entitled to receive a revenue share ranging from a mid-single digit to mid-teen percentage (depending on when such transaction takes place) on Evotec's net revenues resulting from such transaction. Evotec has the right to deduct from its one-time signing fee if we receive any such revenue share or participation fee.

### ***Denali***

In September 2018, we entered into a master agreement with Denali, under which we have agreed to provide laboratory testing services and patient recruitment activities to Denali with respect to LRRK2-Parkinson's disease. The laboratory testing services include the production of test kits, which include the CentoCard and buccal swab kits, analysis of samples, the generation of a medical report accessible via CentoPortal and access to CentoMD. Upon Denali's request, we may also produce our CentoCard product in various languages with a Denali logo. Patient recruitment activities include outreach to medical centers, medical offices, hospitals and academic institutions, initially across Denali's priority geographies. We may also make additional healthcare professionals aware of certain Denali studies and our related laboratory testing services, manage distribution of kits to healthcare professionals or contact healthcare professionals that are treating patients eligible for enrollment in the Denali studies. We agree not to engage in certain territories with any other for-profit companies in patient identification and recruitment activities with respect to LRRK2-Parkinson's disease, and not to assist other third parties in doing so.

Ownership of any patentable inventions generated by either party in its performance of the agreement is to be determined in accordance with U.S. patent law, and we granted Denali a royalty-free, perpetual, sublicensable, worldwide license, for its business purposes, under any such inventions owned by us. We also granted Denali non-exclusive, royalty-free, irrevocable, transferable, worldwide licenses to use and disclose the data generated by our services for its own research and development purposes and to use (but not disclose) other anonymized patient data accessed via CentoMD for its own research and development purposes with respect to Parkinson's disease. Under the master agreement, Denali has paid a one-time €3.5 million fee for access to our know-how and technology. Denali is to be charged per sample analyzed. Additionally, Denali is to be charged between €1 million and €3 million for each phase of patient recruitment activity efforts up to a total of €6 million, excluding laboratory testing service fees. We may receive additional compensation depending on the number of referred patients, calculated per referred patient, up to a total of €1 million and further compensation if a drug developed by Denali for the treatment of Parkinson's disease via the study aided by our solutions achieves marketing authorization, in certain jurisdictions, calculated per referred patient, up to €10 million. We would also then be eligible for additional milestone payments depending on such drug's commercial performance, calculated per referred patient, up to a total of €40 million.

## **Quantitative and Qualitative Disclosures about Market Risk**

### ***Risk Management***

In the ordinary course of our business activities, we are exposed to various risks that are beyond our control, including credit risk, liquidity risk, market and sales risk and currency risk.

### ***Credit Risk***

Our default risk generally arises from trade and other receivables and is influenced mainly by the characteristics of individual international customers, as well as deposits with banks. More than 60% of our customers have had business relationships with us for more than three years. Our customers are pharmaceutical companies, hospitals, insurance providers, doctors and patients. To avoid defaults, prepayment is requested for shipments to patients and doctors.



In addition to the macroeconomic situation generally, the development of international healthcare markets is a key economic factor affecting our business. These markets are closely monitored by our sales and other staff. The maximum default risk for trade receivables as of December 31, 2018 and 2017 by geographical region was as follows:

	As of	
	December 31,	
	2017	2018
	(€ in thousands)	
Europe	1,202	2,697
Middle East	2,982	6,348
North America	1,585	1,074
Latin America	306	595
Other Regions	917	187
Total	6,992	10,901

### **Liquidity Risk**

We are exposed to liquidity risk in both the availability of finance and the repayment of borrowings, as we may not be in a position to meet our financial liabilities as contractually agreed by providing cash or other financial assets. We manage our liquidity in order to ensure that sufficient cash and cash equivalents are available for us to meet our payment obligations when these fall due, without incurring unacceptable losses or damaging our reputation.

We strive to maintain cash and cash equivalents as well as other highly tradable debt instruments at a level above that of the expected cash outflows for financial liabilities (apart from trade payables) during the next 60 days. We also monitor the amount of expected cash inflows from trade and other receivables together with the expected cash outflows for trade payables and other liabilities.

In addition, we have secured credit lines of €4,000 thousand that bear interest at 3.33% to 4.50%, of which €1,915 thousand was utilized as of December 31, 2018, and were unused as of December 31, 2017.

### **Market and Sales Risk**

Market risks primarily arise from changing reimbursement structures as well as pricing pressure and pressure to innovate in the highly dynamic market environment of genetic diagnostic testing. We monitor developments very closely through our local sales teams and their reporting structures. We also closely monitor our individual segmental results by conducting periodic analyses of our competitive landscape, with the aim of enabling rapid pricing and product enhancements, if necessary.

### **Currency Risk**

We are also exposed to currency risks where contracts are concluded in foreign currencies. The vast majority of the products and services we provide, however, are invoiced in Euros. The main

functional currencies of group other than the euro are U.S. dollar, the Canadian dollar (the "CAD"), the Indian rupee (the "INR") and the Saudi Arabian Riyal (the "SAR"), as shown in the table below.

	As of December 31, 2018			
	USD	CAD	INR	SAR
	(€ in thousands)			
Trade receivables	1,674	26	65	4
Trade payables and other liabilities	(2,193)	(13)	(2)	(5)
Net risk statement of financial position	(519)	13	63	(1)

The impact on our earnings before tax or equity of a 20% change in the U.S. dollar exchange rate as compared to the euro would not be material. In the future, we expect our exposure to the U.S. dollar to increase over time as our business grows. The impact on our earnings before tax or equity of a 20% change in the CAD, INR and SAR would not be material.

### Internal control over financial reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of our unaudited interim condensed consolidated financial statements as of and for the nine months ended September 30, 2018, we identified a material weakness in our internal controls as of December 31, 2017, related to the lack of effective review controls over closing entries in our financial statement close process.

Since we identified the material weakness, we have taken steps to remediate the underlying control deficiencies. During 2018, management hired appropriate accounting and financial professionals with the experience and knowledge necessary to review the accounting and internal control processes and procedures to address the material weakness identified. In addition, further internal control procedures were implemented to improve the financial reporting process and additional trainings are planned for our accounting and financial reporting personnel. However, the material weakness was not fully remediated as of December 31, 2018. Specifically, our independent registered public accounting firm determined that we did not have adequate procedures and controls to ensure that accurate financial statements could have been prepared and reviewed on a timely basis for annual reporting purposes. The inadequate financial statement close process and procedures include account reconciliations, the resolution of accounting issues involving significant judgment and estimates and overall review of the financial statements.

We cannot assure you that we have identified all of our existing material weaknesses, or that we will not have additional material weaknesses in the future. Undetected material weaknesses in our internal controls could lead to further financial statement restatements and require us to incur the expense of remediation.

We are working to remediate the material weakness as quickly and efficiently as possible. See "Risk Factors—We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate our material weakness or if we fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to report our financial results accurately or to prevent fraud."

## Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB. Some of the accounting methods and policies used in preparing the financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the circumstances concerned. The actual value of our assets, liabilities and shareholders' equity and of our earnings could differ from the value derived from these estimates if conditions changed and these changes had an impact on the assumptions adopted.

Our significant accounting policies that we believe to be critical to the judgments and estimates used in the preparation of our financial statements are included in "note 6—Accounting Judgments and Estimates" and "note 19—Share-Based Payments" to our financial statements.

## JOBS Act Exemptions and Foreign Private Issuer Status

### *JOBS Act*

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- § the ability to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly reduced disclosure in management's discussion and analysis of financial condition and results of operations in this prospectus;
- § exemption from the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, in the assessment of our internal controls over financial reporting; and
- § to the extent that we no longer qualify as a foreign private issuer, (i) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (ii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

We may take advantage of these exemptions for up to five years or until such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company upon the earliest to occur of (i) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer" with at least \$700 million of equity securities; (iii) the issuance, in any three year period, by our company of more than \$1.0 billion in non-convertible debt securities held by non-affiliates; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We may choose to take advantage of some but not all of these reduced burdens. For example, we intend to take advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F. To the extent that we take advantage of these reduced burdens, the information that we provide shareholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on

the relevant dates on which adoption of such standards is required by the IASB. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

***Foreign Private Issuer***

We are also considered a "foreign private issuer." In our capacity as a foreign private issuer, we are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, members of our management board, supervisory board and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and the rules under the Exchange Act with respect to their purchases and sales of our common shares. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. In addition, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information.

We may take advantage of these exemptions until such time as we are no longer a foreign private issuer. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of the members of our management board or supervisory board are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

We have taken advantage of certain reduced reporting and other requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies.

## BUSINESS

### Overview

Centogene is a commercial-stage rare disease company focused on transforming clinical and genetic data into medical solutions for patients. We are focused on bringing rationality to treatment decisions and accelerating the development of new orphan drugs by using our knowledge of the global rare disease market, including epidemiological, clinical heterogeneity and innovative biomarkers. Our data repository includes epidemiologic, phenotypic and genetic information from over 380,000 patients sourced from over 110 countries thus reflecting the genetic differences in global ethnicities. We believe this represents the only platform that comprehensively analyzes multi-level data to improve the understanding of rare diseases, which can aid in the identification of patients and improve our pharmaceutical partners' ability to bring orphan drugs to the market. As of December 31, 2018 we had over 50 collaboration agreements with over 30 pharmaceutical partners and have commercialized seven biomarkers.

In the United States, a rare disease is generally defined as a condition that affects fewer than 200,000 people. Of the 7,000 identified rare diseases, between 85% and 90% are classified as serious or life-threatening and 30% of rare disease patients die before the age of five. It typically takes an average of five to seven years for a patient with a rare disease to be diagnosed. These statistics underscore the significant unmet need for high-quality genetic information in the rare disease space for the early identification and effective treatment of patients.

Despite legislative initiatives and continued investment in rare disease drug development, significant unmet need still exists. Of the 7,000 identified rare diseases it is estimated that 80%, or 5,600, have a genetic origin and, of these hereditary rare diseases, only approximately 4%, or 230 hereditary rare diseases, have an FDA approved treatment. The introduction of new treatments and development of cost-effective drugs are constrained by a number of factors including a lack of high-quality information regarding the clinical heterogeneity of medical symptoms, lack of comprehensive and curated medical data, difficulties in the early identification of patients, lack of biomarkers and difficulties in understanding market size and epidemiology.

We have developed a proprietary platform and system that we believe will improve methods for identifying and monitoring these rare hereditary diseases and provide solutions that accelerate the development of orphan drugs. At the core of our platform is our data repository, which includes epidemiologic, phenotypic and genetic data and allows us to assemble an extensive knowledge-base in rare hereditary diseases. We collect this detailed level of data in our repository through our easy-to-use CentoCard, a CE-marked dried blood spot collection kit, which is distributed at a low cost through our global network and captures blood samples of potential rare disease patients. We then curate this information using a systematic and scientific approach conducted by professionals to ensure the medical validity of our data prior to feeding it into our central CentoMD database, which we believe is the world's largest curated mutation database for rare diseases.

This systematic process results in information-based services that are beneficial for rare disease drug development by our biotech and pharmaceutical partners. This includes providing epidemiological insights about rare diseases, further identification of rare disease patients as well as the ability to identify new biomarkers, which can accelerate drug development by demonstrating the efficacy of the drugs, performing longitudinal monitoring and informing necessary titration for individual rare disease patients. The additional rare disease patients identified through these partnerships can fuel clinical trial enrollment, which, in turn, adds more diagnostic information to our

repository. This synergistic model allows us to continuously enhance our own expertise and support pharmaceutical knowledge in the rare disease field.

We offer solutions to our pharmaceutical parties and clients through two business segments. Our pharmaceutical segment provides a variety of services to our pharmaceutical partners, including early patient recruitment and identification, epidemiological and patient population sizing insights, biomarker discovery and patient monitoring and follow-up. Our information platforms, our deep access to rare disease patients and our ability to develop proprietary technologies including biomarkers enable us to provide services to our pharmaceutical partners in all phases of the drug development process as well as post-commercialization. Revenues in our pharmaceutical segment are generated primarily from collaboration agreements with our pharmaceutical partners, which can be structured on a fee per sample basis, milestone basis, fixed fee basis, royalty basis or a combination of these. For the year ended December 31, 2018, €17.3 million, or 42.8%, of our total revenues were derived from our pharmaceutical segment.

Our clinical diagnostics segment provides targeted genetic sequencing and diagnostics services to patients through our distribution partners and clients, who are typically physicians, labs or hospitals. As of December 31, 2018, we believe we offer the broadest diagnostic testing portfolio for rare diseases, covering over 3,800 genes using over 9,000 different tests. Revenues from our diagnostics segment are typically generated by set fees per diagnostic test or per bundle of diagnostic tests under contracts with our clients. For the year ended December 31, 2018, €23.2 million, or 57.2%, of our total revenues were derived from our diagnostics segment.

We continuously work on expanding our medical and genetic knowledge of rare genetic diseases. We work with renowned international scientific and academic institutions on a variety of groundbreaking research projects involving a significant number of rare genetic disease patients. These collaborations yield a rich collection of genetic and biochemical data which are used to map out phenotype-genotype correlations and further improve the quality of our database.

From our inception in 2006, Centogene has been focused on changing the way patients with rare diseases are treated. These efforts have been led by our management team, in particular our CEO and founder, Prof. Arndt Rolfs. Our laboratory at our headquarters in Rostock, Germany, as well as our Cambridge, Massachusetts facility, are equipped with the most advanced technologies from thirteen different diagnostic platforms and together employ over 334 highly qualified personnel from over 50 nationalities. In addition to our laboratories, we have sales and administrative offices located in Berlin, Cambridge, Vienna, Dubai and Delhi, allowing us to further expand our international footprint.

## Strategy

Our objective is to improve the diagnosis and treatment of rare diseases by unlocking critical knowledge that will guide every stage of drug development. To achieve this objective our strategy is to:

- § **Transform the rare disease landscape by applying precision medicine techniques.** Rare diseases affect patients of all ages and ethnicities, across the world. We are focused on creating broader awareness of the challenges these patients and their families face, including the lack of accurate diagnostic solutions and the lack of effective therapies. We leverage our global network to access patient populations of varying ethnicities and continue to expand our existing data repository, which we believe is the world's largest for rare hereditary diseases. We believe this central source of knowledge will allow us to apply precision medicine techniques, which will enable more accurate diagnosis as well as

support the more efficient discovery and development of effective new treatment solutions for rare hereditary disease patients.

- § **Bolster our leadership position as the premier source of comprehensive clinical and diagnostic information for rare hereditary diseases.** Since our Company's founding in 2006, we have been focused on collecting clinical, phenotypic and genomic data for patients with rare hereditary diseases. Our data repository currently includes over 380,000 patient samples from over 110 different countries. We plan to continue growing this repository of information through the identification of additional patients by expanding our clinical network, which will facilitate more effective new drug development. This synergistic model will allow us to maintain our competitive advantage of having what we believe is the world's largest curated data repository for rare hereditary diseases.
- § **Accelerate the discovery and development of orphan drugs for our pharmaceutical partners.** We are focused on leveraging our vast knowledge-base to support drug development for the rare disease industry in various ways. We currently have collaboration agreements with over 30 pharmaceutical partners and we intend to continue expanding the scope of these collaborations as well as our network of partners. Our services span the full spectrum of drug development, including *in vitro* molecular screening, epidemiological studies, biomarker development as well as patient recruitment and identification. We believe these services support the speed and efficiency of our pharmaceutical partners' drug development efforts and accelerate bringing new diagnostic and treatment solutions to rare hereditary disease patients.

## Rare Disease Overview

### Overview

The Rare Diseases Act of 2002 defines a rare disease as having a prevalence of fewer than 200,000 affected individuals in the United States. In the European Union, orphan drug designation is intended to promote the development of drugs for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected).

The National Institutes of Health lists 7,000 disorders that qualify as rare diseases. A wide range of conditions qualify as rare diseases and include, but are not limited to:

- § Lysosomal storage disorders such as Gaucher disease, Fabry disease, Pompe disease, the mucopolysaccharidosis disorders, Farber disease, Niemann-Pick disease and Metachromatic leukodystrophy;
- § Neurologic and neuromuscular disorders such as Huntington's disease, Spinal Muscular Atrophy, Duchenne Muscular Dystrophy and Neuronal ceroid-lipofuscinosis type 2; and
- § Non-malignant hematological disorders such as paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome, hemophilia and hemoglobinopathies such as sickle cell disease and  $\beta$ -thalassemia.

### Cause of Rare Diseases

While there are many causes of rare diseases, approximately 5,600 are due to genetic mutations which are hereditary and passed from one generation to the next. Genes direct the production of proteins make up body structures like organs and tissue, as well as control chemical reactions and carry signals between cells. If a cell's DNA is mutated, a dysfunctional protein may be produced, which can lead to a disease. Therefore, one way in which rare diseases can be diagnosed is by identifying the specific mutations in a patient's DNA, even without the manifestation of physical symptoms. To date, there are estimated to be approximately 4,200 rare genetic diseases

that can be diagnosed by diagnostic sequencing tools. Despite these advancements in science and availability of next-generation sequencing ("NGS") technologies, rare diseases are complex and an underlying genetic cause for approximately 1,400 rare diseases is still unknown.

### ***Manifestation and Diagnosis of Rare Diseases***

Because of phenotypic heterogeneity, rare disease manifestations vary in onset and severity and many rare diseases exhibit a number of variations or sub-types. For about half of all rare diseases, symptoms may be observed at birth or in childhood, as is the case with Spinal Muscular Atrophy, neurofibromatosis and chondrodysplasia. The other half of rare diseases manifest symptoms during adulthood. Given the delayed onset and large variance in the symptoms that can manifest, the vast majority of these patients are misdiagnosed.

Given the multifaceted genetic and phenotypical nature of rare diseases, diagnosis is complex and requires specialist knowledge. It is often difficult for rare disease patients to find healthcare professionals with adequate experience. If diagnosis, treatment and management are not led by specialists, it may result in an incorrect diagnosis and inappropriate treatment, which can result in poorer patient outcomes. In addition, comprehensive phenotypical information on rare diseases is not always captured, and as a result, symptoms are often misinterpreted and patients are often not properly diagnosed. Even though genetic testing is the current accepted standard for making a diagnosis, there are still knowledge barriers that prevent the full interpretation of data obtained from such tests.

Delay to diagnosis is commonly experienced by patients and is due to poor awareness of rare diseases by health professionals and the small number of patients affected. This delay in diagnosis can be significant for many patients and may lead to irreversible progression of the patient's condition. For example, in the United Kingdom and the United States, the average time to obtain a correct diagnosis for rare diseases was found to be five to seven years, and in this time there were two to three incorrect diagnoses for a given condition. Pediatric rare disease patients can experience an even more significant delay in diagnosis. Across both pediatric and adult patient populations, approximately 90% of rare disease patients are typically undiagnosed. For example, the National Fabry Disease Foundation estimates that there are approximately 50,000 Fabry disease patients in the United States, whereas only 4,000 to 5,000 are currently diagnosed. As a result of incorrect and delayed diagnosis, unnecessary tests and treatments are often carried out and in some cases treatment windows are missed entirely.

### ***Regulatory Environment and Current Market***

Orphan drug legislation in the United States has made significant improvements in encouraging the development of new drugs to treat rare diseases. Since the passage of the Orphan Drug Act and subsequent amendments to the orphan drug regulations, the FDA has granted over 4,500 orphan drug designations. Moreover, the Orphan Drug Modernization Plan put in place by the FDA in 2017 has streamlined the processing of existing designation requests, which resulted in a 43% increase of orphan drug designations granted by the FDA in 2017 as compared to 2016. The success of orphan drug legislation in the United States led to the adoption of similar legislation in other key markets, most notably in the European Union, where the European Commission grants orphan drug designation after receiving the opinion of the EMA committee.

In the United States, orphan drug designation allows the drug sponsor to benefit from incentives for the development of these products up to marketing approval. The measures apply to all stages of drug development and include tax credits on clinical research, waiver of certain application fees and marketing exclusivity for seven years. In the European Union, financial incentives including fee reductions or waivers are available and market exclusivity is granted for ten years.



Due to these legislative initiatives, there has been an increase in investment and activity in the rare disease drug development space. In 2017, over \$45 billion is estimated to have been spent on discovery and development efforts in the U.S. for the treatment of rare diseases. This represents 10% of overall drug spending in 2017, up from 4% of overall drug spending in 1997. These investments are expected to lead to the approval of new rare disease drugs, which, according to market research, are expected to grow at a CAGR of 11.5% to generate over \$320 billion in worldwide sales in 2025.

### **Key Challenges in Rare Disease Drug Development**

Despite the legislative initiatives to encourage orphan drug development and the consequent increase in investment and activity in the rare disease drug development space, significant unmet needs still exist. Of the 5,600 hereditary rare diseases, only approximately 230 hereditary rare diseases have an FDA approved treatment. The limited number of treatments available for rare diseases is the greatest challenge for patient care and is based on the lack of research on rare diseases and barriers in developing and commercializing treatments.

We believe the following summarizes the key challenges clinicians and the pharmaceutical industry are facing today:

#### ***Lack of high-quality medical data as a result of:***

- § ***Lack of phenotypic understanding.*** Due to their phenotypic heterogeneity, rare diseases have highly diverse clinical manifestations and unpredictable progression rates. These factors make it difficult for physicians to make an accurate diagnosis and determine an optimal treatment strategy.
- § ***Lack of comprehensive and curated information.*** A full understanding of the causes of a rare disease requires proteomic, metabolomic and genomic information at a genetic level, as well as detailed clinical information. Moreover, thorough medical validation processes must be conducted to ensure the quality of this information. While there are a few, limited rare disease databases available to the market, such as parts of ClinVar and HGMD, they are not specifically set up to service the rare disease industry and, due to their nature, lack medical curation. Consequently, this limits the accuracy and utility of that data for clinical diagnoses and decision-making.
- § ***Lack of ethnically diverse datasets.*** The majority of existing rare disease datasets only capture individuals in developed regions of the world, where healthcare expenditure is disproportionately higher. This disparity yields population datasets that are specific to such regions and does not capture the full ethnic and hereditary nature that may be present in various rare diseases. For example, as published in *Nature*, despite the fact that unique genetic mutations are present across many different ethnicities, 87% of all genetic datasets are of European descent.

***Difficulties in the early identification of patients.*** Identifying rare disease patients is difficult, as the small patient populations make it challenging to assemble a knowledge base from which to derive accurate diagnoses. The ability to access relevant patients with a particular rare disease improves the accuracy of disease identification and facilitates the development of new treatments and diagnostic procedures.

***Lack of biomarkers.*** The small patient populations, phenotypic heterogeneity, homogenous datasets and lack of curated information for rare diseases all impede biomarker discovery. Without an identified biomarker, the ability to diagnose and ultimately treat a patient in a timely manner is diminished. Delayed diagnoses and limited knowledge of available treatments can lead to incorrect

patient management, further disease progression and/or invasive or detrimental treatments. In addition, the lack of an identified biomarker can create hurdles in obtaining drug approval as biomarkers can be beneficial in clinical development, specifically in monitoring how effectively a patient is treated by a drug.

**Difficulties in orphan drug development and commercialization as a result of:**

- § *Clinical Trial Recruitment.* Relevant patient populations are typically spread across large geographical regions, making adequate patient recruitment for clinical trials particularly difficult, which can delay development.
- § *Trial Design and Dose Selection.* Small patient populations do not allow for multiple parallel studies in the same indication. This also applies to dosages, where the number of dose levels studied may be limited by the practical considerations of running a trial. As a result of these limitations, careful thought must be given to study design in order to optimize clinical trial success.
- § *Patient Management.* In an orphan drug trial, clinical management of individual patients can be difficult. Understanding the burden of disease and managing the patient and family experience within a study is key. Because of the progressive nature of many rare diseases, it is crucial to enroll patients at a time where treatment has the highest potential to be effective.
- § *Eligibility Criteria.* Eligibility criteria influences the type of patient eligible to participate in a clinical study. Consequently, this dynamic interferes with the establishment of a database that captures clinical efficacy and safety data which can be extrapolated to a larger network of patients with the same disorder.
- § *Understanding the End Market.* Obtaining accurate epidemiological data is crucial for pharmaceutical companies to appropriately size the ultimate end market for a given drug in development. Given the small patient populations, it can be a challenge for pharmaceutical companies to recover the costs of rare disease drug development. As a result, this may impede initial investment in rare disease therapies.
- § *Market Traction.* Once a rare disease drug is commercialized, the limited number of identified patients and challenges associated with diagnosis make it difficult for physicians and pharmaceutical companies to find individuals who would benefit from an approved therapy. In order to more successfully market a commercial drug, improved datasets are needed to aid in patient identification.

**Our Vision**

We believe a detailed, global understanding of the genetic basis and the clinical phenotype of rare hereditary diseases will unlock the ability to target rare diseases and provide critical knowledge that will guide every stage of drug development. The combination of genomics, proteomics and metabolomics provides deep insights in the pathogenesis of rare hereditary diseases. The value in such a holistic diagnostics process has resulted in a shift from data generation to interpretation-based diagnostics, whereby the development of biomarkers is the central element to bring rationality to treatment decisions for rare disease patients. High-quality, standardized clinical information supporting medical interpretation is a crucial element of the diagnostic process and leads to greater knowledge of the causes and symptoms of rare diseases. We believe a combination of worldwide data and detailed access to phenotype, genotype, proteomics and metabolomics data will aid in the development of new treatments and reduce the costs associated with orphan drug development.

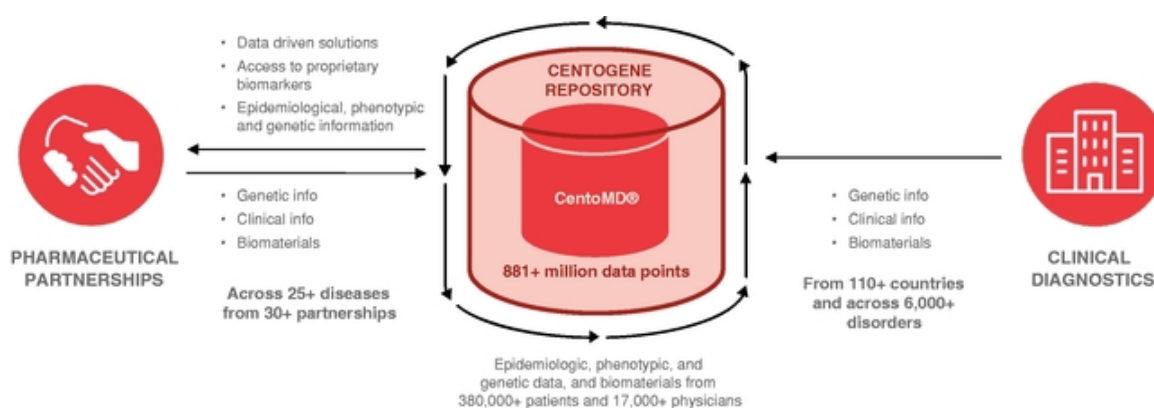
These fundamental principles were the basis of our Company's founding in 2006 by our CEO and founder, Prof. Arndt Rolfs.

## Our Platform—An Integrated, Knowledge-Based System

To deliver on this vision, we have developed a proprietary platform and system that we believe will improve methods for identifying and monitoring rare diseases and provide solutions that accelerate the development of orphan drugs.

At the core of our platform is our data repository, which includes epidemiologic, phenotypic and genetic data and allows us to assemble an extensive knowledge base in rare hereditary diseases. We collect this detailed level of data in our repository through our easy-to-use CentoCard, a CE-marked dried blood spot collection kit, captures blood samples of potential rare disease patients with a low cost of distribution. We then curate this information using a systematic and scientific approach conducted by professionals to ensure the medical validity of our data prior to feeding it into our central CentoMD database, which we believe is the world's largest curated mutation database for rare diseases. As of December 31, 2018, we had over 881 million data points to draw upon for insights which includes CentoMD data, clinical data, analyses performed, biochemistry data and clinical study data.

This systematic and thorough process results in information-based services that are beneficial for our pharmaceutical partners. This includes the ability to derive diagnostic solutions to accurately identify rare disease patients and the ability to identify new biomarkers, which help streamline and accelerate the path to approval for new drugs. As we facilitate the development of new drugs and the identification of more patients, an increasing number of patients are involved in clinical trials, which leads to even more diagnostic information being added to our repository. This synergistic model allows us to continuously enhance our own expertise and support pharmaceutical knowledge in the rare disease field. A graphical description of our system is shown below:



## The Strengths of Our Platform

Access to these solutions is intended to streamline and accelerate the development of treatments for rare diseases and aids in the understanding of how to identify new rare disease patients and how to recognize and quantify market opportunities in patient populations. We believe we offer the following solutions for the rare disease industry:

- § **Extensive repository to identify rare disease patients:** We have developed an extensive data repository which contains phenotypic, genomic and epidemiological data from over 380,000 patients and a biobank which holds biomaterials from the blood samples of these patients. This capability has been facilitated by our development of the CentoCard, a convenient logistical solution. CentoCard is CE-marked and easily stored, allowing for massive amounts of data aggregation from around the world. Additionally, we have express consent from the vast majority of patients in our database, which provides access to their

anonymized clinical records and offers the ability to retest their biobank materials. We are able to provide information about available treatment options to the physicians in our medical reports, therefore adding to the physician's decision-making tools in determining treatment for the patients. We believe this solution reflects the largest repository of rare disease patient data, thereby allowing us to assemble a knowledge base from which to derive accurate diagnoses and epidemiological information. We have relationships with a global network of specialists at rare disease "centers of excellence." With these relationships and the logistical advantages of our CentoCard product, we are able to continuously grow our repository from the collection of new patient samples and related patient data.

§ **Ethnically diverse datasets:** Our repository has the advantage of holding samples from a broad range of ethnicities. Our repository covers a substantial majority of ethnicities, as we have performed diagnostic tests for patients in over 110 countries. Without the ability to recognize ethnicity-specific patterns, the interpretation of genetic variants in patients is difficult and a patient's physician may fail to find an accurate diagnosis. The mutation frequency distribution within one ethnicity can vary significantly from that of other ethnic groups with the same rare disease population. With access to data from a more diverse patient population, we are able to improve the interpretation of genetic variants, whether benign or causative.

§ **Curated information in CentoMD:** We focus on achieving the highest level of quality through data curation and process standardization. As of December 31, 2018, curated data from over 310,000 patients was included in CentoMD. Before adding information from our data repository into CentoMD, our professional experts use evidence-based criteria to validate the interpretation of the data. We use a combination of computer-based tools and manual curation by professional scientists with strong backgrounds in human genetics. Our team of scientists collects, annotates and reviews the phenotypic, genetic and epidemiologic data of patient samples to ensure the highest medical validity of each sample. We also employ Human Phenotype Ontology ("HPO") coding to accurately track and standardize sample phenotype and genotype data. Our methodological approach to information curation ensures we provide highly accurate data relevant to clinical diagnoses and decision-making. CentoMD brings rationality to the interpretation of global genetic data.

Our detailed genetic, proteomic and metabolic analysis is the key to fueling the knowledge base of rare disease patient populations needed to lead the pharmaceutical industry towards the successful development of additional rare disease treatments. Since all phenotypes have been HPO coded, researchers can access the database and query by keywords and identifiers. For example, with the term "renal insufficiency," our system can directly analyze which genes and which pathogenic variants have been found to be causative for this phenotype. By combining multiple HPO codes such as "headache, diplopia, unsteady gait," a list of relevant genes associated with these clinical symptoms with corresponding real diagnosed patients can be extracted and used for further follow-up analysis on a biomarker, which thereby refines our and our client's understanding of variation in rare diseases. We believe this resource speeds up research projects dealing with the in-depth analysis of rare genotypes and phenotypes, which cannot be found in other databases with this level of convenience and reliability.

§ **Discovering biomarkers:** The interpretation of curated data in our repository and the ready access to biomaterials in our biobank are the initial steps in the identification of biomarkers. Our access to a large number of patients with the same disease enables us to build a homogenous sub-cohort of those patients.

We can apply our highly sophisticated tools, such as mass spectrometry technologies and artificial intelligence capabilities, to compare this homogenous patient sub-cohort to a matched control cohort of healthy individuals. The combination of these steps allows us to identify biomarkers in a rapid and efficient manner.

To date, we have commercialized seven proprietary biomarkers and have over 40 additional biomarkers in research and development. Biomarkers further support the diagnosis and monitoring of patients, which help physicians optimize treatment decisions in a timely and effective manner.

Based on the strengths of our platform, we are well placed to address the needs of the pharmaceutical industry. The following examples capture solutions that we have provided to our pharmaceutical partners covering epidemiological study, biomarker development and pharmaceutical diagnostics.

- § *Fabry Disease.* We published research in 2014 demonstrating that Fabry disease is the most frequent monogenic etiology in stroke patients under 55 years of age. Such insight is highly important for both patients and physicians in order to make an accurate and early diagnosis, and for our pharmaceutical partners trying to appropriately size the ultimate end market for Fabry disease.
- § *Gaucher Disease.* We have been able to demonstrate that a mutation within the Gaucher gene (glucocerebrosidase gene) increases the likelihood of developing Parkinson's disease. We believe our biomarker, Lyso-Gb1, demonstrates the highest sensitivity and specificity for the diagnosis and monitoring of Gaucher disease, allowing clinicians and our pharmaceutical partners to gain a better understanding of the disease pathophysiology. In addition, the data generated from Gaucher disease has stimulated new research and treatment strategies for Parkinson's disease.
- § *Niemann-Pick Type C Disease.* Through our studies, we have been able to demonstrate that the majority of adult patients suffering from Niemann-Pick type C disease also exhibit psychiatric symptoms. In addition, our preliminary data suggests our biomarker, Lyso-SM509, is a feasible biomarker for Niemann-Pick type C disease. As we further analyze the sensitivity and specificity of Lyso-SM509, we believe this biomarker has the potential to provide an earlier and more simplified diagnosis of patients with Niemann-Pick type C disease.

## **Our Commercialization Strategy**

We are committed to improving the lives of rare disease patients by improving methods for identifying and monitoring rare diseases and providing solutions that accelerate the development of orphan drugs.

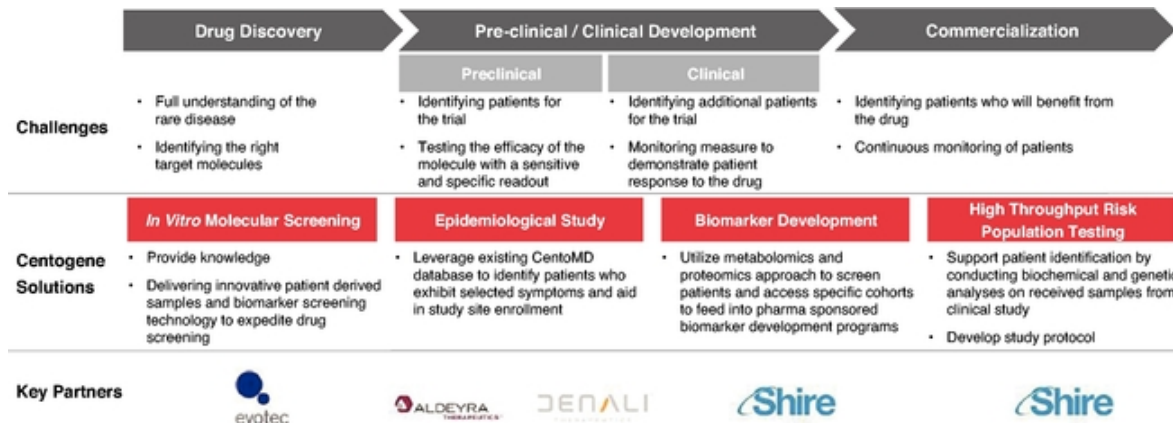
Our solutions are offered to our clients via two channels:

- § **Pharmaceutical:** Our pharmaceutical solutions provide a variety of services to our pharmaceutical partners, including early patient recruitment and identification, epidemiological insights, biomarker discovery and patient monitoring. Our information platforms, deep access to rare disease patients and ability to develop proprietary technologies and biomarkers enable us to provide services to our pharmaceutical partners in all phases of the drug development process as well as post-commercialization. Revenues from our pharmaceutical segment are generated primarily from collaboration agreements with our pharmaceutical partners, which can be structured on a fee per sample basis, milestone basis, fixed fee basis, royalty basis or a combination of these. For the year ended December 31, 2018, €17.3 million, or 42.8%, of our total revenues were derived from our pharmaceutical segment.

§ **Diagnostics:** Our clinical diagnostics segment provides targeted genetic sequencing and diagnostics services to patients through our distribution partners or our clients, who are typically physicians, labs or hospitals. As of December 31, 2018, we offer the broadest diagnostic testing portfolio for rare diseases, covering over 3,800 genes using over 9,000 different tests. Revenues from our diagnostics segment are typically generated by set fees per diagnostic test or per bundle of diagnostic tests under contracts with our clients. In turn, the data collected from our diagnostics services allow us to continue to grow our repository and our CentoMD database. For the year ended December 31, 2018, €23.2 million, or 57.2%, of our total revenues were derived from our diagnostics segment.

**Pharmaceutical Solutions**

We are committed to accelerating the orphan drug development process for our pharmaceutical partners by providing our unique insights into rare diseases. As of December 31, 2018, we had collaboration agreements with over 30 pharmaceutical partners, through which we provide information solutions and diagnostic services in all phases of orphan drug development and treatment, including discovery, preclinical development and clinical development, as well as post-market care. The below chart demonstrates the scope of our pharmaceutical services to each stage of the drug development process:



***In Vitro Molecular Screening***

A full understanding of a given rare disease and the ability to identify and target the right molecules is essential for drug development. With access to our biological samples, we are able to aid *in vitro* molecular screening efforts which can accelerate drug discovery efforts. Combined with access to our biobank and our data repository, our pharmaceutical partners are able to gain novel insights into the natural history of rare diseases, the broad spectrum of the different clinical symptoms as well as the genotype-phenotype correlation. Moreover, in situations where several genes can cause the same clinical symptoms and therefore, potentially cloud an accurate diagnosis, we believe we are able to identify additional genes that aid in the accurate diagnosis with the knowledge gathered in our database.

### ***Epidemiological Studies***

The ability of pharmaceutical companies to identify patients early and to optimize their clinical trials is key to the development of treatments for rare diseases. We offer epidemiological studies that will provide our partners with a more accurate picture and understanding of the scope and size of a particular rare disease population. We can also target these studies to a specific country or region of interest. This detailed epidemiological data can then aid our partners' clinical study enrollment efforts.

After a pharmaceutical partner specifies the rare disease for the clinical trial, we identify the available epidemiological data and enhance the data with genetic and phenotypic information from our repository and curated CentoMD database. From there, our pharmaceutical partner can create a defined list of specific conditions that patients must meet for a clinical study.

We then perform a patient selection and identification program. We start by identifying existing patients in our database who fit the defined criteria. If a patient sample is included in our sample repository but not yet tested to the level required for the trial, we run a diagnostics test to confirm if the patient meets the study criteria. If we need to find a larger cohort of patients than is currently included in our database or in our sample repository, we leverage our global network of partners, key opinion leaders, clinical labs and specialist physicians to help identify new patients who are at risk of developing, or have developed, the particular disease, in line with our pharmaceutical partners' defined patient cohort criteria. As a result, we are able to help our pharmaceutical partners optimize their clinical trials by more effectively selecting relevant patient groups and by leveraging our detailed understanding of the epidemiological data of the specific disease.

### ***Biomarker Development***

Biomarkers are key in rare disease drug development, as they can be used to support a diagnosis, demonstrate the efficacy of a treatment and monitor the progress of the rare disease patients. Biomarkers can also be used to enhance treatment solutions and guide dose titration. Biomarkers enable more efficient and economical patient diagnosis than genetic testing does and enables mass screening programs of a large patient cohort.

To develop a high-quality biomarker for a given rare disease, a homogeneous cohort of patients with known phenotypic and genotypic aspects is needed to simplify the process and increase efficiency. We believe our CentoMD database is the largest curated repository of rare disease patient samples, as well as a vast source of healthy control individuals against whom to identify the biomarker characteristics. Therefore, we believe we are ideally positioned to lead the market in rare disease biomarker development.

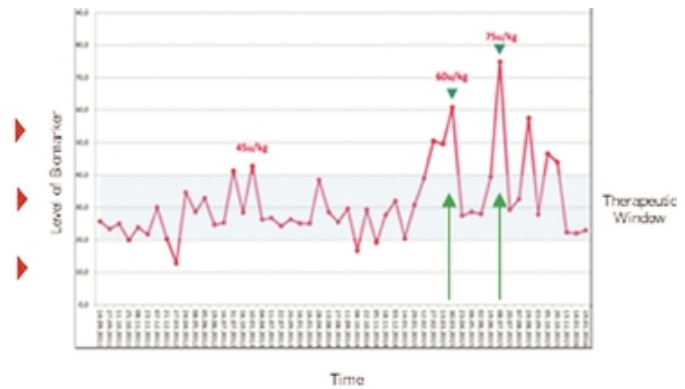
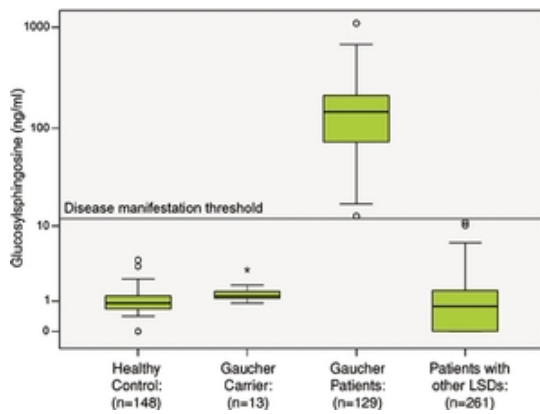
We have developed a suite of biomarkers, of which seven are already commercialized and over 40 are under development as of December 31, 2018. Our seven commercialized biomarkers, each of which is currently used in existing collaborations with our pharmaceutical partners, cover Fabry



disease, Farber disease, Gaucher disease, HAE, Niemann-Pick Type A/B and Niemann-Pick Type C disease. The following table shows a selected list of our biomarkers:

Disease	Target Dev.	Patient Access	Tech. Validation	Proof-of-Concept	Validation Stage I	Validation Stage II	Market
Gaucher Disease (Lyso-Gb1)	✓	✓	✓	✓	✓	✓	✓
Fabry Disease (Lyso-Gb3)	✓	✓	✓	✓	✓	✓	✓
Farber Disease	✓	✓	✓	✓	✓	✓	✓
Niemann-Pick Type A/B Disease (Lyso-509 and Lyso-465)	✓	✓	✓	✓	✓	✓	✓
Niemann-Pick Type C Disease (Lyso-509)	✓	✓	✓	✓	✓	✓	✓
Hereditary Angiodema (SERPING1) - Proteomics	✓	✓	✓	✓	✓	✓	✓
Cystic fibrosis	✓	✓	✓	✓	✓	✓	✓
Monjufo Disease A (MPS IV A)	✓	✓	✓	✓	✓		
Metachromatic Leukodystrophy (ARSA)	✓	✓	✓	✓	✓		
Hunter Disease (MPS II)	✓	✓	✓	✓	✓		
Duchenne muscular dystrophy (DMD)	✓	✓	✓	✓	✓		
NCL2	✓	✓	✓	✓	✓		
Hereditary angioedema- Metabolomics	✓	✓	✓	✓	✓		
Pompe Disease	✓	✓	✓	✓	✓		
Amyloidosis (TTR-FAP)	✓	✓	✓	✓	✓		

With proprietary biomarkers, we can also qualitatively measure a patient's response to approved drugs and to drugs in clinical trials, and using this data helps to determine the optimum treatment dosage for each patient. This not only helps to accelerate the development of orphan drugs by demonstrating the efficacy of the drugs in clinical trials, but also allows patients, physicians and reimbursement agencies to better understand the impact of the drugs. The below graphs demonstrate how Lyso-Gb1, our first commercialized biomarker, can be used for patient screening and monitoring in the context of Gaucher disease:



\* Based on a combination of our biomarker and a genetic confirmatory test

(Rolfs et. al., 2013.)

The left graph demonstrates the sensitivity and specificity of our Lyso-Gb1 biomarker for Gaucher disease. According to a 2017 study, patients who are not suffering from Gaucher disease present with a Lyso-Gb1 level of less than 12 nanograms per ml, whereas patients with Gaucher disease display elevated levels of Lyso-Gb1. Based on the definition of the cut-off of 12ng/ml Lyso-Gb1, we can demonstrate a 100% sensitivity and close to 100% specificity, which means our Lyso-Gb1 biomarker, when combined with a confirmatory genetic test, can provide 100% accuracy in



identifying patients suffering from Gaucher disease, and also those who are not suffering from the disease.

The right graph demonstrates how our Lyso-Gb1 biomarker can also be used to titrate the proper enzyme replacement therapy dosage in each individual patient. An increase of the Lyso-Gb1 level signals that the dosage of the enzyme replacement therapy needs to be adjusted. After adjustment, Lyso-Gb1 levels decreased to an almost normal level. This is valuable for demonstrating drug efficacy to relevant authorities for approval, and also for demonstrating to reimbursement agencies that individualized treatment and dosage may be required for the patient.

### ***High-Throughput Risk Population Testing***

Once a treatment is available for a rare disease, early identification of patients is critical so that patients can be treated before they have reached the stage of irreversible progression. We are able to support our pharmaceutical partners in their patient identification efforts by leveraging our knowledge and performing mass-spectrometry screening on a much broader group of patients with the risk profile of a given rare disease. We do this by using our biomarkers, which is economically efficient. If a positive diagnosis is concluded, we provide physicians with information on relevant treatment options, which helps physicians make clinically relevant decisions for the treatment of their patients. For negative diagnoses, no further confirmatory genetic testing is necessary. We provide each patient's physician with a diagnostic report.

### ***Research and Development Validation***

Based on our extensive expertise in rare diseases and our access to detailed genetic data, our pharmaceutical partners can approach us for guidance during their drug development endeavors. More specifically, our pharmaceutical partners can ask us to review their clinical trial design, evaluate clinical data from an ongoing or recently completed clinical trial and validate related biomarkers. All of these services are aimed at optimizing their clinical development efforts.

## **Key Partnerships**

### ***Shire***

In January 2015, we entered into an agreement with Shire to provide certain diagnostic testing capabilities to Shire and its affiliates in order to enhance early diagnosis of patients suffering from lysosomal storage and other rare diseases, including Fabry disease, Gaucher disease and Hunter syndrome. Our unique expertise and repository of data contributes to Shire's mission to shorten the time it takes for rare disease patients to get diagnosed. In connection with this agreement, we receive a fixed annual fee plus additional service-based payments related to regulatory and diagnostic sequencing activities.

Additionally, Shire sponsors our development of a certain biomarker to improve the prognostic capabilities of certain rare diseases. The project commenced in late 2015 and is anticipated to be completed by mid-2019.

In addition, in 2018, we entered into a new research agreement with Shire relating to their ongoing drug development efforts in HAE. As part of this agreement, we are conducting an extensive epidemiological study leveraging our data repository and network of physicians at centers of excellence to gain unique insights into HAE and to support Shire's ongoing clinical development efforts.

### ***Evotec International GmbH ("Evotec")***

In July 2018, we entered into an agreement with Evotec to support and expedite their identification of new small molecule treatments. Evotec identifies active pharmaceutical ingredients based on the induced pluripotent stem cells ("iPSC") that are generated from fibroblasts we obtain from skin biopsies of patients. We believe our collaboration will aid in the acceleration of drug development through the adoption and application of more accurate cellular models of the target disease and specific biomarkers to monitor such diseases. Our collaboration combines Evotec's iPSC platform and drug discovery capabilities with our medical and genetic insights to develop a high throughput platform to test innovative small molecules in rare hereditary metabolic diseases. In connection with this agreement, we received an initial payment, and will receive milestone payments as well as further royalty fees on net sales of products developed from this collaboration.

### ***Denali Therapeutics ("Denali")***

In September 2018, we entered into a strategic collaboration with Denali for the global identification and recruitment of LRRK2 positive Parkinson's disease patients. We will utilize our CentoCard and extensive network with centers of excellence to conduct a targeted global recruitment campaign focused on the early identification and characterization of LRRK2 positive Parkinson's patients for the recruitment into Denali's clinical trials. Given that we believe Denali's study is the lead clinical investigation of LRRK2 inhibitors for the treatment of Parkinson's disease, there is no large global existing cohort of identified patients with the LRRK2 mutation in the early phase of the disease. We aim to overcome those challenges and accelerate the enrollment of further patients into this clinical study and consequently facilitate Denali's drug development process. In connection with this collaboration, we received an initial payment, and are eligible for success-based and commercial milestones and reimbursement of selected costs.

### ***Aldeyra, Inc. ("Aldeyra")***

In March 2018, we entered into an agreement with Aldeyra to globally identify patients with Sjögren-Larsson Syndrome ("SLS") and understand the clinical spectrum of this disease. The collaboration will support physicians and patients with early diagnosis of SLS through genetic testing, raising awareness for the disease, potentially leading to the identification of novel therapeutic developments. Complementing Aldeyra's registry for patients with SLS, we believe our extensive knowledge base and database of patients with SLS will aid Aldeyra in more rapidly identifying patients with SLS and will provide invaluable information on the epidemiological and non-canonical systems to enable more effective diagnosis of SLS patients. In connection with this agreement, we received an upfront payment and receive additional payments on a per case basis for contacting identified patients of interest through their physicians and providing these patients with Aldeyra's clinical trial information.

## **Our Diagnostic Solutions**

### ***Overview and Product Offering***

Our diagnostic solutions channel provides diagnostic testing services to patients exclusively through our network of distribution partners, who are typically physicians, labs or hospital facilities. Our patient outreach includes over 100 countries due in part to our CentoCard solution enabling an efficient and simple transfer of the sample from the point of care to the lab. Additionally, our online platform, CentoPortal, allows our clients to quickly and easily obtain information related to their patients' test results and benefit from advancements in rare disease research, which we update on a regular basis. We provide a high-quality, end-to-end clinical diagnostics solution, which includes pretest clinical counseling performed by our medical experts, sample preparation, sequencing using NGS technology, medical interpretation using our manual and automated bioinformatics pipelines and medical reporting by our specialists.

As of December 31, 2018, we offer a full testing portfolio of over 9,000 genetic sequencing tests covering more than 3,800 genes, from single gene WES products, using Sanger methodologies and NGS technology. Of this total, we offer 4,000 single gene sequencing products, 3 panel sequencing products on over 210 distinct panels, 27 WES products and 15 WGS products. We also offer differentiated comprehensive testing solutions including 38 biochemistry testing products, 1,465 copy number variation tests ("CNVs") and 2 NIPT products (single and twin). The graphic below outlines the scope of the diagnostics products that we currently offer.



- 1 Sanger**
  - Analysis of whole coding sequence, relevant for splicing and all relevant deep intronic variants in CentoMD and HGMD for an individual gene
  - *Key Statistics: >2,700 genes with Sanger, ~1,300 genes with NGS (+CNVs optional), rare diseases, hereditary cancers*
- 2 NGS Panels**
  - Variable panels targeting genes focused on one or a group of disorders (turnaround time: 25 days)
  - Included genes always encompass whole coding sequence
  - Available as PLUS option with guaranteed 100% coverage of targeted regions
  - CentoDx clinical exome panel targeting over 6,700 genes with clear conclusion and recommendations (turnaround time: 30 days)
  - *Key Statistics: rare disease panels (198) and hereditary cancers and somatic oncogenetics (20), of which NGS panel genomic (159)*
- 3 Exomes/Genomes**
  - CentoXome: WES and covers 20k genes relevant for human phenotypes (turnaround time: 15 days)
  - CentoGenome: WGS with PCR-free library production (turnaround time: 20 days)
  - *Key Statistics: 42 product variety, CentoXome (27), CentoGenome (15)*

- 4 NIPT**
  - CE/IVD workflow with high sensitivity for full chromosome aneuploidies and comparably lowest (<1%) repetition rate (turnaround time: 5 days)
  - Screening test for whole chromosome aneuploidies on single draw of peripheral maternal blood from gestational week 10 onwards (fully non-invasive)
  - *Key Statistics: T21, T18, T13, sex chromosome aneuploidy, with fetal fraction, CE-IVD, enzyme panels (8)*
- 5 CNVs & Mutation Quantification**
  - Genome-wide analysis of structural variants by array technology with detection available in two resolutions (turnaround time: 15 days)
  - Integrated calling of copy number variations from NGS data for panels
  - *Key Statistics: Genome-wide aCGH (2), MLPA (596), qPCR + ddPCR (842), FLA / RPA (25)*
- 6 Biochemistry**
  - Mass spectrometry-based detection of 100% specific biomarkers for selected disorders based on latest MS and UPLC technology (turnaround time: 7 days)
  - Activity test for enzymes relevant for specific disorders based on fluorometric assay setup and quantification (turnaround time: 7 days)
  - *Key Statistics: Biomarkers (5), enzyme activity (25), enzyme panels (8)*
- 7 CentoMD**
  - Bridges gap between genetic variants and clinical interpretation with significant number of unpublished variants
  - Definite diagnosis via independent, manual curation process and validation based on ACMG guidelines and diverse patient population from over 100 countries
  - *Key Statistics: World's largest mutation database for rare hereditary diseases*
- 8 CentoCard**
  - CE-labeled kit for fast and easy sample collection and transportation at room temperature
  - Stability of DNA for all genetic analysis more than 10 years upon storage at ambient temperature
  - *Key Statistics: Simplified Logistics Solution, almost all tests can be performed from CentoCard*

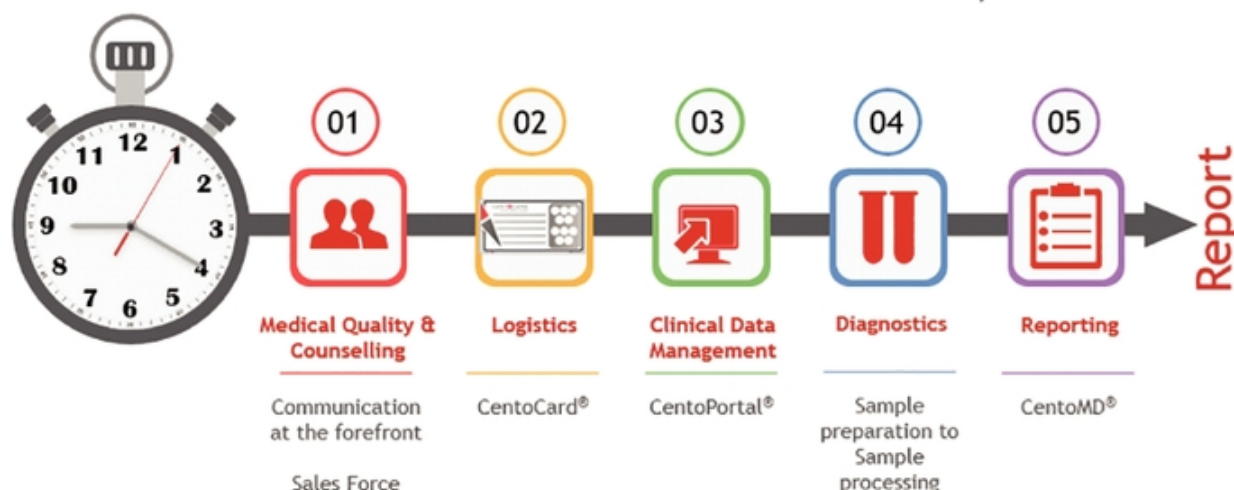
### Overview of the Diagnostic Process

Our diagnostics processes are designed with the aim of providing the highest-quality diagnosis within the shortest turnaround time. We currently perform all of the diagnostic services for our diagnostics and pharmaceutical businesses in our clinical laboratory located in Rostock, Germany, which is certified under CLIA and accredited by the CAP.

We strive to provide the best quality of diagnostics testing, not only by following the strictest quality criteria complying with CAP, CLIA and ISO 15189 certifications supported by our multidiscipline quality management system ("QMS"), but also applicable and market standard Good Laboratory Practice ("GLP") and Good Manufacturing Practice Regulations ("GMP") guidelines. Our

processes are highly efficient and have been designed to deliver our medical report back to the physician within 30 days from receipt of the sample.

Our diagnostics process is defined by our five-step process:



§ **Medical Quality and Counseling:** Genetic specialists review the patient's clinical records and confirm that the physician has requested the appropriate genetic test with regard to the patient's individual circumstances and medical history. In all cases, the physician is required to provide us with a completed patient consent form, which our staff review for adequacy prior to the performance of any diagnostic services.

§ **Logistics:** We use the CentoCard collection method for obtaining the majority of our samples. This standardized procedure allows us to extract high-quality biological material from dried blood spots on the CentoCard, including DNA (for molecular diagnostics), protein (for enzymatic and biomarker assays) and metabolites (for biomarker assays).

§ **Clinical Data Management:** Physicians are able to order our diagnostic tests for a particular patient either online through our CentoPortal platform or by email or mail.

§ **Diagnostics:** Once a patient sample is received, we prepare the biological material for testing by taking an extract of the DNA from the relevant sample. Depending on the test requested by the physician, we would then proceed to run any number of our diagnostic services listed above.

Once produced, the data is entered into a sophisticated series of our proprietary computational algorithms designed to detect and identify known pathogenic variants. The sequenced data is analyzed using our fully validated and automated bioinformatics pipeline and annotated with information from our mutation database, CentoMD. The database is key to the diagnostics process as it is used as the basis of comparison with the patient's sequenced data. This analyzed genetic information together with the patient's medical history and clinical data is then interpreted by our medical experts, a team of trained human geneticists and doctors. All identified mutations along with their annotations will undergo a manual validation against the medical history of the patient in order to ensure accuracy.

Additionally, our bioinformatics pipelines provide a highly automated approach to analysis of variant classification, CNV identification and other genetic data. To augment our bioinformatics pipelines, we have developed a database to store all variant information, which, in addition to CentoMD, is the basis for our evaluation and interpretation of genetic data. We have developed an in-house variant prioritization and classification system, named

Centoprio, to enhance our interpretation capabilities. Centoprio takes advantage of the vast amount of genotypic and phenotypic data stored in our databases. Through the use of proprietary algorithms and machine learning algorithms (artificial intelligence), we combine this data with current medical knowledge to prioritize particular variants that have been identified in previously closed patient cases.

- § **Reporting:** Our test reports deliver clinically relevant information in a manner that seamlessly integrates into physician practices. A standard report contains a summary of the test result, provides our analysis, recommendations and detailed description of the patient's relevant genomic alterations and a full data record for consolidation with the patient's medical records. The report also identifies noteworthy absences of genomic alterations and summaries of, and references to, supporting data from peer-reviewed publications. If requested by the physician, we also provide information on variants in genes not associated with the patient's disease or symptoms but that nonetheless contain medically actionable information (such as incidental or secondary findings).

All of our medical reports are written by professional medical experts facilitated by our automated report writing technology and are reviewed and approved by our Chief Medical Officer before distribution. Physicians obtain one report per patient diagnosis while our pharmaceutical partners obtain genomic information that has been provided with express patient consent and de-identified in accordance with HIPAA and other relevant health information privacy procedures. All reports are easily accessible through our online platform, CentoPortal.

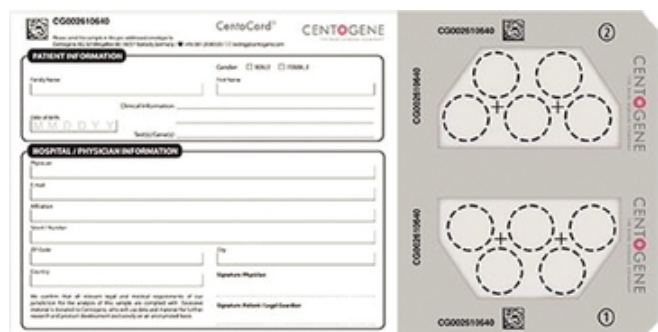
## Our Solutions for Providing High-Quality Data

### *Centocard*

Our sample collection method is a CE-marked dried blood spot collection kit, the Centocard (as shown below), which is translated into more than 30 languages and registered in more than 50 countries. The Centocard is sent to physicians as part of a five-component kit: (1) the Centocard, (2) a genetic testing informed consent form, (3) an instruction leaflet, (4) a self-addressed return envelope and (5) a plastic sleeve for the used Centocard to be sealed in once the sample is obtained. In order to obtain the sample, a small amount of blood is drawn from a patient by his or her physician and placed on designated spots on the Centocard. This sample is then left to dry for approximately two hours, during which time the sample stabilizes. Each Centocard produced has a unique barcode that allows for the card to be traced at all times. It is delivered to our laboratory in Rostock, Germany, along with a signed consent form, from anywhere in the world via regular post. Samples collected on Centocard are considered non-biohazardous materials, which allows them to be mailed across many borders without the need for certain customs declarations.

We use the Centocard collection method to obtain the majority of our samples. This standardized procedure allows us to extract high-quality biological material and perform most of our diagnostic tests from a portion of a single dried blood spot on the Centocard. Using the Centocard, we are able to provide a solution where necessary molecular and biochemical tests can be run simultaneously using the same patient sample. Given that the biomaterial stabilizes on the Centocard, we are able to retest the existing patient samples multiple times for more than 10 years from initial sample collection.

Centocard sample:



### ***Centoportal***

After a physician creates an online account on CentoPortal by following a few easy steps, the physician can order a test product of his or her choosing, provide and sign a patient consent online, obtain an overview of the patient's medical history, track the samples and progress of the diagnostic test and download the final medical report once the process is complete. Access to the CentoPortal requires secured authentication. This helps prevent unauthorized access, unauthorized use or loss of patient data.

### ***Centomd***

We believe our CentoMD database is the world's largest curated mutation database for rare diseases. All approved curated individual data is anonymized and released to CentoMD quarterly, offering the most complete and up-to-date information possible. The patient data we have collected in CentoMD spans a wide range of therapeutic areas. As of December 31, 2018, our database covered patients with metabolic (38%), neurologic (24%), malformation (11%), bone, skin and immunity (7%), liver, kidney and endocrinological (7%), tumoral (5%) and ophthalmological (3%) diseases, among others.

Through CentoMD, we are able to combine variant information with proteomic and metabolomics information, in particular for high-throughput genes where such a functional assay is available. Thus, crucial functional information necessary to support classification decisions, such as variant expression, can be reviewed by users.

### ***Centopharma***

Powered by CentoMD, CentoPharma is an online tool which offers an additional tailored interface where our pharmaceutical partners can generate customized datasets combining phenotype, genotype and biochemistry information. Our pharmaceutical partners can search for patients by a variety of categories, including HPO, requested tests, genetically confirmed diagnoses, home country or geographical region and certain screened genes. The datasets produced help identify patient cohorts exhibiting specific combinations of attributes, enabling the discovery of new targets for drug development and the assessment of market opportunities. CentoPharma also supports the design of clinical trials and the feasibility of recruiting patients to studies operated by our pharmaceutical partners. We grant pharmaceutical partners access to CentoPharma through a singular stand-alone license or as an add-on to part of broader contracted collaboration.

### ***CentolSD***

We have launched CentoLSD in January 2019, which we believe is the world's largest knowledge-driven lysosomal storage disease ("LSD") database, for the purpose to facilitate sharing



our rare disease knowledge and enhance the diagnostic and treatment opportunities for rare disease patients. CentoLSD is accessed via the our website and allows for researchers, pharmaceutical partners and clinicians to access a comprehensive database of variant classifications on a standardized curation workflow. Every variant reported in CentoLSD is linked to at least one clinically described case tested against Gaucher or Fabry disease through a validated and accredited laboratory workflow. CentoLSD's interface is easy to use—users first select a gene of interest and can further filter based on cDNA change, protein change, gDNA change, location of DNA change, coding effect, clinical significance and other variables. Use of CentoLSD is currently free of charge.

### ***Biomarker Development Process***

So long as an adequate patient cohort exists for any of the 7,000 identified rare diseases, of which approximately 5,600 have a genetic origin, we believe a biomarker can be developed. We may either develop a biomarker on our own, in which case we choose the rare disease to be mapped by the biomarker, or we may develop a biomarker at the request of a pharmaceutical company, in which case we typically map a biomarker for a specific rare disease identified by the pharmaceutical company. In both cases, we own the rights to the biomarker, but in circumstances where a pharmaceutical company is funding the biomarker development process, we may agree to parameters for use of the biomarker going forward.

The first step to the biomarker development process is analyzing the data taken from our repository to perform a biomarker target validation. Patients with a phenotype and/or genotype known to be an indicator of the particular rare disease for which we plan to develop the biomarker are compared with a large cohort of healthy control individuals. We can conduct this process with a disease cohort of as few as five to ten patients, although it is our experience that a higher number of patients (i.e., approximately 40) could result in a more specific biomarker target validation. The samples included in the study (patients and controls) must be of the same type (e.g., blood, plasma, tissue). The extraction is performed in a highly standardized manner as the results of the study depend on the stability of the samples and the uniformity of the extraction process. We then run the samples through an untargeted high resolution hybrid mass spectrometric analysis either of the small molecules (full metabolic profile) or of the peptides (full proteomics profile). The resulting differences found between the patient cohort profiles and the control cohort profiles are identified using statistical and mathematical algorithms. Artificial intelligence helps us to perform fully automated pattern recognition on multidimensional data (e.g., retention time, collision cross section, monoisotomic ion mass, fragmentation pattern) obtained from mass spectrometry.

While it may take weeks to months of manual data comparisons, biomarker candidates can be found in just a few minutes with our discovery system. Furthermore, this innovative approach enables us to use multi-peak biomarkers to evaluate even the most difficult patterns in the patient's metabolism. The differences (signals) measured from the mass spectrometer are retested for confirmation, then investigated with another mass spectrometric techniques (fragmentation and targeted mass spectrometry). Proof of concept is performed on anonymized samples using targeted mass spectrometry, in which the identified biomarker candidates are quantified. This part of the process (from project selection to proof of concept) could be completed in three months per biomarker project. We can then use the biomarkers to develop standardized tests for other services such as our patient screening processes.

### **Validation Tests**

As more patients are enrolled to the clinical trials, we are also able to perform further validation tests for the biomarker so that it could be used for longitudinal monitoring. Validation is a three to six month process during which the biomarker and its characteristics are assessed, which helps to determine the range of conditions under which the biomarker will give reproducible and accurate data. Approximately 50 to 100 patients in a disease cohort are needed to complete the validation process and approximately 8,000 different measurements are needed to comply with all CAP/CLIA/ISO requirements.

### **Our Operations**

#### ***Sales and Marketing***

As of December 31, 2018, our CBO leads a team of seven dedicated employees for business development in our pharmaceutical segment. With the importance of the segment, it has been historically closely supported by our CEO due to his network with different pharmaceutical partners, as well as the appreciation of his knowledge of rare diseases by the industry. We anticipate growing our team to support the growing number of partnership opportunities.

As of December 31, 2018, we have a sales force of approximately 27 employees and 23 consultants in our diagnostics business. Our sales employees are all trained in key account management and/or genetic diagnostics and are able to discuss the different diagnostic and workflow needs of doctors, physicians and genetic counselors. To further develop our footprint and to support the rare disease patients in the United States, we established a presence in the United States at the end of 2017 with the hiring of a sales team and the opening of a new laboratory in Cambridge, Massachusetts in October 2018.

In addition, we will continue to expand our sales force in order to further increase the sample volumes in targeted geographic areas, particularly in the North America, Latin America and Asia Pacific regions.

#### ***Information Technology Platforms***

Our IT infrastructure platform is based on state-of-the-art standardized components. We run our systems according to the following hybrid production model in an effort to optimize cost and service levels:

- § Systems that require a short distance-to-lab infrastructure are run in-house;
- § Tailored systems with special requirements and heightened security use outsourced infrastructure as a service provided by Datagroup AG, which is GDPR-compliant. These services are provided by two datacenters in Frankfurt and our lab in Rostock, which are connected by two independent and encrypted 10GB landlines; and
- § Highly standardized, high volume requirements use cloud services provided by Amazon Web Services and Microsoft.

All services are based on virtualized server systems with central storage components accompanied by backup and restore services, centrally managed network services, firewall systems, internet, databases and workplace services. System monitoring and events are implemented for all relevant systems with a central monitoring solution and central network scanner controls. Centrally managed user accounts are handled in the directory system.

Information security is highly valued and the principles of confidentiality, integrity and availability of information are a part of our core values. Information is protected by a variety of controls and procedures, including firewalls, password protections and malware protection tools. All internet-facing



applications are security tested. All personal data processing services are evaluated by our data protection officer and documented in accordance with GDPR. Additionally, our data services are certified across a variety of industry security standards, including ISO 9001 (which aims to ensure we consistently provide services and products that meet customer and regulatory security expectations) and ISO 27001 (which standards ensure the data in our database are secured).

Our workflows and processes are supported by various specialized applications. For example, via our user-friendly online portal "CentoPortal," analyses ranging from individual diagnostic requests to requests for pharmaceutical projects with high throughput testing can be ordered. Physicians can view the status of the samples they submitted and download a complete medical report. Upon receiving samples, we digitalize all information to support a fully digital internal workflow. This starts with a web application for sample entries, where information is transferred automatically by interfaces to our laboratory information system. This information forms the basis of our medical reports, which are made available to doctors for download. Data is shared between CentoPortal and our laboratory information systems through a fully automated interface.

#### *Artificial Intelligence*

We recently launched a program to establish and use artificial intelligence to automate our processes further, obtain new insights about rare diseases from mass data sets and generate new knowledge-driven business models. For example, we use artificial intelligence to enhance our biomarker discovery process. This allows us to shorten data analysis time from weeks to minutes and to identify multiple biomarkers or additional biomarker patterns. We currently have eight employees dedicated to this artificial intelligence effort.

#### **Healthcare Reimbursement**

Reimbursement of genetic testing differs markedly among countries and evolves rapidly based on advancements in technologies and cost. It is a challenge for insurers or public payors to decide when to reimburse for genetic tests that are offered by healthcare providers. One of the reasons this is difficult is that often there are alternative treatments with differing results, which insurers may not be able to easily evaluate.

Depending on the billing arrangement and applicable law, we may be reimbursed for genetic testing services by third-party payors that provide coverage to the patient, such as an insurance company or managed care organization, or by physicians or other authorized parties (such as hospitals or independent laboratories) that order our tests or refer tests to us. We do not receive reimbursement from any United States federal healthcare program, including Medicare or Medicaid. In the year ended December 31, 2018, we derived less than 1% of our total revenue from United States third-party payors, that includes managed care organizations and other healthcare providers. In the year ended December 31, 2018, we derived less than 1% of our total revenue from EU insurance companies and managed care organizations based in the European Union.

We have strategically determined to focus on countries around the globe where the prevalence of rare hereditary diseases is high or the availability of national genetic testing and interpretation is to some extent limited and therefore the complete reimbursement or partial payment by the government for our services is more likely. Therefore, the major markets for our diagnostics business currently include the Middle East and North Africa region, Scandinavia, parts of Central and Eastern Europe, Latin America, Canada and parts of Asia. In most of our markets, our diagnostics tests are billable directly to the party submitting the request for a test to us and we have less than 1% bad debts since the inception of our business.

## **Data Management**

Data is the basis for all of our diagnostic and research processes. We are generating approximately up to 25TB of new data in the lab every month. The data is stored in our own infrastructure as well as in a certified third party data center and with Amazon Web Services. The software solutions supporting these processes are based on modern database architecture, and all of our critical systems are fully redundant and backed up in real-time to these facilities.

Further, we implement our big data concept based on architecture. Because we store a vast amount of raw data in our repository, we are able to aggregate data to gain new insights. We are currently using this for biomarker research and will stepwise roll it out for the entire company in the next 15 months. Data gathering and variant curation are procedures developed and implemented in a web-based software (developed and maintained by Centogene AG) that is compliant with the HUGO Gene Nomenclature Committee (the "HGNC"), the Human Genome Variant Society (the "HGVS") and Human Phenotype Ontology ("HPO") nomenclatures. The software integrates in-house sample management systems and analysis platforms with external databases, utilizes a combination of computer-based tools and manual review in order to assure the accuracy, efficiency and quality of curation process.

All approved curated individual data is then anonymized and released to CentoMD quarterly, offering the most complete and up-to-date information possible.

## **Quality Management System**

We have developed and maintained a QMS that integrates the compliance of our processes with various medical device regulations, clinical trial requirements and clinical laboratory requirements. Our QMS is supported by standard operating procedures, educational and staff training plans, internal and external proficiency and competency programs, internal and external auditing, quality improvement indicators and pre-post analytical quality controls, including equipment maintenance, negative and positive controls, change management, employees and customer health and safety and document control programs. Our QMS integrates the compliance of our processes with the following requirements:

- § the GLP regulations, which are intended to ensure compliance with quality and integrity of the safety data filed pursuant to certain sections of the FDC Act and Public Health Service Act in the United States;
- § the GMP and the Good Clinical Practice Regulations, which exist to control the safety and efficacy of manufacturing operations and conduct of clinical trials;
- § the Code of Federal Regulations Title 21 part 820 and part 821 as amended by ISO 13485:2016, which set forth the requirements for a comprehensive quality management system for the manufacture and tracking of medical devices;
- § CAP and CLIA requirements (see "Regulations—United States Regulation—CLIA and State Regulation");
- § Massachusetts Department of Public Health clinical laboratory program standards (Chapter 105, Section 180.00 et.seq. of the Code of Massachusetts Regulations);
- § ISO 15189:2012 requirements, which specify requirements for quality and competence in medical laboratories; and
- § over 47 different country-specific medical device registration requirements.

We believe our QMS was built to withstand the rigorous review and auditing of medical device regulations, clinical trial requirements and clinical laboratory requirements to ensure our patients and clients receive the highest quality level of care and service.

Client data protection is of high importance to us, as we provide solutions to our clients in more than 110 different countries with varying requirements. We protect our clients and employees through an informed consent process, which goes through a rigorous legal review with in-country specialists and our internal HIPAA and GDPR compliance policies. We continuously monitor all electronically archived and incoming data through these channels (see "Regulations—United States Regulation—HIPAA and HITECH" and "Regulations—European Regulation—General Data Protection Regulation.")

#### *Data Acquisition and Curation*

Curation is the process of collection, association, updating and review of epidemiologic, phenotypic and genetic data of patients analyzed by us into a structured and standardized format. It uses a combination of computer-based tools and manual review in order to assure the accuracy, efficiency and quality of the curation process.

*Data acquisition.* Data gathering and variant curation procedures are developed and implemented in a web-based software which is compliant with the HGNC, HGVS and HPO nomenclatures allowing collection of variants detected in nuclear coding, nuclear non-coding and mitochondrial genes. The software integrates in-house sample management systems and analysis platforms with external databases providing the curator with a comprehensive and straightforward overview of the evidences regarding genotype-phenotype correlation available both in-house and external.

The data is gathered by a combination of manual submission and data importation following an individual-oriented model where characteristics belonging to a particular individual (including patient information, clinical data, methodology and detected genetic variants) are stored and associated together.

Our uniform classification of variants is an important step in improving our understanding of disease pathogenicity. There are approximately 3 billion base pairs in an individual genome, which translates to approximately 200 gigabytes of data that can be obtained from a single sequencing process. As of November 2018, CentoMD had over 7,300 thousand variants. This number is significantly higher than the number of variants in other industry databases such as ClinVar (approximately 500 thousand as of January 2019) and HGMD Pro (approximately 250 thousand as of April 2018). In addition, among the shared variants between CentoMD 5.3, ClinVar and HGMD Pro, 12% and 15% of such shared variants in ClinVar and HGMD Pro, respectively, are discordantly classified. The classification of variants which we record in our CentoMD database follow the American College of Medical Genetics and Genomics guidelines for variant classification, differentiated into five categories: pathogenic, likely pathogenic, uncertain clinical significance, neutral or likely neutral. If a diagnostic test is finalized without a pathogenic indication, we still include the data in CentoMD under an "uncurated" classification. This information can then be used as comparative data for future diagnostic tests. This uniform classification of variants is based on a highly qualified and standardized curation process, which allows us to provide our clients with high-quality clinical interpretations of newly identified variants, and also ensures that changes in variant classification will be communicated and reflected in our clinical interpretations in a timely manner.

As industry knowledge on variant frequencies increases, we reevaluate the variant classifications contained in our database on a regular basis to ensure our system incorporates the most up-to-date information. Additionally, given the number of rare diseases that have yet to be fully diagnosed and the speed of advancements in the rare disease industry, we regularly revisit "uncertain" patient data to reassess prior clinical interpretations against this new industry knowledge.

*Database curators.* Our CentoMD curators are scientists with strong backgrounds in human genetics. They continuously undergo extensive training to ensure curation consistency and standardization. They assure that data is properly associated and interpreted and that there are no inconsistencies or discrepancies against detected in-house observations and from external sources. They close the curation process by manual approval that reviewed and curated data comply with standard in-house procedures.

*Curation workflow.* To provide high-quality data, our curation process is divided in three phases: variant-wise, individual-wise and warnings-wise procedures.

- § *Curation by variant.* To begin the curation process, the variant-linked information is reviewed. This includes approval of variant nomenclature, terminology, accuracy, consistency and record completeness.
- § *Curation by individual.* In order to start curation on a patient-by-patient basis, all variants detected in an individual must be approved. This process aims to assure that the data belonging to an individual follows the guidelines for clinical reporting closely and that all associated data is in agreement with our established guidelines and applicable industry standards. The following factors are considered critical for the clinical statement: variant clinical significance, patient genotype, inheritance pattern of the disorder, the sex of the patient and the phenotypic description, when available.
- § *Curation by warning.* The database generates warnings at different levels (variant, individual, gene database levels) to detect errors, invalid terms and nomenclatures and inconsistencies. These warnings are triggered by additional evidence obtained internally, such as medical reports, or detected externally, such as articles, publications and external databases. Each warning is then manually documented and resolved.

All approved curated individual data is then anonymized and released to CentoMD quarterly, offering the most complete and up-to-date information possible to its users. CentoMD is a constantly growing and enriching its database. As of December 31, 2017, CentoMD included curated data from approximately 170,000 patients. As of December 31, 2018, this number had grown to over 310,000 patients. In addition, whenever additional evidence provided by our in-house medical professionals or by external peer-reviewed literature becomes available, specific variants are revised and reclassified accordingly.

## **Intellectual Property**

Our success depends in part on our ability to obtain and maintain proprietary protection for our genetic rare disease information platform, proprietary biomarkers, products and solutions and other know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing valid and enforceable intellectual property rights of others. We seek to protect our proprietary position by, among other things, filing U.S. and certain foreign patent applications related to our biomarkers, where patent protection is available. Our policy is to seek patent protection and trademark registration for commercially valuable assets we develop, as appropriate, and maintain as trade secrets other aspects of our genetic rare disease information platform, processes and know-how. We also rely on proprietary technologies, methods and processes, product designs and branding that we have developed.

Notwithstanding these efforts, we cannot be sure that patents will be granted with respect to any patent applications we have filed or may file in the future, and we cannot be sure that any issued patents will not be challenged, invalidated, or circumvented or that such patents will be commercially useful in protecting our technology. Moreover, trade secrets can be difficult to protect. While we have confidence in the measures we take to protect and preserve our trade secrets, such measures can

be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. For more information regarding the risks related to our intellectual property, please see "Risk Factors—Intellectual Property Risks Related to Our Business."

### **Patents**

Each patent family in our patent portfolio typically includes one or more priority-forming patent applications on the basis of which an international patent application (an application filed under the Patent Cooperation Treaty ("PCT")) is filed, after which national and regional patent applications are prosecuted in various jurisdictions. As of December 31, 2018, our patent portfolio is as follows:

- § With regard to our biomarker for Gaucher disease, we own two pending U.S. non-provisional patent applications, issued patents in Australia, China, Europe, Israel, Japan and Russia, and eight pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, Europe, Israel, India, Japan and Russia. The issued European patent is currently being validated in several European countries. These issued patents, and any patents granted from such applications, are expected to expire in 2032, without taking potential patent term extensions or adjustments into account. The issued European patent is currently the subject of a third-party opposition proceeding before the EPO. For more information on the European opposition proceeding, please see "Business—Legal Proceedings."
- § With regard to our biomarker for metachromatic leukodystrophy, we own two separate patent families. The first patent family consists of one pending U.S. non-provisional patent application, an issued Israeli patent, and four pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada and Europe. The second patent family contains one European application filed for the purpose of generating a filing date. The issued patent, and any patents granted from such applications, are expected to expire between 2033 and 2038, without taking potential patent term extensions or adjustments into account.
- § With regard to our biomarker for Niemann-Pick disease, we own one issued U.S. patent, three pending U.S. non-provisional patent applications, issued patents in Japan and Mexico, and pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, Europe, Israel, India, Japan, Mexico and Saudi Arabia. These issued patents, and any patents granted from such applications, are expected to expire between 2032 and 2035, without taking potential patent term extensions or adjustments into account.
- § With regard to our biomarker for Farber's disease, we own one pending U.S. non-provisional patent application and eight pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, China, Europe, Mexico, Saudi Arabia and the United Arab Emirates. Any patents granted from such applications are expected to expire in 2035, without taking potential patent term extensions or adjustments into account.
- § With regard to our biomarker for cystic fibrosis, we own two separate patent families. The first patent family consists of one pending U.S. non-provisional patent application and five pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, Israel and India. The second patent family contains one European application filed for the purpose of generating a filing date. Any patents granted from such applications are expected to expire between 2037 and 2038, without taking potential patent term extensions or adjustments into account.
- § We have also filed European priority applications for our biomarkers for HAE, mucopolysaccharidosis type IVA, mucopolysaccharidosis type II, neuronal ceroid lipofuscinosis type 2, dystrophinopathy, transthyretin amyloidosis, Krabbe disease and Pompe disease. Any patents granted from such applications are expected to expire in 2038, without taking potential patent term extensions or adjustments into account.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

We have entered into agreements with the University of Rostock and a related scientific institute pursuant to which such parties have fully transferred to us interests that they had co-owned with us with respect to patents and patent applications relating to our biomarkers for Gaucher disease, metachromatic leukodystrophy and Niemann-Pick disease or to the treatment of cancer or lysosomal storage disorders. Pursuant to the terms of these agreements, we were required to pay a total of €150,000 in upfront transfer fees and are obligated to pay royalties below 1% on net sales generated by the applicable patents in the future.

### ***Trade Secrets and Trademarks***

In addition to patent protection, we also rely on trade secrets, know-how, continuing technological innovation, and confidential information to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including, our genetic rare disease information platform. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties.

Our brand is very important to us, as it is a symbol of our reputation and representative of the goodwill we seek to generate with our customers. Consequently, we have invested significant resources in the protection of our trademarks. We seek trademark protection in the United States and in foreign jurisdictions where available and when appropriate. We own registered trademarks for both "Centogene" and "CentoMD" in the United States and other jurisdictions, including Europe, Canada and Japan.

### **Regulation**

Our diagnostics and pharmaceutical business is highly regulated due to our operation of clinical laboratories in Rostock, Germany and Cambridge, Massachusetts and because of our provision of diagnostic services and our development of proprietary biomarkers. In addition, we are subject to a variety of regulations and industry standards worldwide governing, among other things, data privacy, distribution of our products and patents and trademark licensing.

The key U.S. and European regulations that are applicable to our business are discussed in more detail below. Whether or not we obtain FDA clearance or approval or a CE Mark for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the use of a diagnostic or other product in those countries. The requirements and processes governing patient consents, product registration and pricing vary from country to country.

#### ***United States Regulation***

Our business is subject to and impacted by extensive and frequently changing laws and regulations in the United States at both the federal and state levels. These laws and regulations

include regulations particular to our business and laws and regulations relating to conducting business generally. We also are subject to inspections and audits by governmental agencies. Set forth below are highlights of the key United States regulatory schemes applicable to our business.

#### *CLIA and State Regulation*

Because we operate clinical laboratories, we are required to hold certain United States federal and state licenses and certifications to conduct our business. We are subject to CLIA regulations in the United States, which establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed. Our laboratories in Rostock, Germany and Cambridge, Massachusetts are CLIA-certified and accredited by CAP, as well as CAP ISO 15189 accredited. In addition, we are required to meet certain laboratory licensing requirements for states with regulations beyond CLIA. For more information on state licensing requirements, see "Regulations—State Laboratory Testing."

Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA also requires that we hold a certificate applicable to the type of work we perform and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring that they be certified by the federal government and comply with various operational, personnel, facilities administration quality and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable and timely. Laboratories must register and list their tests with the Centers for Medicare & Medicaid Services, or CMS, the agency that oversees CLIA. CLIA compliance and certification is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries and for many private payors. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

We are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional unannounced inspections. Laboratories performing high-complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory like ours that is certified as "high-complexity" under CLIA may develop, manufacture, validate and use proprietary tests referred to as LDTs. While laboratories that offer LDTs are subject to the FDC Act, in addition to CLIA, the FDA has generally exercised enforcement discretion towards these tests. In compliance with CLIA requirements to establish performance specifications, including accuracy, precision, specificity, sensitivity and a reference range for any LDT used in clinical testing, our LDTs have undergone full analytical validation.

In addition to CLIA requirements, we elect to participate in the accreditation program of CAP. CMS has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of CMS for accredited laboratories. Because we are accredited by the CAP Laboratory Accreditation Program, we are deemed to also comply with CLIA.

#### *State Laboratory Testing*

CLIA also provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or prescribe record maintenance requirements. Our clinical operations at our Cambridge laboratory are required to meet certain state laboratory licensing and other requirements, which in some areas are more stringent than CLIA requirements. Our

Cambridge, Massachusetts lab is also subject to Massachusetts Department of Public Health clinical laboratory permitting requirements. In October 2018, we received our CLIA permit to perform high complexity genetic testing in our Cambridge, Massachusetts lab. Our Massachusetts Department of Public Health clinical laboratory permit application was reviewed and the lab was inspected. It passed accreditation with no deficiencies and was issued a Massachusetts license for high complexity testing in November 2018. We anticipate that we will be granted the Massachusetts permit following the inspections, and will be permitted to begin testing in November 2018. Two states, New York and Washington, are CLIA-exempt, however, and as such have their own regulatory requirements to which we may be subject. CMS deemed both New York and Washington as CLIA-exempt because their licensing and supervisory programs are more stringent than that run by CMS and the CDC. New York requires clinical laboratories that accept specimens from New York residents to have both a CLIA and New York Clinical Laboratory Evaluation Program ("CLEP") permit. CLEP approval can take up to a year, and can be costly and time-consuming. Washington State does not require clinical laboratories to have a CLIA permit, but does require the clinical laboratory to apply for a Washington State lab permit.

Several states in the United States require the licensure of out-of-state laboratories that accept specimens from those states. For example, New York requires a laboratory to hold a permit which is issued after an on-site inspection and approval of testing methodology, and has various requirements over and above CLIA and CAP, including those for personnel qualifications, proficiency testing and physical facility, equipment and quality control standards. Each of our CLIA laboratory locations, including our site in Massachusetts, holds the appropriate licensure for the activities performed at that location. CLEP permit requires LDTs that are offered to New York State patients must be submitted for approval before they can be marketed or offered in New York. The Company is in the process of obtaining the requisite approvals for its LDTs.

From time to time, other states, such as California, Rhode Island, Florida, Maryland, New York and Pennsylvania, may require out-of-state laboratories to obtain licensure in order to accept specimens from the state, even though the laboratory is not located in such state. From time to time, other states may require out of state laboratories to obtain licensure in order to accept specimens from the state. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements. We are currently licensed in Pennsylvania, Maryland and California and are in the process of obtaining a New York State license.

Many states have also implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results. In some cases, we are prohibited from conducting certain tests without a certification of patient consent by the physician ordering the test. Requirements of these laws and penalties for violations vary widely. We review our obligations regarding genetic testing and consent periodically. If we identify states with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow instructions from the state regulators as to how we should comply with such requirements.

#### *FDA*

In the United States, medical devices are subject to extensive regulation by the FDA, under the FDC Act, and its implementing regulations, and other federal and state statutes and regulations. The laws and regulations govern, among other things, medical device development, testing, labeling, storage, premarket clearance or approval, advertising and promotion and product sales and distribution. To be commercially distributed in the United States, medical devices must receive from the FDA prior to marketing, unless subject to an exemption, either approval of a PMA (for most



Class III devices), clearance of a 510(k) premarket notification or classification pursuant to a de novo submission.

IVDs are types of medical devices that can be used in the diagnosis or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals, genetic information or other biomarkers. Predictive, prognostic and screening tests, such as carrier screening tests, can also be IVDs. A subset of IVDs is known as analyte-specific reagents ("ASRs"). ASRs consist of single reagents, and are intended for use in a diagnostic application for the identification and quantification of an individual chemical substance in biological specimens. ASRs are medical devices, but most are exempt from 510(k) review. As medical devices, ASRs have to comply with some QSR provisions and other device requirements, such as establishment registration, device listing and medical device reporting.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Many Class I devices are exempt from FDA premarket review requirements. Class II devices, including some software products to the extent that they qualify as a device, are deemed to be moderate risk, and generally require clearance through the premarket notification, or 510(k) clearance, process in order to be commercially distributed. Class III devices are generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices typically require approval of a PMA by the FDA before they are marketed. A clinical study is almost always required to support a PMA application and is sometimes required for 510(k) clearance. All clinical studies of investigational devices must be conducted in compliance with any applicable FDA and Institutional Review Board requirements. Devices that are exempt from FDA premarket review requirements must nonetheless comply with general post-market controls as described below, unless the FDA has chosen to exercise enforcement discretion and not regulate them.

*510(k) clearance pathway.* To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is substantially equivalent to a previously 510(k)-cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for submission of PMA applications. The previously cleared device is known as a predicate. The FDA's 510(k) clearance pathway usually takes from three to 12 months, but it can take longer, particularly for a novel type of product.

*PMA pathway.* The PMA pathway requires proof of the safety and effectiveness of the device to the FDA's satisfaction. The PMA pathway is costly, lengthy and uncertain. A PMA application must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of its PMA review process, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. The PMA review process typically takes one to three years but can take longer.

*De novo pathway.* If no predicate device can be identified, the product is automatically classified as Class III, requiring a PMA application. However, the FDA can reclassify, or use "de novo classification," for a device for which there was no predicate device if the device is low or moderate risk. The FDA will identify "special controls" that the manufacturer must implement, which often include labeling and other restrictions. Subsequent applicants can rely on the de novo product as a predicate for a 510(k) clearance. The de novo route is less burdensome than the PMA process. A device company can ask the FDA at the outset if the de novo route is available and submit the

application as one requesting de novo classification. The de novo route has been used for many IVD products.

*Post-market general controls.* After a device, including a device exempt from FDA premarket review, is placed on the market, numerous regulatory requirements apply. These include the QSR, labeling regulations, registration and listing, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur) and the Reports of Corrections and Removals regulation (which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDC Act).

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an untitled or public warning letter to more severe sanctions such as fines, injunctions and civil penalties; recall or seizure of products; operating restrictions and partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing 510(k) clearance or PMAs already granted; and criminal prosecution.

*Research use only.* Research use only ("RUO") products belong to a separate regulatory classification under a long-standing FDA regulation. RUO products are not regulated as medical devices and are therefore not subject to the regulatory requirements discussed above. The products must bear the statement: "For Research Use Only. Not for Use in Diagnostic Procedures." RUO products cannot make any claims related to safety, effectiveness or diagnostic utility, and they cannot be intended for human clinical diagnostic use. A product labeled RUO but intended to be used diagnostically may be viewed by the FDA as adulterated and misbranded under the FDC Act and is subject to FDA enforcement activities, including requiring the supplier to seek clearance or approval for the products. Our LDT uses instruments and reagents labeled as RUO in our laboratories.

*Laboratory-developed tests.* LDTs have generally been considered to be tests that are designed, developed, validated and used within a single laboratory. The FDA takes the position that it has the authority to regulate such tests as medical devices under the FDC Act. The FDA has historically exercised enforcement discretion and has not required clearance or approval of LDTs prior to marketing. In addition, New York CLEP separately approves certain LDTs offered to New York State patients. The Company is in the process of obtaining the requisite approvals for its LDTs in New York.

On October 3, 2014, the FDA issued two draft guidance documents regarding oversight of LDTs. These draft guidance documents proposed more active review of LDTs. The draft guidances have been the subject of considerable controversy, and in November 2016, the FDA announced that it would not be finalizing the 2014 draft guidance documents. On January 13, 2017, the FDA issued a discussion paper which laid out elements of a possible revised future LDT regulatory framework, but did not establish any regulatory requirements.

The FDA's efforts to regulate LDTs have prompted the drafting of legislation governing diagnostic products and services that sought to substantially revamp the regulation of both LDTs and IVDs. Congress may still act to provide further direction to the FDA on the regulation of LDTs.

We believe that the majority of the tests we currently offer meet the definition of LDTs, as they have been designed, developed and validated for use in a single CLIA-certified laboratory. If our tests are LDTs, they are currently not subject to FDA regulation as IVDs.

### *HIPAA and HITECH*

Under the administrative simplification provisions of HIPAA, as amended by the HITECH Act, the United States Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the privacy and security of protected health information used or disclosed by healthcare providers and other covered entities. Three principal regulations with which we are required to comply have been issued in final form under HIPAA: privacy regulations, security regulations and standards for electronic transactions, which establish standards for common healthcare transactions. The privacy and security regulations were extensively amended in 2013 to incorporate requirements from the HITECH Act.

The privacy regulations cover the use and disclosure of protected health information by healthcare providers and other covered entities. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a healthcare provider, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity and availability of protected health information that is electronically transmitted or electronically stored. The HITECH Act, among other things, established certain protected health information security breach notification requirements. A covered entity must notify affected individual(s) and the United States Department of Health and Human Services when there is a breach of unsecured protected health information. The HITECH Act also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, other federal and state laws may govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts. The HIPAA privacy and security regulations establish a uniform federal "floor" that healthcare providers must meet and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents that is more prescriptive than HIPAA.

These laws contain significant fines and other penalties for wrongful use or disclosure of protected health information. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and the HITECH Act, payments to us may be delayed or denied.

### *United States Federal and State Fraud and Abuse Laws*

In the United States, there are various fraud and abuse laws with which we must comply and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the DOJ and individual U.S. Attorney offices within the DOJ, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for patient referrals for, or purchasing, leasing, ordering or arranging for the purchase, lease or order of, any healthcare item or service reimbursable under a governmental payor program. Courts have stated that a financial arrangement may violate the Anti-Kickback Statute if any one purpose of the

arrangement is to encourage patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. Violations may result in imprisonment, criminal fines, civil money penalties and exclusion from participation in federal healthcare programs. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition to the administrative simplification regulations discussed above, HIPAA also created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from governmental payor programs.

Finally, another development affecting the healthcare industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or *qui tam* provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The *qui tam* provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from \$11,181 to \$22,363 for each false claim.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program.

#### *Physician Referral Prohibitions*

Under a United States federal law directed at "self-referral," commonly known as the "Stark Law," there are prohibitions, with certain exceptions, on referrals for certain designated health services, including laboratory services, that are covered by the Medicare and Medicaid programs by physicians who personally, or through a family member, have an investment or ownership interest in, or a compensation arrangement with, an entity performing the tests. The prohibition also extends to payment for any testing referred in violation of the Stark Law. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

### *Corporate Practice of Medicine*

Approximately 30 states in the United States have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings.

### *Other United States Regulatory Requirements*

Our laboratories are subject to United States federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

The U.S. Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for healthcare employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

### **European Regulation**

European sales of medical and diagnostic devices are subject to European regulations. The time required to obtain clearance or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different. Set forth below are highlights of the key European regulatory schemes applicable to our business.

#### *European Conformity Marking ("CE Mark") and Certifications*

The primary regulatory body in Europe is the European Commission, which has adopted numerous directives and has promulgated standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical and diagnostic devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE Mark indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union, and other countries that comply with or mirror these directives. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system, review of technical documentation and specific testing of the manufacturer's device. Such an assessment may be required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 13485 certification is a voluntary standard. Quality systems that implement relevant harmonized standards establish the presumption of conformity with the essential requirements for a CE Mark. We have the authorization to affix the CE Mark to our test kit products including CentoCard, CentoMD, CentoGaucher, CentoFabry, and MyLSDApp and to commercialize our devices in the European Union. We currently are able to use CE labels on our CentoCard, CentoMD, CentoGaucher,

Centofabry and MyLSDApp products. The final form of the European Medical Device Regulation, which will replace Europe's Medical Device Directive, was adopted on May 25, 2017 and will become effective on May 25, 2020. The Medical Device Regulation will apply in parallel with the Medical Device Directive for a transition period of three years. Additionally, a new version of ISO 13485 was recently published, beginning a transition period for updating certificates until March 2019. Diagnostic products which qualify as *in vitro* diagnostic medical devices would be subject to European Union legislation on medical devices, IVD-MDD and from May 25, 2022 IVD-MDR. According to IVD MDD and IVD MDR, marketing of *in vitro* diagnostic medical devices requires a CE mark.

#### *Laboratory-Developed Tests*

As currently all of our diagnostic testing is run at our laboratory in Rostock, Germany, the European Union and German legislation on *in vitro* diagnostic medical devices applies. According to the recitals of the IVD-MDD, reagents which are produced within "health-institution laboratories" for use in that environment and which are not subject to commercial transactions are not covered by the Directive. However, the legal framework for applying the exemption clauses for LDTs is not entirely clear as the IVD-MDD lacks an explicit definition and there is no related case law. As of May 2022, when the new IVD-MDR comes into force, diagnostic tests manufactured "on an industrial scale" qualify as IVDs with a need for a conformity assessment.

#### *General Data Protection Regulation*

In May 2016, the European Union formally adopted the GDPR, which applied to all EU member states as of May 25, 2018 and replaced the EU Data Protection Directive. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information," which includes health and genetic information of data subjects residing in the European Union. The GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides an individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. It has increased our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules.

The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of transactions from which we may gain access to personal data. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not yet clear if such authorities will conduct random audits of companies subject to the GDPR or will wait for complaints to be filed by individuals who claim their rights have been violated. Failure to comply with the requirements of the GDPR and the related national data protection laws of EU member states, which may deviate slightly from the GDPR, may result in material fines.

#### *European Fraud and Abuse Laws*

In Europe, various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a

negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010 faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

## **Competition**

We believe we are currently the only company offering comprehensive services to both diagnostics and pharmaceutical partners in the rare disease field, with highly curated data combining genetic, epidemiological and phenotypical information and proprietary biomarkers. Our principal competitors are existing mainstream diagnostics companies or companies specializing in certain rare diseases as well as cloud-based bioinformatic companies and entities that offer open source uncurated genetic databases. However, these companies do not offer curated information or as broad of a testing portfolio for rare diseases in as many geographical regions as we do. For example, we have found that the genetic mutation causing the same rare diseases and the phenotypical patterns may vary depending on the ethnicity of the patients, which we have identified based on our global data sets. Such unique insights may not be available to other companies that do not have the same global scope of patient data.

Our principal competitors in our diagnostics segment include mainstream diagnostic testing companies as well as labs or hospital conglomerates which offer the same services. In our pharmaceutical segment, our competitors include diagnostic testing companies and large pharmaceuticals.

With the continuous development in the NGS technology, the cost of genetic sequencing is anticipated to decrease and there may be companies intending to compete with us by performing massive sequencing at lower prices in order to obtain the relevant data to construct a similar database and repository. However, given the current limitations in the rare diseases fields, as well as the required quantity and quality of the data in order to make any relevant analysis, we are not aware of any competitors that will be able to build up to such scale in the near term.

## **Employees**

As of December 31, 2018, we employed over 350 highly qualified personnel (including consultants) from over 50 nationalities, of which 29% had MD or PhD degrees. We consider our relationship with our employees and consultants to be very good.

## **Facilities**

Our headquarters are located in Rostock, Germany, where we own approximately 8,500 square meters of office and laboratory space owned and constructed by us. In addition, in October 2018 we opened a new office and laboratory facility in Cambridge, Massachusetts, under a lease that expires on June 30, 2022.

## **Legal Proceedings**

Sanofi has filed an opposition proceeding in the EPO against the '725 Patent, a European patent that we own relating to our biomarker for Gaucher disease. The EPO opposition proceeding challenges the patentability of the '725 Patent in its entirety. We cannot predict the outcome of the opposition proceeding and any party may appeal the opposition decision to the Boards of Appeal at

the EPO. If we are unsuccessful in defending this opposition, the '725 Patent may be revoked or maintained in amended form, in whole or in part, which could materially harm our business. For more information regarding risks related to intellectual property, including this opposition proceeding, see "Risk Factors—Intellectual Property Risks Related to Our Business."

In May 2016, we were informed in writing by the Universitair Medisch Centrum Utrecht ("UMCU") that a claim had been initiated against UMCU regarding a prenatal diagnostic test that we conducted at UMCU's request which failed to identify a specific mutation present in a patient. On October 1, 2018, the UMCU and Neon Underwriting Limited brought an action at the Regional Court of Rostock (*Landgericht Rostock*), Germany against us for damages, alleging that our negligence in performing the test resulted in the misdiagnosis of the patient. With the action, UMCU is seeking recovery for compensatory damages as a result of the alleged misdiagnosis. By court order of November 8, 2018, the Regional Court of Rostock set the amount in dispute at €880 thousand and opened the written preliminary proceedings against the Company. On November 12, 2018, we submitted a notice to the Landgericht Rostock of our intention to defend against the claim and on January 3, 2019 we filed a motion to dismiss in which we denied the merits of the claim against us. UMCU and Neon Underwriting Limited responded to this motion on March 15, 2019 with a statement of reply. For more information regarding risks related to liability claims, including this proceeding, see "*Risk Factors—We may become subject to substantial product liability or professional liability claims that could exceed our resources.*"



## MANAGEMENT

Unless otherwise noted, this section presents information about our management upon the consummation of the offering and after giving effect to the corporate reorganization. See "Corporate Reorganization."

### Board Structure

We have a two-tier board structure consisting of a management board (*bestuur*) and a separate supervisory board (*raad van commissarissen*).

### Management Board

Our management board is expected to be composed of four members, who we refer to as our managing directors (and who are also our executive officers). Following the closing of this offering, each managing director of Centogene N.V. will hold office for the term set by our general meeting of shareholders (as set forth in the table below), except in the case of his earlier death, resignation or removal. Our managing directors do not have a retirement age requirement under our articles of association. The current members of the management board of Centogene AG are expected to be appointed as managing directors of Centogene N.V. prior to the closing of this offering.

Our managing directors are responsible for the management and representation of our company. We have a strong centralized management team led by Prof. Arndt Rolfs, our CEO, with broad experience in information technology, strategy, operations, finance, sales, communications and training. Our senior management has an average of 16 years of experience in the biopharmaceutical industry. Many of the members of our management team have worked together as a team for many years.

The following table lists the current members of our management board all of whom we consider key executive officers:

Name	Position	Age	Year of Expiration of Term
Prof. Arndt Rolfs, MD	Chief Executive Officer	59	2019
Dirk H. Ehlers, PhD	Chief Operating Officer	58	2020
Richard Stoffelen	Chief Financial Officer	51	2019
Volkmar Weckesser, PhD	Chief Information Officer	51	2019

The following is a brief summary of the business experience of our managing directors. Unless otherwise indicated, the current business addresses for our managing directors is Am Strande 7, 18055 Rostock, Germany.

*Prof. Arndt Rolfs, MD.* Prof. Rolfs is one of our co-founders. He has served as Chief Executive Officer since 2014 and Chief Medical Officer since 2006. He previously served as Director of the Albrecht-Kossel-Institute for Neuroregeneration at the University of Rostock from 2008 to 2018. Prior to founding Centogene AG, Prof. Rolfs was Vice-Director of the Clinic and Outpatients Department for Neurology at the Centre for Neurology, University of Rostock, from 1997 to 2008. He also served as a Senior Consultant at the Department of Neurology and as Head of the Neurobiological Research Laboratory from 1993 to 2008 at the University of Rostock. From 1991 to 1993, he worked at the Psychiatric Clinic at the University Hospital Rudolf-Virchow in Berlin. From 1989 to 1993 he was the Head of the Laboratory for Neurochemistry at the Free University of Berlin. From 1988 to 1989, Prof. Rolfs worked at the Max-Planck-Institute for Molecular Genetics and from 1985 to 1988

at the Department of Neurology at the Free University of Berlin. Prof. Rolfs is the principal investigator of several international epidemiological studies in the area of rare diseases and actively engaged in biomarker research for several metabolic diseases. He has an extensive track record in medical and scientific publications and is the author of or contributor to more than 300 peer-reviewed publications. Prof. Rolfs received his approbation as physician from the University of Mainz in 1985.

*Dirk H. Ehlers, PhD.* Dr. Ehlers has served as chief operating officer and president of Clinical Diagnostics since April 2018. Prior to joining us, he served as senior vice president and president of the Surgical Solutions Division and as a member of the Group Executive Team at Hill-Rom Holdings, Inc. in Chicago, Illinois. From 2015 to 2018, he was a non-executive board member of Protagen AG. From 2010 to 2014, Dr. Ehlers served as president and CEO of Eppendorf AG. Prior to that, he served as head of Professional Diagnostics and as a member of the Diagnostics Executive Committee at Hoffmann La Roche from 2007 to 2010. From 2001 to 2007, he was chief financial officer and an executive board member of Evotec AG. From 2000 to 2001, Dr. Ehlers served as an Executive Board member and president of the Enteral Nutrition Division of Fresenius Kabi AG. From 1995 to 2000, he served as Diagnostic Systems Division head at Olympus Europe. From 1989 to 1994, he was a management consultant and an engagement manager at McKinsey & Co. Inc. Dr. Ehlers holds a M.Sc. in Physics and received his PhD in Physics with distinction, summa cum laude, both from the University RWTH in Aachen.

*Richard Stoffelen.* Mr. Stoffelen has served as chief financial officer ("CFO") since 2016. He has over 30 years of experience in international roles focused on finance, governance and risk management. Prior to joining us, he was head of Internal Audit at Holcim Group Services from 2013 to 2016. From 2000 to 2013, Mr. Stoffelen worked in various audit and management positions as a partner at KPMG, where he was responsible for audits of clients in a wide variety of industries, including the pharmaceutical industry. Mr. Stoffelen graduated as a Dutch chartered accountant with the NBA and Tilburg University in the Netherlands, with further executive education programs at Harvard Business School, Insead (Executive MBA), the IMD and the IESE business school.

*Volkmar Weckesser, PhD.* Dr. Weckesser has served as chief information officer since 2016. Prior to joining us, he served as chief executive officer and group chief information officer at Gothaer Systems GmbH from 2014 to 2016. He served as a Member of the Executive Council and head of Information Technology at Dekabank Deutsche Girozentrale from 2009 to 2014, as a central division manager of the Information Technology Division of HSH Nordbank AG from 2003 to 2009, division manager of Landesbank Schleswig-Holstein Girozentrale from 1999 to 2003, personal assistant to the CEO at Deutsche Apotheker und Ärztebank EG from 1998 to 1999, project manager at Mitchell Madison Group from 1996 to 1998, consultant and project manager at Monitor Company from 1993 to 1996 and lecturer at Universität Karlsruhe 1991 to 1993. He holds a PhD from Universität Karlsruhe.

The following table lists those of our key executive officers who are not members of our management board:

<u>Name</u>	<u>Position</u>	<u>Age</u>	<u>Year of Expiration of Term</u>
Oved Amitay	Chief Business Officer	53	2021
Prof. Peter Bauer, MD	Chief Scientific Officer	49	2019

*Oved Amitay.* Mr. Amitay has served as CBO since November 2018, prior to which he held the position of president and chief operating officer of Arrett Neuroscience from 2016 to 2018, having lead the company's strategy for developing therapies for Rett syndrome. Prior to this role, he served as Vice President, Head of Commercial at Alnylam Pharmaceuticals from 2012 to 2016, with a lead

role in the organization's transition from a technology-platform focus to a patient-centric drug development and pre-launch enterprise. Mr. Amitay had a long tenure at Genzyme Corporation (now Sanofi Genzyme) from 1998 to 2011 as Vice President, Strategic Development, responsible for program management, business development, market assessment and business planning for the rare genetic diseases franchise, and as General Manager of the Gaucher and MPS business. He is also a Founding Advisor of Splisense Therapeutics, Israel, where he held this role from 2016 to present. Mr. Amitay holds a M.Sc., Pharmacology, from Northeastern University, Boston, MA and a B.Sc., Pharmacy, from the Hebrew University, Jerusalem, Israel.

*Prof. Peter Bauer, MD.* Dr. Bauer has served as chief scientific officer since January 2017, prior to which he served as chief operating officer since joining us in 2016. Dr. Bauer is a professor of human genetics at the University of Tübingen and a board-certified human geneticist with expertise in molecular genetics, diagnostic testing, genetic counselling, functional validation of genetic variants and bioinformatics tools for medical interpretation of clinical sequencing. Prior to joining us, he served as head of the diagnostic and research laboratory at the Institute of Medical Genetics and Applied Genomics, University Hospital Tübingen from 2001 to 2015. Dr. Bauer has been vice president of the German Society of Neurogenetics since 2004. Dr. Bauer received a degree in medicine from the Freie University Berlin and the approbation as physician (German official license to practice medicine) from the Board of Physicians in Berlin in 1998.

## Supervisory Board

We are currently reviewing the composition of our supervisory board and our corporate governance practices in light of this offering and applicable requirements of the SEC and Nasdaq. In subsequent filings with the SEC, we will update any relevant disclosure herein as appropriate.

Our supervisory board is expected to be composed of at least eight members. Following the closing of this offering, each supervisory director will hold office for the term set by our general meeting of shareholders (as set forth in the table below), except in the case of his earlier death, resignation or removal. Our supervisory directors do not have a retirement age requirement under our articles of association. The current members of the supervisory board of Centogene AG are expected to be appointed as supervisory directors of Centogene N.V. prior to the closing of this offering.

The following table presents the names of the current members of our supervisory board.

<b>Name</b>	<b>Position</b>	<b>Age</b>	<b>Year of Expiration of Term</b>
Flemming Ornskov, MD, MPH, MBA	Chairman of the Supervisory Board	61	n/a
Hubert Birner, PhD	Vice-Chairman of the Supervisory Board	52	n/a
Christoph Ehlers, LL.M.	Member of the Supervisory Board	60	2020
Holger Friedrich	Member of the Supervisory Board	52	2020
Jacob Kaluski, M.Sc.	Member of the Supervisory Board	68	2020
Guido Prehn	Member of the Supervisory Board	40	2020
Eric Souëtre, MD	Member of the Supervisory Board	62	2020
Berndt Modig, MBA	Member of the Supervisory Board	60	2020

The following is a brief summary of the business experience of our supervisory directors. Unless otherwise indicated, the current business addresses for our directors is Am Strande 7, 18055 Rostock, Germany.

*Flemming Ornskov, MD, MPH, MBA.* With his term commencing on April 1, 2019, Dr. Ornskov has been approved as a Member and the Chairman of the Supervisory Board of Centogene. He most recently served as Chief Executive Officer and Non-Executive Director of Shire Plc from April 2013 to January 2019 when Shire was acquired by Takeda. He is currently acting in an advisory capacity to the CEO of Takeda for a fixed term ending on March 31, 2019. Dr. Ornskov has extensive international, strategic and operational experience in the pharmaceutical and biotech sectors, as well as medical expertise as a physician with training in pediatrics. He was appointed Non-Executive Director and Chairman of the Board of Recordati S.p.A. in February 2019. He is a Non-Executive Director for the Waters Corporation and the Swiss-American Chamber of Commerce and was the Co-Chair of The Global Commission to End the Diagnostic Odyssey for Children with a Rare Disease. Dr. Ornskov was Non-Executive Chairman of Evotec from 2008 to 2012 and Non-Executive Director of PCI Biotech Holding from 2008 to 2013. From 2010 to 2013, he was Chief Marketing Officer and Global Head, General and Specialty Medicine at Bayer. He also previously held positions as Global President, Pharmaceuticals and Over-the Counter at Bausch & Lomb; Chairman, President and Chief Executive Officer of LifeCycle Pharma; President and Chief Executive Officer of Icaria; and various roles at Merck and Novartis. Dr. Ornskov received his MD from the University of Copenhagen, MBA from INSEAD, and Masters of Public Health from Harvard University.

*Hubert Birner, PhD.* Dr. Birner joined the Supervisory Board of Centogene as Chairman in July 2017. He currently serves as a managing partner at TVM Capital, and is responsible for its overall investment strategy and fund operations in North American and Europe. Dr. Birner joined TVM Capital in 2000 as an investment manager. He currently also serves as Chairman of the supervisory board of SpePharm Holding B.V., leon-nanodrugs GmbH and AL-S Pharma AG. He is a member of the board of directors of Argos Therapeutics, Inc., Proteon Therapeutics Inc, Noxxon Pharma and Acer Therapeutics Inc. Dr. Birner previously served on the board of directors of Horizon Pharma, Inc., Bioxell SA, Evotec AG, Probiodrugs AG and Jerini AG. Prior to his current tenure, he was Head of Business Development Europe and Director of Marketing for Germany at Zeneca Agrochemicals. Dr. Birner joined Zeneca from McKinsey & Company's European Health Care and Pharmaceutical practice and as Assistant Professor for biochemistry at the Ludwig-Maximilian-University ("LMU"). He holds a summa cum laude doctoral degree in biochemistry at LMU. His doctoral thesis was honored with the Hoffmann-La Roche prize for outstanding basic research in metabolic diseases. Dr. Birner also holds an MBA from Harvard Business School.

*Christoph Ehlers, LL.M.* Mr. Ehlers is a co-founder of Centogene. After having been in the executive management from 2008 to 2014, he joined our board as a supervisory director in 2014. Mr. Ehlers, by profession a lawyer, founded Equicore Beteiligungsgesellschaft GmbH in 1997 as a specialized consulting and investment vehicle to assist in the development of early stage LifeScience companies. Since 1999, Mr. Ehlers has also served as one of two founding board members on the board of Stiftung Ordnungspolitik, a leading European economic think-tank. As part of the Equicore business, he holds management positions in other early stage portfolio companies. Prior to Equicore he held various positions at Commerzbank AG from 1984 to 1996, including functions in investment banking, the Chairman's office and leading the southwestern branches. He studied law at the University of Constance, was admitted in 1983 to the German bar and holds an LL.M. from the University of San Diego Law School.

*Holger Friedrich.* Mr. Friedrich joined our board as a supervisory director in 2017. Since 2010, Mr. Friedrich has served as managing director of CORE SE's consulting unit. Prior to this role, he served as chairman of SPM Technologies (acquired by SAP) from 1993 to 2003 and as SAP senior vice president, IT Architecture, from 2003 to 2005. He served as partner at McKinsey from 2005 to 2008 and was responsible for their European Enterprise Architecture practice. He served as board member at Software AG from 2009 to 2010. Mr. Friedrich studied computer science and German

studies and he was one of the founding members of the Institute for Theoretical Computer Science at the University of Potsdam, which is known today as the Hasso Plattner Institute.

*Jacob Kaluski, M.Sc.* Mr. Kaluski joined our board as a supervisory director in 2015. He has served as chairman of Danaka AB since 2005. Prior to joining Danaka AB, he served as co-founder of TKT Europe-5S AB from 2000 to 2004 and in various business and management positions at Pharmacia & Upjohn from 1985 to 1999. He has served on the boards of Belina AB since 2018, Glactone AB since 2014, Pulsetten AB from 2012 to 2016, Bioimics AB from 2010 to 2013, DuoCort AB from 2009 to 2012, Alligator Bioscience from 2007 to 2010, Jederstrom Pharmaceuticals AB from 2006 to 2009, TKT Europe-5S AB from 2000 to 2004 and 5S Pharma AB from 1999 to 2008. He holds an M.Sc. in Pharmaceutical Science from Uppsala University.

*Guido Prehn.* Mr. Prehn joined our board as supervisory director in 2017. Mr. Prehn has over 15 years of experience in the private equity industry. He currently serves on the boards of Omniamed Holding GmbH, Pharmazell GmbH, Calvias GmbH, Everest TopCo B.V., Auerbach Holding AG, Kohlsplitz Holding AG, AWK Group and VTU Group. Mr. Prehn is a managing director of DPE Deutsche Private Equity where he joined in 2008, shortly after its foundation. Between 2002 and 2008, he worked in various positions at Allianz Capital Partners, TPG Capital and Merrill Lynch. Mr. Prehn studied business administration at the European Business School, Oestrich-Winkel, De Paul University Chicago and Universidad Argentina de la Empresa, Buenos Aires.

*Eric Souêtre, MD.* Dr. Souêtre joined our board as a supervisory director in 2017. After various research positions at National Institute of Mental Health, Dr. Souêtre founded "BENEFIT" in 1990, a research and consulting company in health economics (subsequently acquired by QUINTILES Inc. (USA) in 1995). He then served as a board member at QUINTILES Inc, where he was responsible for the global consulting function. In 2003, Dr. Souêtre co-founded LABCO—a network of clinical laboratories—and led the company to a European leadership as chairman and CEO until late 2010. He remained as an active board member until LABCO was sold to CINVEN in 2015. Dr. Souêtre has since co-founded a private equity fund (CAREVENTURES) focused on pan European healthcare service ventures. He currently serves on the board of OPERA SA. Dr. Souêtre holds a PhD in neurosciences by the Marseille University, an MD by the Medical University of Nice and an MBA from HEC school of Paris.

*Berndt Modig, MBA.* Mr. Modig joined our board as a supervisory director in April 2018. He also serves as chief executive officer of Pharvaris B.V. He served as chief financial officer of Prosensa Holding N.V., a public pharmaceutical company, from March 2010 until its acquisition by BioMarin Pharmaceutical Inc. in January 2015. From October 2003 to November 2008, Mr. Modig was chief financial officer at Jerini AG where he directed private financing rounds, its initial public offering in 2005, and its acquisition by Shire plc in 2008. Before that, Mr. Modig served as chief financial officer at Surplex AG from 2001 to 2003 and as finance director Europe of U.S.-based Hayward Industrial Products Inc. from 1999 to 2001. In previous positions, Mr. Modig was a partner in the Brussels-based private equity firm, Agra Industria, from 1994 to 1999 and a senior manager in the Financial Services Industry Group of Price Waterhouse LLP in New York from 1991 to 1994. Mr. Modig currently serves as a director and chair of the audit committee of Axovant Sciences Ltd, supervisory board director and member of the audit committee of Affimed N.V., and supervisory board director and chair of the audit committee of Kiadis Pharma N.V., all of which are publicly held pharmaceutical companies, and he was a director of Mobile Loyalty plc from 2012 to 2013. Mr. Modig received a bachelor's degree in business administration, economics and German language from the University of Lund, Sweden, and an MBA from INSEAD, Fontainebleau, France. He is a certified public accountant (inactive).

## **Committees**

### ***Audit Committee***

The audit committee, which is expected to consist of Berndt Modig, Hubert Birner and Guido Prehn, will assist the supervisory board in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee will be responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our supervisory board has determined that [redacted] satisfies the "independence" requirements set forth in Rule 10A-3 under the Exchange Act and qualifies as an "audit committee financial expert," as such term is defined in the rules of the SEC. The composition of our audit committee is consistent with the best practice provisions of the DCGC.

We intend to rely on the phase-in rules of the SEC and Nasdaq with respect to the independence of our audit committee. These rules require that all members of our audit committee must meet the independence standard for audit committee membership within one year of the effectiveness of the registration statement of which this prospectus forms a part. The audit committee will be governed by a charter that complies with applicable Nasdaq rules, which charter will be posted on our website prior to the listing of our common shares on Nasdaq.

### ***Compensation Committee***

The compensation committee is expected to consist of Hubert Birner, Guido Prehn and Eric Sou  tre. The compensation committee will assist the supervisory board in determining compensation for our executive officers and the members of our management board and supervisory board. The composition of our compensation committee is consistent with the best practice provisions of the DCGC.

Under SEC and Nasdaq rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard director fees. As permitted by the listing requirements of Nasdaq, we will opt out of Nasdaq Listing Rule 5605(d), which requires that a compensation committee consist entirely of independent directors. The compensation committee will be governed by a charter that will be posted on our website prior to the listing of our common shares on Nasdaq.

### ***Nomination and Corporate Governance Committee***

The nomination and corporate governance committee is expected to consist of Hubert Birner, Guido Prehn and Eric Sou  tre. The nomination and corporate governance committee will assist our supervisory board in identifying individuals qualified to become members of our management board or supervisory board consistent with criteria established by us and in developing our code of business conduct and ethics. The composition of our nomination and corporate governance committee is consistent with the best practice provisions of the DCGC.

As permitted by the listing requirements of Nasdaq, we will opt out of Nasdaq Listing Rule 5605(e), which requires independent director oversight of director nominations. The nominating and corporate governance committee will be governed by a charter that will be posted on our website prior to the listing of our common shares on Nasdaq.

## **Compensation of Managing Directors, Supervisory Directors and Officers**

Upon completion of this offering, we will be a foreign private issuer. As a result, in accordance with Nasdaq listing requirements, we will comply with home country compensation requirements and certain exemptions thereunder rather than complying with Nasdaq compensation requirements. Dutch law does not provide for limitations with respect to the aggregate annual compensation paid to

members of our management board or supervisory board, provided that such compensation is consistent with our compensation policy. Such compensation policy requires approval by our general meeting of shareholders. The supervisory board determines the remuneration of individual managing directors with due observance of the remuneration policy. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which managing directors may participate is subject to approval by our general meeting of shareholders. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the management board of directors and the criteria for granting or amendment. The compensation for our supervisory directors is set by the general meeting of shareholders.

For the period ended December 31, 2017, the aggregate compensation accrued or paid to the members of Centogene AG's management board and supervisory board for services in all capacities was €2,543 thousand.

For the period ended December 31, 2018, the aggregate compensation accrued or paid to the members of Centogene AG's management board and supervisory board for services in all capacities was €5,598 thousand.

During the years ended December 31, 2017 and 2018, our performance-based compensation programs included a 2016 Virtual Share Option Plan and a 2017 Virtual Share Option Plan, each as described below.

The amount accrued by us to provide pension, retirement or similar benefits to members of its management board, supervisory board or officers with executive responsibilities amounted to a total of €10 thousand in each of the years ended December 31, 2017 and 2018.

### **2016 Virtual Share Option Plan**

Under Centogene AG's virtual share option program 2016 (our "2016 Plan"), we have granted virtual share options to our employees, management board members and selected consultants. As of the date of this prospectus, the outstanding awards under the 2016 Plan cover an aggregate of 8,223 common shares derived from 802,283 options. Under this program, holders of vested options are entitled to receive a direct cash payment from Centogene AG, which payment to the option holders will be reimbursed by the original shareholders of Centogene AG at the same time as the obligation to pay the option holders arises. The 2016 Plan was subsequently amended to reflect that Centogene AG will not be the listed entity, so that Centogene N.V. is the obligor for the direct cash payment with the original shareholders of Centogene AG assuming a reimbursement obligation towards Centogene N.V. See "Note 19—Share-Based Payments" to our financial statements.

Such share options will remain outstanding after the consummation of this offering. We do not intend to issue any additional awards under the 2016 Plan.

### **2017 Virtual Share Option Plan**

In December 2016, Centogene AG established an additional virtual share option program (our "2017 Plan") for virtual share options granted to employees and management board members. As of the date of this prospectus, the outstanding awards under the 2017 Plan cover an aggregate of 16,374 common shares.

In conjunction with the corporate reorganization, all outstanding awards granted under the 2017 Plan will be converted into awards exercisable for common shares of Centogene N.V. on a



to basis, and after the consummation of this offering, we do not intend to issue any additional awards under the 2017 Plan.

### **2018 Equity Incentive Plan**

In conjunction with the consummation of this offering, we intend to establish a new long-term incentive plan (our "2018 Plan") with the purpose of advancing the interests of our shareholders and other stakeholders by enhancing our ability to attract, retain and motivate individuals who are expected to make important contributions to us. The 2018 Plan will govern issuances of equity and equity-based incentive awards from and after the consummation of this offering. The maximum number of common shares underlying awards granted pursuant to the 2018 Plan (other than replacement awards under the 2018 Plan) shall not exceed 13% of the Company's issued share capital immediately following the completion of this offering. Such maximum number shall be increased on January 1, 2020 and on January 1 of each calendar year thereafter, with an additional number of common shares equal to 3% of the Company's issued share capital on such date (or any lower number of common shares as determined by the management board, supervisory board or compensation committee (as the case may be, as prescribed by the 2018 Plan and, collectively, the "Committee").

*Plan Administration.* The 2018 Plan will be administered by the Committee.

*Eligibility.* Awards under the 2018 Plan may be granted to our employees, the members of our management board and supervisory boards, consultants or other advisors.

*Awards.* Awards under the 2018 Plan may be granted in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, other share-based awards or a combination of the foregoing. The Committee may condition the right of an individual to exercise his or her awards upon the achievement or satisfaction of performance criteria.

*Vesting.* The vesting conditions for awards under the 2018 Plan will be determined by the Committee and will be set forth in the applicable award documentation.

*Termination of Service.* In the event of a good leaver's (as defined in the 2018 Plan) termination of employment or service, all vested awards will be exercised or settled in accordance with their terms within a period specified by the Committee and all unvested awards shall be cancelled automatically unless decided otherwise by the Committee. In the event of a bad leaver's (as defined in the 2018 Plan) termination of employment or service, all vested and unvested awards will be canceled automatically without compensation.

*Change in Control.* In the event of a change in control of the Company (as defined in the 2018 Plan), outstanding awards that will be substituted or exchanged for equivalent replacement awards, will be cancelled. If outstanding awards are not substituted or exchanged for equivalent replacement awards, the awards shall immediately vest and settle in full, unless otherwise decided by the Committee.



## PRINCIPAL SHAREHOLDERS

As of the date of this prospectus, our authorized share capital is € , consisting of common shares, par value €0.12 per share. Each of our common shares entitles its holder to one vote. The following table presents information relating to the beneficial ownership of our common shares as of December 31, 2018 and after giving effect to our corporate reorganization (including the conversion of Centogene AG's Series A preferred shares to common shares on an assumed one-to-one basis) by:

- § each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding shares;
- § each member of our management board and supervisory board; and
- § all members of our management board and supervisory board as a group.

Subsequent to the pricing of this offering and as the initial step of our corporate reorganization, all of the outstanding equity interests in Centogene AG will be exchanged for common shares of Centogene B.V. on a -to- basis. Following the completion of this offering and the corporate reorganization, we will have only one class of shares issued and outstanding, and all outstanding common shares will carry the same voting rights. See "Corporate Reorganization."

Unless otherwise indicated, the business address of each shareholder is c/o Am Strande 7, 18055, Rostock, Germany.

Shareholder	Common shares beneficially owned prior to Offering		Common shares beneficially owned after giving effect to the corporate reorganization and Offering		
	Number	Percentage	Number	Percentage (no exercise of underwriter's option)	Percentage (full exercise of underwriter's option)
<b>&gt;5% Shareholders:</b>					
Entities affiliated with DPE <sup>(1)</sup>	64,197	19.94%			
Entities affiliated with Careventures <sup>(2)</sup>	24,718	7.67%			
TVM Life Science Ventures VII L.P. <sup>(3)</sup>	21,583	6.70%			
Michael Schlenk	16,711	5.19%			
<b>Management Board Members and Key Officers:</b>					
Arndt Rolfs <sup>(4)</sup>	71,725	22.27%			
Dirk Ehlers	250	*			
Richard Stoffelen	500	*			
Volkmar Weckesser	200	*			
Peter Bauer	100	*			
Oved Amitay	—	—			
<b>Supervisory Board Members:</b>					
Hubert Birner	—	—			
Christoph Ehlers <sup>(5)</sup>	55,673	17.29%			
Holger Friedrich <sup>(6)</sup>	10,539	3.27%			
Jacob Kaluski	1,462	*			
Guido Prehn	—	—			
Eric Souetre	—	—			
Berndt Modig	—	—			
<b>All Management Board Members, Key Officers and Supervisory Board Members as a Group</b>					
	151,405	47.02%			

\* Less than 1% ownership.

- (1) Common shares held by entities affiliated with DPE consist of (a) 42,187 common shares held by DPE Deutschland II A GmbH & Co. KG ("DPE II A") and (b) 22,010 common shares held by DPE Deutschland II B GmbH & Co. KG ("DPE II B"). DPE Deutsche Private Equity GmbH is the managing limited partner of DPE II A and DPE II B and may be deemed to beneficially own the common shares held by such entities, but disclaims beneficial ownership of such shares. Marc Thiery and Volker Hichert are the managing directors of DPE Deutsche Private Equity GmbH and have shared power to vote the common shares beneficially owned by DPE Deutsche Private Equity GmbH. The address for DPE Deutsche Private Equity GmbH, DPE II A and DPE II B is Ludwigstrasse 7, 80539 Munich, Germany.
- (2) Common shares held by entities affiliated with Careventures consist of (a) 21,838 common shares held by Careventures Fund II S.C.Sp ("Careventures II") which is managed by Careventures Fund II GP Sarl ("Careventures Fund") and (b) 2,880 common shares held by Careventures S.A. ("Careventures SA"), of which Eric Sou tre of Careventures Fund may be deemed to have voting and investment power over the shares noted above. The address for

Careventures II is 42-44, Avenue de la Gare, 1610 Luxembourg, Luxembourg, and the address of Careventures SA is 55, Val Fleuri, 1526 Luxembourg, Luxembourg.

- (3) The governance, investment strategy and decision-making process with respect to investments held by TVM Life Sciences Ventures VII L.P. is directed by TVM Life Sciences Ventures VII G.P., whose directors are Reshenth Beeby, Hubert Birner, Stefan Fischer, Gary Leatt, Luc Marengere and Helmut Schuhsler and who have shared power to vote the common shares beneficially owned by TVM Life Sciences Ventures VII L.P. As a result, each may be deemed to beneficially own the shares beneficially owned by TVM Life Sciences Ventures VII L.P. The address for TVM Life Sciences Ventures VII L.P. is 204 Notre Dame ouest, suite 350, Montréal (Québec) H2Y 1Z3, Canada.
- (4) Prof. Arndt Rolfs, our CEO and a member of our management board, also directly owns 10% of the shares in Centogene GmbH, Vienna, Austria ("Centogene Vienna"), an immaterial subsidiary of ours. The remaining 90% of the shares in Centogene Vienna are directly owned by Centogene AG.
- (5) Christoph Ehlers beneficially owns common shares through his direct ownership of interests in Equicore Beteiligungs GmbH. The address for Equicore Beteiligungs GmbH is Weiherhofstraße 5, 79104 Freiburg im Breisgau, Germany.
- (6) Common shares are held by CCG-Commercial Coordination Germany GmbH and are beneficially owned by Holger Freidrich. The address for CCG-Commercial Coordination Germany GmbH is Mauerstraße 78, 10117 Berlin, Germany.

Following the completion of this offering and the corporate reorganization, each of our shareholders is entitled to one vote per common share. None of the holders of our shares will have different voting rights from other holders of shares after the closing of this offering. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into since January 1, 2016 with any of our officers, directors and the holders of more than 5% of our voting securities, or any member of the immediate family of any of the foregoing persons.

### **Preferred and Common Share Financing**

#### ***Series A Financing***

On June 9, 2017, we entered into investment and shareholders agreements with certain investors, including existing shareholders such as Prof. Arndt Rolfs, our CEO, Dr. Peter Bauer, our chief scientific officer, Richard Stoffelen, our CFO, Dr. Volkmar Weckesser, our chief information officer, all of whom are members of our management board, Holger Friedrich and Christoph Ehlers, members of our supervisory board, Michael Schlenk, TVM Life Science Ventures VII L.P., DPW Deutschland II A GmbH & Co. KG, DPW Deutschland II B GmbH & Co. KG, Careventures S.A., Careventures CG and CM-CIC Investissement SCR, pursuant to which we agreed to issue and sell an aggregate of 31,390 Series A preferred shares in exchange for a further contribution of €15,000 thousand from such investors and increased the authorised amount of Series A preferred shares by up to 34,010.

On May 22, 2018, pursuant to the Series A Shareholders Agreement we issued an additional 34,010 Series A preferred shares from the authorized shares to certain investors in exchange for a contribution of €10,000 thousand from such investors. On November 7, 2018, pursuant to the Series A Extension Agreement (as described below) we issued an additional 26,162 Series A preferred shares to certain investors in exchange for a contribution of €10,000 thousand from such investors.

#### ***Transactions Involving Members of Our Supervisory or Management Board***

As registered in the commercial register on March 14, 2016, Centogene AG issued 500 common shares to Dreamshape Beheer B.V., which shareholder is beneficially owned by Richard Stoffelen, our Chief Financial Officer and member of our management board. In addition to the nominal value of such shares (€500), Dreamshape Beheer B.V. made cash contributions into the Company's capital reserves of €199,500.

As registered in the commercial register on July 6, 2016, Centogene AG issued 2,877 common shares to Holger Friedrich, a member of our supervisory board, which shares are in part held by CCG-Commercial Coordination Germany GmbH, an entity beneficially owned by Mr. Friedrich. In addition to the nominal value of the shares (€2,877), cash contributions were made into the Company's capital reserves of €2,011,123 for such shares. In addition, as registered in the commercial register on January 25, 2017, Centogene AG issued 14,286 common shares to CCG-Commercial Coordination Germany GmbH. In addition to the nominal value of such shares (€14,286), CCG-Commercial Coordination Germany GmbH made cash contributions into the Company's capital reserves of €4,985,814.

As registered in the commercial register on July 23, 2018, Centogene AG issued 250 common shares to Dirk Elhers, our Chief Operating Officer and member of our management board. In addition to the nominal value of such shares (€250), Mr. Elhers made cash contributions into the Company's capital reserves of €99,750.

## **Investment and Shareholders Agreement**

### ***Series A Shareholders Agreement***

We and the shareholders who subscribed for Series A preferred shares in the Series A financing entered into a shareholders agreement, dated June 9, 2017 (the "Shareholders Agreement"). The Shareholders Agreement provides for certain restrictions on the shareholders party thereto, including restrictions on transfer of the Series A preferred shares, as well as certain tag-along rights, drag-along rights, demand rights, rights of first offer and rights of first refusal. The Shareholders Agreement will terminate as a result of the corporate reorganization.

### ***Series A Investment Agreement***

We and the shareholders who subscribed for Series A preferred shares in the Series A financing entered into an investment agreement, dated June 9, 2017 (the "Investment Agreement"). The Investment Agreement provides for the shareholders' subscription obligations and payment obligations in connection with the Series A financing. According to the agreement, the initial investors were entitled to subscribe for 34,010 additional authorized Series A preferred shares at a price subject to adjustment based on certain thresholds. Such additional shares were issued on May 22, 2018. The Investment Agreement shall terminate as a result of the corporate reorganization.

### ***Series A Extension Agreement***

We and select shareholders who subscribed for Series A preferred shares in the Series A financing entered into an extension investment agreement, dated October 1, 2018 (the "Series A Extension Agreement"). The Series A Extension Agreement provides for the shareholders' subscription obligations and payment obligations in connection with the Series A extension financing. According to the agreement, the initial investors were entitled to subscribe for 26,162 additional authorized Series A preferred shares at a price subject to adjustment based on certain thresholds. Such additional shares were issued on November 7, 2018. The Series A Extension Agreement will terminate as a result of the corporate reorganization.

### ***Payments for IT and Consulting Services***

In the years ended December 31, 2016, 2017 and 2018, we incurred costs of €933 thousand, €476 thousand and €nil, respectively, from CORE SE, an IT provider owned by Holger Friedrich, a member of our supervisory board, for information technology services provided to us. In the years ended December 31, 2016, 2017 and 2018, we incurred costs of €311 thousand, €14 thousand and €64 thousand, respectively, from Equicore Beteiligungsgesellschaft GmbH, a shareholder of ours that is beneficially owned by Christoph Ehlers, a member of our supervisory board, for consultancy services provided to us.

### ***Registration Rights Agreement***

Effective upon consummation of this offering, we intend to enter into a registration rights agreement with certain of our existing shareholders pursuant to which we will grant them customary registration rights for the resale of their common shares. See "Common shares eligible for future sale—Registration Rights."

### ***Indemnification Agreements***

Our articles of association, which will be effected upon consummation of the offering, will require us to indemnify members of our management board and supervisory board to the fullest extent permitted by law.

### ***Employment Agreements***

We intend to enter into employment agreements with certain members of our management board, some of which will provide for notice of termination periods and include restrictive covenants. None of our directors have entered into service agreements with the Company.

## DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

### General

We were incorporated pursuant to the laws of the Netherlands as Centogene B.V. in October 2018 to become a holding company for Centogene AG prior to the closing of this offering. Pursuant to the terms of a corporate reorganization that will be completed prior to the closing of this offering, all of the equity interests in Centogene AG will be exchanged for common shares of Centogene B.V. and, as a result, Centogene AG will become a wholly owned subsidiary of Centogene B.V. Immediately following such exchange, and prior to the listing of our common shares on Nasdaq, we intend to convert into a public company (*naamloze vennootschap*) under Dutch law pursuant to a Dutch notarial deed of amendment and conversion, following which our legal name will be Centogene N.V. See "Corporate Reorganization."

Our affairs are governed by the provisions of our articles of association and internal rules, regulations and policies, as amended and restated from time to time, and by the provisions of applicable Dutch law.

As provided in our articles of association, subject to Dutch law, we have full capacity to carry on or undertake any business or activity, do any act or enter into any transaction consistent with the objects specified in our articles of association, and, for such purposes, full rights, powers and privileges. Our registered office is Am Strande 7, 18055 Rostock, Germany.

As of the execution of our deed of amendment and conversion as part of the corporate reorganization (see "Corporate Reorganization"), our authorized share capital will amount to € , divided into common shares, each with a nominal value of €0.12, and our issued share capital will amount to € . Upon the closing of this offering, our authorized share capital will automatically increase to € , divided into common shares, each with a nominal value of €0.12, and our issued share capital will amount to € . If we increase or decrease the number of shares offered and sold by us in this offering, our authorized share capital will be adjusted to be approximately five times the issued share capital immediately following the closing of this offering (including such increase or decrease in common shares offered and sold in this offering). We intend to apply to list our common shares on Nasdaq under the symbol "CNTG."

Initial settlement of our common shares will take place on the closing date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities. Each person owning common shares held through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the common shares. Persons wishing to obtain certificates for their common shares must make arrangements with DTC.

The following is a summary of relevant information concerning our share capital and our articles of association as they will read upon the closing of this offering. This summary does not constitute legal advice regarding those matters and should not be regarded as such.

### Common Shares

The following summarizes the main rights of holders of our common shares:

- § each holder of common shares is entitled to one vote per share on all matters to be voted on by shareholders generally, including the election of managing directors and supervisory directors;
- § there are no cumulative voting rights;

- § the holders of our common shares are entitled to dividends and other distributions as may be declared from time to time by us out of funds legally available for that purpose, if any;
- § upon our liquidation, dissolution or winding-up, the holders of common shares will be entitled to share ratably in the distribution of all of our assets remaining available for distribution after satisfaction of all our liabilities; and
- § the holders of common shares have preemptive rights in case of share issuances or the grant or rights to subscribe for shares, except if such rights are limited or excluded by the corporate body authorized to do so and except in such cases as provided by Dutch law and our articles of association.

The Company may not make calls on shareholders in excess of the aggregate nominal value of the shares a shareholder has subscribed for.

### **Shareholders' Register**

Pursuant to Dutch law and our articles of association, we must keep our shareholders' register accurate and current. The management board keeps our shareholders' register and records names and addresses of all holders of shares, showing the date on which the shares were acquired, the date of the acknowledgement by or notification of us as well as the amount paid on each share. The register also includes the names and addresses of those with a right of use and enjoyment (*vruchtgebruik*) in shares belonging to another or a pledge (*pandrecht*) in respect of such shares. The common shares offered in this offering will be held through DTC, therefore DTC or its nominee will be recorded in the shareholders' register as the holder of those common shares.

### **Corporate Objectives**

Pursuant to our articles of association, our main corporate objectives are:

- § to develop, license, manufacture and commercialize diagnostic and pharmaceutical products and services;
- § to develop and commercialize diagnostic and pharmaceutical tests and analytical methods;
- § to incorporate, to participate in, to finance, to hold any other interest in and to conduct the management or supervision of other entities, companies, partnerships and businesses;
- § to acquire, to manage, to invest, to exploit, to encumber and to dispose of assets and liabilities;
- § to furnish guarantees, to provide security, to warrant performance in any other way and to assume liability, whether jointly and severally or otherwise, in respect of obligations of group companies or other parties; and
- § to do anything which, in the widest sense, is connected with or may be conducive to the objects described above.

### **Limitations on the Rights to Own Securities**

Our common shares may be issued to individuals, corporations, trusts, estates of deceased individuals, partnerships and unincorporated associations of persons. Our articles of association contain no limitation on the rights to own our shares and no limitation on the rights of nonresidents of the Netherlands or foreign shareholders to hold or exercise voting rights.

### **Limitation on Liability and Indemnification Matters**

Under Dutch law, managing directors, supervisory directors and certain other officers may be held liable for damages in the event of improper or negligent performance of their duties. They may be held jointly and severally liable for damages to the company and to third parties for infringement of the articles of association or of certain provisions of Dutch law. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Subject to certain exceptions, our articles of

association provide for indemnification of our current and former managing directors and supervisory directors (and other current and former officers and employees as designated by our management board). No indemnification shall be given to an indemnified person:

- (a) if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above are of an unlawful nature (including acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person);
- (b) to the extent that his or her financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);
- (c) in relation to proceedings brought by such indemnified person against the company, except for proceedings brought to enforce indemnification to which he is entitled pursuant to our articles of association, pursuant to an agreement between such indemnified person and the company which has been approved by the management board or pursuant to insurance taken out by the company for the benefit of such indemnified person; and
- (d) for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without the company's prior consent.

Under our articles of association, our management board may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

### **Shareholders' Meetings**

General meetings of shareholders may be held in Amsterdam, Arnhem, Assen, The Hague, Haarlem, 's-Hertogenbosch, Groningen, Leeuwarden, Lelystad, Maastricht, Middelburg, Rotterdam, Schiphol (Haarlemmermeer), Utrecht or Zwolle, all in the Netherlands. The annual general meeting of shareholders must be held within six months of the end of each financial year. Additional extraordinary general meetings of shareholders may also be held, whenever considered appropriate by the management board or the supervisory board and shall be held within three months after our management board has considered it to be likely that our equity has decreased to an amount equal to or lower than half of its paid up and called up share capital, in order to discuss the measures to be taken if so required.

Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law who jointly represent at least one-tenth of the issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party/parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting of shareholders. The court shall disallow the application if it does not appear that the applicants have previously requested our management board and our supervisory board to convene a general meeting and neither our management board nor our supervisory board have taken the necessary steps so that the general meeting could be held within six weeks after the request.

General meetings of shareholders can be convened by a notice, which shall include an agenda stating the items to be discussed as well as other information as required by Dutch law, including for



the annual general meeting of shareholders, among other things, the adoption of the annual accounts, appropriation of our profits and proposals relating to the composition of the management board and supervisory board, including the filling of any vacancies in such bodies. In addition, the agenda shall include such items as have been included therein by the management board or the supervisory board. The agenda shall also include such items requested by one or more shareholders, or others with meeting rights under Dutch law, representing at least 3% of the issued share capital. Requests must be made in writing or by electronic means and received by us at least 60 days before the day of the convocation of the meeting. No resolutions shall be adopted on items other than those that have been included in the agenda.

In accordance with the DCGC and our articles of association, shareholders having the right to put an item on the agenda under the rules described above shall exercise such right only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy (for example, the removal of managing directors or supervisory directors), the management board must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, the management board must use such response period for further deliberation and constructive consultation, in any event with the shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, the management board shall report on this consultation and the exploration of alternatives to the general meeting of shareholders. This shall be supervised by our supervisory board. The response period may be invoked only once for any given general meeting of shareholders and shall not apply: (a) in respect of a matter for which a response period has been previously invoked; or (b) if a shareholder holds at least 75% of the company's issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting of shareholders be convened, as described above.

The general meeting is presided over by the chairman of the supervisory board. If no chairman has been elected or if he or she is not present at the meeting, the general meeting shall be presided over by another supervisory director present at the meeting. If no supervisory director is present, the meeting shall be presided over by our CEO. If no CEO has been elected or if he or she is not present at the meeting, the general meeting shall be presided over by another managing director present at the meeting. If no managing director is present at the meeting, the general meeting shall be presided over by any other person appointed by the general meeting. In each case, the person who should chair the general meeting pursuant to the rules described above may appoint another person to chair the general meeting instead. Managing directors and supervisory directors may always attend a general meeting of shareholders. In these meetings, they have an advisory vote. The chairman of the meeting may decide at his or her discretion to admit other persons to the meeting.

All shareholders and others with meeting rights under Dutch law are authorized to attend the general meeting of shareholders, to address the meeting and, in so far as they have such right, to vote.

Each common share confers the right on the holder to cast one vote at the general meeting of shareholders. Shareholders may vote by proxy. No votes may be cast at a general meeting of shareholders on shares held by us or our subsidiaries or on shares for which we or our subsidiaries hold depositary receipts. Nonetheless, the holders of a right of use and enjoyment (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the right of use and

enjoyment (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a right of use and enjoyment (*vruchtgebruik*) or a right of pledge (*pandrecht*). Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a general meeting of shareholders.

Decisions of the general meeting of shareholders are taken by a simple majority of votes cast, except where Dutch law or our articles of association provide for a qualified majority or unanimity.

## **Managing Directors and Supervisory Directors**

### ***Election of Managing Directors and Supervisory Directors***

Under our articles of association, the managing directors and supervisory directors are appointed by the general meeting of shareholders upon binding nomination by our supervisory board. However, the general meeting of shareholders may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting of shareholders overrules the binding nomination, the supervisory board shall make a new nomination.

Prior to the closing of this offering, our supervisory board shall adopt a diversity policy for the composition of our management board and our supervisory board, as well as a profile for the composition of the supervisory board. The supervisory board shall make any nomination for the appointment of a managing director or supervisory director with due regard to the rules and principles set forth in such diversity policy and profile, as applicable.

At a general meeting of shareholders, a resolution to appoint a managing director or supervisory director can only be passed in respect of candidates whose names are stated for that purpose in the agenda of that general meeting of shareholders or in the explanatory notes thereto.

Under Dutch law, when nominating a person for appointment or reappointment as a supervisory director, the nomination must be supported by reasons (if it concerns a reappointment, past performance must be taken into consideration) and the following information about such person must be provided: (i) age and profession; (ii) the aggregate nominal value of the shares held in the company's capital; (iii) present and past positions, to the extent relevant for the performance of the tasks of a supervisory director; and (iv) the name of each entity where such person already holds a position as supervisory director or non-executive director (in case of multiple entities within the same group, the name of the group shall suffice).

### ***Duties and Liabilities of Managing Directors and Supervisory Directors***

Under Dutch law, the management board is charged with the management of the company, subject to the restrictions contained in our articles of association, and the supervisory board is charged with the supervision of the policy of the management board and the general course of affairs of the company and of the business connected with it. Each managing director and supervisory director has a statutory duty to act in the corporate interest of the company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed. Any resolution of

the management board regarding a material change in our identity or character requires approval of the general meeting of shareholders.

## **Dividends and Other Distributions**

### ***Dividends***

We may only make distributions to our shareholders if our shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-up and called-up share capital plus any reserves required by Dutch law or by our articles of association. Under our articles of association, the management board may decide that all or part of the profits are carried to reserves. After reservation by the management board of any profit, the remaining profit will be at the disposal of the general meeting of shareholders for distribution, subject to restrictions of Dutch law and approval by our supervisory board.

We only make a distribution of dividends to our shareholders after the adoption of our annual accounts demonstrating that such distribution is legally permitted. The management board is permitted, subject to certain requirements, to declare interim dividends without the approval of the general meeting of shareholders, but only with the approval of the supervisory board.

Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

We have not adopted a dividend policy with respect to future dividends. Subject the restrictions described above, any dividend policy (if we were to adopt one) will depend on many factors, such as our results of operations, financial condition, cash requirements, prospects and other factors deemed relevant by our management board and supervisory board.

### ***Exchange Controls***

Under Dutch law, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company, subject to applicable restrictions under sanctions and measures, including those concerning export control, pursuant to European Union regulations, the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation, applicable anti-boycott regulations and similar rules.

### ***Squeeze-Out Procedures***

Pursuant to Section 2:92a of the Dutch Civil Code, a shareholder who holds at least 95% of our issued share capital for his own account, alone or together with group companies, may initiate proceedings against the other shareholders jointly for the transfer of their shares to such shareholder. The proceedings are held before the Enterprise Chamber of the Amsterdam Court of Appeal, or the Enterprise Chamber (*Ondernemingskamer*), and can be instituted by means of a writ of summons served upon each of the other shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze-out in relation to the other shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the other shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are

known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation.

### ***Dissolution and Liquidation***

Under our articles of association, we may be dissolved by a resolution of the general meeting of shareholders, subject to a proposal of the management board approved by our supervisory board. In the event of a dissolution, the liquidation shall be effected by the management board, under supervision of our supervisory board, unless the general meeting decides otherwise. To the extent that any assets remain after payment of all debts, those assets shall be distributed to the holders of common shares.

### **Dutch Corporate Governance Code**

As a listed Dutch public company (*naamloze vennootschap*), we will be subject to the DCGC. The DCGC contains both principles and best practice provisions that regulate relations between the management board, the supervisory board and the general meeting of shareholders. The DCGC is based on a "comply or explain" principle. Accordingly, companies are required to disclose in their statutory annual reports, filed in the Netherlands, whether they comply with the provisions of the DCGC. If they do not comply with these provisions (for example, because of a conflicting Nasdaq requirement), the company is required to give the reasons for such non-compliance. See "Risk factors—we are not obligated to, and do not, comply with all best practice provisions of the Dutch Corporate Governance Code."

We do not comply with all principles and best practice provisions of the DCGC. As of the date of this prospectus, we deviate from the DCGC as summarized below, but cannot exclude the possibility of deviating from additional provisions of the DCGC after the date hereof, including in order to follow market practice or governance practices in the United States.

Under our articles of association, managing directors and supervisory directors are to be appointed on the basis of a binding nomination prepared by the supervisory board. This means that the nominee will be appointed, unless the general meeting of shareholders overrules the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital (in which case a new nomination will be prepared for a subsequent general meeting of shareholders). The DCGC recommends that the general meeting of shareholders can pass such a resolution by simple majority, representing no more than one-third of the issued share capital.

Under our articles of association, managing directors and supervisory directors can only be dismissed by the general meeting of shareholders by simple majority, if the supervisory board proposes the dismissal. In other cases, the general meeting of shareholders can only pass such resolution by a two-thirds majority representing at least half of the issued share capital. The DCGC recommends that the general meeting of shareholders can pass a resolution to dismiss a managing director or supervisory director by simple majority, representing no more than one-third of the issued share capital.

The DCGC recommends against providing equity awards as part of the compensation of a supervisory director. However, we expect to deviate from this recommendation and grant equity awards to our supervisory directors, consistent with U.S. market practice.

Our 2018 Plan allows us to set the terms and conditions of equity awards granted thereunder. Under the 2018 Plan, we may grant common shares that are not subject to a lock-up period of at least five years after the date of grant, and we may grant options without restricting the exercisability of those options during the first three years after the date of grant. In those cases, this would cause additional deviations from the DCGC.

### **Dutch Financial Reporting Supervision Act**

On the basis of the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*), or the FRSA, the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*), or AFM supervises the application of financial reporting standards by Dutch companies whose securities are listed on a Dutch or foreign stock exchange.

Pursuant to the FRSA, the AFM has an independent right to (i) request an explanation from us regarding our application of the applicable financial reporting standards and (ii) recommend to us the making available of further explanations. If we do not comply with such a request or recommendation, the AFM may request that the Enterprise Chamber of the Amsterdam Court of Appeal (*Ondernemingskamer*) order us to (i) make available further explanations as recommended by the AFM, (ii) provide an explanation of the way we have applied the applicable financial reporting standards to our financial reports or (iii) prepare our financial reports in accordance with the Enterprise Chamber's orders.

### **Foreign Investment Legislation**

Under existing laws of the Netherlands, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company.

### **Comparison of Netherlands Corporate Law and U.S. Corporate Law**

The following comparison between Dutch corporate law, which applies to us, and Delaware corporation law, the law under which many publicly listed corporations in the United States are incorporated, discusses additional matters not otherwise described in this prospectus. Although we believe this summary is materially accurate, the summary is subject to Dutch law, including Book 2 of the Dutch Civil Code and the DCGC and Delaware corporation law, including the Delaware General Corporation Law.

### **Corporate Governance**

#### *Duties of Managing and Supervisory Directors*

*The Netherlands.* In the Netherlands, a listed company typically has a two-tier board structure with a management board comprised of the managing directors and a supervisory board comprised of the supervisory directors. We have a two-tier board structure consisting of our management board (*bestuur*) and a separate supervisory board (*raad van commissarissen*).

Under Dutch law, the management board is charged with the management of the company, subject to the restrictions contained in our articles of association, and the supervisory board is charged with the supervision of the policy of the management board and the general course of affairs of the company and of the business connected with it. Each managing director and supervisory director has a statutory duty to act in the corporate interest of the company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of

the company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed. Any resolution of the management board regarding a material change in our identity or character requires approval of the general meeting of shareholders.

*Delaware.* The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

#### *Director Terms*

*The Netherlands.* The DCGC provides the following best practice recommendations on the terms for tenure of managing directors and supervisory directors:

- § Managing directors should be appointed for a maximum period of four years, without limiting the number of consecutive terms managing directors may serve.
- § Supervisory directors should be appointed for two consecutive periods of no more than four years. Thereafter, supervisory directors may be reappointed for a maximum of two consecutive periods of no more than two years, provided that any reappointment after an eight-year term of office should be disclosed in the company's annual board report.

The general meeting of shareholders shall at all times be entitled to suspend or dismiss a managing director or supervisory director. Under our articles of association, the general meeting of shareholders may only adopt a resolution to suspend or dismiss such director by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the issued share capital, unless the resolution is passed at the proposal of the supervisory board, in which case a simple majority of the votes cast is sufficient. In addition, the supervisory board may at any time suspend a managing director. A suspension by the supervisory board can at any time be lifted by the general meeting of shareholders.

*Delaware.* The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a "classified" board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

#### *Director Vacancies*

*The Netherlands.* Under Dutch law, managing directors and supervisory directors are appointed and reappointed by the general meeting of shareholders. Under our articles of association, managing directors and supervisory directors are appointed by the general meeting of shareholders upon the binding nomination by our supervisory board. However, the general meeting of shareholders may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the

issued share capital. If the general meeting of shareholders overrules the binding nomination, the supervisory board shall make a new nomination.

Prior to the closing of this offering, our supervisory board shall adopt a diversity policy for the composition of our management board and our supervisory board, as well as a profile for the composition of the supervisory board. The supervisory board shall make any nomination for the appointment of a managing director or supervisory director with due regard to the rules and principles set forth in such diversity policy and profile, as applicable.

Under Dutch law, when nominating a person for appointment or reappointment as a supervisory director, the nomination must be supported by reasons (if it concerns a reappointment, past performance must be taken into consideration) and the following information about such person must be provided: (i) age and profession; (ii) the aggregate nominal value of the shares held in the company's capital; (iii) present and past positions, to the extent relevant for the performance of the tasks of a supervisory director; and (iv) the name of each entity where such person already holds a position as supervisory director or non-executive director (in case of multiple entities within the same group, the name of the group shall suffice).

*Delaware.* The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

#### *Conflict-of-Interest Transactions*

*The Netherlands.* Under Dutch law and our articles of association, our managing directors and supervisory directors shall not take part in any discussion or decision-making that involves a subject or transaction in relation to which he or she has a conflict of interest with us. Our articles of association provide that if as a result of conflicts of interests no resolution of the management board can be adopted, the resolution may be passed by the supervisory board and that, if as a result of conflicts of interests no resolution of the supervisory board can be adopted, the resolution may nonetheless be adopted by the supervisory board as if none of the supervisory directors had a conflict of interest. In that case, each supervisory director is entitled to participate in the discussion and decision-making process and to cast a vote.

The DCGC provides the following best practice recommendations in relation to conflicts of interests:

- § A managing director should report any potential conflict of interest in a transaction that is of material significance to the company and/or to such person to the chairman of the supervisory board and to the other members of the management board without delay. The managing director should provide all relevant information in that regard, including the information relevant to the situation concerning his or her spouse, registered partner or other life companion, foster child and relatives by blood or marriage up to the second degree.
- § A supervisory director should report any conflict of interest or potential conflict of interest in a transaction that is of material significance to the company and/or to such person to the chairman of the supervisory board without delay and should provide all relevant information in that regard, including the relevant information pertaining to his or her spouse, registered partner or other life companion, foster child and relatives by blood or marriage up to the second degree. If the chairman of the supervisory board has a conflict of interest or

potential conflict of interest, he or she should report this to the vice-chairman of the supervisory board without delay.

- § The supervisory board should decide, outside the presence of the management board member or supervisory board member concerned, whether there is a conflict of interest.
- § All transactions in which there are conflicts of interest with management board members or supervisory board members should be agreed on terms that are customary in the market.
- § Decisions to enter into transactions in which there are conflicts of interest with management board members or supervisory board members that are of material significance to the company and/or to the relevant management board members or supervisory board members should require the approval of the supervisory board. Such transactions should be published in the Company's annual report.

*Delaware.* The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- § the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors consent;
- § the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent;
- or
- § the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

#### *Proxy Voting by Directors*

*The Netherlands.* An absent member of the management board may issue a proxy for a specific management board meeting but only to another management board member in writing or by electronic means. An absent member of the supervisory board may issue a proxy for a specific supervisory board meeting but only to another supervisory board member in writing or by electronic means.

*Delaware.* A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

### **Shareholder Rights**

#### *Voting Rights*

*The Netherlands.* In accordance with Dutch law and our articles of association, each issued common share confers the right to cast one vote at the general meeting of shareholders. Each holder of shares may cast as many votes as it holds shares. No votes may be cast on shares that are held by us or our direct or indirect subsidiaries or on shares for which we or our subsidiaries hold depositary receipts. Nonetheless, the holders of a right of use and enjoyment (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of shares held by us or our subsidiaries in our share capital are not excluded from the right to vote on such shares, if the right of use and enjoyment (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such shares were acquired by us or any of our subsidiaries. Neither we nor any of our subsidiaries may cast votes in respect of a share on which we or such subsidiary holds a right of use and enjoyment (*vruchtgebruik*) or a right of pledge (*pandrecht*).

In accordance with our articles of association, for each general meeting of shareholders, the management board may determine that a record date will be applied in order to establish which shareholders are entitled to attend and vote at the general meeting of shareholders. Such record date shall be the 28th day prior to the day of the general meeting. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting which must be published in a Dutch daily newspaper with national distribution at least



15 days prior to the meeting (and such notice may therefore be published after the record date for such meeting).

*Delaware.* Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one-third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

#### *Shareholder Proposals*

*The Netherlands.* Pursuant to our articles of association, extraordinary general meetings of shareholders will be held whenever required under Dutch law or whenever our management board or supervisory board deems such to be appropriate or necessary. Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law representing at least one-tenth of the issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If we have not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party or parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting of shareholders.

Also, the agenda for a general meeting of shareholders shall include such items requested by one or more shareholders, and others entitled to attend general meetings of shareholders, representing at least 3% of the issued share capital, except where the articles of association state a lower percentage. Our articles of association do not state such lower percentage. Requests must be made in writing or by electronic means and received by us at least 60 days before the day of the convocation of the meeting.

In accordance with the DCGC and our articles of association, a shareholder shall exercise the right of putting an item on the agenda only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy (for example, the removal of managing directors or supervisory directors), the management board must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the DCGC from time to time). If invoked, the management board must use such response period for further deliberation and constructive consultation, in any event with the shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, the management board shall report on this consultation and the exploration of alternatives to the general meeting of shareholders. This shall be supervised by our supervisory board. The response period may be invoked only once for any given general meeting of shareholders and shall not apply: (a) in respect of a matter for which a response period has been

previously invoked; or (b) if a shareholder holds at least 75% of the company's issued share capital as a consequence of a successful public bid. The response period may also be invoked in response to shareholders or others with meeting rights under Dutch law requesting that a general meeting of shareholders be convened, as described above.

*Delaware.* Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least \$2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

#### *Action by Written Consent*

*The Netherlands.* Under Dutch law, shareholders' resolutions may be adopted in writing without holding a meeting of shareholders, provided that (i) the articles of association allow such action by written consent, (ii) the company has not issued bearer shares or, with its cooperation, depository receipts for shares in its capital, and (iii) the resolution is adopted unanimously by all shareholders that are entitled to vote. The requirement of unanimity renders the adoption of shareholder resolutions without holding a meeting not feasible for publicly traded companies.

*Delaware.* Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

#### *Appraisal Rights*

*The Netherlands.* Subject to certain exceptions, Dutch law does not recognize the concept of appraisal or dissenters' rights. However, Dutch law does provide for squeeze-out procedures as described under "Dividends and Other Distributions—Squeeze-Out Procedures." Also, Dutch law provides for cash exit rights for dissenting shareholders of a company organized under Dutch law entering into a cross-border merger with an acquiring company organized under the laws of another member state of the EEA. A shareholder of such a Dutch disappearing company who has voted against such cross-border merger, as well as any holder of shares without voting rights, may file a claim with the Dutch company for compensation. Such compensation shall then be determined by one or more independent experts. The shares of such shareholder that are subject to such claim will cease to exist as of the moment of entry into effect of the cross-border merger.

*Delaware.* The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

#### *Shareholder Suits*

*The Netherlands.* In the event a third party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an action on behalf of the company. Only in the event that the cause for the liability of a third party to the company also constitutes a tortious act directly against a shareholder does that shareholder have an individual right of action against such third party in its own name. The Dutch Civil Code provides for the possibility to initiate such actions collectively. A foundation or an association whose objective is to protect the rights of a group of persons having similar interests can institute a collective action. The collective action itself cannot result in an order for payment of monetary damages but may only result in a declaratory judgment (*verklaring voor recht*). In order to obtain compensation for damages, the foundation or association and the defendant may reach—often on the basis of such declaratory judgment—a settlement. A Dutch court may declare the settlement agreement binding upon all the injured parties with an opt-out choice for an individual

injured party. An individual injured party may also itself—outside the collective action—institute a civil claim for damages.

*Delaware.* Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

#### *Repurchase of Shares*

*The Netherlands.* Under Dutch law, when issuing shares, a public company such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its articles of association, acquire shares in its own capital. A listed public company such as ours may acquire fully paid shares in its own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and its articles of association, such company may repurchase fully paid shares in its own capital if (i) the company's shareholders' equity less the payment required to make the acquisition does not fall below the sum of paid-up and called-up share capital plus any reserves required by Dutch law or its articles of association and (ii) the aggregate nominal value of shares of the company which the company acquires, holds or on which the company holds a pledge (*pandrecht*) or which are held by a subsidiary of the company, would not exceed 50% of its then-current issued share capital. Such company may only acquire its own shares if its general meeting of shareholders has granted the management board the authority to effect such acquisitions.

An acquisition of common shares for a consideration must be authorized by our general meeting of shareholders. Such authorization may be granted for a maximum period of 18 months and must specify the number of common shares that may be acquired, the manner in which common shares may be acquired and the price limits within which common shares may be acquired. Authorization is not required for the acquisition of common shares in order to transfer them to our employees. The actual acquisition may only be effected pursuant to a resolution of our management board, with the approval of our supervisory board. Prior to the closing of this offering, our management board, subject to approval by our supervisory board, will be authorized, for a period of 18 months to cause the repurchase of common shares by us of up to 20% of our issued share capital, for a price per share not exceeding 110% of the average market price of our common shares on Nasdaq (such average market price being the average of the closing prices on each of the five consecutive trading days preceding the date the acquisition is agreed upon by us). These shares may be used to deliver shares underlying awards granted pursuant to our equity-based compensation plans.

No authorization of the general meeting of shareholders is required if common shares are acquired by us with the intention of transferring such common shares to our employees under an applicable employee stock purchase plan.

*Delaware.* Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred

shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

#### *Anti-Takeover Provisions*

*The Netherlands.* Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. In this respect, certain provisions of our articles of association may make it more difficult for a third party to acquire control of us or effect a change in our management board and supervisory board. These provisions include: a provision that our managing directors and supervisory directors are appointed on the basis of a binding nomination prepared by our supervisory board which can only be overruled by a two-thirds majority of votes cast representing more than 50% of our issued share capital; a provision that our managing directors and supervisory directors may only be dismissed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our issued share capital (unless the dismissal is proposed by the supervisory board in which case a simple majority of the votes would be sufficient); and a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our management board. In addition, Dutch law allows for staggered multi-year terms of our managing directors and supervisory directors, as a result of which only part of our managing directors and supervisory directors may be subject to election or re-election in any one year.

*Delaware.* In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation's voting stock, within three years after the person becomes an interested stockholder, unless:

- § the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transactions;
- § after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- § after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until 12 months following its adoption.

#### *Inspection of Books and Records*

*The Netherlands.* The management board and the supervisory board provide the general meeting of shareholders, within a reasonable amount of time, all information that the shareholders require for the exercise of their powers, unless this would be contrary to an overriding interest of our

company. If the management board or supervisory board invokes such an overriding interest, it must give reasons.

*Delaware.* Under the Delaware General Corporation Law, any stockholder may inspect for any proper purpose certain of the corporation's books and records during the corporation's usual hours of business.

#### *Dismissal of Directors*

*The Netherlands.* Under our articles of association, the general meeting of shareholders shall at all times be entitled to dismiss a director. The general meeting of shareholders may only adopt a resolution to suspend or dismiss a managing director or supervisory director by at least a two-thirds majority of the votes cast, provided that such majority represents more than half of the issued share capital, unless the proposal was made by the supervisory board, in which latter case a simple majority is sufficient.

*Delaware.* Under the Delaware General Corporation Law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, stockholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

#### *Issuance of Shares*

*The Netherlands.* Under Dutch law, a company's general meeting is the corporate body authorized to resolve on the issuance of shares and the granting of rights to subscribe for shares. The general meeting can delegate such authority to another corporate body of the company, such as the management board, for a period not exceeding five years. Prior to the closing of this offering, our management board, subject to approval of our supervisory board, will be authorized, for a period of five years, to issue shares or grant rights to subscribe for shares up to our authorized share capital from time to time.

*Delaware.* All creation of shares require the board of directors to adopt a resolution or resolutions, pursuant to authority expressly vested in the board of directors by the provisions of the company's certificate of incorporation.

#### *Preemptive Rights*

*The Netherlands.* Under Dutch law, in the event of an issuance of common shares, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder (with the exception of common shares to be issued to employees or common shares issued against a contribution other than in cash or pursuant to the exercise of a previously acquired right to subscribe for shares). Under our articles of association, the preemptive rights in respect of newly issued common shares may be restricted or excluded by a resolution of the general meeting of shareholders. Another corporate body, such as the management board, may restrict or exclude the preemptive rights in respect of newly issued common shares if it has been designated as the authorized body to do so by the general meeting of shareholders. Such designation can be granted for a period not exceeding five years. A resolution of the general meeting of shareholders to restrict or exclude the preemptive rights or to designate another corporate body as the authorized body to do so requires a majority of not less than two-thirds of the

votes cast, if less than one-half of our issued share capital is represented at the meeting. Prior to the closing of this offering, our management board, subject to approval of our supervisory board, will be authorized, for a period of five years to limit or exclude preemptive rights in relation to an issuance of shares or a grant of rights to subscribe for shares that the management board is authorized to resolve upon (see above under "Issuance of Shares").

*Delaware.* Under the Delaware General Corporation Law, stockholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

#### *Dividends*

*The Netherlands.* Dutch law provides that dividends may be distributed after adoption of the annual accounts by the general meeting of shareholders from which it appears that such dividend distribution is allowed. Moreover, dividends may be distributed only to the extent the shareholders' equity exceeds the amount of the paid-up and called-up issued share capital and the reserves that must be maintained under the law or the articles of association. Interim dividends may be declared as provided in the articles of association and may be distributed to the extent that the shareholders' equity exceeds the amount of the paid-up and called-up issued share capital plus any reserves as described above as apparent from our financial statements. Under Dutch law, the articles of association may prescribe that the management board decide what portion of the profits are to be held as reserves.

Under our articles of association, the management board may decide that all or part of the profits are carried to reserves. After reservation by the management board of any profit, the remaining profit will be at the disposal of the general meeting of shareholders for distribution, subject to restrictions of Dutch law and approval by our supervisory board. Our management board is permitted, subject to certain requirements, to declare interim dividends without the approval of the general meeting of shareholders, but only with the approval of the supervisory board. Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

*Delaware.* Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common stock, property or cash.

#### *Shareholder Vote on Certain Reorganizations*

*The Netherlands.* Under Dutch law, the general meeting of shareholders must approve resolutions of the management board relating to a significant change in the identity or the character of the company or the business of the company, which includes:

- § a transfer of the business or virtually the entire business to a third party;
- § the entry into or termination of a long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner in a limited partnership or

general partnership, if such cooperation or termination is of a far-reaching significance for the company; and

- § the acquisition or divestment by the company or a subsidiary of a participating interest in the capital of a company having a value of at least one-third of the amount of its assets according to its balance sheet and explanatory notes or, if the company prepares a consolidated balance sheet, according to its consolidated balance sheet and explanatory notes in the last adopted annual accounts of the company.

*Delaware.* Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

#### *Remuneration of Managing Directors and Supervisory Directors*

*The Netherlands.* Under Dutch law and our articles of association, we must adopt a compensation policy for our management board. Such compensation policy then requires approval by our general meeting of shareholders. The supervisory board determines the remuneration of individual managing directors with due observance of the remuneration policy. A proposal with respect to remuneration schemes in the form of shares or rights to shares in which managing directors may participate is subject to approval by our general meeting of shareholders. Such a proposal must set out at least the maximum number of shares or rights to subscribe for shares to be granted to the management board and the criteria for granting or amendment. The compensation for our supervisory directors is set by the general meeting of shareholders.

*Delaware.* Under the Delaware General Corporation Law, the stockholders do not generally have the right to approve the compensation policy for directors or the senior management of the corporation, although certain aspects of the compensation policy may be subject to stockholder vote due to the provisions of U.S. federal securities and tax law.

#### **Code of Ethics**

Upon the closing of this offering, we will have adopted a code of business conduct and ethics applicable to our management board, our supervisory board, and company personnel.

#### **Transfer Agent and Registrar**

Upon the closing of this offering, the transfer agent and registrar for the common shares will be the American Stock and Transfer Company.

## COMMON SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common shares. Future sales of common shares in the public market after this offering, and the availability of common shares for future sale, could adversely affect the market price of our common shares prevailing from time to time. As described below, most of our currently outstanding common shares will be available for sale immediately after this offering, and the remainder will be available for sale 180 days after the expiration of contractual restrictions on transfers of common shares. Accordingly, sales of substantial amounts of the common shares, or the perception that these sales could occur, could adversely affect prevailing market prices for our common shares and could impair our future ability to raise equity capital.

Based on the number of common shares outstanding as of \_\_\_\_\_, 2019, upon completion of this offering, \_\_\_\_\_ common shares will be outstanding, assuming no outstanding options are exercised. All of the common shares sold in this offering will be freely transferable without restriction or further registration under the Securities Act, except for any common shares sold to our "affiliates." In addition, all of our common shares outstanding before this offering will be freely transferable and may be resold without restriction or further registration under the Securities Act. Under Rule 144 of the Securities Act, an "affiliate" of a company is a person that directly or indirectly controls, is controlled by or is under common control with that company. Affiliates may sell only the volume of shares described below and their sales are subject to additional restrictions described below.

### Rule 144

In general, persons who have beneficially owned restricted common shares for at least six months, and any affiliate of our company who owns either restricted or unrestricted common shares, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act. A non-affiliated person who has beneficially owned restricted securities within the meaning of Rule 144 for at least one year would be entitled to sell those shares without regard to the provisions of Rule 144.

In general, a person who has beneficially owned restricted common shares for at least six months would be entitled to sell its securities pursuant to Rule 144 provided that (1) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (2) we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sale by non-affiliates must also comply with the current public information provision of Rule 144. Persons who have beneficially owned restricted common shares for at least six months, but who are our affiliates at the time of, or at any time during the 90 days preceding a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- § 1.0% of the number of common shares then outstanding, which will equal approximately common shares immediately after the completion of this offering based on the number of common shares outstanding as of \_\_\_\_\_, 2019; and
- § the average weekly trading volume of our common shares on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale, provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales by affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.



## **Regulation S**

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus delivery requirements of the Securities Act. Accordingly, common shares held by our affiliates may be sold in offshore transactions in compliance with Regulation S.

## **Registration Rights**

We intend to enter into a registration rights agreement upon consummation of this offering pursuant to which we will agree under certain circumstances to file a registration statement to register the resale of the shares held by our existing shareholders, as well as to cooperate in certain public offerings of such shares. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See "Related Party Transactions—Registration Rights Agreement."

## **Lock-up Agreements**

We, our supervisory board, our management board and certain of our other existing shareholders have agreed, subject to limited exceptions, not to sell or transfer any common shares or securities convertible into, exchangeable for, exercisable for or repayable with common shares for 180 days after the date of this prospectus without first obtaining the written consent of Cowen and Company, LLC and Evercore Group L.L.C. See "Underwriting—Lock-Up Agreements" for additional information.

## TAXATION

The following summary contains a description of certain Dutch, German and U.S. federal income tax consequences of the acquisition, ownership and disposition of common shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase common shares. The summary is based upon the tax laws of The Netherlands and regulations thereunder and on the tax laws of the United States and regulations thereunder as of the date hereof, which are subject to change.

### Material Dutch Tax Considerations

#### General

The following are the material Dutch tax consequences of the acquisition, ownership and disposal of our common shares, and, to the extent it relates to legal conclusions under current Dutch tax law, and subject to the qualifications it contains, it constitutes the opinion of NautaDutilh N.V., our Dutch counsel. This does not purport to set forth all possible tax considerations or consequences that may be relevant to all categories of investors, some of which may be subject to special treatment under applicable law (such as trusts or other similar arrangements), and in view of its general nature, it should be treated with corresponding caution. Holders or prospective holders of shares should consult with their tax advisors with regard to the tax consequences of investing in the common shares in their particular circumstances.

Please note that this section does not set forth the tax considerations for:

- § holders of common shares if such holders, and in the case of individuals, his/her partner or certain relatives by blood or marriage in the direct line (including foster children), have a substantial interest (*aanmerkelijk belang*) or deemed substantial interest (*fictief aanmerkelijk belang*) in us under the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*). A holder of securities in a company is considered to hold a substantial interest in such company if such holder alone or, in the case of individuals, together with his/her partner (as defined in the Dutch Income Tax Act 2001), directly or indirectly holds (i) an interest of 5% or more of the total issued and outstanding capital of that company or of 5% or more of the issued and outstanding capital of a certain class of shares of that company; or (ii) rights to acquire, directly or indirectly, such interest; or (iii) certain profit sharing rights in that company that relate to 5% or more of the company's annual profits and/or to 5% or more of the company's liquidation proceeds. A deemed substantial interest may arise if a substantial interest (or part thereof) in a company has been disposed of, or is deemed to have been disposed of, on a non-recognition basis;
- § a holder of common shares that is not an individual for which its shareholdings qualify or qualified as a participation (*deelname*) for purposes of the Dutch Corporate Income Tax Act 1969 (*Wet op de vennootschapsbelasting 1969*). A taxpayer's shareholding of 5% or more in a company's nominal paid-up share capital (or, in certain cases, in voting rights) qualifies as a participation. A holder may also have a participation if such holder does not have a shareholding of 5% or more but a related entity (statutorily defined term) has a participation or if the company in which the shares are held is a related entity (statutorily defined term);
- § holders of common shares who are individuals for whom the common shares or any benefit derived from the common shares are a remuneration or deemed to be a remuneration for (employment) activities performed by such holders or certain individuals related to such holders (as defined in the Dutch Income Tax Act 2001); and
- § pension funds, investment institutions (*fiscale beleggingsinstellingen*), exempt investment institutions (*vrijgestelde beleggingsinstellingen*) and other entities that are, in whole or in

part, not subject to or exempt from corporate income tax in the Netherlands, as well as entities that are exempt from corporate income tax in their country of residence, such country of residence being another state of the European Union, Norway, Liechtenstein, Iceland or any other state with which the Netherlands have agreed to exchange information in line with international standards.

Except as otherwise indicated, this section only addresses Dutch national tax legislation and published regulations, whereby the Netherlands and Dutch law means the part of the Kingdom of the Netherlands located in Europe and its law, respectively, as in effect on the date hereof and as interpreted in published case law until this date, without prejudice to any amendment introduced (or to become effective) at a later date and/or implemented with or without retroactive effect. The applicable tax laws or interpretations thereof may change, or the relevant facts and circumstances may change, and such changes may affect the contents of this section, which will not be updated to reflect any such changes.

### ***Dividend Withholding Tax***

We are required to withhold Dutch dividend withholding tax at a rate of 15% from dividends distributed by us (which withholding tax will not be borne by us, but will be withheld by us from the gross dividends paid on the common shares). However, as long as we continue to have our place of management in Germany, and not in the Netherlands, under the Convention between the Federal Republic of Germany and the Netherlands for the avoidance of double taxation with respect to taxes on income of 2012, we will be considered to be exclusively tax resident in Germany and we will not be required to withhold Dutch dividend withholding tax. This exemption from withholding does not apply to dividends distributed by us to a holder who is resident or deemed to be resident in the Netherlands for Dutch income tax purposes or Dutch corporation tax purposes or to holders of common shares that are neither resident nor deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder, in which events the following applies. See "Risk factors—If we pay dividends, we may need to withhold tax on such dividends in both Germany and the Netherlands."

Dividends distributed by us to individuals and corporate legal entities who are resident or deemed to be resident in the Netherlands for Dutch tax purposes ("Dutch Resident Individuals" and "Dutch Resident Entities," as the case may be) or to holders of common shares that are neither resident nor deemed to be resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such non-resident holder are subject to Dutch dividend withholding tax at a rate of 15%. The expression "dividends distributed" includes, among other things:

- § distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital not recognized for Dutch dividend withholding tax purposes;
- § liquidation proceeds, proceeds of redemption of shares, or proceeds of the repurchase of shares by us or one of our subsidiaries or other affiliated entities to the extent such proceeds exceed the average paid-in capital of those shares as recognized for purposes of Dutch dividend withholding tax, unless, in case of a repurchase, a particular statutory exemption applies;
- § an amount equal to the par value of shares issued or an increase of the par value of shares, to the extent that it does not appear that a contribution, recognized for purposes of Dutch dividend withholding tax, has been made or will be made; and
- § partial repayment of the paid-in capital, recognized for purposes of Dutch dividend withholding tax, if and to the extent that we have net profits (*zuivere winst*), unless the holders of shares have resolved in advance at a general meeting to make such repayment

and the par value of the shares concerned has been reduced by an equal amount by way of an amendment of our articles of association.

Dutch Resident Individuals and Dutch Resident Entities can generally credit the Dutch dividend withholding tax against their income tax or corporate income tax liability. The same applies to holders of shares that are neither resident nor deemed to be resident of the Netherlands if the shares are attributable to a Dutch permanent establishment of such non-resident holder.

Pursuant to legislation to counteract "dividend stripping," a reduction, exemption, credit or refund of Dutch dividend withholding tax is denied if the recipient of the dividend is not the beneficial owner (*uiteindelijk gerechtigde*) as described in the Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting 1965*). This legislation targets situations in which a shareholder retains its economic interest in shares but reduces the withholding tax costs on dividends by a transaction with another party. It is not required for these rules to apply that the recipient of the dividends is aware that a dividend stripping transaction took place. The Dutch State Secretary of Finance takes the position that the definition of beneficial ownership introduced by this legislation will also apply in the context of a double taxation convention.

### **Taxes on Income and Capital Gains**

#### *Dutch Resident Individuals*

If a holder of common shares is a Dutch Resident Individual, any benefit derived or deemed to be derived from the shares is taxable at the progressive income tax rates (with a maximum of 51.75%, rate for 2019), if:

(i) the shares are attributable to an enterprise from which the Dutch Resident Individual derives a share of the profit, whether as an entrepreneur (*ondernemer*) or as a person who has a co-entitlement to the net worth (*medegerechtigd tot het vermogen*) of such enterprise, without being an entrepreneur or a shareholder in such enterprise, as defined in the Dutch Income Tax Act 2001; or

(ii) the holder of the shares is considered to derive benefits from the shares that are taxable as benefits from other activities (*resultaat uit overige werkzaamheden*), such as activities with respect to the shares that go beyond ordinary asset management (*normaal, actief vermogensbeheer*).

If the above-mentioned conditions (i) and (ii) do not apply to the individual holder of common shares, such holder will be taxed annually on a deemed, variable return (with a maximum of 5.60% in 2019) of his or her net investment assets for the year at an income tax rate of 30%.

The net investment assets for the year are the fair market value of the investment assets less the allowable liabilities on January 1 of the relevant calendar year. The common shares are included as investment assets. A tax-free allowance may be available. Actual income, gains or losses in respect of the common shares are as such not subject to Dutch income tax. For the net investment assets on January 1, 2019, a deemed return between 1.94% and 5.60% (depending on the amount of such holder's net investments assets on January 1, 2018) will be applied. The deemed, variable return will be adjusted annually on the basis of historic market yields.

#### *Dutch Resident Entities*

Any benefit derived or deemed to be derived from the shares held by Dutch Resident Entities, including any capital gains realized on the disposal thereof, will be subject to Dutch corporate

income tax at a rate of 19% with respect to taxable profits up to €200,000 and 25% with respect to taxable profits in excess of that amount (rates and brackets for 2019).

#### *Non-residents of the Netherlands*

A holder of shares that is neither a Dutch Resident Individual nor a Dutch Resident Entity will not be subject to Dutch taxes on income or on capital gains in respect of any payment under shares or any gain realized on the disposal or deemed disposal of the shares, provided that:

- § such holder does not have an interest in an enterprise which, in whole or in part, is either effectively managed in the Netherlands or is carried out through a permanent establishment, or a permanent representative in the Netherlands and to which enterprise or part of an enterprise the shares are attributable; and
- § in the event such holder is an individual, such holder does not derive benefits from the shares that are taxable as benefits from other activities in the Netherlands, such as activities in the Netherlands with respect to the shares that go beyond ordinary asset management.

#### **Gift and Inheritance Taxes**

##### *Residents of the Netherlands*

Gift or inheritance taxes will arise in the Netherlands with respect to a transfer of the shares by way of a gift by, or on the death of, a holder of shares who is resident or deemed to be resident in the Netherlands at the time of the gift or the holder's death.

##### *Non-residents of the Netherlands*

No Dutch gift or inheritance taxes will arise on the transfer of the shares by way of gift by, or on the death of, a holder of shares who is neither resident nor deemed to be resident in the Netherlands, unless:

- § in the case of a gift of shares by an individual who at the date of the gift was neither resident nor deemed to be resident in the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident in the Netherlands; or
- § the transfer is otherwise construed as a gift, such as a gift that is made under a condition precedent, or inheritance made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident in the Netherlands.

For purposes of Dutch gift and inheritance taxes, a person that holds the Dutch nationality will be deemed to be resident in the Netherlands if such person has been resident in the Netherlands at any time during the 10 years preceding the date of the gift or his/her death. Additionally, for purposes of Dutch gift tax, a person not holding the Dutch nationality will be deemed to be resident in the Netherlands if such person has been resident in the Netherlands at any time during the 12 months preceding the date of the gift.

#### **Other Taxes and Duties**

No Dutch value-added tax (*omzetbelasting*) and no Dutch registration tax, stamp duty or any other similar documentary tax or duty will be payable by a holder of shares on any payment in consideration for the acquisition, ownership or disposal of the shares.

#### **Material German Tax Considerations**

The following section is the opinion of Taylor Wessing Partnerschaftsgesellschaft mbB ("German Tax Counsel") of the material German tax considerations that become relevant when purchasing, holding or transferring the Company's shares. The Company expects and intends to have its sole

place of management in Germany and, therefore, qualifies as a corporation subject to German unlimited income taxation; however, because a company's tax residency depends on future facts regarding the location in which the company is managed and controlled, German Tax Counsel cannot opine as to whether the Company qualifies as a corporation subject to German unlimited income taxation. This section does not set forth all German tax aspects that may be relevant for shareholders. The section is based on the German tax law applicable as of the date of this Prospectus. It should be noted that the law may change following the issuance of this Prospectus and that such changes may have retroactive effect.

The material German tax principles of purchasing, owning and transferring of shares are set forth in the following. This section does not purport to be a comprehensive or complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of shares and does not set forth all tax considerations that may be relevant to a particular person's decision to acquire common shares. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences set forth below. This section does not refer to any U.S. Foreign Account Tax Compliance Act aspects.

Shareholders are advised to consult their own tax advisers with regard to the application of German tax law to their particular situations, in particular with respect to the procedure to be complied with to obtain a relief of withholding tax on dividends and on capital gains (*Kapitalertragsteuer*) and with respect to the influence of double tax treaty provisions, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction. For German tax purposes, a shareholder may include an individual who or an entity that does not have the legal title to the shares, but to whom nevertheless the shares are attributed, based either on such individual or entity owning a beneficial interest in the shares or based on specific statutory provisions.

This section does not constitute a particular tax advice. Potential purchasers of the Company's shares are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of shares in light of their particular circumstances.

### **Taxation of Dividends**

#### *Withholding Tax on Dividends*

Dividends distributed from a company to its shareholders are subject to withholding tax, subject to certain exemptions (for example, repayments of capital from the tax equity account (*steuerliches Einlagekonto*)), as described in the following. The withholding tax rate is 25% plus 5.5% solidarity surcharge (*Solidarit tzuschlag*) thereon (in total 26.375%) of the gross dividend approved by the ordinary shareholders' meeting. Withholding tax is to be withheld and passed on for the account of the shareholders by a domestic branch of a domestic or foreign credit or financial services institution (*Kredit- und Finanzdienstleistungsinstitut*), by the domestic securities trading company (*inl ndisches Wertpapierhandelsunternehmen*) or a domestic securities trading bank (*inl ndische Wertpapierhandelsbank*) which keeps and administers the shares and disburses or credits the dividends or disburses the dividends to a foreign agent, or by the securities custodian bank (*Wertpapiersammelbank*) to which the shares were entrusted for collective custody if the dividends are distributed to a foreign agent by such securities custodian bank (which is referred to as the "Dividend Paying Agent"). In case the shares are not held in collective deposit with a Dividend Paying Agent, the Company is responsible for withholding and remitting the tax to the competent tax office.

Such withholding tax is levied and withheld irrespective of whether and to what extent the dividend distribution is taxable at the level of the shareholder and whether the shareholder is a person residing in Germany or in a foreign country.

In the case of dividends distributed to a company within the meaning of Art. 2 of the amended EU Directive 2011/96/EU of the Council of November 30, 2011 (the "EU Parent Subsidiary Directive") domiciled in another Member State of the European Union, an exemption from withholding tax will be granted upon request if further prerequisites are satisfied (*Freistellung im Steuerabzugsverfahren*). This also applies to dividends distributed to a permanent establishment located in another Member State of the European Union of such a parent company or of a parent company tax resident in Germany if the participation in the Company is effectively connected with this permanent establishment. The key prerequisite for the application of the EU Parent Subsidiary Directive is that the shareholder has held a direct participation in the share capital of the Company of at least 10% for at least one year.

The withholding tax on distributions to other foreign resident shareholders is reduced in accordance with a double taxation treaty if Germany has concluded such double taxation treaty with the country of residence of the shareholder and if the shareholder does not hold his shares either as part of the assets of a permanent establishment or a fixed place of business in Germany or as business assets for which a permanent representative has been appointed in Germany. The reduction of the withholding tax is procedurally granted in such a manner that the difference between the total amount withheld, including the solidarity surcharge, and the tax liability determined on the basis of the tax rate set forth in the applicable double taxation treaty (15% unless further qualifications are met) is refunded by the German tax administration upon request (Federal Central Office for Taxes (*Bundeszentralamt für Steuern*), main office in Bonn-Beuel, An der Kuppe 1, 53225 Bonn, Germany).

In the case of dividends received by corporations whose statutory seat and effective place of management are not located in Germany and who are therefore not tax resident in Germany, two-fifths of the withholding tax deducted and remitted are refunded without the need to fulfill all prerequisites required for such refund under the EU Parent Subsidiary Directive or under a double taxation treaty or if no double taxation treaty has been concluded between the state of residence of the shareholder.

In order to receive a refund pursuant to a double taxation treaty or the aforementioned option for foreign corporations, the shareholder has to submit a completed form for refund (available at the Federal Central Office for Taxes (<http://www.bzst.de>) as well as at the German embassies and consulates) together with a withholding tax certificate (*Kapitalertragsteuerbescheinigung*) issued by the institution that withheld the tax.

The exemption from withholding tax in accordance with the EU Parent Subsidiary Directive or a double tax treaty and the aforementioned options for a refund of the withholding tax (with or without protection under a double taxation treaty) depend on whether certain additional prerequisites (in particular so-called substance requirements) are fulfilled. The applicable withholding tax relief will only be granted if the preconditions of the German anti avoidance rules (so called Directive Override or Treaty Override), in particular Section 50d, paragraph 3, German Income Tax Act (*Einkommensteuergesetz*) are fulfilled.

The aforementioned reductions of (or exemptions from) withholding tax are further restricted if (i) the applicable double taxation treaty provides for a tax reduction resulting in an applicable tax rate of less than 15% and (ii) the shareholder is not a corporation that directly holds at least 10% in the

equity capital of the Company and is subject to tax on its income and profits in its state of residence without being exempt. In this case, the reduction of (or exemption from) withholding tax is subject to the following three cumulative prerequisites: (i) the shareholder must qualify as beneficial owner of the shares in the Company for a minimum holding period of 45 consecutive days occurring within a period of 45 days prior and 45 days after the due date of the dividends, (ii) the shareholder has to bear at least 70% of the change in value risk related to the shares in the Company during the minimum holding period without being directly or indirectly hedged and (iii) the shareholder must not be required to fully or largely compensate directly or indirectly the dividends to third parties. However, these further prerequisites do not apply if the shareholder has been the beneficial owner of the shares in the Company for at least one uninterrupted year upon receipt of the dividends.

For individual or corporate shareholders tax resident outside Germany not holding the shares through a permanent establishment (*Betriebsstätte*) in Germany or as business assets (*Betriebsvermögen*) for which a permanent representative (*ständiger Vertreter*) has been appointed in Germany, the remaining and paid withholding tax (if any) is final (i.e., not refundable) and settles the shareholder's limited tax liability in Germany. For individual or corporate shareholders tax resident in Germany (that are, for example, shareholders whose residence, domicile, registered office or place of management is located in Germany) holding their shares as business assets, as well as for shareholders tax resident outside of Germany holding their shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany, the withholding tax withheld (including solidarity surcharge) can be credited against the shareholder's personal income tax or corporate income tax liability in Germany. Any withholding tax (including solidarity surcharge) in excess of such tax liability is refunded. For individual shareholders tax resident in Germany holding the Company's shares as private assets, the withholding tax is a final tax (*Abgeltungsteuer*), subject to the exceptions described in the following section.

Pursuant to special rules on the restriction of withholding tax credit, the credit of withholding tax is subject to the following three cumulative prerequisites: (i) the shareholder must qualify as beneficial owner of the shares in the Company for a minimum holding period of 45 consecutive days occurring within a period of 45 days prior and 45 days after the due date of the dividends, (ii) the shareholder has to bear at least 70% of the change in value risk related to the shares in the Company during the minimum holding period without being directly or indirectly hedged and (iii) the shareholder must not be required to fully or largely compensate directly or indirectly the dividends to third parties. Absent the fulfillment of all of the three prerequisites, three-fifths of the withholding tax imposed on the dividends must not be credited against the shareholder's (corporate) income tax liability, but may, upon application, be deducted from the shareholder's tax base for the relevant assessment period. A shareholder that has received gross dividends without any deduction of withholding tax due to a tax exemption without qualifying for a full tax credit has to notify the competent local tax office accordingly and has to make a payment in the amount of the omitted withholding tax deduction. The special rules on the restriction of withholding tax credit do not apply to a shareholder whose overall dividend earnings within an assessment period do not exceed €20,000 or that has been the beneficial owner of the shares in the Company for at least one uninterrupted year upon receipt of the dividends.

#### *Taxation of dividend income of shareholders tax resident in Germany holding the Company's shares as private assets*

For individual shareholders (individuals) resident in Germany holding the Company's shares as private assets, dividends are subject to a flat tax rate which is satisfied by the withholding tax actually withheld (*Abgeltungsteuer*). Accordingly, dividend income will be taxed at a flat tax rate of 25% plus 5.5% solidarity surcharge thereon (in total 26.375%) and church tax (*Kirchensteuer*) in



case the shareholder is subject to church tax because of his individual circumstances. An automatic procedure for deduction of church tax by way of withholding will apply to shareholders being subject to church tax unless the shareholder has filed a blocking notice (*Sperrvermerk*) with the German Federal Tax Office (details related to the computation of the concrete tax rate including church tax are to be discussed with the individual tax adviser of the relevant shareholder). Except for an annual lump sum savings allowance (*Sparer-Pauschbetrag*) of up to €801 (for individual filers) or up to €1,602 (for married couples and for partners in accordance with the registered partnership law (*Gesetz über die Eingetragene Lebenspartnerschaft*) filing jointly), private individual shareholders will not be entitled to deduct expenses incurred in connection with the capital investment from their dividend income.

The income tax owed for the dividend income is satisfied by the withholding tax withheld by the Dividend Paying Agent. However, if the flat tax results in a higher tax burden as opposed to the private shareholder's individual tax rate, the private shareholder can opt for taxation at his individual personal income tax rate. In that case, the final withholding tax will be credited against the income tax. However, pursuant to the German tax authorities and a court ruling, private shareholders are nevertheless not entitled to deduct expenses incurred in connection with the capital investment from their income. The option can be exercised only for all capital income from capital investments received in the relevant assessment period uniformly, and married couples as well as partners in accordance with the registered partnership law filing jointly may only jointly exercise the option.

Exceptions from the flat tax rate (satisfied by withholding at source) (*Abgeltungsteuer*) may apply—that is, only upon application—for shareholders who have a shareholding of at least 25% in a company and for shareholders who have a shareholding of at least 1% in the Company and work for a company in a professional capacity. In such a case, the same rules apply as for sole proprietors holding the shares as business assets. See "—Taxation of dividend income of shareholders tax resident in Germany holding the Company's shares as business assets—Sole proprietors".

#### *Taxation of dividend income of shareholders tax resident in Germany holding the Company's shares as business assets*

If a shareholder holds the Company's shares as business assets, the taxation of the dividend income depends on whether the respective shareholder is a corporation, a sole proprietor or a partnership.

#### *Corporations*

Dividend income of corporate shareholders is exempt from corporate income tax, provided that the incorporated entity holds a direct participation of at least 10% in the share capital of a company at the beginning of the calendar year in which the dividends are paid. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the purpose of this rule. Participations in the share capital of the Company which a corporate shareholder holds through a partnership, including co-entrepreneurships (*Mitunternehmerschaften*), are attributable to such corporate shareholder only on a pro rata basis at the ratio of the interest share of the corporate shareholder in the assets of the relevant partnership. However, 5% of the tax exempt dividends are deemed to be non-deductible business expenses for tax purposes and therefore are subject to corporate income tax (plus solidarity surcharge) and trade tax, i.e., tax exemption of 95%. Business expenses incurred in connection with the dividends received are entirely tax-deductible.

For trade tax purposes the entire dividend income is subject to trade tax (i.e., the tax-exempt dividends must be added back when determining the trade taxable income), unless the corporation shareholder holds at least 15% of the Company's registered share capital at the beginning of the

relevant tax assessment period (*Erhebungszeitraum*). In case of an indirect participation via a partnership please refer to the section "Partnerships" below.

If the shareholding is below 10% in the share capital, dividends are taxable at the applicable corporate income tax rate of 15% plus 5.5% solidarity surcharge thereon and trade tax (the rate of which depends on the municipalities the corporate shareholder resides in).

Special regulations apply which abolish the 95% tax exemption if the Company's shares are held as trading portfolio assets in the meaning of Section 340e of the German commercial code (*Handelsgesetzbuch*) by (i) a credit institution (*Kreditinstitut*), (ii) a financial service institution (*Finanzdienstleistungsinstitut*) or (iii) a financial enterprise within the meaning of the German Banking Act (*Kreditwesengesetz*), in case more than 50% of the shares of such financial enterprise are held directly or indirectly by a credit institution or a financial service institution, as well as by a life insurance company, a health insurance company or a pension fund in case the shares are attributable to the capital investments, resulting in fully taxable income.

#### *Sole proprietors*

For sole proprietors (individuals) resident in Germany holding shares as business assets dividends are subject to the partial income rule (*Teileinkünfteverfahren*). Accordingly, only (i) 60% of the dividend income will be taxed at his/her individual personal income tax rate plus 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the dividend income are deductible for tax purposes. In addition, the dividend income is entirely subject to trade tax if the shares are held as business assets of a permanent establishment in Germany within the meaning of the German Trade Tax Act (*Gewerbesteuerengesetz*), unless the shareholder holds at least 15% of the Company's registered share capital at the beginning of the relevant assessment period. The trade tax levied will be eligible for credit against the shareholder's personal income tax liability based on the applicable municipal trade tax rate and the individual tax situation of the shareholder.

#### *Partnerships*

In case shares are held by a partnership, the partnership itself is not subject to corporate income tax or personal income tax. In this regard, corporate income tax or personal income tax (and church tax, if applicable) as well as solidarity surcharge, are levied only at the level of the partner with respect to their relevant part of the profit and depending on their individual circumstances.

If the partner is a corporation, the dividend income will be subject to corporate income tax plus solidarity surcharge. See "—Corporations."

If the partner is a sole proprietor (individual), the dividend income will be subject to the partial income rule. See "—Sole Proprietors."

The dividend income is subject to trade tax at the level of the partnership (provided that the partnership is liable to trade tax), unless the partnership holds at least 15% of a company's registered share capital at the beginning of the relevant assessment period, in which case the dividend income is exempt from trade tax. There are no explicit statutory provisions concerning the taxation of dividends with regard to a corporate shareholder of the partnership. However, trade tax will be levied on 5% of the dividends to the extent they are attributable to the shares of such corporate partners to whom at least 10% of the shares of the Company are attributable on a look-through basis, since such portion of the dividends will be deemed to be non-deductible business expenses.

If a partner is an individual, depending on the applicable municipal trade tax rate and the individual tax situation, the trade tax paid at the level of the partnership is partly or entirely be credited against the partner's personal income tax liability.

In case of a corporation being a partner, special regulations will apply with respect to trading portfolio assets of credit institutions, financial service institutions or financial enterprises within the meaning of the German Banking Act (*Kreditwesengesetz*) or life insurance companies, health insurance companies or pension funds. See "—Corporations."

Thus, the actual trade tax charge, if any, at the level of the partnership depends on the shareholding quota of the partnership and the nature of the partners (e.g., individual or corporation).

#### *Taxation of dividend income of shareholders tax resident outside of Germany*

For foreign individual or corporate shareholders tax resident outside of Germany not holding the shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany, the deducted withholding tax (possibly reduced by way of a tax relief under a double tax treaty or domestic tax law, such as in connection with the EU Parent Subsidiary Directive) is final (that is, not refundable) and settles the shareholder's limited tax liability in Germany, unless the shareholder is entitled to apply for a withholding tax refund or exemption.

In contrast, individual or corporate shareholders tax resident outside of Germany holding the Company's shares through a permanent establishment in Germany or as business assets for which a permanent representative has been appointed in Germany are subject to the same rules as applicable (and described above) to shareholders resident in Germany holding the shares as business assets. The withholding tax withheld (including solidarity surcharge) is credited against the shareholder's personal income tax or corporate income tax liability in Germany.

#### **Taxation of Capital Gains**

##### *Withholding tax on capital gains*

Capital gains realized on the disposal of shares are only subject to withholding tax if a German branch of a German or foreign credit or financial institution, a German securities trading Company or a German securities trading bank stores or administrates or carries out the sale of the shares and pays or credits the capital gains. In those cases the institution (and not the company) is required to deduct the withholding tax at the time of payment for the account of the shareholder and has to pay the withholding tax to the competent tax authority. In case the shares in Centogene N.V. are held (i) as business assets by a sole proprietor, a partnership or a corporation and such shares are attributable to a German business or (ii) in case of a corporation being subject to unlimited corporate income tax liability in Germany, the capital gains are not subject to withholding tax. In case of clause (i), the withholding tax exemption is subject to the condition that the paying agent has been notified by the beneficiary (*Gläubiger*) that the capital gains are exempt from withholding tax. The respective notification has to be filed by using the officially prescribed form.

##### *Taxation of capital gains realized by shareholders tax resident in Germany holding shares as private assets*

For individual shareholders (individuals) resident in Germany holding shares as private assets, capital gains realized on the disposal of shares are subject to final withholding tax. Accordingly, capital gains will be taxed at a flat tax rate of 25% plus a 5.5% solidarity surcharge thereon (in total 26.375%) and church tax, in case the shareholder is subject to church tax because of his individual circumstances. An automatic procedure for deduction of church tax by way of withholding will apply

to shareholders being subject to church tax unless the shareholder has filed a blocking notice (*Sperrvermerk*) with the German Federal Tax Office (details related to the computation of the concrete tax rate including church tax are to be discussed with the individual tax adviser of the relevant shareholder). The taxable capital gain is calculated by deducting the acquisition costs of the shares and the expenses directly related to the disposal from the proceeds of the disposal. Apart from that, except for an annual lump sum savings allowance (*Sparer-Pauschbetrag*) of up to €801 (for individual filers) or up to €1,602 (for married couples and for partners in accordance with the registered partnership law (*Gesetz über die Eingetragene Lebenspartnerschaft*) filing jointly), private individual shareholders will not be entitled to deduct expenses incurred in connection with the capital investment from their capital gain.

In case the flat tax results in a higher tax burden as opposed to the private shareholder's individual tax rate, the private shareholder can opt for taxation at his individual personal income tax rate. In that case, the withholding tax (including solidarity surcharge) withheld will be credited against the income tax. However, pursuant to the German tax authorities the private shareholders are nevertheless not entitled to deduct expenses incurred in connection with the capital investment from their income. The option can be exercised only for all capital income from capital investments received in the relevant assessment period uniformly, and married couples as well as for partners in accordance with the registered partnership law filing jointly may only jointly exercise the option.

Capital losses arising from the sale of the shares can only be offset against other capital gains resulting from the disposition of the shares or shares in other stock corporations during the same calendar year. Offsetting of overall losses with other income (such as business or rental income) and other capital income is not possible. Such losses are to be carried forward and to be offset against positive capital gains deriving from the sale of shares in stock corporations in future years.

The final withholding tax will not apply if the seller of the shares or in case of gratuitous transfer, its legal predecessor has held, directly or indirectly, at least 1% of the Company's registered share capital at any time during the five years prior to the disposal. In that case capital gains are subject to the partial income rule. Accordingly, only (i) 60% of the capital gains will be taxed at his individual personal income tax rate plus a 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the capital gains are deductible for tax purposes. The withholding tax withheld (including solidarity surcharge) will be credited against the shareholder's personal income tax liability in Germany.

#### *Taxation of capital gains realized by shareholders tax resident in Germany holding the Company's shares as business assets*

If a shareholder holds shares as business assets, the taxation of capital gains realized on the disposal of such shares depends on whether the respective shareholder is a corporation, a sole proprietor or a partnership:

##### *Corporations*

Capital gains realized on the disposal of shares by a corporate shareholder are generally exempt from corporate income tax and trade tax. However, 5% of the tax-exempt capital gains are deemed to be non-deductible business expenses for tax purposes and therefore are subject to corporate income tax (plus solidarity surcharge) and trade tax, i.e., tax exemption of 95%. Business expenses incurred in connection with the capital gains are entirely tax-deductible.

Capital losses incurred upon the disposal of shares or other impairments of the share value are not tax-deductible. A reduction of profit is also defined as any losses incurred in connection with a loan or security in the event the loan or the security is granted by a shareholder or by a related party thereto or by a third person with the right of recourse against the before-mentioned persons, and the shareholder holds directly or indirectly more than 25% of the company's registered share capital.

Special regulations apply if the shares are held as trading portfolio assets by a credit institution, a financial service institution or a financial enterprise within the meaning of the German Banking Act (*Kreditwesengesetz*) as well as by a life insurance company, a health insurance company or a pension fund. See "—Corporations."

#### *Sole Proprietors*

If the shares are held by a sole proprietor, capital gains realized on the disposal of the shares are subject to the partial income rule. Accordingly, only (i) 60% of the capital gains will be taxed at his/her individual personal income tax rate plus a 5.5% solidarity surcharge thereon and church tax (if applicable) and (ii) 60% of the business expenses related to the dividend income are deductible for tax purposes. In addition, 60% of the capital gains are subject to trade tax if the shares are held as business assets of a permanent establishment in Germany within the meaning of the German Trade Tax Act (*Gewerbesteuer*gesetz). The trade tax levied, depending on the applicable municipal trade tax rate and the individual tax situation, is partly or entirely credited against the shareholder's personal income tax liability.

#### *Partnerships*

In case the shares are held by a partnership, the partnership itself is not subject to corporate income tax or personal income tax as well as a solidarity surcharge (and church tax) since partnerships qualify as transparent for German tax purposes. In this regard, corporate income tax or personal income tax as well as a solidarity surcharge (and church tax, if applicable) are levied only at the level of the partner with respect to their relevant part of the profit and depending on their individual circumstances.

If the partner is a corporation, the capital gains will be subject to corporate income tax plus a solidarity surcharge. See "—Corporations." Trade tax will be levied additionally at the level of the partner insofar as the relevant profit of the partnership is not subject to trade tax at the level of the partnership. However, with respect to both corporate income and trade tax, the 95% exemption rule as described above applies.

If the partner is a sole proprietor (individual), the capital gains are subject to the partial income rule. See "—Sole Proprietors".

In addition, if the partnership is liable to trade tax, 60% of the capital gains are subject to trade tax at the level of the partnership, to the extent the partners are individuals, and 5% of the capital gains are subject to trade tax, to the extent the partners are corporations. However, if a partner is an individual, depending on the applicable municipal trade tax rate and the individual tax situation, the trade tax paid at the level of the partnership is credited against the partner's personal income tax liability.

With regard to corporate partners, special regulations apply if they are held as trading portfolio assets by credit institutions, financial service institutions or financial enterprises within the meaning of the German Banking Act or life insurance companies, health insurance companies or pension funds, as described above.

#### *Taxation of capital gains realized by shareholders tax resident outside of Germany*

Capital gains realized on the disposal of the shares by a shareholder tax resident outside of Germany are subject to German taxation provided that (i) the Company's shares are held as business assets of a permanent establishment or as business assets for which a permanent representative has been appointed in Germany, or (ii) the shareholder or, in case of a gratuitous

transfer, its legal predecessor has held, directly or indirectly, at least 1% of the company's shares capital at any time during a five-year period prior to the disposal. In these cases, capital gains are generally subject to the same rules as described above for shareholders resident in Germany. However, in case the shares are not attributable to a German permanent establishment or permanent representative the 5% taxation (see "—Corporations—Taxation of capital gains realized by shareholders tax resident in Germany holding the Company's shares as business assets") shall not apply and the capital gains are fully exempt from German tax.

However, except for the cases referred to in clause (i) above, some of the double tax treaties concluded with Germany provide for a full exemption from German taxation.

### ***Inheritance and Gift Tax***

The transfer of the Company's shares to another person by way of succession or donation is subject to German inheritance and gift tax (*Erbschaft- und Schenkungsteuer*) if:

- (i) the decedent, the donor, the heir, the donee or any other beneficiary has his/her/its residence, domicile, registered office or place of management in Germany at the time of the transfer, or is a German citizen who has not stayed abroad for more than five consecutive years without having a residence in Germany; or
- (ii) (irrespective of the personal circumstances) the shares are held by the decedent or donor as business assets for which a permanent establishment in Germany is maintained or a permanent representative is appointed in Germany; or
- (iii) (irrespective of the personal circumstances) at least 10% of the shares are held, directly or indirectly by, the decedent or person making the gift, himself or together with a related party in terms of Section 6 Foreign Tax Act.

Special regulations apply to qualified German citizens who maintain neither a residence nor their domicile in Germany but in a low tax jurisdiction, and to former German citizens, also resulting in inheritance and gift tax. The few double tax treaties on inheritance and gift tax which Germany has entered into provide that German inheritance and gift tax is levied only in case of (i) and, with certain restrictions, in case of (ii).

### ***Other Taxes***

No German capital transfer tax (*Kapitalverkehrsteuer*), value-added tax (*Umsatzsteuer*), stamp duty (*Stempelgebühr*) or similar taxes are levied when acquiring, holding or transferring the Company's shares. No value-added tax will be levied unless the shareholder validly opts for it. Net wealth tax (*Vermögensteuer*) is currently not levied in Germany.

On January 22, 2013, the Council of the European Union approved the resolution of the ministers of finance from eleven EU member states (including Germany) to introduce Financial Transaction Tax ("FTT") within the framework of enhanced cooperation. On February 14, 2013, the European Commission accepted the proposal for a Council Directive implementing enhanced cooperation in the area of financial transaction tax. The plan focuses on levying a financial tax of 0.1% (0.01% for derivatives) on the purchase and sale of financial instruments.

A joint statement issued by 10 of the 11 participating EU member states in October 2016 reaffirmed the intention to introduce FTT. However, at the moment not many details are available. Thus, it is not known to what extent the elements of the European Commission's proposal outlined in the preceding paragraph will be followed in relation to the taxation of shares. The FTT proposal

remains subject to negotiation between the participating Member States and is subject to political discussion. It may, therefore, be altered prior to the implementation, the timing of which remains unclear. Additional EU member states may decide to participate. Only recently the governments of France and Germany have decided to push the FTT initiative and to prepare a proposal based on the French taxation model.

Prospective holders of the shares are advised to seek their own professional advice in relation to FTT.

### **Material U.S. Federal Income Tax Considerations for U.S. Holders**

The following section is the opinion of Davis Polk & Wardwell LLP of the material U.S. federal income tax consequences to the U.S. Holders, as defined below, of owning and disposing of common shares. It does not set forth all tax considerations that may be relevant to a particular person's decision to acquire common shares.

This section applies only to a U.S. Holder that holds common shares as capital assets for U.S. federal income tax purposes. In addition, it does not set forth all of the U.S. federal income tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential application of the provisions of the Code known as the Medicare contribution tax and tax consequences applicable to U.S. Holders subject to special rules, such as:

- § certain financial institutions;
- § dealers or traders in securities who use a mark-to-market method of tax accounting;
- § persons holding common shares as part of a hedging transaction, straddle, wash sale, conversion transaction or other integrated transaction or persons entering into a constructive sale with respect to the common shares;
- § persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- § entities classified as partnerships for U.S. federal income tax purposes;
- § tax-exempt entities, including an "individual retirement account" or "Roth IRA";
- § persons that own or are deemed to own 10% or more of our shares (by vote or value); or
- § persons holding common shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will depend on the status of the partner and the activities of the partnership. Partnerships holding common shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of the common shares.

This section is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between Germany and the United States (the "Treaty") all as of the date hereof, any of which is subject to change or differing interpretations, possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of common shares, who is eligible for the benefits of the Treaty and who is:

- § a citizen or individual resident of the United States;
- § a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or

§ an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of common shares in their particular circumstances.

### ***Taxation of Distributions***

As discussed above under "Dividend policy," we do not currently expect to make distributions on our common shares. In the event that we do make distributions of cash or other property, subject to the passive foreign investment company rules described below, distributions paid on common shares, other than certain pro rata distributions of common shares, will be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). For so long as our common shares are listed on Nasdaq or another established securities market in the United States or we are eligible for benefits under the Treaty, dividends paid to certain non-corporate U.S. Holders will be eligible for taxation as "qualified dividend income," which is taxable at rates not in excess of the long-term capital gain rate applicable to such U.S. Holders. U.S. Holders should consult their tax advisers regarding the availability of the reduced tax rate on dividends in their particular circumstances. The amount of a dividend will include any amounts withheld by us in respect of German income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in euros will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

German income taxes withheld from dividends on common shares at a rate not exceeding the rate provided by the Treaty will be eligible for credit against the U.S. Holder's U.S. federal income tax liability. German taxes withheld in excess of the rate applicable under the Treaty will not be eligible for credit against a U.S. Holder's federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may deduct foreign taxes, including any German income tax, in computing their taxable income. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year. If Dutch income taxes are withheld from dividends payable to U.S. Holders, U.S. Holders are urged to consult their tax advisers regarding the creditability of such Dutch income taxes against their U.S. federal income tax liabilities. See "Risk factors—If we pay dividends, we may need to withhold tax on such dividends payable to holders of our shares in both Germany and the Netherlands."

### ***Sale or Other Disposition of Common Shares***

Subject to the passive foreign investment company rules described below, gain or loss realized on the sale or other disposition of common shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars.



### **Passive Foreign Investment Company ("PFIC") Rules**

Under the Code, we will be a PFIC for any taxable year in which, after the application of certain "look-through" rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income," or (ii) 50% or more of the average quarterly value of our assets consist of assets that produce, or are held for the production of, "passive income." For purposes of the above calculations, we will be treated as if we hold our proportionate share of the assets of, and receive directly our proportionate share of the income of, any other corporation in which we directly or indirectly own at least 25%, by value, of the shares of such corporation.

Passive income includes, among other things, interest, dividends, rents, certain non-active royalties and capital gains. Based on our current operations, income, assets and certain estimates and projections, including as to the relative values of our assets and the treatment of our grants received as gross income that is not passive income, we do not believe that we were a PFIC for our 2018 taxable year. However, there can be no assurance that the IRS will agree with our conclusion. In addition, whether we will be a PFIC in 2019 or any future taxable year is uncertain because, among other things, (i) we currently own, and will own after the closing of this offering, a substantial amount of passive assets, including cash, (ii) the valuation of our assets that generate non-passive income for PFIC purposes, including our intangible assets, is uncertain and may vary substantially over time, (iii) the treatment of grants as income for U.S. federal income tax purposes is unclear, and (iv) the composition of our income may vary substantially over time. Accordingly, there can be no assurance that we will not be a PFIC for any taxable year. If we are a PFIC for any year during which a U.S. Holder holds common shares, we would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds common shares, even if we ceased to meet the threshold requirements for PFIC status, unless the U.S. Holder makes a valid deemed sale or deemed dividend election under the applicable Treasury regulations with respect to its common shares.

If we were a PFIC for any taxable year during which a U.S. Holder held common shares (assuming such U.S. Holder has not made a timely mark-to-market election, as described below), gain recognized by a U.S. Holder on a sale or other disposition (including certain pledges) of the common shares would be allocated ratably over the U.S. Holder's holding period for the common shares. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed on the amount allocated to that taxable year. Further, to the extent that any distribution received by a U.S. Holder on its common shares exceeds 125% of the average of the annual distributions on the common shares received during the preceding three years or the U.S. Holder's holding period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain, described immediately above.

A U.S. Holder can avoid certain of the adverse rules described above by making a mark-to-market election with respect to its common shares, provided that the common shares are "marketable." Common shares will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable Treasury regulations. If a U.S. Holder makes the mark-to-market election, it will recognize as ordinary income any excess of the fair market value of the common shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the common shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the common shares will be adjusted to reflect the income or

loss amounts recognized. Any gain recognized on the sale or other disposition of common shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election).

In addition, in order to avoid the application of the foregoing rules, a United States person that owns stock in a PFIC for U.S. federal income tax purposes may make a QEF Election with respect to such PFIC if the PFIC provides the information necessary for such election to be made. If a United States person makes a QEF Election with respect to a PFIC, the United States person will be currently taxable on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC and will not be required to include such amounts in income when actually distributed by the PFIC. We do not intend to provide information necessary for U.S. Holders to make QEF Elections.

In addition, if we were a PFIC or, with respect to a particular U.S. Holder, were treated as a PFIC for the taxable year in which we paid a dividend or for the prior taxable year, the preferential dividend rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If a U.S. Holder owns common shares during any year in which we are a PFIC, the U.S. Holder must file annual reports, containing such information as the U.S. Treasury may require on IRS Form 8621 (or any successor form) with respect to us, with the U.S. Holder's federal income tax return for that year, unless otherwise specified in the instructions with respect to such form.

U.S. Holders should consult their tax advisers concerning our potential PFIC status and the potential application of the PFIC rules.

#### ***Information Reporting and Backup Withholding***

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

#### ***Reporting With Respect to Foreign Financial Assets***

Certain U.S. Holders who are individuals and certain entities may be required to report information relating to an interest in our common shares by filing a Form 8398 with their U.S. federal income tax return, subject to certain exceptions (including an exception for common shares held in accounts maintained by certain U.S. financial institutions). Failure to file a Form 8398 where required can result in monetary penalties and the extension of the relevant statute of limitations with respect to all or a part of the relevant U.S. tax return. U.S. Holders should consult their tax advisers regarding this reporting requirement.

## UNDERWRITING

We and the underwriters for this offering named below have entered into an underwriting agreement with respect to the common shares being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of common shares set forth opposite its name below. Cowen and Company, LLC and Evercore Group L.L.C. are the representatives of the underwriters.

<u>Underwriter</u>	<u>Number of Common Shares</u>
Cowen and Company, LLC	
Evercore Group L.L.C.	
Robert W. Baird & Co. Incorporated	
BTIG, LLC	
<b>Total</b>	

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters have agreed, severally and not jointly, to purchase all of the common shares sold under the underwriting agreement if any of these common shares are purchased, other than those common shares covered by the option to purchase additional shares described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the common shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

The address of Cowen and Company, LLC is 599 Lexington Avenue, New York, New York 10022, and the address of Evercore Group L.L.C. is 55 East 52nd Street, New York, New York 10055.

### Option to Purchase Additional Common Shares

We have granted to the underwriters an option to purchase up to \_\_\_\_\_ additional common shares at the public offering price, less the underwriting discount, in this offering of common shares. This option is exercisable for a period of 30 from the date of this prospectus. To the extent that the underwriters exercise this option, the underwriters will purchase additional common shares from us in approximately the same proportion as shown in the table above.

### Discounts and Commissions

The following table shows the public offering price, underwriting discount and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

We estimate that the total expenses of this offering of common shares, excluding underwriting discounts and commissions, will be approximately \$ \_\_\_\_\_ and are payable by us. We have also agreed to reimburse the underwriters for certain of their expenses as set forth in the underwriting agreement, including legal fees incurred in the qualification of this offering with the Financial Industry Regulatory Authority, or FINRA, which amount is deemed to be underwriting compensation by FINRA. The underwriters have also agreed to reimburse us for certain of our expenses incurred in connection with this offering.

	<b>Per Common Share</b>	<b>Total Without Underwriters' Option</b>	<b>With Underwriters' Option</b>
Initial public offering price			
Underwriting discounts and commissions			
Proceeds, before expenses, to Centogene			

The underwriters propose to offer the common shares to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the common shares to securities dealers at the public offering price less a concession not in excess of \$ \_\_\_\_\_ per common share. If all of the common shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms. Sales of common shares made outside of the United States may be made by affiliates of certain of the underwriters. Certain of the underwriters may sell common shares to the public through one or more of their affiliates as selling agents.

### Discretionary Accounts

The underwriters do not intend to confirm sales of the common shares to any accounts over which they have discretionary authority.

### Nasdaq Global Market Listing

We intend to apply to list our common shares on the Nasdaq Global Market, or Nasdaq under the symbol "CNTG".

Before this offering, there has been no public market for the common shares. The initial public offering price for the common shares will be determined by negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price will be:

- § the history of, and prospects for, our company and the industry in which we compete;
- § our past and present financial information;
- § an assessment of our management, its past and present operations and the prospects for, and timing of, our future revenues;
- § the present state of our development; and
- § the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the common shares may not develop on the Nasdaq Global Market, or if such a market develops, may not be sustained. It is also possible that after this offering the common shares will not trade in the public market at or above the initial public offering price.

## Price Stabilization, Short Positions and Penalty Bids

In connection with this offering of common shares, the underwriters may engage in stabilizing transactions, overallotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- § Stabilizing transactions permit bids to purchase common shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the common shares while this offering is in progress.
- § Overallotment transactions involve sales by the underwriters of common shares in excess of the number of common shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of common shares over-allotted by the underwriters is not greater than the number of common shares that they may purchase in the overallotment option. In a naked short position, the number of common shares involved is greater than the number of common shares in the overallotment option. The underwriters may close out any short position by exercising their overallotment option and/or purchasing common shares in the open market.
- § Syndicate covering transactions involve purchases of common shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of common shares to close out the short position, the underwriters will consider, among other things, the price of common shares available for purchase in the open market as compared with the price at which they may purchase common shares through exercise of the option to purchase additional common shares. If the underwriters sell more common shares than could be covered by exercise of the option to purchase additional common shares and, therefore, have a naked short position, the position can be closed out only by buying common shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the common shares in the open market that could adversely affect investors who purchase in this offering.
- § Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common shares originally sold by that syndicate member is purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of the common shares or preventing or retarding a decline in the market price of the common shares. As a result, the price of the common shares in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the common shares. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise. They will not necessarily occur and, if commenced, may be discontinued at any time.

Stabilization transactions can only be effected during a period of 30 days after the date of allotment. They may not be effected above the public offering price. Cowen and Company, LLC will act as stabilization agent.

## Lock-Up Agreements

Pursuant to certain "lock-up" agreements, we, our management board members, our supervisory board members and certain of our other existing shareholders, have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of,

or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, or engage in any short selling of, any common shares or securities convertible into or exchangeable or exercisable for any common shares without the prior written consent of Cowen and Company, LLC and Evercore Group L.L.C. for a period of 180 days after the date of the underwriting agreement.

This lock-up provision applies to common shares in this offering, or common shares owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The lock-up agreements include customary exceptions for certain transfers.

Cowen and Company, LLC and Evercore Group L.L.C., in their sole discretion, may release our common shares subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release our common shares from lock-up agreements, Cowen and Company, LLC and Evercore Group L.L.C. will consider, among other factors, the holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time of the request. In the event of such a release or waiver, Cowen and Company, LLC and Evercore Group L.L.C. shall provide us with notice of the impending release or waiver at least three business days before the effective date of such release or waiver and we will announce the impending release or waiver by issuing a press release at least two business days before the effective date of the release or waiver.

### **Electronic Offer, Sale and Distribution of Common Shares**

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representatives may agree to allocate a number of common shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

### **Other Relationships**

Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees.

### **Selling Restrictions**

No action has been taken in any jurisdiction except the United States that would permit a public offering of the common shares, or the possession, circulation or distribution of this prospectus or any other material relating to us or the common shares in any jurisdiction where action for that purpose is required. Accordingly, the common shares may not be offered or sold, directly or indirectly, and neither this prospectus nor any other offering material or advertisements in connection with the common shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction.

## **Canada**

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## **United Kingdom**

Each of the underwriters has, separately and not jointly, represented and agreed that:

- § it has not made or will not make an offer of the securities to the public in the United Kingdom within the meaning of section 102B of the Financial Services and Markets Act 2000 (as amended), or the FSMA, except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority, or FSA;
- § it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which section 21 of FSMA does not apply to us; and
- § it has complied with and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

## **Germany**

No offer of shares, which are the subject of the offering contemplated by this prospectus, has been made or will be made in Germany, unless in reliance on section 3(2) of the German Securities Prospectus Act (*Wertpapierprospektgesetz*) if such offer is made exclusively to persons or entities which are qualified investors (*qualifizierte Anleger*) as defined in section 2 No. 6 of the German Securities Prospectus Act or, to fewer than 150 natural or legal persons (other than qualified investors). This document does not constitute a securities prospectus within the meaning of Article 5 para. 3 of Directive 2003/71/EC of the European Parliament and the Council of 4 November 2003 (as amended, *inter alia*, by Directive 2010/73/EU); it has not been and will not be submitted for approval to the German Financial Services Supervisory Authority.

### **Netherlands**

In addition to the restrictions described in the paragraph 'European Economic Area,' no offer of common shares which are the subject of the offering contemplated by this prospectus, has been made or will be made in the Netherlands, unless (i) such offer is made exclusively to persons or entities which are qualified investors (*gekwalificeerde beleggers*) as defined in Article 1:1 of the Dutch Financial Supervision Act (*Wet op het financieel toezicht*, the DFSA); or (ii) standard exemption logo and wording are disclosed as required by Article 5:20(5) of the DFSA, or such offer is otherwise made in circumstances in which Article 5:20(5) of the DFSA is not applicable, and in each case provided that no such offer of common shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the European Prospectus Directive or supplement a prospectus pursuant to Article 16 of the European Prospectus Directive.

### **Switzerland**

The common shares will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

### **Israel**

In the State of Israel, this prospectus shall not be regarded as an offer to the public to purchase shares of common shares under the Israeli Securities Law, 5728 - 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728 - 1968, including, *inter alia*, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the "Addressed Investors"); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions (the "Qualified Investors"). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 - 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for common shares to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 - 1968. In particular, we may request, as a condition to be offered common shares, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 - 1968 and the regulations promulgated thereunder in connection with the offer to be issued common shares; (iv) that the common shares that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 - 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 - 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, *inter alia*, the Addressed Investor's name, address and passport number or Israeli identification number.



### **European Economic Area**

In relation to each Member State of the EEA, which has implemented the European Prospectus Directive (each, a "Relevant Member State"), an offer of the common shares may not be made to the public in a Relevant Member State other than:

- § to any legal entity, which is a qualified investor, as defined in the European Prospectus Directive;
- § to fewer than 150 natural or legal persons (other than qualified investors as defined in the European Prospectus Directive), subject to obtaining the prior consent of the relevant representatives nominated by us for any such offer; or
- § in any other circumstances falling within Article 3(2) of the European Prospectus Directive; provided that no such offer of common shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the European Prospectus Directive or supplement a prospectus pursuant to Article 16 of the European Prospectus Directive.

For the purposes of this description, the expression an "offer to the public" in relation to the securities in any Relevant Member State means the communication to persons in any form and by any means, presenting sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the expression may be varied in that Relevant Member State by any measure implementing the European Prospectus Directive in that member state, and the expression "European Prospectus Directive" means Directive 2003/71/EC (as amended, including by the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State, or superseded) and includes any relevant implementing measure in each Relevant Member State. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the common shares, other than the underwriters, is authorized to make any further offer of common shares on our behalf or on behalf of the underwriters.

### **Hong Kong**

The contents of this document have not been reviewed or approved by any regulatory authority in Hong Kong. This document does not constitute an offer or invitation to the public in Hong Kong to acquire shares. Accordingly, unless permitted by the securities laws of Hong Kong, no person may issue or have in its possession for the purposes of issue, this document or any advertisement, invitation or document relating to the shares, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong other than in relation to shares, which are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" (as such term is defined in the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) ("SFO") and the subsidiary legislation made thereunder); or in circumstances, which do not result in this document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32, Laws of Hong Kong) ("CO"); or, which do not constitute an offer or an invitation to the public for the purposes of the SFO or the CO. The offer of the shares is personal to the person to whom this document has been delivered, and a subscription for shares will only be accepted from such person. No person to whom a copy of this document is issued may issue, circulate or distribute this document in Hong Kong, or make or give a copy of this document to any other person. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this document, you should obtain independent professional advice.

## **Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common shares may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor pursuant to Section 274 of the Securities and Futures Act, Chapter 289 of Singapore ("SFA"), (ii) to a relevant person (as defined in Section 275(2) of the SFA), or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the common shares are subscribed or purchased pursuant to an offer made in reliance on Section 275 of the SFA by a relevant person which is:

- a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor;

shares, debentures and units of shares and debentures of that corporation, or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for six months after that corporation or that trust has acquired the shares under Section 275 except:

1. to an institutional investor or to a relevant person (as defined in Section 275(2) of the SFA), or any person pursuant to Section 275(1A) of the SFA (in the case of that corporation) or Section 276(4)(i)(B) of the SFA (in the case of that trust);
2. where no consideration is or will be given for the transfer; or
3. where the transfer is by operation of law.

**EXPENSES OF THE OFFERING**

We estimate that our expenses in connection with this offering, other than underwriting discounts and commissions, will be as follows:

<u>Expenses</u>	<u>Amount</u> <u>(in \$)</u>
SEC registration fee	*
Nasdaq listing fee	*
FINRA filing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous costs	*
Total	*

All amounts in the table are estimates except the SEC registration fee, the Nasdaq listing fee and the FINRA filing fee. The Company will pay all of the expenses of this offering.

\* To be provided by amendment.

## **LEGAL MATTERS**

The validity of the common shares and certain other matters of Dutch law will be passed upon for us by NautaDutilh N.V. Certain matters of U.S. federal law will be passed upon for us by Davis Polk & Wardwell LLP. Legal counsel to the underwriters in connection with this offering are Goodwin Procter LLP, New York, New York, with respect to U.S. federal law, and Freshfields Bruckhaus Deringer LLP, with respect to Dutch law.

## **EXPERTS**

The consolidated financial statements of Centogene AG as of December 31, 2017 and 2018, and for each of the three years in the period ended December 31, 2018, appearing in this prospectus and registration statement, have been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The current address of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft is Friedrichstraße 140, 10117 Berlin, Germany.

## ENFORCEMENT OF JUDGMENTS

We are incorporated under the laws of the Netherlands, and our headquarters are located in Germany. Substantially all of our assets are located outside the United States. The majority of our management board and supervisory board reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

There is currently no treaty between the United States and the Netherlands for the mutual recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the U.S. federal securities laws, would not be enforceable in the Netherlands unless the underlying claim is relitigated before a Dutch court of competent jurisdiction. Under current practice, however, a Dutch court will generally, subject to compliance with certain procedural requirements, grant the same judgment without a review of the merits of the underlying claim if such judgment (i) is a final judgment and has been rendered by a court, which has established its jurisdiction vis-à-vis the relevant Dutch companies or Dutch company, as the case may be, on the basis of internationally accepted grounds of jurisdiction, (ii) has not been rendered in violation of principles of proper procedure (*behoorlijke rechtspleging*), (iii) is not contrary to the public policy of the Netherlands, and (iv) is not incompatible with (a) a prior judgment of a Netherlands court rendered in a dispute between the same parties, or (b) a prior judgment of a foreign court rendered in a dispute between the same parties, concerning the same subject matter and based on the same cause of action, provided that such prior judgment is capable of being recognized in the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure. Based on the foregoing, there can be no assurance that U.S. investors will be able to enforce any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities.

Dutch civil procedure differs substantially from U.S. civil procedure in a number of respects. Insofar as the production of evidence is concerned, U.S. law and the laws of several other jurisdictions based on common law provide for pre-trial discovery, a process by which parties to the proceedings may prior to trial compel the production of documents by adverse or third parties and the deposition of witnesses. Evidence obtained in this manner may be decisive in the outcome of any proceeding. No such pre-trial discovery process exists under Dutch law.

The United States and Germany currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, in civil and commercial matters. Consequently, a final judgment for payment or declaratory judgments given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Germany. German courts may deny the recognition and enforcement of a judgment rendered by a U.S. court if they consider the U.S. court not to be competent or the decision to be in violation of German public policy principles. For example, judgments awarding punitive damages are generally not enforceable in Germany. A German court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages.

In addition, actions brought in a German court against us, our management board and supervisory board and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions. In particular, German courts generally do not award punitive damages. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. German procedural law does not provide for pre-trial discovery of documents, nor does Germany support pre-trial discovery of documents under the 1970 Hague Evidence Convention. Proceedings in Germany would have to be conducted in the German language and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, our management board and supervisory board and the experts named in this prospectus.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will send the transfer agent a copy of all notices of shareholders' meetings and other reports, communications and information that are made generally available to shareholders. The transfer agent has agreed to mail to all shareholders a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the transfer agent and will make available to all shareholders such notices and all such other reports and communications received by the transfer agent.

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## Report of Independent Registered Public Accounting Firm

To the Shareholders and the Supervisory Board of Centogene AG

### Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Centogene AG (the Company) as of December 31, 2017 and 2018, the related consolidated statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ INGO RÖDERS

Wirtschaftsprüfer  
(German Public Auditor)

/s/ CHRISTIAN PATZELT

Wirtschaftsprüfer  
(German Public Auditor)

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2010.  
Berlin, Germany  
March 28, 2019

**Centogene AG**  
**Consolidated statements of comprehensive loss for the years ended December 31, 2016, 2017 and 2018**  
**(in EUR thousand)**

	Note	2016	2017	2018
Revenue from customers/ revenue	7	27,669	31,689	40,478
Cost of sales		12,856	14,939	19,941
Gross profit		14,813	16,750	20,537
Research and development expenses		5,885	6,396	6,300
General administrative expenses		8,888	9,498	18,610
Selling expenses		5,364	5,897	7,474
Other operating income	8.1	1,295	1,043	2,306
Other operating expenses	8.2	908	457	1,065
Operating loss		(4,937)	(4,455)	(10,606)
Interest and similar income		26	14	33
Interest and similar expenses		856	1,021	1,075
Financial costs, net	8.3	(830)	(1,007)	(1,042)
Loss before taxes		(5,767)	(5,462)	(11,648)
Income tax expenses/(benefits)	9	(408)	14	(310)
Loss for the period		<u>(5,359)</u>	<u>(5,476)</u>	<u>(11,338)</u>
Other comprehensive income/(loss), all attributable to equity holders of the parent		9	10	(8)
Total comprehensive loss		<u>(5,350)</u>	<u>(5,466)</u>	<u>(11,346)</u>
Attributable to:				
Equity holders of the parent		(5,221)	(5,351)	(10,971)
Non-controlling interests		(129)	(115)	(375)
		<u>(5,350)</u>	<u>(5,466)</u>	<u>(11,346)</u>
Loss per share—Basic and diluted		<u>(25)</u>	<u>(22)</u>	<u>(40)</u>

*The accompanying notes form an integral part of these audited condensed consolidated financial statements.*

**Centogene AG**  
**Consolidated statements of financial position as at December 31, 2017 and 2018**  
(in EUR thousand)

<b>Assets</b>	<b>Note</b>	<b>Dec 31, 2017</b>	<b>Dec 31, 2018</b>
<b>Non-current assets</b>			
Intangible assets	12	7,480	8,795
Property, plant and equipment	11	33,837	39,115
Other assets	14	729	—
		<b>42,046</b>	<b>47,910</b>
<b>Current assets</b>			
Inventories	13	779	1,346
Trade receivables	14	6,992	10,901
Other assets	14	2,512	7,295
Cash and cash equivalents	15	3,157	9,222
		<b>13,440</b>	<b>28,764</b>
		<b>55,486</b>	<b>76,674</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Issued capital	16	262	322
Capital reserve	16	25,467	46,923
Retained earnings and other reserves		(8,993)	(19,964)
Non-controlling interests		(382)	(757)
		<b>16,354</b>	<b>26,524</b>
<b>Non-current liabilities</b>			
Non-current loans	18	2,000	12,915
Lease liabilities	18	1,851	1,712
Deferred tax liabilities	9	397	—
Other liabilities	18.4, 19	11,076	11,240
		<b>15,324</b>	<b>25,867</b>
<b>Current liabilities</b>			
Investment subsidies	18.4	368	794
Current loans	18.1	13,837	3,702
Lease liabilities	18.2	1,653	1,350
Liabilities from income taxes		86	10
Trade payables	18.4	5,289	5,429
Other liabilities	18.4, 19	2,575	12,998
		<b>23,808</b>	<b>24,283</b>
		<b>55,486</b>	<b>76,674</b>

*The accompanying notes form an integral part of these audited condensed consolidated financial statements*

**Centogene AG**  
**Consolidated statements of cash flows for the years ended**  
**December 31, 2016, 2017 and 2018**  
**(in EUR thousand)**

	<u>Note</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
<b>Operating activities</b>				
Loss before taxes		(5,767)	(5,462)	(11,648)
Adjustments to reconcile earnings to cash flow from operating activities				
Amortization and depreciation	11,12	2,085	3,237	5,175
Interest income	8.3	(26)	(14)	(33)
Interest expense	8.3	856	1,021	1,075
(Loss)/(gain) on the disposal of non-current assets		6	(60)	—
Share-based payment expenses		964	894	5,521
Other non-cash items		(596)	(32)	(966)
Changes in operating assets and liabilities:				
Inventories	13	340	(412)	(567)
Trade receivables	14	1,161	(2,430)	(3,909)
Other assets		255	314	(919)
Trade payables	18.4	2,041	(728)	140
Other liabilities		71	(664)	1,554
<b>Cash flow used in operating activities</b>		<b>1,390</b>	<b>(4,336)</b>	<b>(4,577)</b>
<b>Investing activities</b>				
Cash paid for investments in intangible assets	12	(3,728)	(2,471)	(3,059)
Cash paid for investments in property, plant and equipment	11	(7,739)	(15,564)	(8,710)
Grants received for investment in property, plant and equipment	18.4	2,754	6,802	3,042
Cash received from disposals of property, plant and equipment		—	65	—
Interest received		26	14	33
<b>Cash flow used in investing activities</b>		<b>(8,687)</b>	<b>(11,154)</b>	<b>(8,694)</b>
<b>Financing activities</b>				
Cash received from equity contributions, net	16	2,214	19,034	20,073
Cash received from loans	18.1	8,655	9,990	3,631
Cash repayments of loans	18.1	(853)	(8,749)	(2,851)
Cash repayments of financial leases	18.2	(1,293)	(1,580)	(442)
Interest paid	8.3	(856)	(1,013)	(1,075)
<b>Cash flow from financing activities</b>		<b>7,867</b>	<b>17,682</b>	<b>19,336</b>
Changes in cash and cash equivalents		570	2,192	6,065
Cash and cash equivalents at the beginning of the period		395	965	3,157
Cash and cash equivalents at the end of the period		<u>965</u>	<u>3,157</u>	<u>9,222</u>

*The accompanying notes form an integral part of these audited condensed consolidated financial statements*

**Centogene AG**  
**Consolidated statements of changes in equity for the years ended December 31, 2016, 2017 and 2018**

	Attributable to the equity holders of the parent						Non-controlling interests	Total equity
	Note	Issued capital	Capital reserve	Currency translation reserve	Retained earnings	Total		
<b>As of January 1, 2016</b>		<b>212</b>	<b>3,254</b>	<b>(27)</b>	<b>1,606</b>	<b>5,045</b>	<b>(138)</b>	<b>4,907</b>
Loss for the period		—	—	—	(5,230)	(5,230)	(129)	(5,359)
Other comprehensive income		—	—	9	—	9	—	9
<b>Total comprehensive loss</b>		<b>—</b>	<b>—</b>	<b>9</b>	<b>(5,230)</b>	<b>(5,221)</b>	<b>(129)</b>	<b>(5,350)</b>
Share-based payments		—	964	—	—	964	—	964
Issuance of shares	16	4	2,210	—	—	2,214	—	2,214
<b>As of December 31, 2016</b>		<b>216</b>	<b>6,428</b>	<b>(18)</b>	<b>(3,624)</b>	<b>3,002</b>	<b>(267)</b>	<b>2,735</b>

	Attributable to the owners of the parent						Non-controlling interests	Total equity
	Note	Issued capital	Capital reserve	Currency translation reserve	Retained earnings	Total		
<b>As of January 1, 2017</b>		<b>216</b>	<b>6,428</b>	<b>(18)</b>	<b>(3,624)</b>	<b>3,002</b>	<b>(267)</b>	<b>2,735</b>
Loss for the period		—	—	—	(5,361)	(5,361)	(115)	(5,476)
Other comprehensive income		—	—	10	—	10	—	10
<b>Total comprehensive loss</b>		<b>—</b>	<b>—</b>	<b>10</b>	<b>(5,361)</b>	<b>(5,351)</b>	<b>(115)</b>	<b>(5,466)</b>
Share-based payments	19	—	51	—	—	51	—	51
Issuance of shares	16	46	19,404	—	—	19,450	—	19,450
Transaction cost		—	(416)	—	—	(416)	—	(416)
<b>As of December 31, 2017</b>		<b>262</b>	<b>25,467</b>	<b>(8)</b>	<b>(8,985)</b>	<b>16,736</b>	<b>(382)</b>	<b>16,354</b>

	Attributable to the owners of the parent						Non-controlling interests	Total equity
	Note	Issued capital	Capital reserve	Currency translation reserve	Retained earnings	Total		
<b>As of January 1, 2018</b>		<b>262</b>	<b>25,467</b>	<b>(8)</b>	<b>(8,985)</b>	<b>16,736</b>	<b>(382)</b>	<b>16,354</b>
Loss for the period		—	—	—	(10,963)	(10,963)	(375)	(11,338)
Other comprehensive loss		—	—	(8)	—	(8)	—	(8)
<b>Total comprehensive loss</b>		<b>—</b>	<b>—</b>	<b>(8)</b>	<b>(10,963)</b>	<b>(10,971)</b>	<b>(375)</b>	<b>(11,346)</b>
Share-based payments	19	—	1,443	—	—	1,443	—	1,443
Issuance of shares	16	60	20,013	—	—	20,073	—	20,073
<b>As of December 31, 2018</b>		<b>322</b>	<b>46,923</b>	<b>(16)</b>	<b>(19,948)</b>	<b>27,281</b>	<b>(757)</b>	<b>26,524</b>

*The accompanying notes form an integral part of these audited condensed consolidated financial statements*

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018**

**1 General company information**

The parent company of the Group is Centogene AG ("the Company"). The Company's registered office is located at Am Strande 7 in 18055 Rostock, Germany, and the Company is registered in the Rostock commercial register under the HRB no. 13225. The Company, together with its subsidiaries, is referred to in these financial statements as "the Group".

The Company is a commercial-stage rare disease company focused on transforming clinical and genetic data into medical solutions for patients. The Company is committed to "un-rare" rare diseases by using its worldwide knowledge in the rare disease market and is focused on bringing rationality to treatment decisions and accelerating the development of new orphan drugs.

**2 Basis of preparation**

The consolidated financial statements of the Group were prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board (the "IASB").

The accounting policies used in the fiscal year 2018 generally correspond to the policies applied in the prior year, except for certain amendments to the standards which are effective for annual periods beginning on or after January 1, 2018 (see note 3).

These consolidated financial statements are presented in euro, which is the Company's functional currency. Unless otherwise specified, all financial information presented in euro is rounded to the nearest thousand (EUR k) in line with customary commercial practice, except when otherwise indicated.

**3 Effects of new accounting standards**

**(a) New standards adopted by the Group as of January 1, 2018**

**IFRS 15 Revenue from Contracts with Customers**

IFRS 15 supersedes IAS 11 Construction Contracts, IAS 18 Revenue and related Interpretations and it applies to all revenue arising from contracts with customers, unless those contracts are in the scope of other standards (such as the standards governing leases and financial instruments).

The new standard establishes a five-step model to account for revenue arising from contracts with customers. Revenue from contracts with customers is recognized when the Group transfers control of the related good or service to a customer. Customers are those counterparties which contract with the Company to obtain goods and services that are an output of ordinary activities in exchange for consideration. The Group considers its collaboration agreements, diagnostic testing services, agreements to provide CentoCards, access to CentoMD and other such arrangements to be contracts for the purposes of the standard.

An important aspect of the five-step model is the identification of the Group's performance obligations that are distinct and therefore accounted for separately. Depending on the nature of contractual promises such items may need to be combined into one unit of account for revenue recognition purposes.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**3 Effects of new accounting standards (Continued)**

Under IFRS 15, revenue is recognised at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer. The contracts entered into by Centogene generally provide for consideration that partly consists of variable consideration in the form of milestones or sales-based royalties. Milestones are only included in the expected consideration when it is highly probable that a significant reversal in the cumulative amount of revenue will not occur when the contingency is resolved (often referred to as "the constraint" on variable consideration). Sales-based royalties are only recognized when the related services have been performed. Expected consideration may need to be allocated between distinct performance obligations based on relative stand-alone selling prices, which are either observable from the Group's business or need to be estimated.

Depending on the pattern of transfer of the good or services, revenue is either recognized at a point in time or over the period during which the goods or services are transferred to the customer. For performance obligations which are satisfied over time, the Group selects an appropriate method for measuring progress. The Group determines the appropriate method to measure progress based on the nature of the respective agreement.

The standard requires entities to exercise judgement, taking into consideration all of the relevant facts and circumstances when applying each step of the model to contracts with their customers. The standard also specifies accounting for the incremental costs of obtaining a contract and the costs directly related to fulfilling a contract. Incremental costs of obtaining a contract have to be capitalized, unless it is expected that such costs would be amortized within 12 months. The cost of fulfilling a contract has to be capitalized either if required by another applicable standard (e.g. IAS 38) or, if no such other standard is applicable, in accordance with IFRS 15. At this time, there are no costs to be capitalized under IFRS 15.

The Group has adopted IFRS 15 for the period commencing January 1, 2018 using the modified retrospective transition method, which does not require retrospective application to comparative periods. The adoption of IFRS 15 did not have a material impact on the recognition or measurement of revenue for transactions entered into by the Group for the year ended December 31, 2018 as compared to the prior period (see note 5 regarding accounting policy for revenue recognition).

**IFRS 9 Financial Instruments**

IFRS 9 Financial Instruments replaces IAS 39 Financial Instruments: Recognition and Measurement for annual periods beginning on or after January 1, 2018, bringing together all three aspects of accounting for financial instruments: classification and measurement; impairment; and hedge accounting.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

### **3 Effects of new accounting standards (Continued)**

IFRS 9 changed the way financial instruments are classified. Financial assets are classified at initial recognition, and then subsequently measured, at i) amortised cost, ii) fair value through other comprehensive income (OCI), or iii) fair value through profit or loss. The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing the financial assets. With the exception of trade receivables that do not contain a significant financing component, the Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15.

For purposes of subsequent measurement, financial assets are classified in four categories:

- § Financial assets at amortised cost (debt instruments)
- § Financial assets at fair value through OCI with recycling of cumulative gains and losses (debt instruments)
- § Financial assets designated at fair value through OCI with no recycling of cumulative gains and losses upon derecognition (equity instruments); and
- § Financial assets at fair value through profit or loss

The Group only has a limited number of financial assets and liabilities which are classified and measured at amortised cost under IFRS 9. Therefore, the Group is not affected by the changes to the classification guidance.

In addition, the adoption of IFRS 9 has changed the Group's accounting for impairment losses for financial assets by replacing IAS 39's incurred loss approach with a forward-looking expected credit loss (ECL) approach.

The adoption of IFRS 9 did not have a material impact on the Group's consolidated financial statements.

#### **Amendments to IFRS 2 Classification and Measurement of Share-based Payment Transactions**

The IASB issued amendments to IFRS 2 Share-based Payment that address three main areas: the effects of vesting conditions on the measurement of a cash-settled share-based payment transaction; the classification of a share-based payment transaction with net settlement features for withholding tax obligations; and accounting where a modification to the terms and conditions of a share-based payment transaction changes its classification from cash settled to equity settled. On adoption, entities are required to apply the amendments without restating prior periods, but retrospective application is permitted if elected for all three amendments and other criteria are met. The Group's accounting policy for cash-settled share-based payments is consistent with the approach clarified in the amendments. In addition, the Group has no share-based payment transactions with net settlement features for withholding tax obligations and had not made any modifications to the terms and conditions of its share-based payment transactions. Therefore, these amendments do not have any impact on the Group's consolidated financial statements.



**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**3 Effects of new accounting standards (Continued)**

**(b) New standards not yet effective**

Furthermore, the IASB has published the standards and interpretations listed below, the adoption of which was not yet mandatory for the fiscal year 2018. The Group has chosen not to early adopt any standards, interpretations or amendments that have been issued but are not yet effective.

**IFRS 16 Leases**

IFRS 16 was issued in January 2016 and it replaces IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for all leases under a single on-balance sheet model similar to the accounting for finance leases under IAS 17. The standard includes two recognition exemptions for lessees—leases of 'low-value' assets (e.g. personal computers) and short-term leases (i.e., leases with a lease term of 12 months or less). At the commencement date of a lease, a lessee will recognise a liability to make lease payments (i.e. the lease liability) and an asset representing the right to use the underlying asset during the lease term (i.e. the right-of-use asset). Lessees will be required to separately recognise the interest expense on the lease liability and the depreciation expense on the right-of-use asset.

Lessees will be also required to remeasure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee will generally recognise the amount of the remeasurement of the lease liability as an adjustment to the right-of-use asset. The Group plans to adopt the new standard on the required effective date using the modified retrospective method. The effects for the existing operating leases will not have a material effect on the consolidated financial statements since the Company has a limited number of operating leases (see note 23).

**IFRIC Interpretation 23 Uncertainty over Income Tax Treatment**

The Interpretation addresses the accounting for income taxes when tax treatments involve uncertainty that affects the application of IAS 12 and does not apply to taxes or levies outside the scope of IAS 12, nor does it specifically include requirements relating to interest and penalties associated with uncertain tax treatments. The Interpretation specifically addresses the following:

- § Whether an entity considers uncertain tax treatments separately
- § The assumptions an entity makes about the examination of tax treatments by taxation authorities
- § How an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates
- § How an entity considers changes in facts and circumstances

An entity has to determine whether to consider each uncertain tax treatment separately or together with one or more other uncertain tax treatments. The approach that better predicts the resolution of the uncertainty should be followed. The interpretation is effective for annual reporting periods beginning on or after 1 January 2019, but certain transition reliefs are available. The Group

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**3 Effects of new accounting standards (Continued)**

will apply the interpretation from its effective date. The Interpretation is not expected to have a material effect on the consolidated financial statements since the Company and the subsidiaries are in tax loss positions and do not have any outstanding income tax liabilities.

**4 Basis of consolidation**

The basis of consolidation includes the entities over which Centogene AG has control within the meaning of IFRS 10 Consolidated Financial Statements. According to IFRS 10, Centogene AG has control of an investee when it has direct or indirect power over the investee, exposure, or rights to variable returns from its involvement with the investee and the ability to use its power over the investee to affect those returns. Control is established when it is possible to influence operating and financial policies of the investee, typically with a share in the voting rights or shareholding of more than 50% in the investee. An entity is included in the Group's basis of consolidation from the point in time when Centogene AG has obtained control of the entity. Profit or loss and each component of other comprehensive income are attributed to the equity holders of Centogene AG and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full upon consolidation.

**5 Accounting and measurement principles**

The Group applied the following accounting policies consistently for all of the periods presented in these consolidated financial statements.

**Foreign currency and currency translation**

Transactions in foreign currency are translated into the respective entity's functional currency at the spot rate prevailing on the date of the transaction.

The functional currency of each entity is the respective local currency, since the entities carry out their business activities independently from a financial, economic and organizational perspective.

Monetary assets and liabilities denominated in foreign currency are translated to the functional currency using the closing rate at the reporting date. Currency translation differences are recognized immediately through profit or loss. Non-monetary items denominated in a foreign currency that are measured at historical cost are not translated at the reporting date.

On consolidation, the assets and liabilities of foreign operations are translated into euros using the closing rate on the reporting date. Income and expenses of foreign operations are translated using the exchange rate prevailing on the date of the transaction or the annual average exchange rate. Equity is translated using historical rates until the entity is removed from the Group's basis of consolidation. Any resulting currency translation differences are recorded in other comprehensive income and recognized under the currency translation reserve in equity if the exchange difference is not allocable to the non-controlling interests.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

The exchange rates used are presented in the following table:

	Average rate			Closing rate		
	2016	2017	2018	Dec 31, 2016	Dec 31, 2017	Dec 31, 2018
USD (EUR 1)	1.1069	1.1297	1.1779	1.0541	1.1993	1.1419
AED (EUR 1)	3.9989	4.1549	4.2713	3.8101	4.3874	4.1396
INR (EUR 1)	72.9318	73.5324	79.3177	70.2059	76.6055	78.5156

**Revenue**

The Group provides pharmaceutical solutions and diagnostic tests enabled by its knowledge and interpretation-based platform. Revenue from contracts with customers is recognized when control of the goods or services are transferred to the customer at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services, usually on delivery of the goods.

**(a) Diagnostics segment**

Revenues from the Group's diagnostics segment are typically generated from targeted genetic sequencing and diagnostics services that the Group provides to clients, who are typically physicians, laboratories or hospitals, either directly or through distributors. Revenues are based on a negotiated price per test or on the basis of agreements to provide certain testing volumes over defined periods. The Group has concluded that the services rendered in the diagnostics segment comprise one performance obligation. The Group has also concluded that the revenues in the diagnostics segment will continue to be recognized over time, using an input method to measure progress towards complete satisfaction of the service similar to the previously applied accounting policy. In order to measure progress, the Group uses a standardized process which measures progress to completion by stages, consisting of (i) a preparation stage, (ii) a clarification stage, (iii) a sequencing stage, and (iv) an output stage. The percentages attributed to those stages are indicative of the cost incurred in performing the respective stage in relation to total cost.

**(b) Pharmaceutical segment**

The Group's contracts with customers relate to a variety of solutions provided to the Group's pharmaceutical partners in order to accelerate their development of treatments for rare diseases, including early patient recruitment and identification, epidemiological insights, biomarker discovery and patient monitoring. The collaboration agreements are structured on a fee per sample basis, milestone basis, fixed fee basis, royalty basis or a combination of these. In addition, some of the Group's contracts with its pharmaceutical partners also include sales of CentoCard for the collection of biological samples from patients.

The Group recognizes revenue from pharmaceutical partners either over time or at a point in time, depending on the nature of the service provided, as detailed below.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

- (i) Revenue from early patient recruitment and identification, epidemiological insights, biomarker discovery and patient monitoring is based on fee per sample, milestone fees and fixed fees. The revenues from these solutions are recognized over time using an input method based on the work rendered in order to measure progress towards complete satisfaction of the services.
- (ii) Revenue from the licensing of intellectual property for an unlimited period, usually in the structure of an upfront fee, is recognized at a point in time, when the right (or license) to use intellectual property is conveyed.
- (iii) Revenues from the licensing of intellectual property for a certain period, being a right to access such intellectual property as defined in IFRS 15, is recognized over time over the licensing period.
- (iv) Revenue from the sale of CentoCards is recognized at a point in time when the control of the CentoCards has transferred to the customer, which typically occurs on delivery.
- (c) Presentation and disclosure requirements

IFRS 15 introduced new descriptions for financial statement line items. The standard distinguishes between receivables (unconditional claims to receive consideration), contract assets (claims to consideration not yet invoiced) and contract liabilities (performance obligations still not satisfied). In line with the modified retrospective approach to adopting the standard, the Group only uses such new terminology in relation to the current reporting period. Refer, for example, to note 14.

The Group has disaggregated revenue recognised from contracts with customers into categories that depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors. The Group has also disclosed information about the relationship between the disclosure of disaggregated revenue and the revenue information disclosed for each reportable segment. See note 7 for the disclosure on disaggregated revenue.

(d) Contract balances

(i) Contract assets

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If the Group performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognised for the earned consideration that is conditional.

(ii) Trade receivables

A receivable represents the Group's right to an amount of consideration that is unconditional (i.e. only the passage of time is required before payment of the consideration is due). Refer to accounting policies of financial assets in section "Financial instruments—initial recognition and subsequent measurement".

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

(iii) Contract liabilities

A contract liability is the obligation to transfer goods or services to a customer for which the Group has received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before the Group transfers goods or services to the customer, a contract liability is recognised when the payment is made or the payment is due (whichever is earlier). Contract liabilities are recognised as revenue when the Group performs under the contract.

**Finance income and finance costs**

Interest income and expenses are recognized in the period which they relate to through profit or loss using the effective interest rate method.

**Intangible assets**

***Research and development***

Expenses for research activities are recognized through profit or loss in the period in which they are incurred.

Internally generated intangible assets are only recognized from the date the Group can demonstrate:

- § the development costs can be measured reliably
- § the product or process is technically and commercially feasible
- § a future economic benefit is probable
- § the Group has the intention and
- § the Group has sufficient resources to complete the development and to use or sell the asset.

The Group's research and development activities mainly relate to development of biomarkers and IT driven solutions. With respect to biomarkers, the development stage is usually considered to be achieved when the target validation process is completed and commercialization is probable. With respect to IT driven solutions, the development stage is considered to be achieved upon the completion of the Group's internal validation test. Before such dates, any development costs are recognized in profit or loss and may not be subsequently capitalized.

Capitalized development costs are recognized at cost less accumulated amortization and any accumulated impairment losses. They are only amortised as from the date the asset is ready for its intended use, which in the case of biomarkers is normally at the time the patent application for such biomarker is made. Amortization expense commences when the assets are ready to be put in use, and is recorded in cost of sales and research and development expenses.

Capitalized development costs which are still under development are tested for impairment annually and when circumstances indicate that the carrying value may be impaired.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

***Other intangible assets***

Other intangible assets purchased by the Group with finite useful lives are recognized at cost less accumulated amortization and any accumulated impairment losses. Subsequent expenditure is only capitalized if it increases the future economic benefits of the respective asset.

Intangible assets are amortized over their estimated useful life using the straight-line method and assessed for impairment whenever there is an indication that the intangible asset may be impaired.

The estimated useful lives are as follows:

- § Software, patents and trademarks: 3-7 years; and
- § Capitalized development costs: 7 years

The useful lives and depreciation methods are reviewed annually to ensure that the methods and periods of depreciation are consistent with the expected economic benefit from the asset.

**Property, plant and equipment**

Property, plant and equipment are carried at cost less any accumulated depreciation and any accumulated impairment losses.

The cost of property, plant and equipment comprises its purchase price including customs duties and non-refundable acquisition taxes, and proportionate VAT not deductible from input tax as well as any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Subsequent expenditure is only capitalized if it is probable that the future economic benefits associated with the expenditure will flow to the Group.

Depreciation is calculated over the estimated useful life using the straight-line method. The Group has assessed that none of its property, plant and equipment has a residual value. The estimated useful lives of significant property, plant and equipment are as follows:

- § Freehold land is not depreciated
- § Buildings: 33 years and
- § Plant and other equipment, furniture and fixtures: 2-15 years

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the statement of comprehensive loss when the asset is derecognized.

The depreciation methods, useful lives and residual values are reviewed, and adjusted prospectively if appropriate, as of each reporting date.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

Assets under construction are reported at cost and are allocated to property, plant and equipment until they are completed and put into operational use, from which point onwards they are depreciated.

**Leases**

Assets that are held by the Group under a lease that transfers the key risks and rewards of ownership to the Group are classified as finance leases. The leased asset is initially measured at the lower of fair value and the present value of the minimum lease payments. After initial recognition, the asset is carried in accordance with applicable accounting policy for the asset.

Finance lease payments are apportioned between finance costs and the reduction of the outstanding liability. The finance costs are allocated to each period during the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability.

The Group has mainly entered into finance leases for production facilities and laboratory equipment. These lease arrangements generally have a term of three to five years.

Assets from other leases are classified as operating leases and the respective lease expenses are recognised in profit or loss on a straight-line basis over the lease term .

**Impairment of non-financial assets**

Property, plant and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Whenever the carrying amount of an asset exceeds its recoverable amount, an impairment loss is recognized in profit or loss. The recoverable amount is measured as the higher of fair value less costs to sell and value in use. Recoverable amounts are estimated either for individual assets or, if an individual asset does not generate cash flows independently of other assets, for the whole cash-generating unit.

**Inventories**

Inventories are measured at the lower of cost and net realizable value. Inventories are recognized at cost based on the first in first out (FIFO) method.

Net realisable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

**Government grants**

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with.

Government grants which relate to an asset are initially recognized as deferred income at fair value. They are subsequently released to profit or loss on a systematic basis over the useful life of the asset.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

Grants that are intended to compensate the Group for expenses incurred are recognized through profit or loss on a systematic basis over the periods in which expenses are recognized.

**Share-based payments**

*Equity settled transactions*

Equity-settled share-based payments are recognized as expenses based on the fair value of the granted options when the grant is made, using a Black-Scholes Model.

The cost of the share-based payment is recognized in employee benefits expense (see note 8.4), together with a corresponding increase in equity (capital reserves), over the period in which the service conditions are fulfilled (the vesting period). The cumulative expense recognised for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest.

*Cash-settled transactions*

A liability is recognized for the fair value of cash-settled transactions. The fair value is measured initially and at each reporting date up to and including the settlement date, with changes in fair value recognized in employee benefits expense (see note 8.4). The fair value per option is determined using the Black-Scholes model, further details of which are given in note 19. The fair value per option is then multiplied by the Group's best estimate of the number of awards expected to vest and the portion of the expired vesting period (period in which the service conditions are fulfilled). The cumulative amount of expense recognized will be equal to the cash that is paid on settlement.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

No expense is recognised for awards that do not ultimately vest because non-market performance and/or service conditions have not been met. Where awards include a market or non-vesting condition, the transactions are treated as vested irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

**Provisions**

A provision is recognized when the Group has a present obligation (legal, contractual or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. Provisions are reviewed at each reporting date and adjusted to reflect the current best estimate.



**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

If the requirements for recognizing a provision are not satisfied, the corresponding obligations are recorded as contingent liabilities unless the possibility of an outflow of resources embodying economic benefits is remote.

**Income taxes**

Tax expense comprises current and deferred taxes. Current taxes and deferred taxes are recognized through profit or loss apart from those amounts relating to items recognized directly in equity or in other comprehensive income.

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

Deferred taxes are set up for temporary differences between the carrying amounts of assets and liabilities for group financial reporting purposes and the amounts used for tax purposes. Deferred taxes are not recognized for:

- § temporary differences arising from the initial recognition of assets or liabilities in the course of a business transaction that is not a business combination and does not affect either the accounting profit or the taxable profit; or
- § temporary differences associated with investments in subsidiaries if the Group controls the timing of the reversal of the temporary differences, and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for unused tax losses, unused tax credits and deductible temporary differences to the extent that it is probable that the future taxable profit will be available against which they can be utilized. The utilization of deferred tax assets is reassessed on each reporting date.

Deferred taxes are calculated on the basis of tax rates that are expected to apply to the temporary differences when the asset is realized or the liability is settled, based on tax rates that have been enacted or substantively enacted by the end of the reporting period.

Unrecognized deferred tax assets are reassessed at each end of the reporting period and recognized to the extent that it has become probable that future taxable profit will allow them to be realized.

Deferred tax assets and deferred tax liabilities are offset against each other if certain conditions are met.

**Financial instruments**

***(i) Financial assets***

The Group's financial assets principally consist of those accounted for as Receivables and Contract assets.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

***Receivables and contract assets***

Receivables, including contract assets, are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Contract assets and trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15. Refer to the accounting policies under "Revenue".

After initial recognition, Receivables and contract assets are subsequently carried at amortized cost using the effective interest rate method less any impairment losses. Gains and losses are recognized in the profit or loss for the period when the loans and receivables are derecognized or impaired.

***Derecognition***

A financial asset or a part of a financial asset is derecognized when the Group no longer has the contractual rights to the asset or the right to receive cash flows from the asset have expired.

***Impairment***

Further disclosures relating to impairment of trade receivables, including contract assets, are in note 20.2.

The Group recognises an allowance for expected credit losses (ECLs). ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate.

The Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

The Group considers in general a financial asset in default when contractual payments are 180 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

***(ii) Financial liabilities***

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade and other payables, as well as loans and borrowings including bank overdrafts.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**5 Accounting and measurement principles (Continued)**

***Loans and borrowings***

Loans and borrowings are initially recognized at fair value and subsequently measured at amortized cost using the effective interest rate method, taking into account any principal repayments and any discount or premium on acquisition and including transaction costs and fees that are an integral part of the effective interest rate.

Gains or losses are recognized through profit or loss at the time the liabilities are derecognized or disposed of.

***Derecognition***

A financial liability is derecognized when the obligation underlying the liability is discharged, canceled or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognized through profit or loss.

**Cash and cash equivalents**

Cash and cash equivalents comprise cash on hand and bank balances, including short-term, highly liquid investments that can be quickly converted into cash amounts. These have original maturities of three months or less and are subject to a low risk of fluctuation in value.

**6 Accounting judgments and estimates**

The preparation of the consolidated financial statements requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results could differ from those estimates. Estimates and underlying assumptions are reviewed on an ongoing basis and revisions of estimates are recorded prospectively.

**6.1 Judgments**

***Development costs***

Development costs are recognized in accordance with the accounting policy for certain internally generated assets. The Group's research and development activities mainly relate to development of biomarkers and IT driven solutions. With respect to biomarkers, the development stage is usually considered to be achieved when the target validation process is completed and commercialization is probable. With respect to IT driven solutions, the development stage is considered to be achieved upon the completion of the Group's internal validation test. Before such date, any development costs are recognized in profit or loss and may not be subsequently capitalized. As of December 31, 2018, the carrying amount of capitalized development costs was EUR 8,795k (2017: EUR 7,480k). This amount includes investments in the development of biomarkers and IT driven solutions (e.g. the Group's CentoMD database and CentoPortal online platform).

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

## **6 Accounting judgments and estimates (Continued)**

### ***Deferred tax asset on loss carryforwards***

The tax losses carried forward do not expire. In the light of the Company's loss history, the recognition of deferred taxes for tax losses carried forward and deductible temporary differences is limited to the future reversal of existing taxable temporary differences.

## **6.2 Assumptions and estimation uncertainties**

Information concerning assumptions and estimation uncertainty that have a significant risk of causing a material adjustment to the fiscal year ending on December 31, 2018 are presented in the following disclosures. The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

### ***Share-based payments***

Estimating fair value for share-based payment transactions requires a determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. The Group measures the fair value of cash-settled transactions with employees using the Black-Scholes model to determine the liability incurred at the end of each reporting period. For the measurement of the fair value of equity-settled transactions at the grant date, the Group also uses the Black-Scholes model.

### ***Valuation of Share Options***

The Black-Scholes option pricing model requires the input of subjective assumptions, including assumptions about the expected life of share-based awards and share price volatility. In addition, as a privately held company, one of the most subjective inputs into the Black-Scholes option pricing model is the estimated fair value of the Group's common shares.

As a privately held company, the Group's share price does not have sufficient historical volatility for us to adequately assess the fair value of the share option grants. As a result, management considered the historical volatility of other comparable publicly traded companies and, based on this analysis, concluded that a volatility of 70% (2017:60% ; 2016: 60%) was appropriate for the valuation of the share options.

The Group intends to continue to consistently apply this methodology using the same comparable companies until a sufficient amount of historical information regarding the volatility of the Group's own share price as a public company becomes available.

The expected life of the option, beginning with the option grant date, was used in valuing the share options. The expected life used in the calculation of share-based payment expense is the time from the grant date to the expected exercise date. The life of the options depends on the option expiration date and vesting features.

The valuation of share options also requires the use of the risk-free interest rate of the country in which the entity's principal business operations are conducted, with a remaining term equal to the

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**6 Accounting judgments and estimates (Continued)**

expected life of the option. The Group applied the appropriate risk-free rate using the Euro denominated German Sovereign Strips as at the respective share option grant dates.

***Valuation of Common Shares***

There are significant judgments and estimates inherent in the determination of the fair value of the Group's common shares. These judgments and estimates include assumptions regarding future operating performance, the likelihood and time to complete an IPO or other liquidity event, the related company valuations associated with such events, and the determinations of the appropriate valuation methods. If different assumptions were made, the share-based payment expense, loss for the year and total comprehensive loss, on both an absolute and per-share basis, could have been significantly different.

The Group has hired a third party valuation firm to derive the fair value of the Group's shares and share options as of the respective dates.

The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in note 19.

**7 Segment information**

For management purposes, the Group is organized into business units based on its products and services and has two reportable segments, as follows:

- § **Pharmaceutical segment:** This segment provides a variety of solutions to the Group's pharmaceutical partners, including early patient recruitment and identification, epidemiological insights, biomarker discovery and patient monitoring, in order to accelerate the development of treatments for rare diseases; and
- § **Diagnostics segment:** This segment provides targeted genetic sequencing and diagnostics services to the Group's clients, who are typically physicians, laboratories or hospitals, either directly or through distributors.

Residual operating activities of the Group are reported as 'Corporate'. These include the group functions for communications, human resources, finance (including treasury and taxes), legal, research and development and other supporting activities.

The Group's revenue is principally derived from the provision of pharmaceutical solutions and diagnostic tests. Revenues in pharmaceutical segment are primarily generated from solutions to the pharmaceutical partners to accelerate their development of treatments for rare diseases. Contracts are structured on a fee per sample basis, milestone basis, fixed fee basis, royalty basis or a combination of these.

Revenues from the diagnostics segment are typically generated from targeted genetic sequencing and diagnostics services that are provided to the clients, who are typically physicians, laboratories or hospitals, either directly or through distributors. Revenues are based on a negotiated price per test or on the basis of agreements to provide certain testing volumes over defined periods.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**7 Segment information (Continued)**

The management board is the Chief Operating Decision Maker and monitors the operating results of its business units separately for the purpose of making decisions about resource allocation and performance assessment. Segment performance is evaluated based on segment results and is measured with reference to the Adjusted EBITDA, which is operating loss presented in the consolidated statements of comprehensive loss, adjusted for corporate expenses, depreciation and amortization as well as share-based payment expenses.

in EUR k	2016			
	Pharmaceutical	Diagnostics	Corporate	Total
Rendering of services	10,875	15,321	—	26,196
Sales of goods	1,473	—	—	1,473
<b>Revenues from external customers</b>	<b>12,348</b>	<b>15,321</b>	<b>—</b>	<b>27,669</b>
<b>Adjusted EBITDA</b>	<b>10,865</b>	<b>(122)</b>	<b>(12,631)</b>	<b>(1,888)</b>
<b>Capital Expenditures</b>	<b>2,147</b>	<b>5,945</b>	<b>7,683</b>	<b>15,775</b>
Additions to property, plant and equipment	410	5,945	5,692	12,047
Additions to intangible assets	1,737	—	1,991	3,728
<b>Other segment information</b>				
Depreciation and amortization	944	667	474	2,085
Research and development expenses	28	—	5,857	5,885

in EUR k	2017			
	Pharmaceutical	Diagnostics	Corporate	Total
Rendering of services	12,326	17,758	—	30,084
Sales of goods	1,605	—	—	1,605
<b>Revenues from external customers</b>	<b>13,931</b>	<b>17,758</b>	<b>—</b>	<b>31,689</b>
<b>Adjusted EBITDA</b>	<b>10,870</b>	<b>2,552</b>	<b>(13,746)</b>	<b>(324)</b>
<b>Capital Expenditures</b>	<b>1,464</b>	<b>607</b>	<b>15,964</b>	<b>18,035</b>
Additions to property, plant and equipment	241	607	14,716	15,564
Additions to intangible assets	1,223	—	1,248	2,471
<b>Other segment information</b>				
Depreciation and amortization	793	1,311	1,133	3,237
Research and development expenses	35	—	6,361	6,396

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**7 Segment information (Continued)**

in EUR k	2018			
	Pharmaceutical	Diagnostics	Corporate	Total
Rendering of services	16,077	23,171	—	39,248
Sales of goods	1,230	—	—	1,230
<b>Revenues from external customers</b>	<b>17,307</b>	<b>23,171</b>	<b>—</b>	<b>40,478</b>
Recognized over time	12,077	23,171	—	35,248
Recognized at a point in time	5,230	—	—	5,230
<b>Revenues from external customers</b>	<b>17,307</b>	<b>23,171</b>	<b>—</b>	<b>40,478</b>
<b>Adjusted EBITDA</b>	<b>13,641</b>	<b>2,285</b>	<b>(15,836)</b>	<b>90</b>
<b>Capital Expenditures</b>				
Additions to property, plant and equipment	1,225	1,917	5,568	8,710
Additions to intangible assets	1,948	—	1,111	3,059
<b>Other segment information</b>				
Depreciation and amortization	1,222	1,838	2,115	5,175
Research and development expenses	334	—	5,966	6,300

**Adjustments**

Interest and similar income and expenses and share-based payment expenses are not allocated to individual segments as the underlying instruments are managed on a group basis. Current taxes, deferred taxes are allocated to Corporate as they are also managed on a group basis.

Capital expenditure consists of additions of property, plant and equipment and intangible assets.

**Reconciliation of segment Adjusted EBITDA to Group Loss for the Period**

	2016	2017	2018
<b>Reportable segment Adjusted EBITDA</b>	<b>10,743</b>	<b>13,422</b>	<b>15,926</b>
Corporate expenses	(12,631)	(13,746)	(15,836)
	(1,888)	(324)	90
Share-based payment expenses	(964)	(894)	(5,521)
Depreciation and amortization	(2,085)	(3,237)	(5,175)
<b>Operating loss</b>	<b>(4,937)</b>	<b>(4,455)</b>	<b>(10,606)</b>
Financial costs, net	(830)	(1,007)	(1,042)
Income taxes	408	(14)	310
<b>Loss for the year</b>	<b>(5,359)</b>	<b>(5,476)</b>	<b>(11,338)</b>

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**7 Segment information (Continued)**

**Geographical information**

in EUR k	For the year ended December 31, 2016		
	Pharmaceutical	Diagnostics	Total
<b>Revenues</b>			
Europe	313	4,968	5,281
—Germany	—	—	—
Middle East	—	7,014	7,014
—Saudi Arabia	—	3,728	3,728
North America	12,035	1,998	14,033
—United States	12,035	123	12,158
Latin America	—	747	747
Asia Pacific	—	594	594
<b>Total</b>	<b>12,348</b>	<b>15,321</b>	<b>27,669</b>

in EUR k	For the year ended December 31, 2017		
	Pharmaceutical	Diagnostics	Total
<b>Revenues</b>			
Europe	493	5,183	5,676
—Germany	—	—	—
Middle East	—	8,846	8,846
—Saudi Arabia	—	4,926	4,926
North America	13,438	1,459	14,897
—United States	13,438	44	13,482
Latin America	—	1,474	1,474
Asia Pacific	—	796	796
<b>Total</b>	<b>13,931</b>	<b>17,758</b>	<b>31,689</b>

in EUR k	For the year ended December 31, 2018		
	Pharmaceutical	Diagnostics	Total
<b>Revenues</b>			
Europe	654	6,196	6,850
—Germany	654	407	1,061
Middle East	—	12,401	12,401
—Saudi Arabia	—	5,475	5,475
North America	16,653	1,460	18,113
—United States	16,653	643	17,296
Latin America	—	2,185	2,185
Asia Pacific	—	929	929
<b>Total</b>	<b>17,307</b>	<b>23,171</b>	<b>40,478</b>

We collaborated with the majority of our pharmaceutical partners on a worldwide basis in 2016, 2017 and 2018. In addition, in cases where pharmaceutical partners are developing a new rare disease treatment, it is generally anticipated that the final approved treatment will be made available globally. As a result, revenues of pharmaceutical segment by geographical region are allocated by



**Notes to the consolidated financial statements of Centogene AG  
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## 7 Segment information (Continued)

reference to the location where each pharmaceutical partner mainly operates, which is based on the region from which most of their revenues are generated. The allocation of revenues in diagnostics segment is based on the location of each customer.

During the year ended December 31, 2018, revenues from one pharmaceutical partner represented 27% of the Group's total revenues (2017: 38%; 2016: 43%)

Non-current assets of the Group consist of property, plant and equipment, as well as intangible assets. All of such assets are located in Germany, which is the country of the incorporation of the Company, except for property, plant and equipment of EUR 718k (2017: EUR Nil), which is located in the United States.

## Notes to the consolidated statements of comprehensive income

### 8 Other income and expenses

#### 8.1 Other operating income

<u>in EUR k</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Government grants	787	637	1,611
Exchange rate gains	95	159	147
Income from the reversal of provisions	277	—	309
Others	136	247	239
<b>Total other operating income</b>	<b>1,295</b>	<b>1,043</b>	<b>2,306</b>

Government grants contain performance-based grants to subsidize research, development and innovation in the state of Mecklenburg-Western Pomerania from funds granted by the European Regional Development Fund. Furthermore, government grants contain the release of deferred income from investment related grants.

#### 8.2 Other operating expenses

<u>in EUR k</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Currency losses	—	84	250
Recognized impairments on trade receivables	625	367	792
Loss on sale of property, plant and equipment	6	—	—
Other	277	6	23
<b>Total other operating expenses</b>	<b>908</b>	<b>457</b>	<b>1,065</b>

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**8 Other income and expenses (Continued)**

**8.3 Financial costs, net**

<u>in EUR k</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Interest expenses from loans	(645)	(827)	(922)
Unwinding of the discount on lease liabilities	(184)	(194)	(153)
Change in measurement of interest derivatives	(27)	—	—
Interest income from loans and receivables	26	14	33
<b>Total</b>	<b>(830)</b>	<b>(1,007)</b>	<b>(1,042)</b>

**8.4 Employee benefits expense**

<u>in EUR k</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Wages and salaries	12,672	13,505	17,965
Social security contributions	1,941	2,144	2,492
Share-based payments	964	894	5,521
Termination benefits	26	35	56
<b>Total</b>	<b>15,603</b>	<b>16,578</b>	<b>26,034</b>

Social security contributions include contributions to state pension scheme of EUR 1,046k (2017: EUR 987k; 2016: EUR875k) as defined contribution plan expenses.

**9 Income taxes**

Taxes recognized through profit or loss

<u>in EUR k</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
<b>Current tax expenses</b>	<b>(35)</b>	<b>(23)</b>	<b>(87)</b>
Current year	(77)	(27)	(87)
Adjustments for prior periods	42	4	—
<b>Deferred tax income/(expense)</b>	<b>443</b>	<b>(9)</b>	<b>397</b>
Temporary differences	(368)	31	527
Tax losses	811	(22)	(130)
<b>Total income tax benefit/(expenses)</b>	<b>408</b>	<b>(14)</b>	<b>310</b>

No income taxes were recognized directly in other comprehensive income for the years ended December 31, 2018, 2017 and 2016.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**9 Income taxes (Continued)**

A reconciliation of the effective tax rate to the Group's statutory rate of 31.1% for each of the years ended December 31, 2016, 2017 and 2018 is presented in the table below.

in EUR k	2016	2017	2018
<b>Loss before tax</b>	<b>(5,767)</b>	<b>(5,462)</b>	<b>(11,648)</b>
Taxes on the basis of the Company's domestic tax rate	1,795	1,701	3,623
Tax rate effect of foreign tax jurisdictions	121	228	406
Non-deductible expenses	(69)	(78)	(105)
Current year losses for which no deferred tax assets were recognized	(1,482)	(1,842)	(3,528)
Tax income related to prior years	42	4	—
Other effects	1	(27)	(86)
<b>Income tax benefit/(expenses)</b>	<b>408</b>	<b>(14)</b>	<b>310</b>

The domestic tax rate of 31.1% is composed of the corporate income tax rate of 15%, the solidarity surcharge of 5.5% of this corporate income tax, as well as trade tax of 15.3%. The tax rate effects from foreign tax jurisdictions are primarily attributable to the tax-exempt profit of a Group subsidiary located in Dubai.

Tax losses carryforwards for which no deferred tax assets were recognized amount to EUR 21,728k in Germany (2017: EUR 9,994k; 2016: EUR 3,989k) and to EUR 788k in other countries (2017: EUR 790k; 2016: EUR 253k).

Tax losses carried forward in Germany do not expire. Foreign tax losses carried forward may be restricted. In the light of the Group's loss history, the recognition of deferred taxes for tax losses carried forward and deductible temporary differences was limited to the future reversal of existing taxable temporary differences.

For temporary differences associated with investments in the amount of EUR 3,049k (2017: EUR 1,791k; 2016: EUR 1,181k), no deferred tax liability has been recognized because the company is able to control the timing of the reversal and it is probable that the difference will not reverse in the foreseeable future.

**Notes to the consolidated financial statements of Centogene AG  
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**9 Income taxes (Continued)**

The below table shows a breakdown of deferred taxes in the Group's statement of financial position.

<b>in EUR k</b>	<b>December 31, 2017</b>		<b>December 31, 2018</b>	
	<b>Deferred tax assets</b>	<b>Deferred tax liabilities</b>	<b>Deferred tax assets</b>	<b>Deferred tax liabilities</b>
Intangible assets	—	(1,664)	—	(2,053)
Other assets (costs relating to anticipated initial public offering)	—	—	—	(807)
Measurement of service contracts	—	(108)	—	(125)
Share-based payments	468	—	2,208	—
Unused tax losses	907	—	777	—
Sum	<b>1,375</b>	<b>(1,772)</b>	<b>2,178</b>	<b>(2,985)</b>
Offset	(1,375)	1,375	(2,985)	2,985
<b>Deferred Taxes</b>	<b>—</b>	<b>(397)</b>	<b>—</b>	<b>—</b>

**10 Loss Per Share**

Basic loss per share is calculated by dividing loss for the period attributable to equity holders of Centogene AG by the weighted average number of shares outstanding during the period. Diluted loss per share is calculated by adjusting the weighted average number of shares outstanding for the dilutive effect of common shares equivalents outstanding during the period. Preferred shares are considered to be equivalent to common shares for the purposes of the calculated and diluted loss per share calculation. The weighted average number of outstanding shares are determined as the total of common and preferred shares (2018: 286,510; 2017: 245,318; 2016: 214,048).

Shares to be issued to participants under equity-settled share-based payment transactions are not reflected in diluted earnings per share since they would ultimately be antidilutive.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**Notes to the statements of financial position**

**Assets**

**11 Property, plant and equipment**

Please refer to the following table for the development from January 1, 2017 to December 31, 2018:

in EUR k	Land	Buildings	Plant	Other equipment, furniture and fixtures	Assets under construction	Total
<b>Acquisition and production cost</b>						
As of Jan 1, 2017	2,149	—	11,818	2,051	7,620	23,638
Additions	—	—	1,051	1,455	13,058	15,564
Disposals	—	—	—	(5)	—	(5)
<b>As of Dec 31, 2017</b>	<b>2,149</b>	<b>—</b>	<b>12,869</b>	<b>3,501</b>	<b>20,678</b>	<b>39,197</b>
Additions	—	—	3,142	1,154	4,414	8,710
Reclass	—	24,891	—	201	(25,092)	—
<b>As of Dec 31, 2018</b>	<b>2,149</b>	<b>24,891</b>	<b>16,011</b>	<b>4,856</b>	<b>—</b>	<b>47,907</b>
<b>Accumulated depreciation and impairment</b>						
As of Jan 1, 2017	—	—	2,417	958	—	3,375
Depreciation	—	—	1,672	313	—	1,985
<b>As of Dec 31, 2017</b>	<b>—</b>	<b>—</b>	<b>4,089</b>	<b>1,271</b>	<b>—</b>	<b>5,360</b>
Depreciation	—	612	2,089	731	—	3,432
<b>As of Dec 31, 2018</b>	<b>—</b>	<b>612</b>	<b>6,178</b>	<b>2,002</b>	<b>—</b>	<b>8,792</b>
<b>Carrying amounts</b>						
<b>As of Dec 31, 2017</b>	<b>2,149</b>	<b>—</b>	<b>8,780</b>	<b>2,230</b>	<b>20,678</b>	<b>33,837</b>
<b>As of Dec 31, 2018</b>	<b>2,149</b>	<b>24,279</b>	<b>9,833</b>	<b>2,854</b>	<b>—</b>	<b>39,115</b>

**Finance leases**

The Group leases production facilities and laboratory equipment under a number of finance lease agreements. The leased assets serve as collateral for the lease obligations (see note 18.2). As of December 31, 2018, the Group's net carrying amount of the leased plant and equipment was EUR 5,364k (2017: EUR 4,927k).

**Assets under construction**

The Group progressed and completed the construction of a new laboratory and headquarters in Rostock. Additions to assets under construction during the reporting period were EUR 4,414k (2017: EUR 13,058k) and assets under construction totaling EUR 25,092k were transferred to Plant and Buildings upon completion.

The Syndicated Loan Facility is secured by a land charge in the amount of EUR 19,910k and by the assignment of certain laboratory equipment (see note 18).

**Notes to the consolidated financial statements of Centogene AG  
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**12 Intangible assets**

Reconciliation of carrying amounts

in EUR k	Internally generated /acquired biomarkers	Internally developed database	Purchased rights, licenses, software	Total
<b>Acquisition and production cost</b>				
As of Jan 1, 2017	4,589	1,684	2,065	8,338
Additions	1,223	1,120	128	2,471
As of Dec 31, 2017	5,812	2,804	2,193	10,809
Additions	1,321	561	1,177	3,059
As of Dec 31, 2018	7,133	3,365	3,370	13,868
<b>Accumulated amortization and impairment</b>				
As of Jan 1, 2017	1,125	226	726	2,077
Amortization	657	307	288	1,252
As of Dec 31, 2017	1,782	533	1,014	3,329
Amortization	878	513	352	1,743
As of Dec 31, 2018	2,660	1,047	1,366	5,073
<b>Carrying amounts</b>				
As of Dec 31, 2017	4,030	2,271	1,179	7,480
As of Dec 31, 2018	4,473	2,318	2,004	8,795

**Development costs and amortization**

Internally generated intangible assets include capitalized development costs for biomarkers and IT driven solutions like CentoPortal and the CentoMD mutation database (see notes 5 and 6 regarding recognition and measurement).

The amortization of patents, trademarks and development costs is expensed and recorded under "cost of sales" to the extent the related intangible is used in generating revenue and recorded in research and development expenses to the extent the related intangibles are used for R&D purposes.

**13 Inventories**

in EUR k	Dec 31, 2017	Dec 31, 2018
Raw materials, consumables and supplies	704	1,323
Finished goods and merchandise	75	23
<b>Inventories</b>	<b>779</b>	<b>1,346</b>

**Notes to the consolidated financial statements of Centogene AG  
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**13 Inventories (Continued)**

In the year ended December 31, 2018, raw materials, consumables and changes in inventories of finished goods and work in process recorded as expenses under "cost of sales" amounted to EUR 9,473k (2017: EUR 6,588k; 2016: EUR 6,368k).

**14 Trade and other receivables and other assets**

<u>in EUR k</u>	<u>Dec 31, 2017</u>	<u>Dec 31, 2018</u>
<b>Non-current</b>		
Receivables against shareholders	729	—
	<b>729</b>	<b>—</b>
<b>Current</b>		
Trade receivables	4,580	8,572
Contract assets/ Service contracts not yet invoiced	2,412	2,329
Receivables due from shareholders	—	2,170
Other assets	2,512	5,125
	<b>9,504</b>	<b>18,196</b>

Trade receivables are non-interest bearing and are generally due in 30 to 90 days. In general, portfolio-based bad debt allowances are recognized on trade receivables (see note 20.2).

The Group's trade receivables and contract assets were designated as collateral in respect of existing Loan agreements (see note 18).

**Other assets**

Other assets include VAT receivables of EUR 1,317k (2017: EUR 1,372k), prepaid expenses of EUR 476k (2017: EUR 603k) as well as receivables from grants of EUR 489k (2017: EUR 335k). Other assets also include costs relating to anticipated initial public offering of EUR 2,591k (2017: EUR Nil).

**15 Cash and short-term deposits**

The Group has pledged a part of its short-term deposits to fulfil collateral requirements related to its overdraft facility currently used up to EUR 2.5 million. See note 18 for further details. The restriction applying to the collateral in the amount of EUR 1.5 million may be terminated at any time subject to the full amount of the overdraft being repaid.

**Notes to the consolidated financial statements of Centogene AG  
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**Equity and liabilities****16 Equity****Issued capital and capital reserve**

The authorized but unissued ordinary share capital as at December 31, 2018 and 2017 amounted to EUR 29,750 and EUR nil respectively. The authorized but unissued preferred share capital as at December 31, 2018 and 2017 amounted to EUR nil and EUR 34,010 respectively.

<u>in thousands of shares</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Common shares issued as of Jan 1	212	216	230
Issued against cash contributions	4	14	0
Common shares issued as of Dec 31	216	230	230

<u>in thousands of shares</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Preferred A shares issued as of Jan 1	0	0	32
Issued against cash contributions	0	32	60
Preferred shares issued as of Dec 31	0	32	92

<u>in thousands of shares</u>	<u>as of Dec 31, 2017</u>	<u>as of Dec 31, 2018</u>
Ordinary shares of EUR 1.00 each	0	30
Preferred A shares of EUR 1.00 each	34	—
<b>Authorized Capital</b>	<b>34</b>	<b>30</b>

**Common shares**

The holders of common shares are entitled to the Company's approved dividends and have one voting right per share at the Company's annual general meetings. The Group does not hold any treasury shares.

**Preferred A shares**

The Company has issued preferred shares to investors to fund its development activities. The preferred shares each have one voting right per share and do not contain a redemption feature or a contractual right to fixed dividends. The preferred shareholders are entitled to a disproportionate share of the net assets of the Company in case of certain "exit events", which are further disclosed in note 19.

**Issuance of shares**

In the extraordinary shareholders meeting of December 23, 2016, a resolution was passed to increase the Company's existing authorized share capital of EUR 215,597 (the "Authorized Capital 2015") by an additional EUR 14,286 to EUR 229,883. The recording of the capital increase into the register of the Chamber of Commerce took place at January 25, 2017.

On June 1, 2017, the management board resolved, with the approval of the supervisory board, to increase share capital by an additional 312 shares to 230,195 shares (the "Authorized Capital 2017") from the Authorized Capital 2015. The recording of the capital increase into the register of the Chamber of Commerce took place on June 2, 2017.



**Notes to the consolidated financial statements of Centogene AG  
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**16 Equity (Continued)**

In the annual shareholders meeting of June 9, 2017, a resolution was passed to issue 31,390 Preferred A shares to increase the share capital by EUR 31,390. In addition, the existing Authorized Capital 2015 was terminated in full and new Authorized Capital 2017 was resolved, allowing the Group to issue a further EUR 34,010 Preferred A shares in the future. The recording of the termination of the Authorized Capital 2015 and the capital increase into the register of the Chamber of Commerce took place on July 3, 2017.

By decisions taken on April 24, 2018 and on May 3, 2018, the Management Board, with the approval of the Supervisory Board, resolved to issue 34,010 Preferred A shares from the Authorized Capital 2017 to increase the overall share capital by EUR 34,010 to EUR 295,595. The share capital increase was entered into the commercial register of the local court of Rostock on May 22, 2018.

By a decision of the main shareholders' meeting on April 24, 2018, new capital in an amount 30,000 common shares at a nominal value of EUR 30,000 was authorized (the "Authorized Capital 2018") and entered into the commercial register of the local court of Rostock also on May 22, 2018. The Authorized Capital 2018 can be issued by a resolution of the Management Board with approval of the Supervisory Board under certain circumstances to members of the Management Board and to the management of the Company's subsidiaries.

By a decision taken on June 27, 2018, the Management Board, with the approval of the Supervisory Board, resolved to issue 250 common shares from the Authorized Capital 2018 to increase the overall share capital by EUR 250 to EUR 295,845. The share capital increase was entered into the commercial register of the local court of Rostock on July 23, 2018.

By a decision of the main shareholders' meeting on October 8, 2018, the Company issued 26,162 new Preferred A shares in a nominal value of EUR 26,162 to increase the overall share capital to EUR 322,007. The capital increase was entered into the commercial register of the local court of Rostock on November 7, 2018.

**Capital reserve**

In 2018, a share premium of EUR 20,013k was received (2017: EUR 19,404k) from the capital increases described above.

The capital reserve consists of the share premium account and amounts recorded in respect of share-based payments. For additional information on the share-based payments, please refer to note 19.

**17 Capital management**

The Group's objective is to maintain a strong capital base in order to ensure the Group's sustainable development. In particular, care is taken to ensure that the advantages of financing growth through debt capital are in balance with the Group's equity base.

The Group monitors the deployment of capital, especially with respect to the investment calculation, timing and amount of returns. During the years ended December 31, 2016, 2017 and

**Notes to the consolidated financial statements of Centogene AG  
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**17 Capital management (Continued)**

2018, the Group largely deployed debt capital for investments with an return on investments of 1-2 years as well as for the development of a company building in Rostock.

In addition, the Group also monitors its short-term solvency and the compliance of covenants to ensure that the Group can operate on a going concern basis.

**18 Financial liabilities****18.1 Interest-bearing loans**

in EUR k	<u>Dec 31, 2017</u>	<u>Dec 31, 2018</u>
<b>Non-current liabilities</b>		
Non-current portion of secured bank loans	—	12,055
Municipal loans	2,000	860
<b>Total non-current loans</b>	<b>2,000</b>	<b>12,915</b>
Finance lease liabilities	1,851	1,712
<b>Total non-current liabilities</b>	<b>3,851</b>	<b>14,627</b>
<b>Current liabilities</b>		
Current portion of secured bank loans	13,837	1,787
Bank overdrafts	—	1,915
<b>Total current loans</b>	<b>13,837</b>	<b>3,702</b>
Current portion of liabilities from finance leases	1,653	1,350
<b>Total current liabilities</b>	<b>15,490</b>	<b>5,052</b>
<b>Total non-current and current liabilities</b>	<b>19,341</b>	<b>19,679</b>

Financial covenants apply to secured bank loans which stipulate quarterly targets for the company's solvency ratio and net debt ratio as well as covenants related to revenue and EBITDA for the year ended December 31, 2017. During the year ended December 31, 2017, these covenants were not met by the Group, which would permit the lenders to require repayment of the loans. The Group obtained waivers from the lenders for breaches of such financial covenants in the year ended December 31, 2017. Since the formal written waiver was received from the lenders on April 6, 2018 in respect of the year ended December 31, 2017, the secured bank loans were respectively disclosed as current liabilities. Considering the formal written waiver, the Group did not breach any covenants in 2018 and as a result the secured bank loans were disclosed as current and non-current liabilities based on the contractual maturity of such loans.

**Notes to the consolidated financial statements of Centogene AG  
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**18 Financial liabilities (Continued)**
**Conditions and statement of liabilities**

The outstanding loans as of December 31, 2018 have the following conditions:

in EUR k	Currency	Nominal interest rate	Maturity	Dec 31, 2017		Dec 31, 2018	
				Nominal amount	Carrying amount	Nominal amount	Carrying amount
Secured bank loan	EUR	3.50%	2016 - 19	18	18	6	6
Secured bank loan	EUR	2.50%	2017 - 25	5,129	5,129	5,633	5,633
Secured bank loan	EUR	2.50%	2017 - 25	6,469	6,469	5,633	5,633
Secured bank loan	EUR	2.50%	2017 - 25	2,060	2,060	2,570	2,570
Secured bank loan	EUR	12.63%	Rollover	4	4	—	—
Secured bank loan	EUR	6.25%	Rollover	157	157	—	—
Finance lease liabilities	EUR	5.4% - 8.9%	2017 - 23	3,504	3,504	3,062	3,062
Municipal loan	EUR	8.25%; plus 1.5% profit-related; 0.75% on losses	2021	500	500	500	500
Municipal loan	EUR	6.5%; plus 1.5% profit-related; 0.75% on losses	2021	140	140	—	—
Municipal loan	EUR	8%; plus 1.5% profit-related; 0.75% on losses	2022	360	360	360	360
Municipal loan	EUR	7.49%; plus 2.0% profit-related; 1.50% on losses	2023	1,000	1,000	—	—
Bank overdrafts	EUR	4.46%	Rollover	—	—	—	—
Bank overdrafts	EUR	3.75%	Rollover	—	—	1,915	1,915
Bank overdrafts	EUR	3.59%	Rollover	—	—	—	—
Bank overdrafts	EUR	6.25%	Rollover	—	—	—	—
<b>Total interest-bearing financial liabilities</b>				<b>19,341</b>	<b>19,341</b>	<b>19,679</b>	<b>19,679</b>

The secured bank loans are secured by trade and other receivables, including contract assets, with a carrying amount of EUR 10,901k (2017: EUR 7,589k) (see note 14) as well as certain property, plant and equipment (see note 11).

The bank overdrafts of EUR 1,915k as of December 31, 2018 were secured by short-term deposits with a carrying amount of EUR 1,500k (2017: EUR Nil) (see note 15).

The municipal loan due to MBMV (Mittelständische Bürgschaftsbank Mecklenburg-Vorpommern) of EUR 860k (2017: EUR 2,000k) with a remaining term between 4-6 years and an interest rate of 8.25%/8% is secured by guarantees provided by the Group's shareholders.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**18 Financial liabilities (Continued)**
**18.2 Finance lease liabilities**

Liabilities from finance leases have the following maturities:

in EUR k	Future minimum lease payments		Interest payments	
	Dec 31, 2017	Dec 31, 2018	Dec 31, 2017	Dec 31, 2018
Less than one year	1,653	1,350	124	104
Between one and five years	1,851	1,712	228	76

In 2018, the Group has entered into new financial leases for various equipment amounting to EUR 1,534k (2017: nil).

**18.3 Reconciliation of liabilities arising from financing activities**

in EUR k	Jan 1, 2018	Cash flows	Non-cash changes				Dec 31, 2018
			Currency changes	Additions	Fair value changes	Changes in maturity	
<b>Long-term financial liabilities</b>	<b>3,851</b>	<b>(1,373)</b>	—	<b>856</b>	—	<b>11,293</b>	<b>14,627</b>
Long-term bank loans	2,000	(1,140)	—	—	—	12,055	12,915
Long-term financial leases	1,851	(233)	—	856	—	(762)	1,712
<b>Current financial liabilities</b>	<b>15,490</b>	<b>267</b>	—	<b>588</b>	—	<b>(11,293)</b>	<b>5,052</b>
Current bank loans	13,837	1,920	—	—	—	(12,055)	3,702
Current financial leases	1,653	(1,653)	—	588	—	762	1,350
<b>Total</b>	<b>19,341</b>	<b>(1,106)</b>	—	<b>1,444</b>	—	—	<b>19,679</b>

**18.4 Trade payables and other liabilities**

in EUR k	Dec 31, 2017	Dec 31, 2018
Trade payables	5,289	5,429
Government grants (deferred income)	9,866	12,034
Liability for Virtual Stock Option Program	1,572	7,093
Deferred income	680	297
Amounts to be refunded to customers	58	111
Others	1,929	5,507
<b>Trade payables and other liabilities</b>	<b>19,394</b>	<b>30,471</b>
Non-current	11,076	11,240
Current	8,318	19,231

The investment-related government grants were received for the purchase of certain items of property, plant and equipment for the research and development facilities in Mecklenburg-Western Pomerania, including the Rostock facility. The grants were issued in the form of investment subsidies as part of the joint federal and state program, "Verbesserung der regionalen Wirtschaftsstruktur" (improvement of the regional economic structure) in connection with funds from the European Regional Development Fund. The amount received in 2018 during the year amounted to EUR 3,042k (2017: EUR 6,802k).

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**18 Financial liabilities (Continued)**

In addition, other liabilities include personnel-related liabilities for vacation and bonuses totaling EUR 1,955k (2017: EUR 1,046k) as well as liabilities for wage and church tax of EUR 307k (2017: EUR 228k). Other liabilities also include costs relating to anticipated initial public offering of EUR 1,695k (2017: EUR Nil).

**19 Share-based payments**

At December 31, 2018, the Group had the following share-based payment arrangements.

**(i) Virtual share option program 2016 (Cash-settled)**

On July 1, 2016, the Group established a virtual share option program ("2016 VSOP") that entitles the management board to grant virtual share options to individuals, in regard to services they provide and their continuous commitment to the Company. The 2016 VSOP allows the management board to grant up to 1,000,000 virtual options, representing 5% of the original 205,000 shares which are issued and owned by the original shareholders. The share options are subject to service conditions. Options that are not vested shall vest immediately in full upon an exit event. Under this program, holders of vested options are entitled to receive a direct cash payment from the Company, which is determined based on the exit price of the Company's shares, upon the occurrence of any one of the following events ("Exit event"):

- § The completion of an Initial Public Offering ("IPO")
- § The consummation of a sale and transfer of at least 75% of all existing shares of the Company by the existing shareholders to one or more purchasers, and whereby at least 50% of the consideration will be paid to shareholders in cash
- § The consummation of a sale and transfer of at least 75% of all existing shares of the Company by the existing shareholders to one or more purchasers, and whereby the total consideration paid to the shareholders consists of shares in the purchasers

The payment to the option holders will then be reimbursed by the original shareholders to the Company at the same time as the obligation to pay the options holders arises. A respective receivable against shareholders was recorded (see note 14). As this is a shareholder transaction, the respective receivable against shareholders was recorded against equity (capital reserve).

	2017		2018	
	Number	WAEP	Number	WAEP
Outstanding at January 1	842,283	3.36	802,283	3.22
Forfeited during the year	(40,000)	6.15	—	—
<b>Outstanding at December 31</b>	<b>802,283</b>	<b>3.22</b>	<b>802,283</b>	<b>3.22</b>
Vested at December 31	648,283	3.45	756,083	3.30
Exercisable at December 31	—	—	—	—

The weighted average remaining contractual life for the share options outstanding as at December 31, 2018 was seven years (2017: eight years).

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**19 Share-based payments (Continued)**

The weighted average fair value of options outstanding as of December 31, 2018 was €2.74 (2017: EUR 1.2). The range of exercise prices for options outstanding as of December 31, 2018 was EUR 1.0 to EUR 6.1 (2017: EUR 1.0 to EUR 6.1).

The intrinsic value of the options vested as of December 31, 2018 was EUR 2,169k (2017: EUR 1,316k).

**(ii) Virtual share option program 2017 (Cash-settled)**

In 2017, the Group established an additional virtual share option program ("2017 VSOP") that entitles the management board to grant virtual share options to individuals, in regard to services they provide and their continuous commitment to the Company. The 2017 VSOP allows the management board to grant up to 46,539 virtual options, representing approximately 5% of the total shares which are issued and anticipated to be issued after additional investment by the investors. Under this program, holders of vested options are entitled to receive a direct cash payment from the Company, which is determined based on the exit price of the Company's shares, upon the occurrence of any of the Exit events as defined above for the virtual share option program 2016. The vesting period shall be three years commencing on the day of grant, where one-third of the granted options shall be vested at the end of each year of grant. Upon an exit event, the vesting of any unvested awards will be accelerated.

	2017		2018	
	Number	WAEP	Number	WAEP
Outstanding at January 1	—	—	4,318	1.0
Granted during the year	4,318	1.0	6,178	1.0
Outstanding at December 31	<b>4,318</b>	<b>1.0</b>	<b>10,496</b>	<b>1.0</b>
Vested at December 31	<b>1,478</b>	<b>1.0</b>	<b>5,040</b>	<b>1.0</b>
Exercisable at December 31	—	—	—	—

The weighted average remaining contractual life for the share options outstanding as at December 31, 2018 was eight years (2017: nine years).

The weighted average fair value of options outstanding as of December 31, 2018 was EUR 540.3 (2017: EUR 354.8). The exercise price for options outstanding as of December 31, 2018 was EUR 1 (2017: EUR 1).

The intrinsic value of the options vested as of December 31, 2018 was EUR 2,722k (2017: EUR 377k).

**(iii) Equity share option 2017 (Equity-settled)**

In 2017, an agreement was entered between certain shareholders and an individual of the key management. According to which, a total of 2,500 options, each option representing one common share, have been granted to the individual employee at a price of EUR 400 per option. Upon the exercise of the options at one of the Exit events defined above, the individual employee will pay the exercise price to the shareholders in exchange for the ownership of common shares of the

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**19 Share-based payments (Continued)**

Company. As the agreement was entered with the member of management for his commitment and services provided to the Company, the share options were considered as a share-based payment under IFRS 2. The options vested at the time they were granted in 2017.

No equity-settled share options were granted or forfeited in 2018.

**Valuation of Options**

The fair values of both the virtual options and the equity share options have been calculated based on the enterprise value of the Company, which is determined by discounting the future cash flows to be generated by the Company, and using the Black-Scholes option pricing model.

The key assumptions used in estimating the Company's share price, which is a key input into the option pricing model used, are set out below. The values assigned to the key assumptions represent management's assessment of future trends in the relevant industries and have been based on historical data from both external and internal sources.

The cash flow projections include specific estimates for ten years and a terminal growth rate thereafter.

<b>in percent</b>	<b>2017</b>	<b>2018</b>
Discount rate (%)	15.0	15.0
Terminal value growth rate (%)	2.0	2.0

The discount rate was a post-tax measure estimated based on the historical industry average weighted average cost of capital, with a possible debt leveraging of 5% (2017: 5%) at a market interest rate of 5% (2017: 6%).

The key assumptions used to derive the option value are set out below:

	<b>2017</b>	<b>2018</b>
Volatility (%)	60	70
Risk-free interest rate (%)	(0.7)	(0.8)
Dividend yield (%)	0	0
Option term (years)	1.8	0.4

Exit events were reflected in measurement based on the likelihood of their occurrence.

	<b>2017</b>	<b>2018</b>
Expenses arising from equity-settled share-based payment transactions	286	—
Expenses arising from cash-settled share-based payment transactions	608	5,521
<b>Total expenses arising from share-based payment transactions</b>	<b>894</b>	<b>5,521</b>

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**Financial instruments**

**20 Financial instruments—fair values and risk management**

**20.1 Classifications and fair values**

The carrying values of the Group's financial assets and financial liabilities approximate their fair value.

**20.2 Financial risk management**

The Group is exposed to the following risks from the use of financial instruments:

- § *Credit risk*
- § *Liquidity risk*
- § *Currency risk*

***Credit risk***

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. Default risk generally arises from trade and other receivables, as well as deposits with banks.

The carrying amount of the financial assets corresponds to the maximum default risk.

***Trade and other receivables***

The Group utilizes a receivables management system that closely manages open items of major customers. The Group's customers in the pharmaceutical segment are mainly pharmaceutical companies which are usually listed companies, or strongly financed by private equity funds. The Group's customers in the diagnostics segment are mainly hospitals, labs and physicians, of which more than 60% of the customers have had business relationships with the Group for more than three years. To avoid default, the Company may request prepayment for new business with physicians.

In addition to the macroeconomic situation generally, the development of international healthcare markets is a key economic factor in assessing the default risk related to trade and other receivables. These markets are closely monitored by the Group.

An impairment analysis is performed at each reporting date using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns (i.e. by customers from different segment; customers from different geographical region and customer type). The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions. The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in note 14. The Group does not hold collateral as security and does not request letters of credit or other forms of credit insurance. The Group evaluates the concentration of risk with respect to trade receivables and contract assets and recorded credit losses reflecting the expected lifetime loss, based on different type of customers.



**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**20 Financial instruments—fair values and risk management (Continued)**

Considering the major exposure to the credit risk arising from the diagnostics segment, the Group focused its impairment analysis on the trade receivables due from customers in the diagnostic segment, in particularly the MENA and Europe regions as they represent the majority of that segment's revenue. In addition to applying the provision matrix, the Group performed an individual customer analysis on major debtors, with reference to the past history (such as sales and collection in the previous periods) and the assessment of their current financial condition and other relevant factors and evaluate if additional specific impairment losses would be necessary.

Set out below is the information regarding the credit risk exposure of the Group's trade receivables and contract assets using a provision matrix

As of December 31, 2017					
in EUR k	Total Gross amount	Not past due	Past due 1 to 30 day	Past due 31-90 days	Past due by more than 90 days
Middle East	3,560	1,065	574	997	924
Europe	1,453	650	441	87	275
Latin America	318	239	27	20	32
North America	1,585	1,313	135	56	81
Other regions	917	905	2	10	—
<b>Total</b>	<b>7,833</b>	<b>4,172</b>	<b>1,179</b>	<b>1,170</b>	<b>1,312</b>

As of December 31, 2018					
in EUR k	Total Gross amount	Not past due	Past due 1 to 30 day	Past due 31-90 days	Past due by more than 90 days
Middle East	7,766	3,065	401	1,560	2,740
Europe	2,900	2,052	356	240	252
Latin America	604	415	81	74	34
North America	1,074	728	230	79	37
Other regions	190	175	10	—	5
<b>Total</b>	<b>12,534</b>	<b>6,435</b>	<b>1,078</b>	<b>1,953</b>	<b>3,068</b>
<b>Expected credit loss rate</b>	<b>13.0%</b>	<b>0.1%</b>	<b>0.5%</b>	<b>2%</b>	<b>51.6%</b>
<b>Expected credit loss</b>	<b>1,633</b>	<b>6</b>	<b>5</b>	<b>39</b>	<b>1,583</b>

The development of impairment losses relating to trade and other receivables during the year was as follows.

in EUR k	Specific bad debt allowances	Collective impairment losses
<b>As of Jan 1, 2017</b>	<b>626</b>	<b>80</b>
Recognized impairment	367	—
Utilized	(152)	(80)
<b>As of Jan 1, 2018</b>	<b>841</b>	<b>—</b>
Recognized impairment	692	100
<b>As of Dec 31, 2018</b>	<b>1,533</b>	<b>100</b>

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**20 Financial instruments—fair values and risk management (Continued)**

***Cash and cash equivalents***

As of December 31, 2018, the Group held cash and cash equivalents of EUR 9,222k (2017: EUR 3,157k). This total, therefore, also represents the maximum default risk with regard to these assets. The cash and cash equivalents are deposited at banks or financial institutions that have a rating of BAA to AA.

***Liquidity risk***

The liquidity risk is the risk of the Group possibly not being in a position to meet its financial liabilities as contractually agreed by providing cash or other financial assets. Managing liquidity within the Group is intended to ensure that—as far as possible—sufficient cash and cash equivalents are always available to meet payment obligations when these fall due, in both normal and challenging conditions, without incurring unacceptable losses or damaging the Group's reputation.

The Group strives to maintain cash and cash equivalents at a level above that of the expected cash outflows for financial liabilities (apart from trade payables) during the next 60 days. Approximately 25.6% of the Group's interest-bearing loans will mature in less than one year at December 31, 2018 (2017: 80.1%) based on the carrying value of borrowings reflected in the financial statements. The Group assessed the concentration of risk and concluded it to be low.

The Group has access to a sufficient variety of sources of funding, including the amount of expected cash inflows from trade and other receivables. As of December 31, 2018, the expected cash flows from trade and other receivables due within two months amounts to EUR 3,830k (2017: EUR 2,515k), which was less than the amount of trade payables due within two months as of December 31, 2018 of each year (refer to table below). In addition, the Group has secured credit lines for a total amount of EUR 4,000k. These bear interest of 3.33% - 4.50% (2017: EUR 4,000k; 3.33% - 4.50%). EUR 1,915k were utilized as of December 31, 2018 (2017: EUR Nil).

The table below presents the residual contractual terms of the financial liabilities on the reporting date, including estimated interest payments. For 2017, it was prepared considering that waivers in respect to the covenant breaches have been received (refer to note 18.1). The figures are undiscounted gross amounts, including estimated interest payments and interest on undrawn loan funds, but without showing the impact of offsetting.

Dec 31, 2017 in EUR k	Carrying amount	Contractually agreed cash flows				
		Total	Less than 2 months	2 to 12 months	1 to 5 years	More than 5 years
Secured bank loans	13,836	16,436	261	1,482	6,382	8,311
Finance lease liabilities	3,504	3,504	207	827	2,470	—
Municipal Loans	2,000	2,903	—	156	626	2,121
Trade payables	5,289	5,289	3,510	1,779	—	—
	<b>24,629</b>	<b>28,132</b>	<b>3,978</b>	<b>4,244</b>	<b>9,478</b>	<b>10,432</b>

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**20 Financial instruments—fair values and risk management (Continued)**

Dec 31, 2018 in EUR k	Carrying amount	Contractually agreed cash flows				
		Total	Less than 2 months	2 to 12 months	1 to 5 years	More than 5 years
Bank overdrafts	1,915	1,915	1,915	—	—	—
Secured bank loans	13,842	15,985	236	1,965	5,808	7,976
Finance lease liabilities	3,062	3,234	239	1,196	1,799	—
Municipal Loans	860	1,273	—	—	—	1,273
Trade payables	5,429	5,429	3,920	1,509	—	—
	<b>25,108</b>	<b>27,836</b>	<b>6,310</b>	<b>4,670</b>	<b>7,607</b>	<b>9,249</b>

**Currency risk**

The Group is exposed to currency risk in cases where contracts are concluded in foreign currencies. The vast majority of goods delivered and services the Company provided, including those for international customers, are invoiced in euro.

The main functional currencies of group companies are the euro, USD, the Canadian dollar, the Indian rupee and the Arab Emirates Dirham'. The following table presents the net foreign currency exposure of the Group as at December 31, 2017 and 2018.

in EUR k	Dec 31, 2017			
	USD	CAD	INR	AED
Trade receivables	711	70	—	16
Trade payables and other liabilities	-75	—	—	—
<b>Net exposure</b>	<b>636</b>	<b>70</b>	<b>—</b>	<b>16</b>

in EUR k	Dec 31, 2018			
	USD	CAD	INR	AED
Trade receivables	1,674	26	65	4
Trade payables and other liabilities	-2,193	-13	-2	-5
<b>Net exposure</b>	<b>-519</b>	<b>13</b>	<b>63</b>	<b>-1</b>

**Sensitivity analysis relating to changes in exchange rates:**

Given the exposure to foreign currencies as above, the impact to the Group's earnings before tax or equity from a 10% change in the US dollar and the Canadian dollar exchange rates would not be material.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

## 21 List of subsidiaries

The major subsidiaries of the Group are listed below.

Name	Country in which primary activities are pursued	Equity interests (%)	
		Dec 31, 2017	Dec 31, 2018
Centogene IP GmbH	Germany	100	100
Centogene Shared Service GmbH	Germany	100	100
Centogene Fzllc, Dubai	Dubai	100	100
Ludewig Wasserbau GmbH	Germany	100	100
Centogene US LLC, Burlington, USA	USA	100	100
Centogene GmbH, Vienna	Austria	90	90
Centogene India Pvt. Ltd	India	51	51
LPC GmbH	Germany	51	51

## 22 Non-controlling interests

The table below shows information on each subsidiary of the Group with material, non-controlling interests before intercompany eliminations.

Dec 31, 2018 in EUR k	Centogene India Pvt. Ltd	LPC GmbH
	49%	49%
Net assets/(liabilities)	(951)	(490)
Carrying amount of non-controlling interests	(466)	(240)
Revenue	722	67
Profit/(loss)	(445)	(158)
Profit/(loss) allocated to non-controlling interests	(218)	(77)

## 23 Operating leases

### *Leases—the Group as lessee*

The Group leases various items of office equipment under operating leases, as well as the office in Berlin, Germany. Most of these leases will have expired by year 2020, and at the end of this period include an option to extend the lease or acquire the equipment.

### *Future minimum lease payments*

As of December 31, the future minimum lease payments of non-cancelable operating leases are payable as follows:

	2017	2018
Less than one year	192	197
Between one and five years	336	55

### *Amounts recognized in profit or loss*

in EUR k	2017	2018
Lease expense	246	311

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

## 24 Future payment obligations

During 2018, the Group concluded agreements with suppliers, for goods and services to be provided in 2019 with a total payment obligation of around EUR 1,013k (2017: EUR 1,049k).

## 25 Related parties

Centogene had transactions with related parties in the reporting period in the ordinary course of business.

The Group considers its related parties to be key management personnel and the following shareholders, along with entities controlled by, jointly controlled or under significant influence from such shareholders:

	<u>Dec 31, 2018</u>
Centogene Pooling UG & Co. KG	42.44%
Michael Schlenk	5.19%
CM-CIC Investissement SCR	3.09%
Deutsche Private Equity	19.94%
Careventures	7.68%
TVM Life Science Venture VII L.P.	6.70%
<b>Total</b>	<b>85.04%</b>

Shareholders with smaller interests are considered related due to their representation on the supervisory board.

Based on a shareholder agreement from January 2016 the payment to the option holders of the VSOP 2016 will be reimbursed by the original shareholders to the Company at the same time when the obligation to the options holders is settled. A respective receivable against shareholders was recorded (refer to note 14). The shareholder agreement has a term till December 31, 2023.

### **Transactions with members of management in key positions**

#### *Remuneration of members of key management*

<u>in EUR k</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Short-term employee benefits	1,483	1,843	2,354
Post-employment pension and medical benefits	10	10	10
Share-based payment transactions	744	530	2,893
<b>Total compensation paid to key management</b>	<b>2,237</b>	<b>2,383</b>	<b>5,257</b>

There are no pension commitments for members of the management board.

The supervisory board received remuneration for its activities of EUR 341k in the reporting year (2017: EUR 160k; 2016: EUR 160k).

Furthermore remuneration of EUR 64k (2017: EUR 490k; 2016: EUR 1,242k) was provided to an entity controlled by key management personnel in respect of consulting services.

**Notes to the consolidated financial statements of Centogene AG  
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

**25 Related parties (Continued)**

The management board and supervisory board hold either directly or indirectly the following shares:

	<u>2017</u>	<u>2018</u>
	Number of shares (%)	Number of shares (%)
Shares management board and supervisory board	230,572 (88%)	270,148 (84%)

**26 Contingent liabilities**

In May 2016, the Company was informed in writing by the Universitair Medisch Centrum Utrecht ("UMCU") that a claim had been initiated against UMCU regarding a prenatal diagnostic test that the Company conducted at their request which failed to identify a specific mutation present in a patient. On November 8, 2018, the UMCU and Neon Underwriting Limited formally filed a legal claim in the local court in Rostock, Germany against the Company alleging that the Company's negligence in performing the test resulted in the misdiagnosis of the patient. UMCU is seeking recovery for compensatory damages as a result of the alleged misdiagnosis. By court order of November 8, 2018 the Regional Court of Rostock set the amount in dispute at EUR 880 k.

The Company intends to rigorously defend its position and considers that it is not probable the legal claim towards the Company will be successful and as a result has not recognized a provision for this claim as of December 31, 2018. In addition, in case a settlement would be required, the Company believes that the corresponding liability will be fully covered by the respective insurance coverage.

These consolidated financial statements were approved by management on March 28, 2019.

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Shares

CENTOGENE

CENTOGENE B.V.

Common Shares

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PRELIMINARY PROSPECTUS

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**Cowen**

**Baird**

**Evercore ISI**

**BTIG**

, 2019

Through and including , 2019 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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## PART II

### INFORMATION NOT REQUIRED IN THE PROSPECTUS

#### Item 6. Indemnification of Members of the Management Board and Supervisory Board.

Under Dutch law, members of our management board and members of our supervisory board may be held liable by the registrant for damages in the event of improper or negligent performance of their duties. They may be jointly and severally liable for damages to the registrant and third parties for infringement of our articles of association or certain provisions of Dutch law. In certain circumstances, they may also incur additional specific civil and criminal liabilities.

The liability of members of our management board and members of our supervisory board and other key employees will be covered by a directors' and officers' liability insurance policy. This policy will contain customary limitations and exclusions, such as willful misconduct or intentional recklessness (*opzet of bewuste roekeloosheid*).

Our current and former managing directors and supervisory directors (and such other current or former officer or employee as designated by the management board) have the benefit of the following indemnification provisions in our articles of association:

Indemnified persons shall be reimbursed for:

- a. any financial losses or damages incurred by such indemnified person; and
- b. any expense reasonably paid or incurred by such indemnified person in connection with any threatened, pending or completed suit, claim, action or legal proceedings of a civil, criminal, administrative or other nature, formal or informal, in which he becomes involved, in each case to the extent this relates to his current or former position with the company and/or a group company and in each case to the extent permitted by applicable law.

No indemnification shall be given to an indemnified person:

- a. if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such indemnified person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above are of an unlawful nature (including acts or omissions, which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such indemnified person);
- b. to the extent that his financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);
- c. in relation to proceedings brought by such indemnified person against the company, except for proceedings brought to enforce indemnification to which he is entitled pursuant to our articles of association, pursuant to an agreement between such indemnified person and the company, which has been approved by the management board or pursuant to insurance taken out by the company for the benefit of such indemnified person;



d. for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without the company's prior consent.

Under our articles of association, our management board may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

#### **Item 7. Recent Sales of Unregistered Securities.**

Set forth below are the sales of all securities sold by the registrant within the past three years (i.e., since January 1, 2015 up to the date of this registration statement) which were not registered under the Securities Act:

As registered in the commercial register on June 30, 2017, Centogene AG issued 31,390 Series A preferred shares. In addition to the nominal value of the shares (€31,390), the shareholders made cash contributions into the Company's capital reserves of €15 million.

As registered in the commercial register on May 22, 2018, Centogene AG issued an additional 34,010 Series A preferred shares. In addition to the nominal value of the shares (€34,010), the shareholders made cash contributions into the Company's capital reserves of €10 million.

As registered in the commercial register on November 7, 2018, Centogene AG issued an additional 26,162 Series A preferred shares. In addition to the nominal value of the shares (€26,162), the shareholders made cash contributions into the Company's capital reserves of €10 million.

As registered in the commercial register on January 19, 2015, Centogene AG issued 5,000 common shares. In addition to the nominal value of the shares (€5,000), the shareholders made cash contributions into the Company's capital reserves of €28,000.

As registered in the commercial register on June 10, 2015, Centogene AG issued 7,000 common shares. In addition to the nominal value of the shares (€7,000), the shareholders made cash contributions into the Company's capital reserves of €2,043,000.

As registered in the commercial register on September 27, 2015, Centogene AG issued 220 common shares. In addition to the nominal value of the shares (€220), the shareholders made cash contributions into the Company's capital reserves of €131,780.

As registered in the commercial register on March 14, 2016, Centogene AG issued 500 common shares. In addition to the nominal value of the shares (€500), the shareholders made cash contributions into the Company's capital reserves of €199,500.

As registered in the commercial register on July 6, 2016, Centogene AG issued 2,877 common shares. In addition to the nominal value of the shares (€2,877), the shareholders made cash contributions into the Company's capital reserves of €2,011,123.

As registered in the commercial register on January 25, 2017, Centogene AG issued 14,286 common shares. In addition to the nominal value of the shares (€14,286), the shareholders made cash contributions into the Company's capital reserves of €4,985,814.

As registered in the commercial register on June 1, 2017, Centogene AG issued 312 common shares. In addition to the nominal value of the shares (€312), the shareholders made cash contributions into the Company's capital reserves of €124,488.

As registered in the commercial register on July 23, 2018, Centogene AG issued 250 common shares. In addition to the nominal value of the shares (€250), the shareholders made cash contributions into the Company's capital reserves of € 99,750.

The issuances of restricted securities in the transactions described above were deemed to be exempt from registration under the Securities Act in reliance upon the Section 4(a)(2) of the Securities Act and/or Regulation S promulgated under the Securities Act.

## **Item 8. Exhibits and Financial Statement Schedules.**

### (a) Exhibits

The following documents are filed as part of this registration statement:

- 1.1 Form of Underwriting Agreement.\*
- 3.1 Form of Articles of Association of Centogene N.V. (translated into English), as they will be in effect immediately following the completion of the corporate reorganization.\*\*
- 3.2 Form of rules of the Management Board of Centogene N.V.\*\*
- 3.3 Form of rules of the Supervisory Board of Centogene N.V.\*\*
- 3.4 Form of Share Issue Deed.\*\*
- 4.1 Form of Registration Rights Agreement.\*
- 5.1 Form of opinion of NautaDutilh N.V., Dutch counsel of Centogene, as to the validity of the common shares.
- 8.1 Form of opinion of NautaDutilh N.V., Dutch counsel of Centogene, as to Dutch tax matters.\*\*
- 8.2 Form of opinion of Taylor Wessing Partnerschaftsgesellschaft von Rechtsanwälten, as to German tax matters.\*\*
- 8.3 Form of opinion of Davis Polk & Wardwell LLP, as to U.S. tax matters.\*\*
- 10.1 Global Master Services Agreement between Centogene AG and Shire International GmbH, dated January 1, 2015.†
- 10.2 Supply Agreement between Centogene AG and Shire Pharmaceuticals Ireland Ltd, dated January 1, 2016.†
- 10.3 Amendment to the Global Master Services Agreement and Supply Agreement among Centogene AG, Shire International GmbH and Shire Pharmaceuticals Ireland Ltd., dated May 3, 2017.†
- 10.4 Amendment to the Global Master Services Agreement and Supply Agreement among Centogene AG, Shire International GmbH and Shire Pharmaceuticals Ireland Ltd., dated July 2, 2018.†
- 10.5 Form of Long Term Incentive Plan of Centogene N.V.\*\*
- 14.1 Code of Ethics of Centogene.\*\*
- 21.1 List of subsidiaries.\*\*
- 23.1 Consent of Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft.\*
- 23.2 Consent of NautaDutilh N.V. (included in Exhibits 5.1 and 8.1).

23.3 Consent of Taylor Wessing Partnerschaftsgesellschaft von Rechtsanwälten (included in Exhibit 8.2).

23.4 Consent of Davis Polk & Wardwell LLP (included in Exhibit 8.3).

24.1 Powers of attorney (included on signature page to the registration statement).

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\* To be filed by amendment.

\*\* Previously filed.

† Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested will be filed separately with the Securities and Exchange Commission.

(b) Financial Statement Schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or has been included in the consolidated financial statements and notes thereto.

**Item 9. Undertakings.**

The undersigned hereby undertakes:

(a) To provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(d) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

## EXHIBIT INDEX

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- 24.1 Powers of attorney (included on signature page to the registration statement).

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\* To be filed by amendment.

\*\* Previously filed.

† Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested will be filed separately with the Securities and Exchange Commission.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in \_\_\_\_\_ on \_\_\_\_\_, 2019.

CENTOGENE B.V.

By: \_\_\_\_\_

Name:

Title: *Chief Executive Officer*

By: \_\_\_\_\_

Name:

Title: *Chief Financial Officer*

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints \_\_\_\_\_ and \_\_\_\_\_ and \_\_\_\_\_ each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the U.S. Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on \_\_\_\_\_, 2019 in the capacities indicated:

<u>Name</u>	<u>Title</u>
_____	Chief Executive Officer (principal executive officer)
_____	Chief Financial Officer (principal financial officer and principal accounting officer)
_____	Member of the Supervisory Board

<u>Name</u>	<u>Title</u>
_____	Member of the Supervisory Board
_____	Member of the Supervisory Board
_____	Member of the Supervisory Board
_____	Member of the Supervisory Board
_____	Member of the Supervisory Board
_____	Member of the Supervisory Board
_____	Member of the Supervisory Board
_____	Authorized Representative in the United States





P.O. Box 7113  
1007 JC Amsterdam  
Beethovenstraat 400  
1082 PR Amsterdam  
T +31 20 71 71 000  
F +31 20 71 71 111

Amsterdam, [*date*] 2019.

To the Company

Ladies and Gentlemen:

We have acted as legal counsel as to Netherlands law to the Company in connection with the Offering. This opinion letter is rendered to you in order to be filed with the SEC as an exhibit to the Registration Statement.

Capitalised terms used in this opinion letter have the meanings set forth in Exhibit A to this opinion letter. The section headings used in this opinion letter are for convenience of reference only and are not to affect its construction or to be taken into consideration in its interpretation.

This opinion letter is strictly limited to the matters stated in it and may not be read as extending by implication to any matters not specifically referred to in it. Nothing in this opinion letter should be taken as expressing an opinion in respect of any representations or warranties, or other information, contained in the Reviewed Documents.

In rendering the opinions expressed in this opinion letter, we have reviewed and relied upon drafts of the Reviewed Documents and pdf copies or drafts, as the case may be, of the Corporate Documents and we have assumed that the Reviewed Documents shall be entered into for bona fide commercial reasons. We have not investigated or verified any factual matter disclosed to us in the course of our review.

This opinion letter sets out our opinion on certain matters of the laws with general applicability of the Netherlands, and, insofar as they are directly applicable in the Netherlands, of the European Union, as at today's date and as presently interpreted under published authoritative case law of the Netherlands courts, the General Court and the Court of Justice of the European Union. We do not express any opinion on Netherlands or European competition law, tax law or regulatory law. No undertaking is assumed on our part to revise, update or amend this opinion letter in connection with or to notify or inform you of, any developments and/or changes of Netherlands law subsequent to today's date. We do not purport to opine on the consequences of amendments to the Reviewed Documents or the Corporate Documents subsequent to the date of this opinion letter.

The opinions expressed in this opinion letter are to be construed and interpreted in accordance with Netherlands law. The competent courts at Amsterdam, the Netherlands, have exclusive jurisdiction to settle any issues of interpretation or liability arising out of or in connection with this opinion letter. Any legal relationship

Amsterdam

Brussels

London

Luxemburg

New York

Rotterdam

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arising out of or in connection with this opinion letter (whether contractual or non-contractual), including the above submission to jurisdiction, is governed by Netherlands law and shall be subject to the general terms and conditions of NautaDutilh. Any liability arising out of or in connection with this opinion letter shall be limited to the amount which is paid out under NautaDutilh's insurance policy in the matter concerned. No person other than NautaDutilh may be held liable in connection with this opinion letter.

In this opinion letter, legal concepts are expressed in English terms. The Netherlands legal concepts concerned may not be identical in meaning to the concepts described by the English terms as they exist under the law of other jurisdictions. In the event of a conflict or inconsistency, the relevant expression shall be deemed to refer only to the Netherlands legal concepts described by the English terms.

For the purposes of this opinion letter, we have assumed that:

- a. drafts of documents reviewed by us will be signed in the form of those drafts, each copy of a document conforms to the original, each original is authentic, and each signature is the genuine signature of the individual purported to have placed that signature;
- b. the Registration Statement has been declared effective by the SEC in the form of the draft reviewed by us;
- c. the Current Articles are the Articles of Association currently in force and the Revised Articles are the Articles of Association as they will be in force at each Relevant Moment;
- d. the resolutions recorded in the Resolutions are in full force and effect, the factual statements made and the confirmations given in the Resolutions and the Deed of Issue are complete and correct and the Resolutions correctly reflect the resolutions recorded therein;
- e. the Deed of Issue has been validly signed and executed on behalf of the Company;
- f. the Offering, to the extent made in the Netherlands, has been, is and will be made in conformity with the FSA and the rules promulgated thereunder;
- g. the Option (i) has been validly granted as a right to subscribe for Common Shares (*recht tot het nemen van aandelen*), (ii) shall be in full force and effect upon being exercised and (iii) shall have been validly exercised in accordance with the terms of the Underwriting Agreement;

and

- h. at the Relevant Moment, each of the assumptions made in this opinion letter will be correct in all aspects by reference to the facts and circumstances then existing.

Based upon and subject to the foregoing and subject to the qualifications set forth in this opinion letter and to any matters, documents or events not disclosed to us, we express the following opinions:

**Corporate Status**

1. The Company has been duly incorporated as a *besloten vennootschap met beperkte aansprakelijkheid* and, upon the execution of the Deed of Conversion, shall be validly existing as a *naamloze vennootschap*.

**Offer Shares and Option Shares**

2. Subject to receipt by the Company of payment in full for the Offer Shares and the Option Shares as provided for in the Reviewed Documents, and when issued and accepted in accordance with the Resolutions and the Reviewed Documents, the Offer Shares and the Option Shares shall be validly issued, fully paid and non-assessable.

The opinions expressed above are subject to the following qualifications:

- A. Opinion 1 must not be read to imply that the Company cannot be dissolved (*ontbonden*). A company such as the Company may be dissolved, inter alia by the competent court at the request of the company's board of directors, any interested party (*belanghebbende*) or the public prosecution office in certain circumstances, such as when there are certain defects in the incorporation of the company. Any such dissolution will not have retro-active effect.
- B. Pursuant to Section 2:7 NCC, any transaction entered into by a legal entity may be nullified by the legal entity itself or its liquidator in bankruptcy proceedings (*curator*) if the objects of that entity were transgressed by the transaction and the other party to the transaction knew or should have known this without independent investigation (*wist of zonder eigen onderzoek moest weten*). The Netherlands Supreme Court (*Hoge Raad der Nederlanden*) has ruled that in determining whether the objects of a legal entity are transgressed, not only the description of the objects in that legal entity's articles of association (*statuten*) is decisive, but all (relevant) circumstances must be taken into account, in particular whether the

interests of the legal entity were served by the transaction. Based on the objects clause contained in the Current Articles and in the Revised Articles, we have no reason to believe that, by entering into the Reviewed Documents, the Company would transgress the description of the objects contained in its Articles of Association. However, we cannot assess whether there are other relevant circumstances that must be taken into account, in particular whether the interests of the Company are served by entering into the Reviewed Documents since this is a matter of fact.

- C. Pursuant to Section 2:98c NCC, a *naamloze vennootschap* may grant loans (*leningen verstrekken*) only in accordance with the restrictions set out in Section 2:98c NCC, and may not provide security (*zekerheid stellen*), give a price guarantee (*koersgarantie geven*) or otherwise bind itself, whether jointly and severally or otherwise with or for third parties (*zich op andere wijze sterk maken of zich hoofdelijk of anderszins naast of voor anderen verbinden*) with a view to (*met het oog op*) the subscription or acquisition by third parties of shares in its share capital or depository receipts. This prohibition also applies to its subsidiaries (*dochtervennootschappen*). It is generally assumed that a transaction entered into in violation of Section 2:98c NCC is null and void (*nietig*). Based on the content of the Reviewed Documents, we have no reason to believe that the Company or its subsidiaries will violate Section 2:98c NCC in connection with the issue of the Offer Shares or the Option Shares. However, we cannot confirm this definitively, since the determination of whether a company (or a subsidiary) has provided security, has given a price guarantee or has otherwise bound itself, with a view to the subscription or acquisition by third parties of shares in its share capital or depository receipts, as described above, is a matter of fact.
- D. The opinions expressed in this opinion letter may be limited or affected by:
- a. any applicable bankruptcy, insolvency, reorganisation, moratorium or other similar laws or procedures now or hereafter in effect, relating to or affecting the enforcement or protection of creditors' rights generally;
  - b. the provisions of fraudulent preference and fraudulent conveyance (*Actio Pauliana*) and similar rights available in other jurisdictions to liquidators in bankruptcy proceedings or creditors;
  - c. claims based on tort (*onrechtmatige daad*);

- d. sanctions and measures, including but not limited to those concerning export control, pursuant to European Union regulations, under the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation;
  - e. the Anti-Boycott Regulation and related legislation; and
  - f. the rules of force majeure (*niet toerekenbare tekortkoming*), reasonableness and fairness (*redelijkheid en billijkheid*), suspension (*opschorting*), dissolution (*ontbinding*), unforeseen circumstances (*onvoorziene omstandigheden*) and vitiated consent (i.e., duress (*bedreiging*), fraud (*bedrog*), abuse of circumstances (*misbruik van omstandigheden*) and error (*dwaling*)) or a difference of intention (*wil*) and declaration (*verklaring*).
- E. The term “non-assessable” has no equivalent in the Dutch language and for purposes of this opinion letter such term should be interpreted to mean that a holder of a share will not by reason of merely being such a holder be subject to assessment or calls by the Company or its creditors for further payment on such share.
- F. This opinion letter does not purport to express any opinion or view on the operational rules and procedures of any clearing or settlement system or agency.

We consent to the filing of this opinion letter as an exhibit to the Registration Statement and also consent to the reference to NautaDutilh in the Registration Statement under the caption “Legal Matters”. In giving this consent we do not admit or imply that we are a person whose consent is required under Section 7 of the United States Securities Act of 1933, as amended, or any rules and regulations promulgated thereunder.

Sincerely yours,

/s/ NautaDutilh N.V.

NautaDutilh N.V.

## EXHIBIT A

### LIST OF DEFINITIONS

<b>“Anti-Boycott Regulation”</b>	The Council Regulation (EC) No 2271/96 of 22 November 1996 on protecting against the effects of the extra-territorial application of legislation adopted by a third country, and actions based thereon or resulting therefrom.
<b>“Articles of Association”</b>	The Company’s articles of association ( <i>statuten</i> ) as they read from time to time.
<b>“Commercial Register”</b>	The Netherlands Commercial Register ( <i>handelsregister</i> ).
<b>“Common Shares”</b>	Common shares in the Company’s capital, with a nominal value of EUR 0.12 each.
<b>“Company”</b>	Centogene B.V., a private company with limited liability ( <i>besloten vennootschap met beperkte aansprakelijkheid</i> ), registered with the Commercial Register under number 72822872, and to be renamed Centogene N.V. pursuant to the Deed of Conversion.
<b>“Corporate Documents”</b>	The Deed of Incorporation, the Deed of Conversion, the Current Articles, the Revised Articles, the Resolutions and the Registration Statement.
<b>“Current Articles”</b>	The Articles of Association as contained in the Deed of Incorporation.
<b>“Deed of Incorporation”</b>	The Company’s deed of incorporation ( <i>akte van oprichting</i> ), dated October 11, 2018.
<b>“Deed of Conversion”</b>	The draft deed of conversion and amendment to the Articles of Association prepared by us with reference number 82042626 M 25004107.
<b>“Deed of Issue”</b>	The draft deed of issue of the Offer Shares or Option Shares, as the case may be, prepared by us with reference 82042626 M 25004109 and 82042626 M 25004110, respectively.
<b>“FSA”</b>	The Netherlands Financial Supervision Act ( <i>Wet op het financieel toezicht</i> ).
<b>“General Meeting”</b>	The Company’s general meeting of shareholders ( <i>algemene vergadering van aandeelhouders</i> ).
<b>“Management Board”</b>	The Company’s management board ( <i>bestuur</i> ).
<b>“NautaDutilh”</b>	NautaDutilh N.V.
<b>“NCC”</b>	The Netherlands Civil Code ( <i>Burgerlijk</i>

Wetboek).

<b>“the Netherlands”</b>	The European territory of the Kingdom of the Netherlands.
<b>“Offering”</b>	The offering of the Offer Shares and, if relevant, the Option Shares, and the admission to listing and trading of those Common Shares on the NASDAQ Stock Market as contemplated by the Registration Statement.
<b>“Offer Shares”</b>	[•] Common Shares.
<b>“Option”</b>	The option to acquire Option Shares to be granted to the Underwriters pursuant to the Underwriting Agreement and the Resolutions.
<b>“Option Shares”</b>	Up to [•] Common Shares, or such lesser number of Common Shares in respect of which the Option is exercised.
<b>“Registration Statement”</b>	The Company’s registration statement on Form F-1 filed or to be filed with the SEC in connection with the Offering on or about the date of this opinion letter, in the form reviewed by us.
<b>“Relevant Moment”</b>	Each time that Offer Shares or Option Shares are issued pursuant to the execution of a Deed of Issue.
<b>“Resolutions”</b>	<ol style="list-style-type: none"><li>i. The [draft] [written resolution][minutes of the meeting] of the Management Board, [dated][held on][prepared by us with reference] [•];</li><li>ii. the [draft] [written resolution][minutes of the meeting] of the Supervisory Board, [dated][held on][prepared by us with reference] [•];</li><li>iii. the [draft] [written resolution][minutes of the extraordinary meeting] of the General Meeting, [dated][held on][prepared by us with reference] [•]; and</li><li>iv. the draft [written resolution][minutes of the meeting] of the pricing committee established by the Management Board and the Supervisory Board prepared by</li></ol>

us with reference [•].

<b>“Reviewed Documents”</b>	The Deed of Issue and the Underwriting Agreement.
<b>“Revised Articles”</b>	The Articles of Association as they will read immediately after the execution of the Deed of Conversion.
<b>“SEC”</b>	The United States Securities and Exchange Commission.
<b>“Supervisory Board”</b>	The Company’s supervisory board ( <i>raad van commissarissen</i> ).
<b>“Underwriters”</b>	The Underwriters, as defined in the Underwriting Agreement.
<b>“Underwriting Agreement”</b>	The draft underwriting agreement to be entered into between the Company and the Underwriters in connection with the Offering, in the form reviewed by NautaDutilh.



CONFIDENTIAL TREATMENT REQUESTED UNDER RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

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**Global Master Services Agreement**

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between

**Shire International GmbH**

and

**Centogene AG**

[\*\*\*\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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This **Global Master Services Agreement** is entered into as of 1 January 2015 (“**Effective Date**”) by and between

- (1) **Shire International GmbH**, a Swiss limited liability company having its registered office at Zählerweg 10, 6301 Zug, Switzerland, (“**Shire**”); and
- (2) **Centogene AG**, a German stock corporation incorporated under the laws of the Federal Republic of Germany with principal office in Freiburg i.Br., registered with the district court (“**Amtsgericht**”) in Freiburg in Br. under HRB 706872 and having a business address at Schillingallee 68, 18057 Rostock, Germany, (“**Centogene**”).

#### **PREAMBLE**

- (A) Shire is a global biopharmaceutical company focusing in particular on the development of treatments for rare diseases (e.g. Morbus Fabry, Morbus Hunter and Morbus Gaucher).
- (B) Centogene is a global diagnostic company focusing on genetic and biochemical testing of rare diseases including lysosomal storage diseases.
- (C) Shire, Shire Human Genetic Therapies inc., Shire Deutschland GmbH and other Affiliates (jointly, “**Shire Group Companies**”) and Centogene have a long standing commercial and development relationship. In this respect, Centogene has provided certain services to Shire Group Companies in the area of certain enzymatic and genetic testing of dried-blood-sample cards as well as of tubes with blood samples for several lysosomal storage diseases on the basis of certain service agreements with certain Shire Group Companies and certain research & development services on the basis of certain collaboration and services agreements.
- (D) The parties recognize each other as global leaders in the field of diagnosing respectively treating lysosomal storage diseases and acknowledge their resulting responsibility for patients suffering from one of these rare diseases. Facile worldwide access to appropriate diagnostic testing is a significant unmet need for these patients. Already in the past, one central aim of the cooperation between Shire and Centogene has been the identifying of undiagnosed patients suffering from one of these diseases. Although past joint efforts of the parties have partially addressed this unmet patient need, a significant number of patients remain unidentified. Shire and Centogene do not accept this situation and have therefore agreed to pursue the common mission of finding any remaining unidentified patients by the year 2020. In order to achieve this ambitious objective, Shire and Centogene intend to collaborate with regards to (i) identifying patients suffering from Morbus Fabry, Morbus Gaucher and Morbus Hunter as well as (ii) research & development.
- (E) The Shire Group Companies and Centogene aim to extend the existing cooperation and to consolidate their activities under the umbrella of this Global Master Services Agreement, which shall, after expiration or termination of any currently existing agreements between Shire Group Companies and Centogene, eventually cover all activities between any Shire Group Company and Centogene.

(F) The research & development services to be provided by Centogene will be further set out in statements of works that the Parties may agree in writing from time to time, all subject to the provisions of this Global Master Services Agreement.

**Now, therefore, Shire and Centogene, intending to be legally bound, hereby agree as follows:**

## **1. Definitions**

In this Agreement, the following terms shall have the following meanings:

“**Additional Processing Fee**” shall have the meaning set forth in Section 3.2(a).

“**Alliance Manager**” shall have the meaning set forth in Section 6.1.

“**Affiliate**” shall mean and include in relation to each Party, any person, firm, corporation or other entity: (i) if at least fifty percent (50%) of the voting stock or other equity interest thereof is owned, directly or indirectly, by that Party; (ii) which owns, directly or indirectly, at least fifty percent (50%) of the voting stock or other equity interest of that Party; or (iii) if at least fifty percent (50%) of the voting stock or other equity interest thereof is owned, directly or indirectly, by a person, firm, corporation or other entity that owns, directly or indirectly, at least fifty percent (50%) of the voting stock or other equity interest of that Party.

“**Agreement**” shall mean this Global Master Services Agreement and all Exhibits attached hereto.

“**Anti-Bribery Laws**” shall have the meaning set forth in Section 10.2.

“**Applicable Laws**” shall mean (i) all applicable laws, statutes, constitutions, treaties, rules, regulations, ordinances, codes of conduct, statutory guidance, codes and guidance having the force of law, directives and regulations; and (ii) all applicable judicial, executive, legislative or administrative orders, directives, decrees, injunctions, judgments, permits, agreements, and other legal requirements applicable to the provision of Test Kits to Physicians in the Territory, the submission of Samples to Centogene, the conducting of Diagnostic Tests, the provision of Results to Physicians and other activities in the course of rendering Services under this Agreement; and (iii) all applicable guidance documents and guidelines issued by Regulatory Authorities in its current version or as amended from time to time.

“**Business Continuity Plan**” shall have the meaning set forth in Section 3.13(a).

“**Business Day**” shall mean any day (other than Saturday or Sunday) on which banks are open for business in Zug, Switzerland, and Rostock, Germany.

“**Centogene Background Intellectual Property**” shall mean any and all Intellectual Property that is owned or controlled by Centogene prior to the Effective Date.

“**Centogene DBS Cards**” shall mean any DBS Cards that were manufactured by or on behalf of Centogene.

“**Change of Control**” means with respect to Centogene: (i) the sale of all or substantially all of Centogene’s assets or business relating to this Agreement; (ii) a merger, reorganization or consolidation involving Centogene after which the voting securities of Centogene outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity as a consequence of such merger, reorganization or consolidation; or

(iii) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of Centogene.

“**Confidential Information**” shall mean and include all know-how, data, documents, materials and information, not in the public domain, relating to the Services, business affairs, finance plans, contractual relationships of the Parties.

“**Current Test Kits**” shall mean any Test Kits in use by Shire Group Companies which contain either Centogene DBS Cards or Old DBS Cards.

“**DBS Cards**” shall mean dried-blood-sample cards.

“**Designated Third Party Laboratory**” shall have the meaning set forth in Section 3.13(b).

“**Diagnostic Services**” shall mean the performance of Diagnostic Tests by Centogene on the basis of Samples for the purpose of identifying patients suffering from Morbus Fabry, Morbus Gaucher and Morbus Hunter and such other rare diseases that are identified on the Testing Request Form.

“**Diagnostic Tests**” shall mean the diagnostic tests used by Centogene in the testing of Samples for the purpose of identifying patients suffering from Morbus Fabry, Morbus Gaucher and Morbus Hunter and other rare diseases that are identified on the Testing Request Form.

“**Diagnostic Test Results**” shall mean the results of the Diagnostic Tests performed by Centogene.

“**Effective Date**” shall mean 1 January 2015.

“**Excess Diagnostic Tests**” shall have the meaning set forth in Section 3.6(c).

“**Excess Payments**” shall have the meaning set forth in Section 3.6(e).

“**Existing Agreements**” shall mean any agreements, including statements of work governed by such agreements, between Shire Group Companies and Centogene or an Affiliate of Centogene existing and in full force and effect as of the Effective Date. The Existing Agreements are listed in Exhibit 2.

“**Facility**” shall mean the facility of Centogene at Schillingallee 68, 18057 Rostock, Germany where the Diagnostic Services are to be performed.

“**General Records**” shall have the meaning set forth in Section 3.7.

“**Good Laboratory Practices**” or “**GLP**” shall mean all applicable Good Laboratory Practice standards, including, as applicable, (i) as set forth in European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices, as may be amended from time to time, as well as the OECD Series on Principles of Good Laboratory Practice, (ii) the then-current good laboratory practice standards, promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, each as may be amended and applicable from time to time.

“**Intellectual Property**” shall mean and include any intellectual property of whatever nature relating, including without limitation patents, patentable inventions, design rights, copyright, trademarks, service marks, domain names, know how, whether registered, registrable or otherwise and including all applications (or rights to apply), renewals and extensions for such rights.

“**Joint Steering Committee**” or “**JSC**” shall have the meaning set forth in Section 6.2.

“**Minimum Financial Commitment**” shall have the meaning set forth in Section 3.6(a).

“**New General Diagnostic Testing Intellectual Property**” shall have the meaning set forth in Section 9.4.

“**New Test Kits**” shall mean Test Kits that the Parties mutually agree on after the Effective Date pursuant to Section 3.2(b).

“**Old DBS Cards**” shall mean any DBS Cards in use by Shire Group Companies as of the Effective Date as well as any DBS Cards that are based on and essentially similar to DBS Cards in use by Shire Group Companies as of the Effective Date, which cannot be processed by Centogene in an automated manner and which therefore require substantial manual processing by Centogene. For the avoidance of doubt, Centogene DBS Cards are not Old DBS Cards.

“**Party**” or “**Parties**” shall mean Shire or Centogene or Shire and Centogene, respectively.

“**Patients**” shall mean individual persons whose Samples are tested by Centogene by using the Diagnostic Tests for rare diseases identified on the Testing Request Form as part of the Diagnostic Services.

“**Physicians**” shall mean physicians in the Territory which have received Test Kits and which submit Samples to Centogene for Diagnostic Services.

“**Project**” shall mean an actual or proposed R&D Services project of Centogene alone or together with Shire Group Companies and/or Third Parties that is the subject of a Statement of Works, or is the subject of discussions with a view to making it the subject of a Statement of Works.

“**Project Results**” shall mean any idea, invention, discovery, know-how, materials, methods, techniques and other information, that are discovered, conceived, reduced to practice, developed or otherwise generated by Centogene and/or Third Parties participating in a Project for Shire or a Shire Group Company as a result or in connection with a Project, including but not limited to Shire Product Information, and any Intellectual Property Rights pertaining to the foregoing, *provided, however, that* “Project Results” shall exclude New General Diagnostic Testing Intellectual Property.

“**Reports**” shall have the meaning set forth in Section 3.4.

“**R&D Services**” shall mean certain research & development services as described and mutually agreed in an SOW.

“**Regulatory Authority(ies)**” shall mean any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity in each country in the Territory having competence over any activities in relation to this Agreement, including the provision of Test Kits to Physicians in the Territory, the submission of Samples to Centogene, the conducting of Diagnostic Tests, the provision of Results to Physicians and other activities in the course of rendering Services under this Agreement.

“**Samples**” shall mean blood samples of Patients in the Territory in the form of Test Kits or full blood samples submitted to Centogene by Physicians for the purposes of carrying out Diagnostic Tests.

“**Services.**” shall mean the Diagnostic Services and the R&D Services to be performed by Centogene in accordance with this Agreement.

“**Service Failure**” shall mean (A) Centogene’s inability to provide for any period of at least (i) [\*\*\*\*\*] an average of [\*\*\*\*\*] percent ([\*\*\*\*\*]%), or (ii) [\*\*\*\*\*] an average of [\*\*\*\*\*] percent ([\*\*\*\*\*]%), or (iii) [\*\*\*\*\*] an average of [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of the Target Volumes on a pro-rata basis for such period or (B) Centogene’s sudden and total inability to provide any Diagnostic Services due to a force majeure event. The Parties agree that Centogene’s inability to provide Target Volumes as per (A) (i), (ii) or (iii) shall not constitute a Service Failure if and to the extent that Centogene can demonstrate that its inability was directly caused by circumstances beyond Centogene’s reasonable control and was inevitable from the perspective of a prudent businessman.

“**Shire Group Companies**” shall mean Shire, Shire Human Genetic Therapies Inc., Shire Deutschland GmbH and other Affiliates in the Territory.

“**Shire Product(s)**” shall mean any medicinal products under development or commercialized by or on behalf of any Shire Group Companies in the Territory for the treatment of Morbus Fabry, Morbus Gaucher or Morbus Hunter or other similar rare diseases for which such products are authorized.

“**Shire Product Information**” shall mean any information resulting from the Services and relating directly to Shire Products.

“**Specifications**” shall mean the specifications for R&D Services, if any, identified or set out in the relevant Statement of Works.

“**Statement(s) of Works**” or “**SOW**” shall mean statements of works describing the details of the R&D Services, payments, and other terms governing the conduct of Projects, as executed from time to time by a Shire Group Company and Centogene and incorporated into this Agreement by reference. A sample SOW is attached hereto as Exhibit 3.

“**Suspension Event**” shall have the meaning set forth in Section 7.1.

“**Target Volumes**” and “**Marty Target Volume**” shall have the meaning set forth in Section 3.5.

“**Technical Quality Agreement**” shall mean the technical quality agreement which sets forth the Parties’ respective obligations in relation to the Diagnostic Services to ensure quality standards appropriate to their intended use and meeting all relevant international guidelines and standards.

“**Territory**” mean worldwide.

“**Testing Request Form**” shall mean the request forms included in the Test Kits and submitted by **Physicians** directly to Centogene.

“**Test Kits**” shall mean DBS Cards or other test kits provided by or on behalf of Shire Group Companies to Physicians in the Territory for the purpose of identifying patients suffering from Morbus Fabry, Morbus Gaucher and Morbus Hunter and such other rare diseases that are identified on the Testing Request Form.

“**Third Party**” shall mean any legal entity or natural person other than the Parties or their Affiliates.

## 2. **Scope of the Agreement**

2.1. Scope. This Agreement defines the terms and conditions under which Centogene shall provide Diagnostic Services and R&D Services to Shire Group Companies.

- 2.2. Diagnostic Services. The Diagnostic Tests to be used by Centogene in the Diagnostic Services are set forth in Exhibit 1 as amended by the Parties from time to time in writing.
- 2.3. R&D Services. R&D Services to be performed by Centogene will be agreed and defined in separate SOWs.
- 2.4. Existing Agreements. The Shire Group Companies and Centogene aim to eventually consolidate their entire collaboration under this Global Master Services Agreement. Any activities currently on-going under statements of work governed by Existing Agreements shall continue to be rendered by Centogene in accordance with the terms of the respective agreements until complete fulfillment of the services agreed under such statements of work governed by Existing Agreements. Existing Agreements will be terminated or shall expire in accordance with the terms of such agreements. After termination or expiration of the Existing Agreements any and all activities between Shire Group Companies and Centogene shall be covered by this Agreement.

### 3. **Diagnostic Services**

- 3.1. Performance of Diagnostic Services. Centogene will perform Diagnostic Services in accordance with generally accepted professional standards, GLP and Applicable Laws. In particular, Centogene will use the Diagnostic Tests to test Samples that are submitted by Physicians directly to Centogene and will provide the Diagnostic Test Results to the Physicians. Centogene shall only perform Diagnostic Tests for diseases/indications explicitly requested by the Physician on the relevant Testing Request Form. Centogene shall not be obliged to test and process full blood samples from any country for which Centogene has not routinely processed full blood samples for Shire prior to the Effective Date (e.g. for Germany processing of full blood samples was agreed prior to the Effective Date).
- 3.2. Test Kits. Centogene shall process Tests Kits provided by or on behalf of Shire Group Companies to Physicians as follows:
- (a) Centogene shall continue processing during the term of this Agreement all Current Test Kits, which have been or will be provided by or on behalf of Shire Group Companies to Physicians after the Effective Date in a given country, *provided, however*, that Centogene shall have the right to charge an additional processing fee per Old DBS Card which is processed by Centogene and for which Diagnostic Test Result(s) are sent out to Physicians in accordance with the terms of the N. Agreement as follows:
- € [\*\*\*\*\*] for the first [\*\*\*\*\*] Old DBS Cards in a given calendar year and
  - € [\*\*\*\*\*] for any additional Old DBS Cards in a given calendar year
- (“Additional Processing Fee”).**
- For the avoidance of doubt, Centogene shall process any Current Test Kits containing Centogene DBS Cards or full blood samples, which Centogene is obliged to process in accordance with Sec. 3.1, without any additional processing fee.
- (b) The Parties shall work collaboratively in good faith to identify and agree on New Test Kits as soon as reasonably possible. Shire shall use commercially reasonable efforts to submit for regulatory approval for New Test Kits in all countries as soon

as reasonably possible and Centogene shall provide all data, information and shall perform all testing necessary for the development and regulatory submission of New Test Kits within agreed upon timelines for each activity. Within sixty (60) days after the Effective Date the Parties shall agree on a development plan that defines the specific work packages and the corresponding time lines for each Party. Clinically relevant information will be included in the New Test Kits, provided that such inclusion is, on a country-by-country basis, permitted by Applicable Laws. For the avoidance of doubt, Centogene shall process New Test Kits without the Additional Processing Fee.

(c) If Centogene does not provide all data and information and/or does not perform all testing necessary for the development and regulatory submission of a New Test Kit within the agreed upon timelines for each activity as set forth in the development plan, Centogene's right to charge the Additional Processing Fee shall automatically lapse until the respective data and information has been provided and/or the respective activity(ies) have been performed by Centogene.

3.3. Timeframes. Centogene shall process submitted Samples, perform Diagnostic Tests and send out Diagnostic Results to Physicians within [\*\*\*\*\*] Business Days after receipt of the relevant Sample, provided the Test Kits and/or Testing Request Forms submitted to Centogene contain sufficient testing material and all information required by the Test Kits and/or Testing Request Forms (e.g. patient consent, sender information, target, clinically relevant information as regards to New Test Kits, etc.). In case Centogene is unable to send out, over a period of three (3) consecutive months, at least [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of the Diagnostic Results within [\*\*\*\*\*] Business Days in accordance with the sentence above, Shire shall have the right to reduce the monthly payment pursuant to Section 3.6(b) by [\*\*\*\*\*] percent ([\*\*\*\*\*]%) for as long as [\*\*\*\*\*] percent ([\*\*\*\*\*]%) or more of the Diagnostic Results are not sent out within [\*\*\*\*\*] Business Days, provided the *prorated* Target Volumes are not exceeded by more than [\*\*\*\*\*] percent ([\*\*\*\*\*]%) on average during a On calendar quarter.

3.4. Reports. Centogene shall provide Shire, within fourteen (14) calendar days after the end of a calendar month, with calendar monthly written reports which shall include the details set forth in Exhibit 4 ("**Reports**"). Centogene shall not pass any personal data of Patients to Shire so that identification of Patients would not be possible for Shire. Centogene agrees to the data transfer and the processing and use of data for the aforementioned purpose.

3.5. Target Volumes. The Parties aim to have the following numbers of Diagnostic Tests performed, Samples tested and Diagnostic Test Results sent out to Physicians by Centogene per calendar year:

2015: [\*\*\*\*\*]

2016: [\*\*\*\*\*]

2017: [\*\*\*\*\*]

2018: [\*\*\*\*\*]

2019: [\*\*\*\*\*]

(each yearly target volume a "**Yearly Target Volume**" and collectively, the "**Target Volumes**"). Centogene acknowledges that Shire has no obligation to order Diagnostic Tests in the above Target Volumes or to ensure achievement of any Yearly Target Volume,



but shall be obliged to make the Minimum Financial Commitment pursuant to Section 3.6(a).

3.6. Payments.

Shire shall make payment for the Diagnostic Services on the basis of the prices and fees set forth on Exhibit 1 as follows:

- (a) Shire will make the following annual minimum payments to Centogene equivalent to the Target Volumes,, even if the Target Volumes are not actually achieved (“**Minimum Financial Commitment**”):

2015: € [\*\*\*\*\*] ([\*\*\*\*\*] Euro)

2016: € [\*\*\*\*\*] ([\*\*\*\*\*] Euro)

2017: € [\*\*\*\*\*] ([\*\*\*\*\*] Euro)

2018: € [\*\*\*\*\*] ([\*\*\*\*\*] Euro)

204.9: € [\*\*\*\*\*] ([\*\*\*\*\*] Euro)

- (b) Within fourteen (14) calendar days after the end of a calendar month, Centogene shall invoice on a calendar monthly basis the Minimum Financial Commitment on a *pro rata* basis for such calendar month, i.e. an amount equal to 1/12 of the Minimum Financial Commitment for the respective calendar year. Shire shall make payment within thirty (30) calendar days upon receipt of a proper invoice and receipt of accurate and complete Reports for the preceding calendar month, whichever is later.
- (c) Within thirty (30) calendar days after the end of each calendar quarter, Centogene shall provide Shire with a detailed summary of Diagnostic Services actually rendered in the previous calendar quarter as evidenced in the Reports and as documented in the General Records, including the difference between (i) the Minimum Financial Commitment (prorated up to this point in time), and (ii) the prices and fees for Diagnostic Services actually rendered during such calendar quarter. In case Centogene performed more Diagnostic Tests during such calendar quarter in accordance with this Agreement than covered by the Minimum Financial Commitment (as evidenced in the Reports and as documented in the General Records) and provided a year-to-date cumulative calculation also exceeds the Minimum Financial Commitment (prorated up to this point in time), the payments for such excess Diagnostic Tests (the “Excess Diagnostic Tests”) shall be calculated on the basis of the prices and fees set forth in Exhibit 1 and Centogene shall submit an invoice of such Excess Diagnostic Tests within such thirty (30) calendar days period. Shire shall make payment within thirty (30) calendar days upon receipt of a proper invoice and a detailed summary of Diagnostic Services, whichever is later.
- (d) Within thirty (30) calendar days after the end of each calendar quarter, Centogene shall provide Shire with a list of all Current Test Kits containing Old DBS Cards processed during the previous calendar quarter as evidenced in the Reports and as documented in the General Record and shall submit an invoice for the resulting Additional Processing Fee. Shire shall make payment within thirty (30) calendar days upon receipt of a proper invoice and the above-mentioned list, whichever is

later. For the avoidance of doubt, the Additional Processing Fee is in addition to any other amounts due under this Agreement and is not subject to Section 3.6(e).

- (e) Further, within thirty (30) calendar days after the 1 January of each calendar year, Centogene shall provide Shire with a detailed summary of Diagnostic Services actually rendered in the previous calendar year as evidenced in the Reports and as documented in the General Records, including (i) the Minimum Financial Commitment paid, and (ii) the prices and fees for Diagnostic Services actually rendered during such calendar year, and (iii) the payments for Excess Diagnostic Tests made under Section 3.6(c), if any. In case Centogene performed fewer Diagnostic Tests during a given calendar year than covered by the Minimum Financial Commitment (as evidenced in the Reports and as documented in the General Records), but received payment for Excess Diagnostic Tests pursuant to Section 3.6(c) with respect to any calendar quarter during such calendar year (the “**Excess Payment(s)**”), Centogene shall issue a credit note covering such Excess Payments made by Shire, together with the provision of the yearly detailed summary.
- (f) Any prices and fees are in Euros and exclusive of VAT.
- (g) As of 1 January 2016 the prices as well as the technology access fees listed in Exhibit 1 will be increased by [\*\*\*\*\*] percent ([\*\*\*\*\*]%) on each 1 January for the years 2016, 2017, 2018 and 2019.
- (h) Centogene shall be reasonably committed to developing and implementing continuous cost and quality improvement programs, including by seeking productivity improvements, by purchasing quality materials at lower cost and by improving testing processes. Centogene shall inform Shire of any substantial cost saving opportunities and the Parties agree to negotiate in good faith reductions to the respective prices set forth in Exhibit 1 and the Minimum Financial Commitment set forth in Section 3.6(a). If, in Shire’s reasonable opinion based on general developments in the area of genetic and biochemical testing, costs for genetic and biochemical testing decrease substantially during the term of this Agreement, Shire shall have the right to propose an adjustment of the prices set forth in Exhibit 1 and the resulting Minimum Financial Commitment set forth in Section 3.6(a) and Centogene shall consider in good faith such proposal within sixty (60) days after receipt of Shire’s adjustment proposal. Should the Parties be unable to reach agreement within sixty (60) days after Centogene’s receipt of Shire’s adjustment proposal, the adjustment, if any, shall be determined by an independent expert appointed in accordance with the WIPO Expert Determination Rules. The language to be used in the expert determination proceedings shall be English.

3.7. Maintenance of Records; Audits. Centogene shall maintain accurate and complete records of all Testing Request Forms, Samples received, correspondence, invoices, and/or other information in Centogene’s possession relating to the Diagnostic Services (collectively, “**General Records**”). The General Records shall be maintained in accordance with recognized commercial accounting practices and retained during the term of the Agreement and thereafter for a period of three (3) years or such longer period required by Applicable Laws. Not more than once per calendar year during the term and not more than once within three (3) years after the end of the term, upon reasonable prior written notification and during normal business hours and with the purpose of confirming Centogene’s compliance with the terms of this Agreement in providing the Diagnostic Services, Centogene agrees to permit independent auditors bound to professional secrecy selected by Shire and reasonably acceptable to Centogene to examine and audit the

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General Records at no charge to Shire by Centogene. The independent auditors shall be bound by the confidentiality and non-use obligations set forth in Sections 3.8 and 8 of this Agreement. For clarity, any such inspection (or failure to inspect) shall not relieve Centogene of its obligation to comply with Applicable Laws and the provisions of this Agreement and does not constitute a waiver of any right otherwise available to Shire. Shire shall bear the full cost of such independent auditors, unless such audit shall reveal that Centogene overstated the number of tested Samples by more than [\*\*\*\*\*] percent ([\*\*\*\*\*]%), in which case Centogene shall reimburse Shire for the reasonable cost of such audit.

3.8. Data Protection. Centogene shall comply with all Applicable Laws on data protection in the provision of Diagnostic Services. Notwithstanding the foregoing, Centogene shall take appropriate organizational and technical protection measures in accordance with Section 9 of the German Federal Act on Data Protection (*Bundesdatenschutzgesetz; BDSG*) and the Appendix to Section 9 BDSG or the corresponding applicable data protection laws and regulations of the German states (*Länder*). Centogene will design its internal organization so that it meets the specific data protection requirements and so that data collected during the Diagnostic Services, including pseudonymized data of Patients and Physicians, are protected from misuse, unauthorized access and loss. The privacy of Patients and Physicians shall be respected in all circumstances. Centogene shall treat personal data, including pseudonymized data of Patients and Physicians, strictly confidential. Centogene will use only those employees for providing Diagnostic Services who are contractually bound to maintain data confidentiality pursuant to Section 5 BDSG or the corresponding applicable data protection laws and regulations of the German states (*Länder*). Centogene shall use any data collected in the course of Diagnostic Services and the pseudonymized data of Patients and Physicians exclusively for the purpose of providing Diagnostic Services in accordance with the terms of this Agreement. Centogene shall not merge pseudonymized data of Patients with other data in a manner such that a reference to a certain person can be made.

3.9. Facility. Centogene shall, at its own cost and expense, ensure that at all times during the term, the Facility is in a qualified and validated state appropriate for provision of Diagnostic Services as required by GLP, the terms of this Agreement, Applicable Laws and Regulatory Authorities. Centogene shall be responsible for validating the equipment used for the Diagnostic Tests (including conducting installation, operational and performance qualification).

3.10. Notification of Contaminants. In the event Centogene reasonably identifies a potential problem of cross-contamination in the Facility or a problem with respect to any regulatory requirements in connection therewith, Centogene shall immediately inform Shire in writing and the Parties shall meet and cooperate, through the JSC, in good faith to resolve the problem.

3.11. Technical Quality Agreement. Within sixty (60) days upon signing of this Agreement the Parties shall enter into a Technical Quality Agreement. The Technical Quality Agreement sets forth, among other things, certain tasks and responsibilities to be performed by each Party with respect to the Diagnostic Services and shall incorporate provisions permitting Shire and Shire Group Companies to audit the Facility and any alternate facility as well as other customary provisions, including the key terms regarding quality systems set forth in Section 3.12. In the event of any discrepancy or inconsistency between the tasks listed in such Technical Quality Agreement and the terms of this Agreement, the terms of the

Technical Quality Agreement will govern with respect to quality matters, and the terms of this Agreement shall govern with respect to all other matters..

- 3.12. Quality Systems. Centogene shall maintain systems of operation and quality assurance that are consistent with Applicable Laws and GLP and as otherwise may be required by Applicable Laws. Such systems shall include written policies and procedures that address, at a minimum, the following: quality systems including: training, supplier & purchasing controls, supplier audits, vendor change notifications, facilities and equipment, exception / deviation notification, complaint reporting and CAPA; facilities and equipment systems; laboratory control systems; data protection, protection of IT networks.
- 3.13. Business Continuity.
- (a) Centogene acknowledges the importance to Shire of an uninterrupted provision of Diagnostic Services. Centogene shall take, throughout the term of the Agreement, all necessary steps to identify and mitigate potential threats to its ability to provide Diagnostic Services. In particular, Centogene shall prepare within sixty (60) calendar days after the Effective Date a written business continuity and risk mitigation plan designed to maintain continuity of the provision of Diagnostic Services under adverse conditions (“**Business Continuity Plan**”).
  - (b) Such Business Continuity Plan shall be reasonably satisfactory to Shire and shall include (i) the future establishment of an alternate facility operated by Centogene in case of a Service Failure as well as (ii) the identification of an alternate facility of a Third Party GLP compliant contract laboratory designated by Centogene and reasonably acceptable to Shire (“**Designated Third Party Laboratory**”) in case Shire terminates the Agreement pursuant to Section 12.3(c).
  - (c) The alternate facility operated by Centogene shall be capable of providing Diagnostic Services at the Target Volumes in case of a Service Failure within a ramp-up period of sixty (60) calendar days upon occurrence of a Service Failure. The Designated Third Party Laboratory shall be generally capable of providing Diagnostic Services at the Target Volumes in case Shire terminates the Agreement pursuant to Section 12.3(c).
  - (d) Centogene shall implement the Business Continuity Plan during the term of the Agreement, including escrow deposits of complete and comprehensible descriptions of Centogene’s diagnostic testing technology for technology transfer to an alternate facility operated by Centogene or agreed Designated Third Party Laboratory, to ensure that the alternate facilities will actually be capable of providing Diagnostic Services at the Target Volumes in case of a Service Failure within sixty (60) calendar days upon occurrence of a Service Failure or in case of a termination by Shire pursuant to Section 12.3(c), as the case may be.
  - (e) During the term of the Agreement Centogene shall promptly notify Shire in writing of any potential disruption to the provision of Diagnostic Services. Centogene shall evaluate and update the Business Continuity Plan on a yearly basis. Upon request of Shire at any time, Centogene will present the Business Continuity Plan to Shire, including documentation on the implementation of such Business Continuity Plan. Centogene shall consider in good faith any reasonable comments that Shire may have with respect to the Business Continuity Plan and shall incorporate Shire’s comments in the Business Continuity Plan as agreed by the Parties without undue delay.
- 3.14. Service Failure. Without limiting any other rights or remedies of Shire, if there is, or the Parties mutually determine there is likely to be, a Service Failure, then Shire shall have the right to request that Centogene and Centogene shall be obliged to immediately take all

necessary measure to start providing Diagnostic Services from an alternate facility operated by Centogene as soon as possible and in any event no later than within [\*\*\*\*\*] calendar days upon occurrence of a Service Failure. Shire shall not be obliged to make the Minimum Financial Commitment under Section 3.6(a) (on a prorated basis) for the period in which a Service Failure existed and Centogene shall reimburse Shire for any Minimum Financial Commitment payments made during such period. However, if Centogene successfully ramps-up the alternate facility operated by Centogene within [\*\*\*\*\*] calendar days, Shire shall make the Minimum Financial Commitment under Section 3.6(a) (on a prorated basis) for such period.

#### 4. R&D SERVICES

- 4.1. Research and Development. Shire recognizes the unmet need to fund research in diagnostic services and strategies to meet the goal of identifying all patients suffering from Marbus Fabry, Gaucher and Hunter Syndrome and such other rare diseases that are identified on the Testing Request Form. Shire is willing to fund one or more Projects up to a combined total of € [\*\*\*\*\*] ([\*\*\*\*\*] Euro) per calendar year subject always to Shire having first evaluated and agreed to any such Project in accordance with this Section 4, in particular Section 4.4.
- 4.2. Performance of R&D Services. Centogene will perform R&D Services in accordance with the relevant Statement of Works, the Specifications, if any, generally accepted professional standards, GLP and Applicable Laws; provided, however, that this Agreement shall not establish any obligation of either Party to enter into any Statements of Works.
- 4.3. Project Proposals. From time to time, Centogene shall have the right to propose Projects to meet the goal of identifying all patients suffering from Fabry, Gaucher and Hunter Syndrome and other similar rare diseases agreed by the Parties or using diagnostics to improve the treatment of these patients. In such case, Centogene shall submit to Shire, through the JSC, a proposal, which shall contain, at a minimum, information supporting the rationale for such Project, the scientific merit, the alignment with Shire's strategic goal of improving the use of diagnostics modalities to identify patients with lysosomal storage diseases or other rare diseases, the proposed tasks and responsibilities of the Parties, other proposed Third Parties to be involved, as well as an estimate of the timeframe for and cost of such Project.
- 4.4. Project Evaluation. Shire will review and evaluate Centogene's proposal within ninety (90) calendar days after such proposal is submitted by Centogene. Shire is willing to fund, subject to the funding cap specified in Section 4.1, a Project, if such Project, in Shire's discretion, (i) is of scientific merit and aligned with Shire's strategic goal of improving the use of diagnostics modalities to identify patients with lysosomal storage diseases; (ii) is positively evaluated per Shire's standard processes and includes full transparency of the role of each Party and all Third Parties and/or Shire Group Companies potentially involved in the research endeavor; and (iii) meets any Applicable Laws, internal Shire guidelines and the European and national Codices applicable to the pharmaceutical industry, including but not limited to the EFPIA Code.
- 4.5. Statements of Works. If agreement between Shire and Centogene is reached to conduct a proposed Project, a Statement of Work for the Project shall be executed and such Statement of Work shall be attached to this Agreement. To the extent that Third Parties are involved in the research endeavor, Centogene shall ensure that such Third Parties have executed appropriate agreements with Centogene containing substantially similar terms regarding confidentiality, Intellectual Property and publications as those set out in this Agreement. Where academic institutions are participating in a Project, Centogene shall

ensure full transparency of the scope and the payments in relation to that Project as well as the academic individuals involved towards the academic institution. This Agreement shall apply to every SOW and to any R&D Services performed pursuant thereto. While each such SOW shall constitute a separate and distinct agreement between the Parties, the terms and conditions of this Agreement shall be deemed incorporated by reference in each such SOW. In addition, Shire or any other, additional, Shire Group Company may from time to time request Centogene to provide R&D Services. When such a request is made, Shire or the respective Shire Group Company and Centogene will negotiate with each other with a view to reaching agreement with regard to that Project.

- 4.6. **Governance.** In the event of contradictions or inconsistencies between this Agreement and any terms and conditions appearing or referred to in any such SOW, this Agreement shall prevail, unless the SOW makes express reference that the Parties intend a provision of the SOW to overrule the corresponding provision in the Agreement with respect to such SOW only.
- 4.7. **Payments.** A payment schedule for the performance of R&D Services shall be set out in each Statement of Works. Whenever any payment is due, Centogene shall submit an invoice to Shire, together with such evidence as Shire may reasonably request for the purpose of verifying that the R&D Services in respect of which the payment in question is due have been actually rendered, provided however, that Shire's financial contribution in respect of the totality of all existing Projects shall not exceed € [\*\*\*\*\*] ([\*\*\*\*\*] Euro) per calendar year, i.e. not more than € [\*\*\*\*\*] ([\*\*\*\*\*] Euro) for the initial term of five (5) years. Shire shall make payment within (30) thirty calendar days upon receipt of a proper invoice and the above mentioned evidence.
- 4.8. **Project Manager.** Each Party shall appoint a project manager for each Project, who shall be named in the relevant SOW. Centogene's project manager shall be responsible for the overall conduct of the Project and either Party's project managers shall be the principal point of contact for the other Party for all matters relating to such Project. Neither Party shall change the project manager without the other Party's prior written consent.
- 4.9. **Variation.** Shire may request and Centogene shall not unreasonably withhold its consent to amend and/or supplement a Project. Further, Centogene may propose to amend and/or supplement a Project and Shire shall consider in good faith such change proposal and inform Centogene of its decision within forty-five (45) days of receipt of Centogene's change proposal. Centogene shall use all reasonable efforts to implement any change requests or change proposals agreed by the Parties as soon as possible and with no further financial adjustment. In the event that a change request or change proposal would result in cost increases or reductions and/or failures to meet agreed time lines, Centogene shall be obliged to notify such consequences in writing together with Centogene's change proposal or within twenty (20) Business Days after having received Shire's change request. Should the Parties be unable to reach agreement on any change request or change proposal the JSC shall discuss the issue in good faith.

## 5. GENERAL SERVICES OBLIGATIONS

- 5.1. **Personnel.** Centogene shall exercise, and ensure that its personnel exercise, all reasonable skill, care, and diligence in the performance of the Services. Centogene shall ensure that all its personnel who perform the Services are technically competent and suitably qualified to carry out the parts of the Services assigned to them.
- 5.2. **Subcontracting.** Centogene shall not subcontract any activities under this Agreement to a Third Party without Shire's prior written consent. Centogene may propose to subcontract

certain defined activities under this Agreement to a Third Party and Shire shall consider in good faith such proposal and inform Centogene of its decision within thirty (30) days of receipt of the consent request. Any consent given by Shire shall require that the agreements between Centogene and such Third Parties are made in writing and fully correspond to the agreements between Shire and Centogene. Centogene shall ensure that Centogene's obligations under this Agreement regarding Intellectual Property, publications, confidentiality and data protection will be fulfilled. In particular, Centogene shall ensure that such Third Parties have executed appropriate agreements with Centogene containing substantially similar terms regarding confidentiality, Intellectual Property and publications as those set out in this Agreement. In the event that Centogene fulfils its obligations through a permitted subcontractor, Centogene shall remain fully liable for the fulfilment of its obligations under this Agreement. Centogene shall be responsible for the qualification and validation of any subcontractor.

- 5.3. **No Conflict.** Centogene shall not, during the term of this Agreement, enter into any agreements that limit its capacities and resources which are required to meet the quality and quantity obligations assigned in this Agreement or a SOW. Centogene will provide all staff necessary to provide the Services in accordance with the terms of this Agreement.
- 5.4. **No Exclusivity.** Nothing in this Agreement shall prevent Shire from appointing a Third Party to conduct services that are the same as, or similar to, Services. Vice versa, nothing in this Agreement shall prevent Centogene from providing services to Third Parties that are the same as, or similar to, Services.

## 6. ALLIANCE MANAGERS; JOINT STEERING COMMITTEE

- 6.1. **Alliance Managers.** Promptly following the Effective Date, each Party shall designate two (2) individuals - one individual with respect to Diagnostic Services and one individual with respect to R&D Services — to serve as main points of contact for each Party for such Services to exchange information, facilitate communication and coordinate the Parties' activities under this Agreement and to provide day-to-day support (each, an "**Alliance Manager**"). Each Alliance Manager shall be experienced in project management and shall have appropriate experience in the pharmaceutical industry. The Alliance Managers shall attend all meetings between the Parties, including JSC meetings. Each Party may change its designated Alliance Managers from time to time upon written notice to the other Party; provided, that the Parties recognize and agree as to the importance of continuity in their relationship and the activities hereunder.
- 6.2. **Joint Steering Committee (JSC).** Promptly after the Effective Date the Parties shall establish and during the term of this Agreement the Parties shall operate a joint steering committee, which shall have the primary role in ensuring the overall success of the cooperation ("**Joint Steering Committee**"). The Joint Steering Committee will act as a forum between the Parties to ensure a smooth cooperation, regular business reviews and long-term planning. The JSC shall be comprised of an equal number of three (3) managing directors or board members of each Party. The initial JSC members shall be

- For Shire: [\*\*\*\*\*]
- For Centogene: [\*\*\*\*\*]

The JSC shall meet at such time as the JSC shall agree from time to time with the aim to meet calendar quarterly, but shall meet at least every calendar half year. Shire shall

designate the chairman of the JSC who shall be responsible to call the regular meetings and special meetings at either Party's request. The meeting place shall alternate between the offices of Shire and Centogene, or as otherwise decided by the JSC. JSC meetings may be conducted in person, by telephone or videoconference, provided, however, that at least one (1) meeting per calendar year shall be held in person. Each Party shall provide the other Party with written notice of its new representatives for the JSC immediately upon replacement. Each Party may invite guests to the meetings, in order to discuss special technical or commercial topics. Shire shall keep accurate and complete minutes of the JSC meetings and shall circulate such minutes in English to Centogene within ten (10) Business Days after each meeting, and the Parties shall agree on the minutes of such meeting promptly. Each Party shall be responsible for the expenses incurred by its employees and its members of the JSC. All decisions of the JSC are to be made in good faith and in the best interest of the Agreement, and the Parties shall use their reasonable efforts to take decisions unanimously. The JSC shall not have any power to amend, modify or waive compliance with this Agreement. Each Party shall retain its rights, powers and discretion and no such rights, powers or discretion shall be delegated or vested in the JSC unless the Parties expressly so agree in writing.

## 7. SUSPENSION OF DIAGNOSTIC SERVICES

7.1. Suspension. Shire may, at its reasonable discretion, suspend the provision of Diagnostic Services, in whole or in part, immediately by providing written notice

- (a) in the event of any substantial supply issues with, withdrawal of or suspension of one of the Shire Products;
- (b) if the provision of Test Kits to Physicians and the performance of Diagnostic Tests with Samples in any country of the Territory is (i) found or alleged by any Regulatory Authority, court, industry association or other entity with competence over any Shire Group Company to be impermissible, or (ii) in the reasonable opinion of Shire's compliance function likely to be impermissible; or
- (c) if Centogene loses any governmental authorizations required to provide the Diagnostic Services in accordance with Applicable Laws and GLP.

(any of the foregoing a "**Suspension Event**"), provided that with regards to the Suspension Events listed in Sections 7.1 (a) and (b) Shire may only suspend the provision of Diagnostic Services with respect to the respective Shire Product(s) and/or country(ies) directly affected by such Suspension Event(s).

7.2. Effect of Suspension. Upon suspension of Services under Section 7.1 Shire shall not be obliged to make the Minimum Financial Commitment for as long as and to the extent that any or all Suspension Events continue to exist. If the Suspension Event only applies to less than the totality of Shire Products and/or the whole Territory under this Agreement, Shire and Centogene shall promptly meet and re-negotiate in good faith the Target Volumes as well as the Minimum Financial Commitment, provided, however, that any reduction of the Minimum Financial Commitment shall only take effect after a grace period of ninety (90) days after the suspension by Shire. When such Suspension Event no longer exists, the amended Target Volumes and Minimum Financial Commitment agreed pursuant to the preceding sentence of this Section 7.2 shall no longer apply and Centogene's originally agreed Target Volumes and Shire's obligation to make the originally agreed Minimum Financial Commitment shall revive from such moment on a pro rata basis for the respective calendar year. Shire's exercise of its right of suspension under this Section 7 shall not function as a waiver of any right of termination that it may have under this Agreement.



7.3. Resumption of Services. Shire may, at its reasonable discretion, end the partial or complete suspension, in whole or in part, at any time by providing written notice to Centogene. Upon receipt of Shire's written notice, Centogene shall re-establish the suspended Services as soon as reasonably practicable and Shire shall then resume the originally agreed Minimum Financial Commitment payments.

## 8. CONFIDENTIALITY

8.1. Confidentiality. All Confidential Information disclosed, revealed or otherwise made available by one Party ("**Disclosing Party**") to the other Party ("**Receiving Party**") under, or as a result of, this Agreement is furnished to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party's Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party's Confidential Information available to any Third Party, without the prior written authorization of the Disclosing Party. The same shall apply to any Confidential Information disclosed with regards to the Services to be provided under this Agreement before the Effective Date.

8.2. Safeguards. In furtherance of the Receiving Party's obligations under Section 8.1 hereof, the Receiving Party shall take all appropriate steps, and shall implement all appropriate safeguards, to prevent the unauthorized use or disclosure of any of the Disclosing Party's Confidential Information. Without limiting the generality of this Section 8.2, the Receiving Party shall disclose any of the Disclosing Party's Confidential Information only to those of its officers, employees, commercial agents, distributors, consultants, licensees, potential licensees and financial investors that have a need to know the Disclosing Party's Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement, and only if such officers, employees, agents, consultants, licensees, potential licensees and financial investors have executed appropriate non-disclosure agreements containing substantially similar terms regarding confidentiality as those set out in this Agreement or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use or disclosure of the Disclosing Party's Confidential Information. The Receiving Party shall furnish the Disclosing Party with immediate written notice of any unauthorized use or disclosure of any of the Disclosing Party's Confidential Information and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party's Confidential Information.

8.3. Exceptions. The Receiving Party's obligations under Section 8.1 and 8.2 hereof shall not apply to the extent that the Receiving Party can prove by written evidence that the respective Confidential Information:

- (a) passes into the public domain, or becomes generally available to the public through no fault of the Receiving Party;
- (b) was known to the Receiving Party prior to disclosure hereunder by the Disclosing Party;
- (c) is disclosed, revealed or otherwise made available to the Receiving Party by a Third Party that is under no obligation of non-disclosure and/or non-use to the Disclosing Party;
- (d) is required to be disclosed under applicable law or by court order; *provided, however*, that the Receiving Party shall furnish the Disclosing Party's with as much prior written notice of such disclosure requirement as reasonably practicable, so as

to permit the Disclosing Party, in its sole discretion, to take appropriate action in order to prevent the Disclosing Party's Confidential Information from passing into the public domain or becoming generally available to the public; or

(e) is independently developed by the Receiving Party without breach of this Agreement as evidenced by contemporaneous written records.

8.4. **Return of Information.** Upon expiration or termination of this Agreement for any reason whatsoever, the Receiving Party shall return to the Disclosing Party, or destroy, as the Disclosing Party shall specify in writing, all copies of all documents and other materials that contain or embody any of the Disclosing Party's Confidential Information, except to the extent that the Receiving Party is required by applicable law or permitted under this Agreement to retain such documents and materials. Within thirty (30) calendar days after the date of expiration or termination of this Agreement, the Receiving Party shall furnish the Disclosing Party with a written certificate, confirming that the Receiving Party has complied with its obligations under this Section 8.4.

8.5. **Survival.** All of the Receiving Party's obligations under Section 8.1 and 8.2 hereof, with respect to the protection of the Disclosing Party's Confidential Information, shall survive the expiration or termination of this Agreement for any reason whatsoever.

## 9. INTELLECTUAL PROPERTY

9.1. **Ownership of Centogene Background Intellectual Property.** Nothing in this Agreement shall affect Centogene's ownership of the Centogene Background Intellectual Property.

9.2. **Rights in Reports.** The Parties agree that Shire shall own all right, title and interest in and to the Reports with the details set forth in Exhibit 4 that Centogene provides to Shire in the course of the Diagnostic Services. Centogene hereby assigns and transfers to Shire and shall continue to assign and transfer to Shire during the term of this Agreement all of its rights, title and interest in the Reports, and Shire hereby accepts such assignment and transfer. Only to the extent such transfer is not possible under applicable copyright laws, Centogene hereby irrevocably grants to Shire an exclusive and transferable license (unlimited in time, territory and scope, and including the right to grant sublicenses) to the Reports. For the avoidance of doubt, nothing in this Section 9.2 shall be construed to limit Centogene from using the Diagnostic Test Results.

9.3. **Rights in Project Results.** All Project Results shall be provided promptly to Shire or the relevant Shire Group Company. The Parties agree that Shire shall own all right, title and interest in and to the Project Results. Centogene hereby assigns and transfers to Shire and shall continue to assign and transfer during the term of this Agreement to Shire all of its right, title and interest in the Project Results, and Shire hereby accepts such assignment and transfer. At Shire's written instructions and expense, Centogene agrees to make or procure all assignments, and shall require Centogene's personnel involved in the performance of R&D Services to execute any documents required to confirm Shire's ownership right, which are necessary to give effect to this Section 9.3 and to do all acts and assist Shire or any Shire Group Company in every way reasonable required to obtain, maintain and enforce Intellectual Property Rights covering Project Results. In particular, Centogene shall assume any patentable invention made by any of Centogene's employees in the course of performing R&D Services in accordance with the German Act on Employee Inventions (*Arbeitnehmererfindungsgesetz, ArbNErfG*). Centogene shall promptly and fully disclose to Shire details of all discoveries, inventions, and improvements

conceived or developed by in the course of the provision of R&D Services. For the avoidance of doubt, Centogene shall have the right to publish Project Results in accordance with Section 9.8 below.

- 9.4. **New General Diagnostic Testing Intellectual Property.** Centogene shall own all right, title and interest in “**New General Diagnostic Testing Intellectual Property**”, which as used in this Agreement means Intellectual Property that is developed, conceived, invented, reduced to practice or made solely in the course of performance of the Services by Centogene, and that (i) arises from or relates to the practice of Centogene Background Intellectual Property; (ii) is severable from Shire Products; and (iii) does not reveal or disclose any Shire Confidential Information or any Shire Product Information.
- 9.5. **Personnel.** Centogene shall have and will continue to have agreements with its personnel to give effect to the provisions of this Section 9, and shall enforce such agreements to provide Shire with the benefit of this Section 9.
- 9.6. **Shire’s Licenses to Centogene.** Shire hereby grants to Centogene a non-exclusive, worldwide, fully paid-up, irrevocable license (transferable/sublicensable only in combination with a transfer of or (sub-)license to Centogene Background Intellectual Property), to use Project Results (i) in an aggregate manner as part of Centogene’s diagnostic testing database, provided that under no circumstances will this license grant the right to separate or single out subsets of data generated in the course of a Project and use such subsets for any purposes other than that expressly agreed to in writing by the Parties, and (ii) only to the extent necessary or useful to develop, test, manufacture, market, commercialize and make any other use of the New General Diagnostic Testing Intellectual Property.
- 9.7. **Centogene’s License to Shire.** Centogene hereby grants to Shire and any Shire Group Company a non-exclusive, worldwide, fully paid-up, irrevocable and transferable license, with the right to grant sublicenses, to the Centogene Background Intellectual Property and New General Diagnostic Testing Intellectual Property only to the extent necessary or useful to develop, test, manufacture, market, commercialize and make any other use of the Project Results. For the avoidance of doubt, such license shall not include any right to use Centogene Background Intellectual Property and/or New General Diagnostic Testing Intellectual Property for the performance of diagnostic testing activities.
- 9.8. **Publication Rights.** Centogene shall not, and shall cause any Third Party participating in a given Project not to, publish or present any Project Results until such time as either the Project Results are published in a cooperative publication or for a period of [\*\*\*\*\*] after termination or completion of the relevant Project, whichever shall first occur. The Parties will use all reasonable efforts to publish or present Project Results in a cooperative publication as soon as reasonably possible after termination or completion of the relevant Project. After that time, Centogene and any Third Party participating in a given Project may publish Project Results in scientific journals or present Project Results at symposia or other professional meetings in accordance with the following provisions: At least [\*\*\*\*\*] days prior to submitting an abstract, manuscript, or other document for publication or presentation, a copy of the proposed publication or presentation will be provided to Shire for review. Upon Shire’s request, Centogene shall, and shall cause any Third Party participating in a given Project to, remove any and all Confidential Information of Shire and any Shire Product Information identified in the publication or presentation and to delay such submission or presentation for an additional [\*\*\*\*\*] period in order to allow Shire time to file any patent application(s). All publications and presentations of Project Results shall appropriately reference any previous cooperative publication, if any, or the fact that the Project Results are a subset of data resulting from a certain Project or study conducted by or on behalf of any Shire Group Company.

9.9. Third Party IP. In the event either Party becomes aware of any Third Party Intellectual Property Rights which might interfere with the use and exploitation of the Reports or the Project Results, it shall immediately inform the other Party hereof. Each Party shall reasonably assist the other Party or any Affiliate of the other Party, at the other respective Party's expense, in defending itself against a Third Party claim, which would impair the use and exploitation of the Reports or Project Results. Each Party shall furnish the other Party with written notice of any and all infringements and other unauthorized uses by any Third Party of the Reports or Project Results promptly after it receives notice thereof.

## 10. REPRESENTATIONS AND WARRANTIES

10.1. Centogene Warranties. Centogene warrants and represents that

- (a) it has all governmental and other approvals necessary for it to carry out the Services;
- (b) it is not party to any agreement that would prevent it from fulfilling its obligations under this Agreement;
- (c) it has and will maintain during the term the experience, the scientific know how, the human resources and the capacities required to meet the Target Volumes and to perform the Services in accordance with Applicable laws, GLP and the terms of this Agreement;
- (d) it will perform the Diagnostic Tests and submit the Diagnostic Test Results in accordance with the terms of this Agreement;
- (e) to its present knowledge, as of the Effective Date, the Centogene Background Intellectual Property Rights for purposes of this Agreement do not infringe any Third Party Intellectual Property Rights;
- (f) as of the Effective Date, no material litigation, arbitration or administrative proceeding is pending or threatened in relation to the Diagnostic Tests;
- (g) as of the Effective Date, Centogene conducts no activity that involves or relates to or is alleged to involve or relate to fraud, the proceeds of crime, corruption or any other similar matter; and
- (h) in the course of providing Diagnostic Services it will not make any statement on any Shire Product to any Physician or any Third Party and will not provide any treatment recommendation.

10.2. Anti-Bribery. Centogene represents, warrants and covenants that neither Centogene nor any Affiliate of Centogene nor any officer, employee or agent of Centogene (or any of its Affiliates) has, nor shall it, offer, promise, give or receive, any financial or other advantage in violation of the Bribery Act 2010 (UK) or Foreign Corrupt Practices Act 1977 (USA), as amended from time to time, respectively, or any comparable laws in any country from which or to which services are provided by or for Centogene under this Agreement (collectively, "**Anti-Bribery Laws**") and Centogene and its Affiliates shall each maintain procedures designed to prevent bribery falling within the Bribery Act 2010. Centogene further represents, warrants and covenants that no person employed by Centogene and no person acting as agent of Centogene in connection with Centogene's obligations under this Agreement (other than those persons who have been notified from time to time by

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Centogene to Shire and in respect of whom Shire has provided its prior written approval), is an official of the Government of any country (or of any agency of such government), and that no part of any monies or consideration paid to Centogene under this Agreement shall accrue for the benefit of any such official. For the purposes of enabling Shire to monitor its compliance with Anti-Bribery Laws, Centogene shall make available for audit by Shire or its designee, upon Shire's reasonable request at any time during the Term, books, records and other documentation relevant to Centogene's business activities conducted pursuant to this Agreement.

10.3. Insurance. Centogene shall maintain liability and other appropriate forms of insurance at levels sufficient to support its indemnification obligations assumed herein but in no case shall this insurance be less than the minimum limits shown below:

- (a) workers compensation and/or employers liability to limits required by Applicable Law;
- (b) General liability insurance in amounts of €[\*\*\*\*\*] per occurrence and €[\*\*\*\*\*] in the annual aggregate;
- (c) Products liability insurance in amounts of €[\*\*\*\*\*] per occurrence; and €[\*\*\*\*\*] in the annual aggregate
- (d) Errors & omissions liability insurance in amounts of €[\*\*\*\*\*] per occurrence and in the annual aggregate;
- (e) Technology errors and omissions liability (including coverage for electronic media activities, network operations security liability, privacy liability and miscellaneous professional liability in amounts of €[\*\*\*\*\*] per claim and in the annual aggregate; and
- (f) Crime coverage (employee dishonesty and computer fraud), including an endorsement and/or coverage amendment for Third Party coverage (client coverage) in the amounts of €[\*\*\*\*\*] per each and every event.

Should any insurances be provided on a 'claims made' basis such insurance shall be maintained for a period of five (5) years following the expiration or termination of this Agreement. All such insurances will be provided by a company or companies licensed to do business in Germany having a financial rating of not less than A- VIII in the most current edition of Best's Key Rating Guide. Centogene shall provide a certificate of insurance evidencing such coverage as requested by Shire. The minimum limits of insurance required shall not be construed to create a limit of Centogene's liability or indemnification obligations under this Agreement.

## 11. INDEMNIFICATION

11.1. Indemnification by Centogene. Centogene shall, at its sole expense, indemnify, defend and hold harmless Shire, its Affiliates and their respective officers, directors, agents and employees (the "**Shire Indemnitees**") from and against any and all losses, damages, liabilities, costs and expenses

(including reasonable attorneys' fees and court costs) (collectively, "**Losses**") arising out of Third Party claims due to

- (a) a failure to provide Diagnostic Services in accordance with GLP and applicable data protection laws;
- (b) incorrect Diagnostic Test Results;

- (c) the malperformance of the Services;

*provided, however*, that Centogene will not be liable to indemnify the Shire Indemnitees for any Losses to the extent that such Losses were caused by the negligence or willful misconduct of the Shire Indemnitees.

- 11.2. **Procedure.** Shire shall notify Centogene promptly in writing upon learning of any Third Party action in respect of which indemnification may be sought under Section 11.1. Centogene shall (i) actively defend against every claim using counsel approved by Shire, such approval not to be unreasonably withheld or delayed; (ii) shall promptly inform Shire and its attorneys of all developments concerning Shire; and (iii) shall generally consult with Shire regarding the strategy of the defense of any claim. The Shire Indemnitees shall reasonably cooperate with Centogene in defending or settling any such claim. No settlement of any claim for which indemnification is sought, shall be made without the prior written approval of Centogene. Centogene will have sole control over the defense and/or settlement, subject to the Shire Indemnitees' right to select and use their own counsel at their sole cost and expense.

## 12. TERM, TERMINATION

- 12.1. **Initial Term.** This Agreement shall come into force at the Effective Date and shall remain in full force for an initial term of five (5) years, unless terminated in accordance with Section 12.3 et seq.
- 12.2. **Additional Term.** Shire shall have the right to extend the Agreement for a period of two (2) additional years by providing at least twelve (12) months prior written notice before the expiration of the initial term. In this event Section 3.6(g) shall apply accordingly.
- 12.3. **Termination by Shire.** Shire shall have the right to terminate the Agreement and/or any SOWs with immediate effect by providing written notice to Centogene in case
- (a) Centogene experiences a Change of Control in which a company or group of companies is the acquirer (by asset purchase, merger, consolidation, reorganization or otherwise) who, (i) is a direct competitor of Shire or any Shire Group Company with regards to Shire Products; or (ii) causes a conflict of interest in providing Services or (iii) may, as a result of such Change of Control, cause Centogene's lack of the technical, personnel or other organizational excellence necessary to perform the Services in accordance with the Parties' intention to find any remaining unidentified patients of lysosomal storage diseases by the year 2020;
  - (b) Subject to Section 12.5, Centogene commits a material breach or default of any of its obligations hereunder, which shall include (i) inability or unwillingness to at all provide any Services for a period longer than two (2) months, (ii) persistent failure to process submitted Samples in accordance with this Agreement, (iii) failure to perform Diagnostic Services and/or to maintain the Facility in accordance with GLP or significant deviation from quality standards defined in the Technical Quality Agreement, including material findings in an audit, (iv) breach of a representation and warranty under Section 10;
  - (c) Centogene's financial situation substantially deteriorates; or
  - (d) Centogene ceases to provide diagnostic laboratory services.

- 12.4. Termination by Centogene. Centogene shall have the right to terminate the Agreement and/or any SOWs with immediate effect by providing written notice to Shire in case
- (a) Subject to Section 12.5, Shire commits a material breach or default of any of its obligations hereunder, which shall include Shire's failure to meet its payment obligations after appropriate written reminders by Centogene by more than sixty (60) days in three (3) consecutive calendar months; or
  - (b) Shire's financial situation substantially deteriorates.
- 12.5. Material Breach. In the event that either Party commits a material breach or default of any of its obligations hereunder, the other Party shall give the breaching Party written notice of such material breach or default, and shall request that such material breach or default be cured as soon as reasonably practicable. In the event the breaching Party fails to cure such breach or default within thirty (30) calendar days after the date of the non-breaching Party's notice thereof, the non-breaching Party may terminate this Agreement and/or any SOWs pursuant to Section 12.3(b) or 12.4(a), as the case may be. In case the breach is incapable of cure, the non-breaching party is entitled to terminate this Agreement and/or any SOWs with immediate effect without the need to grant a cure period. Termination of this Agreement in accordance with Section 12.3(b) or 12.4(a), as the case may be, shall not affect or impair the non-breaching Party's right to pursue any legal remedy, including, but not limited to, the right to recover damages, for any harm suffered or incurred by the non-breaching Party as a result of such breach or default.
- 12.6. Additional Termination by Shire.
- (a) Shire shall have the right to terminate a Statement of Works with three (3) months prior written notice on the grounds that, following a review of the data and other know-how generated during the Project, in Shire's reasonable opinion there is insufficient scientific or commercial value to justify continuing the Project; and
  - (b) Shire shall have the right to terminate a Statement of Works, which relates to the Biomarker Lyso GB1, with three (3) months prior written notice if (i) Shire does not within thirty (30) calendar days accept a written offer from Centogene to Shire to obtain an exclusive license to the Biomarker Lyso GB1 on identical terms and conditions, which Centogene has negotiated with a Third Party (preemption right), and (ii) Centogene grants a Third Party such an exclusive license without violating Shire's preemption right.
- 12.7. Consequences of Termination. Shire shall pay to Centogene the fees for Services actually rendered until the effective date of termination, *provided that* in the event of termination in accordance with Section 12.3 above, Shire shall have no further obligation to make the Minimum Financial Commitment for the respective year. Any Projects which are still ongoing at the time of termination shall continue to be effective in accordance with the terms of this Agreement and the relevant SOW until completion of such Project, unless Shire has terminated the SOW in accordance with Section [\*\*\*\*\*].
- 12.8. Survival. Termination of this Agreement for whatever reason shall not affect the accrued rights of the Parties under or out of this Agreement, and Sections 1 (Definitions), 3.7 (Maintenance of Records; Audits), 8 (Confidentiality), 9 (Intellectual Property), 10.3 (Insurance), 11 (Indemnification), 12.7 through 12.9 and 13 (Miscellaneous) of this Agreement shall survive the termination and remain in full force and effect.
- 12.9. Designated Third Party Laboratory. Without limiting any other rights or remedies of Shire, if Shire terminates the Agreement pursuant to Section 12.3(c), then Shire shall have the

right to enter into a direct contractual agreement with the Designated Third Party Laboratory and to have the Diagnostic Services performed by such Designated Third Party Laboratory. Centogene shall take all necessary operational measures, including escrow deposits of complete and comprehensible descriptions of Centogene's diagnostic testing technology during the term of the Agreement, and shall - on customary arms-length licensing terms and conditions between Centogene and the Designated Third Party Laboratory - grant to such Designated Third Party Laboratory all required licenses to the Centogene Background Intellectual Property to ensure that such Designated Third Party Laboratory possesses all technical knowledge and holds all licenses to any Centogene Intellectual Property to use the Diagnostic Tests and to provide Diagnostic Services.

### 13. MISCELLANEOUS

- 13.1. Governing Laws: Dispute Resolution. This Agreement shall be governed and construed in accordance with the laws of Germany, without reference to conflict of laws principles. If there is a dispute between the Parties relating to this Agreement, the Parties shall in the first instance attempt to solve the dispute amicably. If they cannot do so, the dispute shall be referred to the JSC which shall meet to try to resolve the matter. If the JSC is unable to agree upon a resolution within sixty (60) calendar days of the referral of the dispute to them, the dispute shall be finally settled in accordance with the Arbitration Rules of the German Institution of Arbitration (DIS) without recourse to the ordinary courts of law. The place of arbitration shall be Berlin. The number of arbitrators shall be three (3). The language of the arbitral proceedings shall be English. Nothing in this Section shall prevent or delay a Party from seeking interim relief in any court of competent jurisdiction.
- 13.2. Assignment. This Agreement may not be assigned by either Party in whole or in part without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, *provided, however*, that the prior written consent of Centogene shall not be required for Shire to assign this Agreement to an Affiliate. The Parties agree that it would be unreasonable for Shire to withhold or delay its consent for Centogene AG to assign this Agreement to an Affiliate if (i) the assignment is part of a larger restructuring project as already envisaged prior to the Effective Date; if (ii) the assignee is and continues to be after the assignment a wholly held (100%) subsidiary of Centogene AG; and if (iii) Centogene AG guarantees to Shire in writing the fulfillment of all obligations under this Agreement for the duration of such obligations and in accordance with this Agreement.
- 13.3. Severability. The invalidity of any provision or provisions of this Term Sheet shall not affect the other provisions contained therein. Any invalid provision shall be deemed to have been replaced by a provision which achieves as closely as legally permissible what the invalid provision was intended to achieve for commercial purposes.
- 13.4. No Authority. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party or its Affiliates, without the prior written consent of the other Party.
- 13.5. Amendments. Any amendment to this Agreement shall be effective only if made in writing and signed by the Parties. This also applies to a waiver of the written form requirement.
- 13.6. Interpretation. In this Agreement the headings are used for convenience only and shall not affect its interpretation. Where the word 'including' is used it shall be understood as meaning 'including without limitation'.
- 13.7. Entire Agreement. This Agreement, including its Exhibits, sets out the entire agreement between the Parties relating to its subject matter and is intended to eventually supersede



all Existing Agreements between Centogene and any Shire Group Company relating to such subject matter.

- 13.8. Costs. Each Party shall bear the costs of its own accountants, attorneys, consultants and other professional advisors in connection with the negotiation and execution of this Agreement.

Exhibits:

- Exhibit 1 Diagnostic Tests and Prices
- Exhibit 2 Existing Agreements
- Exhibit 3 Template for Statement of Work
- Exhibit 4 Content of Reports

*[signature page follows]*

Place: Zug

Place: Rostock

Date: 11/12/2014

Date: 16/12/2014

**for and on behalf of  
Shire International GmbH**

**for and on behalf of  
Centogene AG**

/s/ Enrico Maria Dolfini

/s/ Prof. Dr. Arndt Rolfs

Name: Enrico Maria Dolfini

Name: Prof. Dr. Arndt Rolfs

Title: Proxy Holder

Title: CEO

**Exhibit 1**

**Diagnostic Tests and Prices**

The below prices include (where indicated) an additional technology access fee of € [\*\*\*\*\*] per tested Sample

Test	Costs In €
<b>Gaucher</b>	
[*****]	[*****] technology access fee
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
If a mutation in a family is found there will be an additional charge	[*****] sample processing fee + [*****] per exon (Total [*****] for a homozygous mutation and [*****] for an heterozygous mutation)
For a prenatal analysis there is an additional charge	[*****] for sample analysis + [*****] for contamination control with maternal material
<b>Fabry</b>	
[*****]	[*****] technology access fee
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
If a mutation in a family is found there will be an additional charge	[*****] sample processing fee + [*****] per exon
For a prenatal analysis there is an additional charge	[*****] for sample analysis + [*****] for contamination control with maternal material
<b>MPS II (Hunter Disease)</b>	
[*****]	[*****] technology access fee
[*****]	[*****]

**MPS IIIa (SGSH)**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**MPS IIIb (NAGLU)**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**MPS IIIc (HGSNAT)**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**MPS III d (GNS)**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**MLD (SGSH)**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**MPS I and VI**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee each  
[\*\*\*\*\*] [\*\*\*\*\*]

## Exhibit 2

### Existing Agreements

1. **Service Agreement** between Shire Pharmaceuticals de Mexico, S.A. de C.V. and Centogene GmbH of 13 August 2010 (as amended by Replacement Agreement of 16 May 2012)
2. **Master Service Agreement** between Shire Human Genetic Therapies, Inc. and Centogene GmbH of 14 October 2011
  - a. **Statement of Work** between Shire Human Genetic Therapies, Inc. and Centogene GmbH of 22 November 2011
  - b. **Statement of Work** between Shire Human Genetic Therapies, Inc. and Centogene AG of 7 February 2013
  - c. **Statement of Work** between Shire Human Genetic Therapies, Inc. and Centogene AG of 9 July 2013
  - d. **Statement of Work** between Shire Human Genetic Therapies, Inc. and Centogene AG of 21 March 2014
3. **Service Agreement** between Shire AG and Centogene GmbH of 15 August 2012 (as amended by Amending Agreement of 31 July 2014)

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## Exhibit 3

### Template for Statements of Works

This Statement of Works dated 20[—] is between:

- (1) **[Shire Group Company]**, a company incorporated in [*country of incorporation*] under [*company registration number*], whose principal place of business is at [*address*] (“**Shire**”); and
- (2) **Centogene AG**, incorporated under the laws of the Federal Republic of Germany with principal office in Freiburg i.Br., registered with the district court (‘Amtsgericht’) in Freiburg in Br. under HRS 706872 and having a business address at Schillingallee 68, 18057 Restock, Germany, (“**Centogene**”); and

#### PREAMBLE

This Statement of Works is made subject to the provisions of the Global Master Services Agreement entered into by Shire [*Alternatively: Shire International GmbH, an Affiliate of Shire*] and Centogene entered into as of 1 January 2015 (“**Agreement**”).

#### The Parties agree as follows:

##### 1. DEFINITIONS

Capitalized terms shall have the meaning set forth in the Agreement, unless specifically defined otherwise in this Statement of Works.

##### 2. OBLIGATIONS

Centogene shall perform the R&D Services as described in this Statement of Works, subject to the provisions of this Statement of Works and the Agreement.

##### 3. THE PROJECT

[Include a description of the Project and expected Project Results, name of project manager, etc.]

##### 4. SPECIFICATIONS

[Include a description of the Specifications, if any.]

##### 5. TIMELINES

[Include a timetable for the delivery of the R&D Services here.]

##### 6. MILESTONE AND PAYMENTS

[Include a schedule of payments here.]

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7. **ADVERSE EVENTS REPORTING**

[Include Shire standard clause I standard form on adverse events reporting, if applicable.]

Place:

Place:

Date:

Date:

**for and on behalf of**  
**[Shire Group Company]**

**for and on behalf of**  
**Centogene AG**

\_\_\_\_\_  
Name: \_\_\_\_\_

\_\_\_\_\_  
Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Place:

Place:

Date:

Date:

**for and on behalf of**  
**[[additional participants, if any]**

**for and on behalf of**  
**[[additional participants, if any]**

\_\_\_\_\_  
Name: \_\_\_\_\_

\_\_\_\_\_  
Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

## Exhibit 4

### Content of Reports

The Patient-blinded Reports to be provided by Centogene shall contain the following information, per month and cumulative for the year to date, on a country-by-country basis and, where permitted by local regulation and requested by the relevant Shire Group Company, on a ZIP-code basis:

[\*\*\*\*\*]



CONFIDENTIAL TREATMENT REQUESTED UNDER RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

Confidential

Execution Version

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**SUPPLY AGREEMENT**

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between

**Shire Pharmaceuticals Ireland Ltd.**

and

**Centogene AG**

[\*\*\*\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

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**This Supply Agreement** is entered into as of 1 January 2016 (“**Effective Date**”) by and between

- (1) **Shire Pharmaceuticals Ireland Ltd.**, an Irish limited liability company having its registered office at 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland, Eircode D241W13 (“**Shire**”); and
- (2) **Centogene AG**, a German stock corporation incorporated under the laws of the Federal Republic of Germany with principal office in Rostock, registered with the district court (‘Amtsgericht’) in Restock under HRB 13225 and having a business address at Schillingallee 68, 18057 Restock, Germany, (“**Centogene**”).

**PREAMBLE**

- (A) With effect of 1 January 2015 Shire International GmbH and Centogene have entered into a global master services agreement under which Centogene shall provide certain diagnostic testing services on the basis of dried-blood-spot (DBS) cards for the purpose of identifying patients suffering from lysosomal storage and other rare diseases to Shire and other affiliates of Shire.
- (B) Shire and other companies from the Shire group intend to provide test kits containing DBS cards and other components to physicians in certain countries of the world for the purpose of identifying patients suffering from lysosomal storage diseases and other rare diseases including, but not limited to, Gaucher and Fabry diseases, MPS I, MPSII, MPS VI.
- (C) Centogene has developed a certain DBS test kit to identify patients suffering from lysosomal storage diseases and other rare diseases and has obtained a CE mark for use in all EU countries, as well as regulatory approval in other geographic locations.
- (D) Shire and Centogene intend to enter into this Agreement under which Centogene will (i) develop new DBS test kits for use in certain countries as required by Shire on the basis of Centogene’s existing DBS test kits, (ii) manufacture such new DBS test kits and (iii) supply Shire and its affiliates with such new DBS test kits in accordance with the terms of this Agreement.
- (E) This Agreement shall serve as a framework agreement under which Shire will request from Centogene the development and/or supply with certain new DBS test kits from time to time on the basis of individual development orders and/or purchase orders. Centogene will act as the legal manufacturer of the DBS test kits in the EU and/or the license holder in applicable non-EU countries.

**NOW, THEREFORE, SHIRE AND CENTOGENE, INTENDING TO BE LEGALLY BOUND, HEREBY AGREE AS FOLLOWS:**

## 1. Definitions

In this Agreement, the following terms shall have the following meanings:

“**Alliance Manager**” shall have the meaning set forth in the Global Master Services Agreement.

“**Affiliate**” shall mean and include in relation to each Party, any person, firm, corporation or other entity: (i) if at least fifty percent (50%) of the voting stock or other equity interest thereof is owned, directly or indirectly, by that Party; (ii) which owns, directly or indirectly, at least fifty percent (50%) of the voting stock or other equity interest of that Party; or (iii) if at least fifty percent (50%) of the voting stock or other equity interest thereof is owned, directly or indirectly, by a person, firm, corporation or other entity that owns, directly or indirectly, at least fifty percent (50%) of the voting stock or other equity interest of that Party.

“**Aging Study Proposal**” shall mean the Shelf Life Study Proposal (including Appendix A) prepared by Centogene, dated 18 December 2015.

“**Agreement**” shall mean this Supply Agreement and all Exhibits attached hereto.

“**Anti-Bribery Laws**” shall have the meaning set forth in Section 13.3.

“**Applicable Laws**” shall mean (i) all laws, statutes, constitutions, treaties, rules, regulations, ordinances, codes of conduct, statutory guidance, codes and guidance having the force of law, directives and regulations; and (ii) all judicial, executive, legislative or administrative orders, directives, decrees, injunctions, judgments, permits, agreements, and other legal requirements both (i) and (ii) applicable to the manufacture, import, export and distribution of the Contract DBS Test Kits in the Territory, including the collection of the Patient’s informed consent, and applicable to the performance of Diagnostic Testing Services, including but not limited to Directive 98/79/EC regarding in vitro diagnostic medical devices, applicable national laws on medical devices in the Territory; and (iii) all applicable guidance documents and guidelines on medical devices applicable in the Territory, including but not limited to the MEDDEV guidance documents in its current versions.

“**Business Continuity Plan**” shall have the meaning set forth in Section 9.3(a).

“**Business Day**” shall mean any day (other than Saturday or Sunday) on which banks are open for business in Dublin, Ireland, and Restock, Germany.

“**Centogene Intellectual Property**” shall mean any and all Intellectual Property owned or controlled by Centogene covering Existing DBS Test Kits and/or Contract DBS Test Kits.

“**Change of Control**” means with respect to Centogene: (i) the sale of all or substantially all of Centogene’s assets or business relating to this Agreement; (ii) a merger, reorganization or consolidation involving Centogene after which the voting securities of Centogene outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity as a consequence of such merger, reorganization or consolidation; or (iii) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of Centogene.

“**Complaint**” shall mean any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device after it is released for distribution.

“**Confidential Information**” shall mean and include all know-how, data, documents, materials and information, not in the public domain, relating to the manufacture, distribution and provision of Contract DBS Test Kits to Physicians in the Territory, business affairs, finance plans, contractual relationships of Centogene and any Shire Group Companies.

“**Contract DBS Test Kits**” shall mean the country specific DBS test kits to be developed by Centogene as specified in separate Development Orders and to be supplied to Shire in accordance with the Specifications, the relevant Purchase Order and the terms of this Agreement for distribution in

the Territory; Contract DBS Test Kits will be developed by Centogene as requested by Shire International GmbH in accordance with the respective Development Order on the basis of Existing DBS Test Kits. Each Contract DBS Kit that is not identical from any other Contract DBS Kit in layout and/or language shall be seen as one individual and separate Contract DBS Kit hereunder and shall be treated as such.

“**DBS Cards**” shall mean dried-blood-spot cards.

“**Delivery**” shall have the meaning set forth in Section 4.8.

“**Development Order**” shall mean any written development order which Centogene and Shire International GmbH may execute from time to time and which governs a certain specified Kit Development project. A sample Development Order is attached hereto as Exhibit 4.

“**Diagnostic Testing Services**” shall mean diagnostic testing services as defined under the Global Master Services Agreement.

“**Effective Date**” shall mean the date set forth in the Introductory Clause.

“**Existing Countries**” shall mean the countries as listed in Exhibit 1 in which Existing DBS Test Kits are available or about to be available (Regulatory Approvals pending/in-process) for use as of the Effective Date.

“**Existing DBS Test Kits**” shall mean Centogene’s DBS test kits that are, as of the Effective Date, available or about to be available (Regulatory Approvals pending/in-process) for use in the Existing Countries and that contain the following components:

- Filter card-with requested
- Patient/clinician information
- Plastic sleeve
- Self-addressed envelope
- Informed consent form
- Instruction flyer
- Large envelope (for kit production)

“**Facility**” shall mean the facility of Centogene’s Third Party subcontractor where the Contract DBS Test Kits are to be manufactured.

“**Forecast**” shall have the meaning set forth in Section 4.4.

“**Global Master Services Agreement**” shall mean the Global Master Services Agreement effective as of 1 January 2015 between Shire International GmbH and Centogene under which Centogene shall provide Diagnostic Testing Services on the basis of dried-blood-samples for the purpose of identifying patients suffering from lysosomal storage and other rare diseases to Shire and Shire Group Companies.

“**Good Laboratory Practices**” or “**GLP**” shall mean that part of quality assurance which embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. GLP helps assure that the data can therefore be relied upon when making risk/safety assessments. Additionally, for the purposes of this Agreement, this includes all the principles and guidelines for G.MP stated in the EU Directives for in vitro medical devices Directive 98/79/EC and standards such as EN ISO 13485 (quality management system) and EN ISO 14971 (risk management).

“**Good Manufacturing Practices**” or “**GMP**” shall mean all standards relating to current Good Manufacturing Practices for medical devices and IVDs as well as, or published guidance documents (including advisory opinions, compliance policy guides and guidelines) promulgated by any Regulatory Authority in the Territory.

“**Incident**” shall mean in accordance with Applicable Laws any malfunction or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.

“**Intellectual Property**” shall mean and include any intellectual property of whatever nature relating, including without limitation patents, patentable inventions, design rights, copyright, trademarks, service marks, domain names, know how, whether registered, registrable or otherwise and including all applications (or rights to apply), renewals and extensions for such rights.

“**Joint Steering Committee**” or “**JSC**” shall mean the joint steering committee established under the Global Master Services Agreement.

“**Kit Development**” shall mean the development of certain Contract DBS Test Kits in accordance with the relevant Development Order for distribution in accordance with Applicable Laws in the Territory.

“**Legal Manufacturer**” shall mean the manufacturer of a medical device in the meaning of the German Medical Devices Act (*Hersteller*), Directive 98/79/EC and other Applicable Laws, i.e. the natural or legal person who is responsible for the design, manufacture, packaging and labeling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a Third Party.

“**New Country**” shall mean any country other than an Existing Country which has been requested by Shire International GmbH as described in Section 2.2(ii) or which has been agreed as described in Section 2.2(iii).

“**Party**” or “**Parties**” shall mean Shire or Centogene or Shire and Centogene, respectively.

“**Patients**” shall mean individual persons whose dried-blood samples are tested by Centogene by using the Contract DBS Test Kits for rare diseases identified on the Testing Request Form as part of the Diagnostic Testing Services.

“**Physicians**” shall mean physicians in the Territory which have received Contract DBS Test Kits and which submit dried-blood samples to Centogene for Diagnostic Testing Services.

“**Project Manager**” shall have the meaning set forth in Section 3.7.

“**Purchase Order**” shall mean any written purchase order which Centogene and Shire may execute from time to time and which governs the manufacture and supply with Contract DBS Test Kits.

“**Quality System**” means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products and services as specified in ISO 13485.

“**Regulatory Approval**” shall mean the CE certification and any other certifications, licenses, permits, approvals and authorizations for IVD devices that are necessary in order to permit the manufacture, storage, marketing, promotion, distribution and provision of Contract DBS Test Kits in the Territory under Applicable Laws.

“**Regulatory Authority(ies)**” shall mean any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity as well as notified bodies in each country in the Territory having competence over any activities in relation to this Agreement, including the manufacture, export, import, distribution and provision of Contract DBS Test Kits to Physicians in the Territory and other activities set forth under this Agreement.

“**Supply Failure**” shall mean (A) Centogene’s inability to provide for any period of at least (i) [\*\*\*\*\*] an average of [\*\*\*\*\*] percent ([\*\*\*\*\*]%), or (ii) [\*\*\*\*\*] an average of [\*\*\*\*\*] percent ([\*\*\*\*\*]%), or (iii) [\*\*\*\*\*] an average of [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of the binding amounts of the Forecast or (B) Centogene’s sudden and total inability to supply any Contract DBS Test Kits due to a force majeure event. The Parties agree that Centogene’s inability to provide the target volumes as per (A) (i), (ii) or (iii) shall not constitute a Supply Failure if and to the extent that Centogene can demonstrate that its inability was directly caused by circumstances beyond Centogene’s reasonable control and was inevitable from the perspective of a prudent businessman, as shall be the case in a force majeure event.

“**Shire Group Companies**” shall mean Shire, Shire International GmbH, Shire Human Genetic Therapies Inc., Shire Deutschland GmbH and other Affiliates in the Territory.

“**Shire Inc.**” shall mean Shire Inc., 300 Shire Way, Lexington, MA 02421, USA.

“**Shire International GmbH**” shall mean Shire International GmbH, Zahlerweg 10, 6301 Zug, Switzerland.

“**Shire Product(s)**” shall mean any medicinal products under development or commercialized by or on behalf of any Shire Group Companies in the Territory for the treatment of Morbus Fabry, Morbus Gaucher or Morbus Hunter or other similar rare diseases for which such products are authorized.

“**Specifications**” shall mean the specifications for Contract DBS Test Kits identified and agreed in the relevant Development Order or Purchase Order, as the case may be.

“**Standards**” shall mean any applicable and generally accepted international standards relating to the manufacture, quality control, quality assurance, risk management and vigilance of the Contract DBS Test Kits, including but not limited to, EN ISO 13485, EN ISO 14971 and EN ISO 9001 in its current and applicable versions.

“**Territory**” shall mean those countries in which Contract DBS Test Kits will be distributed by or on behalf of Shire Group Companies as agreed between the Parties from time to time.

“**Testing Request Form**” shall mean the request form included as part of the DBS Card contained within the Contract DBS Test Kits and submitted by Physicians directly to Centogene.

“**Third Party**” shall mean any legal entity or natural person other than the Parties or their Affiliates.

“**Turnaround Time**” or “**TAT**” shall mean the time period between Centogene’s receipt of a written Development Order or Purchase Order, as the case may be, and the outgoing of the ordered Contract DBS Test Kit at the Facility.

“**Yearly Review**” shall have the meaning set forth in Section 5.5.

## 2. **Scope of the Agreement**

2.1 **Scope.** This Agreement defines the terms and conditions under which Centogene shall diligently, within the agreed timeframes and at a standard to be expected from a reputable, specialized and professional manufacturer:

- (i) modify and develop, on the basis of Existing DBS Test Kits, Contract DBS Test Kits for use in the Territory as requested by Shire International GmbH from time to time in a Development Order; and
- (ii) manufacture and supply Shire with Contract DBS Test Kits in accordance with a Purchase Order.

2.2 Territory. As of the Effective Date,

- (i) Centogene hereby covenants that Existing DBS Test Kits are available or about to be available (Regulatory Approvals pending/in-process) for use in the Existing Countries listed in Exhibit 1; and
- (ii) the Parties plan or target the countries as set forth in Exhibit 2. Shire International GmbH may request from time to time from Centogene in a separate Development Order to develop a Contract DBS Kit for use in a certain country as listed in Exhibit 2 in accordance with Section 3.1 below; and
- (iii) Centogene will discuss with Shire International GmbH in accordance with the procedure under Section 3.1 below and on the basis of the financial terms set forth under this Agreement how to develop a Contract DBS Kit for use in a certain country not listed in Exhibit 2 as of the Effective Date.

Without limiting the generality of the foregoing, Shire and Centogene will review a business model for [\*\*\*\*\*] and consider such business model.

2.3 Contract DBS Test Kits. The Contract DBS Test Kits will not bear any logo of or reference to Shire or any Shire Group Company. Contract DBS Test Kits will contain the following components:

- Filter card-with requested
- Patient/clinician information
- Plastic sleeve
- Self-addressed envelope
- Informed consent form
- Instruction flyer
- Large envelope (for kit production).

2.4 Legal Manufacturer. Centogene shall act as the Legal Manufacturer of the Contract DBS Test Kits and shall, subject to the provisions hereunder, solely bear all related legal and regulatory responsibility as the Legal Manufacturer of the Contract DBS Test Kits under Applicable Laws in the Territory as set forth under this Agreement. Subject to the provisions hereunder, Centogene shall bear the responsibility that the regulatory requirements for importation and distribution, within the agreed countries of the Territory are met.

2.5 Release and Placing on the Market. Centogene shall release and place on the market the Contract DBS Test Kits in accordance with the Specifications, Applicable Laws and Standards as the Legal Manufacturer under its own name in each country of the Territory. In particular and subject to the provisions hereunder, Centogene shall be responsible that the Contract DBS Test Kits comply with Applicable Laws in each country of the Territory.

2.6 Conformity with Applicable Laws. The Parties are aware of the importance of the Contract DBS Test Kits' conformity with Applicable Laws, in particular the informed consent forms' conformity with applicable data protection and gene diagnostic laws in each agreed country of the Territory as well as in the country where the Diagnostic Testing Services are performed. To ensure conformity with Applicable Laws in the Territory, Centogene will perform initial reviews and Yearly Reviews pursuant to Section 5.5, the costs of such reviews to be borne by the Parties pursuant to the provisions under Section 8.4.

2.7 Distribution; withdrawal from a Country. Shire and the Shire Group Companies shall have the right, but not the obligation, to distribute the Contract DBS Test Kits in the Territory. Shire and the Shire Group Companies shall have the right to withdraw from distributing Contract DBS Test Kits in one or more countries of the Territory and to terminate corresponding payment obligations under Section 8 at any time by providing four (4) weeks prior written notice to



Centogene; provided, however, that Shire shall remain to be bound to order the amounts as provided in the latest Forecast and/or to any Development Orders or Purchase Orders already issued at the time of withdrawal and any payments pursuant to Section 8 where the respective cost estimate had already been approved by Shire and the respective Third Party thereupon irrevocably been contracted by Centogene.

- 2.8 **Framework Agreement.** This Agreement shall serve as a framework agreement under which Shire or Shire International GmbH, as indicated hereunder, may request from Centogene the Kit Development and/or supply with certain Contract DBS Test Kits from time to time on the basis of individual Development Orders and Purchase Orders, as the case may be. This Agreement shall apply to any development, manufacture and supply of Contract DBS Test Kits under a Development Order and/or Purchase Order. This Agreement shall not establish any obligation of Shire or any Shire Group Company to enter into any Development Orders and/or Purchase Orders. Each such Development Order or Purchase Order shall constitute a separate and distinct agreement and the terms and conditions of this Agreement shall be deemed incorporated by reference in each such Development Order and/or Purchase Order. In the event of any ambiguity, doubt or conflict between this Agreement and any terms and conditions appearing or referred to in any Development Order and/or Purchase Order, the terms and conditions of this Agreement shall take precedence over any terms and conditions of such Development Order and/or Purchase Order, unless such Development Order and/or Purchase Order makes explicit reference that the parties intend that a provision of such Development Order and/or Purchase Order takes precedence with respect to this Development Order and/or Purchase Order.

### 3. **Development of Contract DBS Test Kits**

- 3.1 **General.** Shire International GmbH may request from time to time from Centogene in a request for quotation (RFQ) to develop a Contract DBS Test Kit for use in one or more countries in accordance with Applicable Laws and Regulatory Approvals. Centogene will submit a project proposal to Shire within [\*\*\*\*\*] Business Days upon receipt of the request for quotation for a respective country together with a proposal for a specific development plan and the estimated cost in accordance with the prices set forth in Exhibit 3. In the project proposal Centogene shall identify the suggested development steps for each of the countries requested by Shire, propose detailed timelines for the Kit Development and specify the development of the design and matrix for the filter cards, instructions and informed consents. Contract DBS Test Kits developed during the period of the Agreement by Centogene may contain some artwork content changes from the Existing DBS Test Kit and may require translation into additional languages. Subject to a further agreement between the parties on the specific Kit Development project, Shire International GmbH may submit a respective Development Order in accordance with such further agreement which shall be binding upon the parties of the Development Order.
- 3.2 **Regulatory Approvals: Local Requirements.** The Kit Development by Centogene shall include obtaining all Regulatory Approvals for Contract DBS Test Kits and meeting all regulatory requirements under Applicable Laws of the respective destination country required to import, distribute, supply and use the individual Contract DBS Test Kit in the respective destination country. Centogene shall make all reasonable efforts to develop and submit regulatory filings and obtain Regulatory Approvals for agreed Contract DBS Test Kits as fast as reasonably possible.
- 3.3 **Performance of Kit Development.** Centogene shall perform Kit Development in accordance with the relevant agreed Development Order, the Specifications, generally accepted professional standards, GLP, GMP and Applicable Laws and Standards. As the parties may agree in the relevant Development Order, the Kit Development may be done using the existing Centogene manufacturing platform for the DBS card and making necessary language and content changes to the Existing DBS Test Kit, as needed to meet Applicable laws in the respective destination country or as reasonably requested by Shire International GmbH. Kit Development may include, but no be limited, to the following scenarios:

	Scenario	Example
1	Slightly modify Existing DBS Test Kits (e.g. unformed consent form) for use in a country that is listed in Exhibit 1 without regulatory filing'	e.g. [*****]
2	Develop for use in a certain country that is not listed in Exhibit 1 without regulatory filing	e.g. [*****]
3	Develop for use in a certain country that is not listed in Exhibit: 1 with regulatory filing	e.g. [*****]
4	Modify Existing DBS Test Kit in a country that is not listed in Exhibit 1 With regulatory filing	e.g. [*****]

("use an existing kit in a new geography")

*Centogene — Shire Kit Development — for illustrative purposes only*

- 3.4 **Time Frames.** Centogene shall make all reasonable efforts to develop Contract DBS. Test Kits in the time frames agreed and identified in the relevant Development Order. Centogene agrees to a Turnaround Time of [\*\*\*\*\*] Business Days for Development Orders, whereas Centogene may request a clock-stop during time periods that are required by Shire to review reasonable queries from Centogene.
- 3.5 **Subcontracting of Kit Development.** Centogene may propose to subcontract certain registration activities to. Third Party service providers with expertise in the, global registration process of in vitro diagnostics and Shire will reimburse documented expenditures in accordance with Section 8.4, provided that Centogene has obtained Shire's prior written approval. Any agreements between Centogene and such Third Parties shall be made in writing and fully correspond to the agreements between Shire and Centogene. Centogene shall ensure that Centogene's obligations under this Agreement will be fulfilled. In the event that Centogene fulfills its obligations through a notified subcontractor, Centogene shall remain fully liable for the fulfillment of its obligations under this Agreement Centogene shall be responsible for the qualification and validation of any subcontractor.
- 3.6 **Kit Component Aging Studies.** Centogene shall initiate promptly after the Effective Date and complete kit component aging studies aiming for establishing a [\*\*\*\*\*] shelf life of the Contract DBS Kits as set forth in Exhibit 5. Shire agrees to bear the cost set forth in Exhibit 5 up to [\*\*\*\*\*] €. In case Centogene decides to offer DBS test kits with a [\*\*\*\*\*] shelf life to customers other than Shire, Centogene will reimburse Shire of [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of the cost of the aging studies set forth in Exhibit 5.
- 3.7 **Project Manager.** Each Party shall appoint an individual as project manager for each Kit Development project, who shall be named in the relevant Development Order ("Project Manager"). Centogene 's Project Manager shall be responsible person for the overall conduct of the Kit Development project and either Party's Project Managers shall be the principal point of contact for the other Party for all matters relating to such Kit Development project. Ne her Party shall change the Project Manager without the other Party's prior written consent.
- 3.8 **Variation.** Shire may request and Centogene shall not unreasonably withhold its consent to amend and/or supplement a Kit Development project. Further, Centogene may propose to amend and/or supplement a Kit Development project and Shire shall consider in good faith such change proposal and inform Centogene of its decision within ten (10) Business Days of receipt of Centogene's change proposal. Centogene shall use all reasonable efforts to implement any change requests or change proposals agreed by the Parties as soon as possible and with no further financial adjustment. In the event that a change request or

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change proposal would result in cost increases or reductions and/or failures to meet agreed time lines, Centogene shall be obliged to notify such consequences in writing together with Centogene's change proposal or within ten (10) Business Days after having received Shire's change request. Should the Parties be unable to reach agreement on any change request or change proposal the JSC shall discuss the issue in good faith.

#### 4. Supply with Contract DBS Test Kits; Forecast Delivery

- 4.1 **Supply.** Centogene shall supply Shire with Contract DBS Test Kits as set forth in the relevant Purchase Order. Each Purchase Order will specify the respective Contract DBS Test Kit(s), the respective countries, languages, Specifications and other criteria to be met by Centogene under such Purchase Order. Any Purchase Order becomes valid upon acceptance by Centogene as outlined in Section 4.5.
- 4.2 **Resources.** Centogene shall be responsible for the purchase, including adequate stocking, of adequate supplies of all materials and components as necessary to manufacture Contract DBS Test Kits for supply to Shire under this Agreement in accordance with the relevant Purchase Order, Specifications and Applicable Laws. Centogene shall be responsible that all manufacturing takes place at the Facility with appropriately trained staff to fulfill Centogene's obligations under this Agreement. Centogene shall ensure through its Third Party subcontractor at its own expense, that the Facility and all equipment required for the manufacture of Contract DBS Test Kits are in a state of repair and operating efficiency consistent with the requirements of GMP, Standards and Applicable Laws. In any case Centogene shall remain fully liable to manufacture and supply the Contract DBS Test Kits in accordance with the terms and conditions of this Agreement.
- 4.3 **Qualification, Validation.** Centogene shall be responsible for the performance of all needed qualification and validation activities of the Facility, equipment and cleaning and maintenance processes employed in the manufacturing process of Contract DBS Test Kits in accordance with GMP, GLP, Applicable Laws, Standards and Regulatory Approvals.
- 4.4 **Rolling Forecast.** Shire will provide Centogene with a rolling forecast for a period of up to eighteen (18) months ("Forecast"). Shire will update the Forecast quarterly at the latest in each case thirty (30) days before 1 January, 1 April, 1 July and 1 October. The Forecast will therein be binding as follows:
- (i) hundred percent (100%) of the forecasted amounts for months one to three (1 - 3) will be binding for both Parties, i.e. Shire commits to order the forecasted amounts and Centogene agrees to supply Shire with the forecasted amounts and up to one hundred percent (120%) of

the forecasted amounts in the agreed Turnaround Times as stated In Section 3.4 and 4.7; exceeding amounts can be ordered by Shire and will be supplied by Centogene on timelines to be agreed; and

(ii) the amounts forecasted for months four to eighteen (4 -18) are non-binding for both Parties.

- 4.5 Purchase Orders. Shire will issue Purchase Orders which set forth (i) the quantities of Contract DBS Test Kits on a quarterly basis and (ii) requested Delivery dates. Purchase Orders shall become binding if Centogene has not rejected the Purchase Order in writing within five (5) Business Days from receipt of the Purchase Order. For clarity, any addition by Centogene in an order acceptance or similar document that is different from the terms of the Purchase Order Purchase will be deemed a rejection of Shire's Purchase Order. Any terms that are in addition to or different from the terms of the Purchase Order that are contained in any order acceptance or similar document issued by Centogene will be of no force or effect unless expressly accepted by Shire in writing.
- 4.6 Minimum Order. Shire agrees to receive and pay a minimum purchase quantity of [\*\*\*\*\*] Contract DBS Test Kits for each Contract DBS Test Kit per language., provided that Shire shall order at least [\*\*\*\*\*] Contract DBS Test Kits In each single Purchase Order, such Purchase Order to contain [\*\*\*\*\*] language-specific Contract DBS Test Kits; apart from that no minimum purchase volumes shall exist. Centogene will produce Contract DBS Test Kits so as

to supply Shire with Contract DBS Test Kits as forecasted and bindingly committed under Section 4.4(i).

- 4.7 Minimum Stock: Turnaround Times. Centogene shall manufacture and store, or cause its Third Party subcontractor to produce and/or store, under appropriate conditions a minimum stock of Contract DBS Test Kits, including raw materials for such Contract DBS Test Kits, as mutually agreed between the Parties. Centogene agrees to Turnaround Times for Purchase Orders of [\*\*\*\*\*] Business Days.
- 4.8 Delivery. Unless a deviating delivery term (pursuant to Incoterm 2010) has been agreed within the relevant Purchase Order, Centogene shall deliver the Contract DBS Test Kits in accordance with the Specifications DDP (delivered duty paid as defined by Incoterms 2010), which means that Centogene delivers the Contract DBS Test Kits when the Contract DBS Test Kits are placed at the disposal of Shire, a certain Shire Group Company indicated by Shire in the Purchase Order or any Third Party designated by Shire, cleared for import on the arriving means of transport ready for unloading at the place of destination and at the date specified in the relevant Purchase Order (“**Delivery**”). Subject to this Section 4.8, Centogene shall bear all the costs and risks involved in bringing the Contract DBS Test Kits to the named place. Centogene has to clear the Contract DBS Test Kits for export and import and to carry out any customs formalities for export, transportation and import, *provided, however*, that (i) Shire shall reasonably assist Centogene with customs clearance, in particular that Shire shall provide any documentation and execute any documents required to assist customs clearance and to meet the import customs formalities of any country of the Territory; and (ii) that Shire shall reimburse Centogene of any reasonable and documented costs to meet the import customs formalities of the relevant country of the Territory.
- 4.9 Delays. Centogene shall ensure prompt Delivery to Shire, a certain Shire Group Company indicated by Shire in the Purchase Order or to any Third Party designated by Shire on the Delivery date agreed in the Purchase Order. In the event Centogene becomes aware that it cannot deliver Contract DBS Test Kits in accordance with the timelines mutually agreed by the Parties in accordance with Sections 3.4 and 4.7 and set forth in a Purchase Order to Shire, the indicated Shire Group Company or to any Third Party designated by Shire, because Centogene will not meet the Specifications, GMP or for any other reason, Centogene shall promptly notify Shire of such occurrence. The Parties shall promptly discuss the reasons for such occurrence through the Project Managers. Centogene shall present possible solutions and propose an alternate Delivery date. Centogene shall promptly adhere to all instructions provided by Shire to solve the issue and shall promptly implement all actions required to meet the new Delivery date.
- 4.10 Reporting. Centogene shall provide Shire on a monthly basis with a status report on the Kit Development, manufacture and supply of Contract DBS Test Kits. The monthly status report shall include, but not be limited to the following:
- Development Orders and Purchase Orders received per country/language (numbers and date in)
  - Contract DBS Test Kits delivery per country/language(numbers date out)
  - Turnaround Time between Centogene’s receipt of the Development Order Purchase Order and DBS shipment out and variance (numbers shipped versus ordered)
  - Contract DBS Test Kits returned (date of return) - e.g. if expired
  - Contract DBS Test Kits recalled (type of Contract DBS Test Kits; date of recall); in case of quality/safety issue: number of Contract DBS Test Kits received back (type, date, quantity)
  - List of countries/languages where Contract DBS Test Kits are distributed
- 4.11 Non-Conforming Product. If Shire notifies Centogene and specifies in reasonable detail that a certain Delivery of Contract DBS Test Kits does not meet the Specifications or Applicable

Laws in the Territory, was not developed according to the relevant Development Order or was not manufactured according to GMP and the relevant Purchase Order, Shire is, subject to the procedure set forth in Section 4.12 in case of disagreement, entitled to reject all or any part of a delivered batch of Contract DBS Test Kits. In any case Centogene shall answer any of Shire's questions without undue delay not to exceed ten (10) Business Days after receipt of Shire's question and provide Shire with all information requested or necessary to evaluate the batch in question. If such non-conformance is not due (in whole) to acts or omissions of Shire or any Third Party after Delivery, Centogene shall, subject to the procedure set forth in Section 4.12 in case of disagreement, at Shire's discretion, (i) refund that part of the payment that relates to the production of such defective Contract DBS Test Kits (ii) or replace such Contract DBS Test Kits at its own cost and expense and further refund all transportation costs regarding the return of Contract DBS Test Kits to Centogene. In the event Centogene is required to replace such defective Contract DBS Test Kits; Centogene shall use best efforts to replace such Contract DBS Test Kits with a minimum delay.

4.12 **Independent Expert.** In case of any disagreement between the Parties as to whether a certain Delivery of Contract DBS Test Kits conforms to the applicable Specifications, the Alliance Managers will discuss in good faith or attempt to resolve any such disagreement and Centogene and Shire will follow the respective SOPs to determine the conformity of the Contract DBS Test Kits to the Specifications. If the foregoing discussions do not resolve the disagreement in a reasonable time (which will not exceed thirty (30) days), a representative sample of such Contract DBS Test Kits will be submitted to an independent testing laboratory mutually agreed upon by the Parties for tests and final determination of whether such Contract DBS Test Kits conforms with such Specifications. The laboratory must be of recognized standing in the industry, and consent to the appointment of such laboratory will not be unreasonably withheld or delayed by either Party. Such laboratory will use the test methods contained in the applicable Specifications. Absent manifest error, determination of conformance by such laboratory with respect to all or part of such batch of Contract DBS Test Kits will be final and binding on the Parties. The Party against whom the determination is made will pay the fees and expenses of the laboratory incurred in making such determination.

## 5. **Regulatory**

5.1 **General.** Centogene will release and place on the market the Contract DBS Test Kits manufactured by Centogene in accordance with the Specifications, Applicable Laws and Standards as the Legal Manufacturer under its own name. Subject to the provisions of Section 5.5, Centogene will be responsible that the Contract DBS Test Kits, including but not limited to the Patient's informed consent forms, comply at the point of time of the Yearly Review with Applicable Laws and Standards of the respective destination country.

5.2 **Regulatory Approvals.** All Regulatory Approvals in the Territory, to the extent necessary under Applicable Laws, will be held in the name of Centogene. Where necessary under Applicable Laws, Centogene shall be solely responsible for all regulatory activities, regulatory reporting and maintenance requirements and medical information services, in each case relating to an individual Contract DBS Test Kit and its respective destination country. In particular, Centogene shall obtain and constantly maintain all Regulatory Approvals required to market and distribute an individual Contract DBS Test Kit in its destination country or parts thereof. Centogene shall be responsible for all regulatory filings and related regulatory pre-submission and post-submission activities with respect to an individual Contract DBS Test Kit in its destination country and shall bear all costs in connection with obtaining and maintaining Regulatory Approvals in the Territory. Centogene will be the sole interface with and otherwise handle all correspondence, meetings and other interactions with the relevant Regulatory Authorities concerning the Regulatory Approvals of the individual Contract DBS Test Kits in their respective destination countries.

5.3 **Regulatory Data.** Centogene will maintain and store all regulatory data relating to Contract DBS Test Kits, such as results of experimentation and testing, processes, laboratory records, clinical, analytical and quality control data, data analyses, reports, manufacturing data, techniques, processes and summaries, other information contained in the technical files of the Contract DBS Test Kits and any updates thereof.

- 5.4 Regulatory Activities. Where necessary under Applicable Laws, Centogene will make all reasonable efforts to develop and submit regulatory filings and obtain Regulatory Approval for Contract DBS Test Kits as fast as reasonably possible. Centogene, on an on-going basis and at any time upon request, will keep Shire informed of its planned and actual regulatory activities and its communications with Regulatory Authorities regarding Contract DBS Test Kits. Centogene shall timely inform Shire of any scheduled meetings with Regulatory Authorities in the Territory.
- 5.5 Monitoring and Information Obligation. Centogene will, as part of the activities covered by the General QM fee., diligently monitor Applicable laws or Standards of the Territory in accordance with Centogene's internal quality system and Applicable Laws to ensure compliance of the Contract DBS Test Kits, in particular the informed consent form, with Applicable Laws and Standards, so that compliance is ensured at least once every twelve (12) months starting from January 1, 2016 and thereupon every January 1 of each subsequent calendar year ("Yearly Review"). Centogene shall provide Shire on a quarterly basis with a rolling overview of the status of the Yearly Review on a country-by- country basis in the format set forth in Exhibit 6. Centogene shall inform Shire of any changes immediately after it becomes aware of any changes to Applicable Laws or Standards that would affect the manufacture, supply, distribution and provisions of any Contract DBS Test Kits in any country of the Territory.
- 6. Quality**
- 6.1 Quality Systems. Centogene shall be obliged to maintain and diligently document a quality assurance system and a risk management system for the manufacture and supply of Contract DBS Test Kits in accordance with Applicable Laws, Standards and Regulatory Approvals as evidenced by certificates from Regulatory Authorities, such certificates to be based on Applicable Laws and Standards governing the manufacture and distribution of the product, as classified on the Effective Date. In the EU, the Contract DBS Kit is, as of the Effective Date, classified as a Class I IVD device. Centogene's quality systems shall include written policies and procedures that address, at a minimum, the following: Quality System including: design control, training, supplier & purchasing controls, supplier audits, vendor change notifications, facilities and equipment, exception / deviation notification, Complaint reporting and CAPA; facilities and equipment systems; laboratory control systems; data protection, protection of IT networks.
- 6.2 Shire Audit Requirements. Shire, Shire Group Companies or a mutually agreed Third Party may, upon written request, conduct an audit once every two (2) years at Centogene's facilities in Restock during normal business hours of the manufacturing controls, quality control testing, Centogene's oversight of assembly/manufacturing operations and storage, including appropriate quality records. Shire may also conduct 'for cause' audits at shorter notice to address serious or on-going supply or quality issues.
- 6.3 Validation Studies. Centogene shall perform, where required under Applicable Laws, and provide Shire with updated validation studies and stability studies on a yearly basis at its own costs.
- 7. Vigilance**
- 7.1 Vigilance System. Centogene shall maintain and document a vigilance system for Contract DBS Test Kits which is in accordance with Regulatory Approvals, Applicable Laws and Standards. To the extent required by Applicable Laws, Centogene shall be responsible for literature review, maintaining a global safety database, Incident reporting, Incident follow-up reports, preparation and submission of all safety reports towards Regulatory Authorities, as well as deciding upon and conducting any field safety corrective notices/ actions, subject to the terms of this Agreement.
- 7.2 Shire Assistance. Shire will report Incidents, to Centogene and assist in the conduct of field corrective actions, e.g. recalls, under responsibility of Centogene. Shire shall notify Centogene of any Incident immediately, but not later than one (1) calendar day after awareness of Shire. Such notice shall be forwarded to Centogene by email and include the

name, address, and telephone number of the person making the Complaint or report of an Incident, the Contract DBS Test Kit(s) involved and the nature of the incident.

- 7.3 **Incident Investigation.** Centogene shall be responsible for the evaluation of reported Incidents. Centogene shall investigate any report of an Incident. Shire shall cooperate with, and provide reasonable and necessary information and assistance to, Centogene in connection with such investigation. Centogene shall immediately notify Shire of the results of any investigation related to Contract DBS Test Kits.
- 7.4 **Meetings.** Centogene and Shire shall meet, in a timely fashion and from time to time as may be reasonably required, to discuss and implement Incident reporting and consultation procedures for Incidents as well as problem solutions.
- 7.5 **Field Safety Actions; Cost.** To the extent required by Applicable Laws, Centogene shall be responsible for any field safety notices and field safety corrective actions regarding the Contract DBS Test Kits in the Territory. Centogene shall then bear the cost and expense of any field safety notices and field safety corrective actions resulting from the manufacture and quality assurance of the Contract DBS Test Kits to the extent that the Contract DBS Test Kits was manufactured and quality assured by Centogene, except to the extent that such field safety notices or field safety corrective action results from Shire's negligence or willful misconduct.

## **8. Price and Terms of Payment**

- 8.1 **Prices.** The prices for Kit Development, manufacture and supply of Contract DBS Test Kits and other specified services to be rendered by Centogene are set forth in Exhibit 3. Notwithstanding Section 8.8, the Parties will negotiate in good faith on a bi-annual basis volume,-based discounts to the prices set forth in Exhibit 3.
- 8.2 **Supply.** Centogene shall invoice Shire upon Delivery of Contract DBS Test Kits.
- 8.3 **Kit Development.** Kit Development fees as defined in Exhibit 3 will be invoiced by Centogene to Shire Inc. immediately upon completion (i.e. obtaining Regulatory Approval for the relevant country(ies)) of the respective Contract DBS Test Kit. It is expressly agreed between the Parties that Centogene will develop and obtain Regulatory Approval for Contract DBS Test Kit for use in [\*\*\*\*\*] in the English language at its own costs and that Shire will not bear any Kit Development fees or Third Party costs under Section 8.4(i) and (iii) for use in [\*\*\*\*\*] in the English language.
- 8.4 **Third Party Expenditures to be borne by Shire.** Centogene shall bear all costs for the use of Third Party consultants, unless Shire Inc. participates in the costs as set forth under this Section 8.4. Only upon provision of a detailed cost estimate and subject to prior written approval by Shire International GmbH, actual and documented costs by Centogene for use of certain Third Party consultants will be reimbursed by Shire Inc. together with a [\*\*\*\*\*]% mark-up as follows:
- (i) use of a Third Party regulatory service provider to obtain Regulatory Approval for any country; or
  - (ii) use of a legal counsel reasonably acceptable to Shire as part of the Yearly Review to ensure compliance of tile informed consent form of an individual Contract DBS Test Kit with Applicable Laws in an Existing Country for which Shire was the only customer in the preceding [\*\*\*\*\*] months and where Shire and/or the responsible physicians on the basis of the previously delivered individual Contract DBS Test Kits did not send in [\*\*\*\*\*] for Diagnostic Testing Services to Centogene in the [\*\*\*\*\*] months preceding the start of the latest Yearly Review; or
  - (iii) use of a legal counsel reasonably acceptable to Shire for the initial review and as part of the Yearly Review to ensure compliance of the informed consent form with Applicable Laws in a New Country in which (apart from distribution through a Shire Group Company) no Existing DBS Test Kits are being commercialized or distributed by Centogene, directly or indirectly through a Third Party.

Third Party expenditures shall be invoiced immediately after payment of such expenditures by Centogene to Shire Inc. together with the [\*\*\*\*\*]% mark-up, provided that Centogene presents originals of the Third Party invoices.

In cases of (ii) and (iii) above, Centogene shall upon receipt of the Forecast pursuant to Section 4.4 within ten (10) Business Days inform Shire in writing of any country included in Shire's Forecast in which Centogene would cease distributing or commercializing (directly or indirectly through a Third Party) Existing DBS Test Kits in the Territory or Contract DBS Test Kits if no Contract DBS. Test Kits were ordered by Shire, provided, however, that any such cease would not occur less than six (6) months from the date of information to Shire hereunder.

- 8.5 Third Party Expenditures to be Shared. Centogene shall not commercialize or distribute, directly or indirectly through a Third Party, Existing DBS Test Kits or Contract DBS Test Kits in any country for which Shire Inc. has to bear the costs for use of a legal counsel pursuant to Sections 8.4(ii) or 8.4(iii), unless Centogene agrees to bear the costs for use of the legal counsel with respect to such country as follows: In case Centogene decides at any time during the Term of the Agreement to commercialize or distribute DBS test kits in any country for which Shire Inc. has to bear the costs for use of a legal counsel pursuant to Sections 8.4(ii) or 8.4(iii), Centogene shall immediately inform Shire of its decision in writing and costs for use of such legal counsel shall be shared equally (50% / 50%) between Shire Inc. and Centogene with respect to such country.
- 8.6 Annual Fees. Annual QM fee and storage fee will be invoiced by Centogene to Shire Inc. annually as mutually agreed; annual fees will be prorated for any time period that is less than one year (e.g. - last months of the contract). Quality control steps Will be paid within thirty (30) days after completion and receipt of the report of test results. The annual QM fee and storage fee shall become due for the first contract year of the term thirty (30) days after signature of this Agreement
- 8.7 Payment Term. Payment Will be made within thirty (30) days of receipt of invoice.
- 8.8 Cost and Quality Improvement. Notwithstanding Section 8.1, Centogene shall be reasonably committed to developing and implementing continuous cost and quality improvement programs. including by seeking productivity improvements, by purchasing quality materials at lower cost and by improving testing processes. Centogene shall inform Shire of any substantial cost saving opportunities and the Parties agree to negotiate in good faith reductions to the respective prices set forth in Exhibit 3. If, in Shire's reasonable opinion based on general developments in the area of DBS test kit manufacturing, costs for DBS test kit manufacturing decrease substantially during the term of this Agreement, Shire shall have the right to propose an adjustment of the prices set forth in Exhibit 3 and Centogene shall consider in good faith such proposal within sixty (60) days after receipt of Shire's adjustment proposal. Should the Parties be unable to reach agreement within sixty (60) days after Centogene's receipt of Shire's adjustment proposal, the adjustment, if any, shall be determined by an independent expert appointed in accordance with the WIPO Expert Determination Rules. The language to be used in the expert determination proceedings shall be English.
- 9. General Obligations**
- 9.1 Personnel. Centogene shall exercise, and ensure that any personnel involved exercise, all reasonable skill, care, and diligence in the performance of the activities under this Agreement. Centogene shall ensure that any personnel who perform the activities under this Agreement are technically competent and suitably qualified to carry out the parts of the activities assigned to them.
- 9.2 Facility. Centogene shall, at its own cost and expense, ensure that at all times during the term, the Facility is in a qualified and validated state appropriate for the manufacture of Contract DBS Test Kits as required by GLP, GMP, the terms of this Agreement, Applicable Laws, Standards and Regulatory Authorities. Centogene shall be responsible for validating



the equipment used for the manufacture of Contract DBS Test Kits (including conducting installation, operational and performance qualification).

9.3 **Business Continuity.**

- (a) Centogene acknowledges the Importance to Shire of an uninterrupted supply of Contract DBS Test Kits. Centogene shall take, throughout the term of the Agreement, all necessary steps to identify and mitigate potential threats to its ability to manufacture and supply Contract DBS Test Kits. In particular Centogene shall prepare within sixty (60) calendar days after the Effective Date a written business continuity and risk mitigation plan designed to maintain continuity of the manufacture and supply with Contract DBS Test Kits under adverse conditions (“Business Continuity Plan”). Such Business Continuity Plan shall be reasonably satisfactory to Shire. Centogene shall implement the Business Continuity Plan during the term of the Agreement.
- (b) During the term of the Agreement Centogene shall promptly notify Shire in writing of any potential disruption to the manufacturing and supply of Contract DBS Test Kits. Centogene shall evaluate and update the Business Continuity Plan on a yearly basis. Upon request of Shire at any time, Centogene will present the Business Continuity Plan to Shire, including documentation on the implementation of such Business Continuity Plan. Centogene shall consider in good faith any reasonable comments that Shire may have with respect to the Business Continuity Plan and shall incorporate Shire’s comments in the Business Continuity Plan as agreed by the Parties without undue delay.

9.4 **Supply Failure.** Without limiting any other rights or remedies of Shire, if any, particularly in case of a force majeure event, if there is, or the Parties mutually determine there is likely to be, a Supply Failure, then Shire shall have the right to purchase DBS test kits from any Third Party manufacturer and Centogene shall process such DBS cards without additional processing fee (as defined in Section 3.2 of the Global Master Services Agreement), as will be set forth in an amendment to the Global Master Services Agreement.

9.5 **No Conflict.** Centogene shall not, during the term of this Agreement, enter into any agreements that limit its capacities and resources which are required to meet the obligations assigned in this Agreement or a Development Order and/or Purchase Order. Centogene will ensure all staff necessary to provide the activities under this Agreement in accordance with the terms of this Agreement.

9.6 **No Exclusivity.** Nothing in this Agreement shall prevent Shire from obtaining its demand for DBS test kits, which are not processed by Centogene under the Global Master Services Agreement, from any Third Party.

**10. Alliance Managers; Joint Steering Committee**

10.1 **Alliance Managers.** The individuals identified as Alliance Managers under the Global Master Services Agreement for diagnostic services shall serve as main points of contact also for the activities under this Agreement.

10.2 **Joint Steering Committee (JSC).** The Joint Steering Committee established under the Global Master Services Agreement shall also ensure the overall success of the activities under the Agreement.

**11. Confidentiality**

11.1 **Confidentiality.** All Confidential Information disclosed, revealed or otherwise made available by one Party and its Affiliates (“**Disclosing Party**”) to the other Party and its Affiliates (“**Receiving Party**”) under, or as a result of, this Agreement is furnished to the Receiving Party solely to permit the Receiving Party to exercise its rights, and perform its obligations, under this Agreement. The Receiving Party shall not use any of the Disclosing Party’s Confidential Information for any other purpose, and shall not disclose, reveal or otherwise make any of the Disclosing Party’s Confidential Information available to any Third

Party, without the prior written authorization of the Disclosing Party. The same shall apply to any Confidential Information disclosed with regards to the activities to be provided under this Agreement before the Effective Date.

- 11.2 **Safeguards.** In furtherance of the Receiving Party's obligations under Section 11.1 hereof, the Receiving Party shall take all appropriate steps, and shall implement all appropriate safeguards, to prevent the unauthorized use or disclosure of any of the Disclosing Party's Confidential Information. Without limiting the generality of this Section 11.2, the Receiving Party shall disclose any of the Disclosing Party's Confidential Information only to those of its officers, employees, commercial agents, distributors, consultants, licensees, potential licensees and financial investors that have a need to know the Disclosing Party's Confidential Information, in order for the Receiving Party to exercise its rights and perform its obligations under this Agreement and only if such officers, employees, agents, consultants, licensees, potential licensees and financial investors have executed appropriate non-disclosure agreements containing substantially similar terms regarding confidentiality as those set out in this Agreement or are otherwise bound by obligations of confidentiality effectively prohibiting the unauthorized use or disclosure of the Disclosing Party's Confidential Information. The Receiving Party shall furnish the Disclosing Party with immediate written notice of any unauthorized use or disclosure of any of the Disclosing Party's Confidential Information and shall take all actions that the Disclosing Party reasonably requests in order to prevent any further unauthorized use or disclosure of the Disclosing Party's Confidential Information.
- 11.3 **Exceptions.** The Receiving Party's obligations under Section 11.1 and 11.2 hereof shall not apply to the extent that the Receiving Party can prove by written evidence that the respective Confidential Information:
- (a) passes into the public domain, or becomes generally available to the public through no fault of the Receiving Party;
  - (b) was known to the Receiving Party prior to disclosure hereunder by the Disclosing Party;
  - (c) is disclosed, revealed or otherwise made available to the Receiving Party by a Third Party that is under no obligation of non-disclosure and/or non-use to the Disclosing Party;
  - (d) is required to be disclosed under Applicable Laws or by court order; *provided, however,* that the Receiving Party shall furnish the Disclosing Party with as much prior written notice of such disclosure requirement as reasonably practicable, so as to permit the Disclosing Party, in its sole discretion, to take appropriate action in order to prevent the Disclosing Party's Confidential Information from passing into the public domain or becoming generally available to the public; or
  - (e) is independently developed by the Receiving Party without breach of this Agreement as evidenced by contemporaneous written records.
- 11.4 **Return of Information.** Upon expiration or termination of this Agreement for any reason whatsoever, the Receiving Party shall return to the Disclosing Party, or destroy, as the Disclosing Party shall specify in writing, all copies of all documents and other materials that contain or embody any of the Disclosing Party's Confidential Information, except to the extent that the Receiving Party is required by Applicable Laws or permitted under this Agreement to retain such documents and materials. Within thirty (30) calendar days after the date of expiration or termination of this Agreement, the Receiving Party shall furnish the Disclosing Party with a written certificate, confirming that the Receiving Party has complied with its obligations under this Section 11.4.
- 11.5 **Survival.** All of the Receiving Party's obligations under Section 11.1 and 11.2 hereof, with respect to the protection of the Disclosing Party's Confidential Information, shall survive the expiration or termination of this Agreement for any reason whatsoever.

## 12. Intellectual Property

- 12.1 Ownership of Centogene Intellectual Property. Nothing in this Agreement shall affect Centogene's ownership of the Centogene Intellectual Property.
- 12.2 Centogene's License to Shire. Centogene hereby grants to Shire and any Shire Group Company a non-exclusive, worldwide, fully paid-up, irrevocable and transferable license, with the right to grant sublicenses, to the Centogene Intellectual Property only to the extent necessary or useful to distribute and provide Contract DBS Test Kits to Physicians in the Territory.
- 12.3 Third Party IP. In the event either Party becomes aware of any Third Party Intellectual Property Rights which might interfere with the Kit Development, manufacture, supply and distribution of Contract DBS Test Kits, it shall immediately inform the other Party hereof. Each Party shall reasonably assist the other Party or any Affiliate of the other Party, at the other respective Party's expense, in defending itself against a Third Party claim, which would impair the Kit Development, manufacture, supply and distribution of Contract DBS Test Kits. Each Party shall furnish the other Party with written notice of any and all infringements and other unauthorized uses by any Third Party of Contract DBS Test Kits promptly after it receives notice thereof.

## 13. Representations And Warranties

- 13.1 General Centogene Warranties. Centogene warrants and represents that
- (a) it has all governmental and other approvals necessary for ii to manufacture and supply Contract DBS Test Kits in accordance with the terms of this Agreement the relevant Development Order and/or Purchase Order, Regulatory Approvals, Applicable Laws and Standards;
  - (b) it is not party to any agreement that would prevent it from fulfilling its obligations under this Agreement;
  - (c) it has and will maintain during the term the experience, the scientific know-how, the human resources and the capacities required to manufacture and supply the amounts of Contract DBS Test Kits set forth in the Forecast;
  - (d) to its present knowledge, as of the Effective Date, the Centogene Intellectual Property Rights for purposes of this Agreement do not infringe any Third Party Intellectual Property Rights;
  - (e) as of the Effective Date, Centogene has not received any communication from any Third Party that the Existing DBS Test Kit. including the informed consent form, is not in compliance with any Applicable Laws;
  - (f) as of the Effective Date, no material litigation, arbitration or administrative proceeding is pending or threatened in relation to the Existing DBS Test Kits, except for proceedings required to obtain necessary regulatory approvals; and
  - (g) as of the Effective Date, Centogene conducts no activity that involves or relates to or is alleged to involve or relate to fraud, the proceeds of crime, corruption or any other similar matter.
- 13.2 Contract DBS Test Kit Warranties upon Delivery. Centogene warrants and represents that upon Delivery and with regard to the specific Contract DBS Test Kit delivered
- (a) such Contract DBS Test Kits will comply to the Specifications and GMP;
  - (b) such Contract DBS Test Kits, in particular the informed consent form delivered , at least (i) complied to Applicable Laws and Standards in the respective intended destination country as of the date of the last Yearly Review undertaken or (ii) were

reviewed for compliance and complied even after the date of the last Yearly Review; and

(c) unencumbered title to such Contract DBS Test Kits will be transferred to Shire or the respective Shire Group Company.

13.3 **Anti-Bribery.** Centogene represents, warrants and covenants that neither Centogene nor any Affiliate of Centogene nor any officer, employee or agent of Centogene (or any of its Affiliates) has, nor shall it, offer, promise, give or receive, any financial or other advantage in violation of the Bribery Act 2010 (UK) or Foreign Corrupt Practices Act 1977 (USA), as amended from time to time, respectively, or any comparable laws in any country from which or to which services are provided by or for Centogene under this Agreement (collectively, “**Anti-Bribery Laws**”) and Centogene and its Affiliates shall each maintain procedures designed to prevent bribery falling within the Bribery Act 2010. Centogene further represents, warrants and covenants that no person employed by Centogene and no person acting as agent of Centogene in connection with Centogene’s obligations under this Agreement (other than those persons who have been notified from time to time by Centogene to Shire and in respect of whom Shire has provided its prior written approval), is an official of the Government of any country (or of any agency of such government), and that no part of any monies or consideration paid to Centogene under this Agreement shall accrue for the benefit of any such official. For the purposes of enabling Shire to monitor its compliance with Anti-Bribery Laws, Centogene shall make available for audit by Shire or its designee, upon Shire’s reasonable request at any time during the Term, books, records and other documentation relevant to Centogene’s business activities conducted pursuant to this Agreement.

13.4 **Insurance.** Centogene shall maintain liability and other appropriate forms of insurance at levels sufficient to support its indemnification obligations assumed herein but in no case shall this insurance be less than the minimum limits shown below:

- (a) workers compensation and/or employers liability to limits required by Applicable Laws;
- (b) General liability insurance in amounts of € [\*\*\*\*\*] per occurrence and € [\*\*\*\*\*] in the annual aggregate;
- (c) Products liability insurance in amounts of € [\*\*\*\*\*] per occurrence; and € [\*\*\*\*\*] in the annual aggregate
- (d) Errors & omissions liability insurance in amounts of € [\*\*\*\*\*] per occurrence and in the annual aggregate;
- (e) Technology errors and omissions liability (including coverage for electronic media activities, network operations security liability, privacy liability and miscellaneous professional liability in amounts of € [\*\*\*\*\*] per claim and in the annual aggregate; and
- (f) Crime coverage (employee dishonesty and computer fraud), including an endorsement and/or coverage amendment for Third Party coverage (client coverage) in the amounts of € [\*\*\*\*\*] per each and every event.

Should any insurance be provided on a ‘claims made’ basis such insurance shall be maintained for a period of five (5) years following the expiration or termination of this Agreement. All such insurances will be provided by a company or companies licensed to do business in Germany having a financial rating of not less than A- VIII in the most current edition of Best’s Key Rating Guide. Centogene shall provide a certificate of insurance evidencing such coverage as requested by Shire. The minimum limits of insurance required shall not be construed to create a limit of Centogene’s liability or indemnification obligations under this Agreement.

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## 14. Indemnification

14.1 **No Liability.** Shire does not accept any liability or damage claims related to the manufacture, quality control, release and placing on the market of any Contract DBS Test Kits in the Territory.

14.2 **Indemnification by Centogene.** Centogene shall, at its sole expense, indemnify, defend and hold harmless Shire, its Affiliates and their respective officers, directors, agents and employees (the “**Shire Indemnitees**”) from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys’ fees and court costs) (collectively, “**Losses**”) due to

- (a) a failure to manufacture, quality control, release, supply and placing on the market of Contract DBS Test Kits in the Territory in accordance with Regulatory Approvals, GMP or GLP; or
- (b) any negligent or willful actor omission of Centogene in the Kit Development; or
- (c) any breach of a warranty under Section 13.1 or 13.2 above;

*provided, however,* that Centogene will not be liable to indemnify the Shire Indemnitees for any Losses to the extent that such Losses were caused by the negligence or willful misconduct of the Shire Indemnitees.

14.3 **Procedure.** Shire shall notify Centogene promptly in writing upon learning of any Third Party action in respect of which indemnification may be sought under Section 14.1. Centogene shall (i) actively defend against every claim using counsel approved by Shire, such approval not to be unreasonably withheld or delayed; (ii) shall promptly inform Shire and its attorneys of all developments concerning Shire Indemnitees; and (iii) shall generally consult with Shire regarding the strategy of the defense of any claim. The Shire Indemnitees shall reasonably cooperate with Centogene in defending or settling any such claim. No settlement of any claim for which indemnification is sought, shall be made without the prior written approval of Centogene. Centogene will have sole control over the defense and/or settlement, subject to the Shire Indemnitees’ right to select and use their own counsel at their sole cost and expense.

## 15. Term, Termination

15.1 **Initial Term.** This Agreement shall come into force at the Effective Date and shall remain in full force for the term of the Global Master Services Agreement.

15.2 Termination by Shire. Shire shall have the right to terminate the Agreement and/or any Development Order and/or Purchase Order for certain Contract DBS Test Kits with immediate effect by providing written notice to Centogene in case

- (a) Centogene experiences a Change of Control in which a company or group of companies is the acquirer (by asset purchase, merger, consolidation, reorganization or otherwise) who, (i) is a direct competitor of Shire or any Shire Group Company with regards to Shire Products; or (ii) causes a conflict of interest in providing Services or (iii) may, as a result of such Change of Control, cause Centogene's lack of the technical, personnel or other organizational excellence necessary to perform Diagnostic Testing Services in accordance with the Parties' intention to find any remaining unidentified patients of lysosomal storage diseases by the year 2020;
- (b) Subject to Section 15.4, Centogene commits a material breach or default of any of its obligations hereunder, which shall include (i) inability or unwillingness to at all manufacture and supply Contract DBS Test Kits for a period longer than two (2) months, (ii) failure to deliver Contract DBS Test Kits in accordance with the provisions hereunder, (iii) failure to manufacture Contract DBS Test Kits and/or maintain the Facility in accordance with GMP, GLP or material findings in an audit, (iv) breach of a representation and warranty under Section 13;

- (c) Centogene's financial situation substantially deteriorates; or
- (d) Centogene ceases to provide diagnostic laboratory services,
- (e) Centogene loses any regulatory authorizations or certification required to provide Diagnostic Testing Services or to manufacture and supply Contract DBS Test Kits In accordance with Applicable Laws, Standards, GMP and GLP.

15.3 Termination by Centogene. Centogene shall have the right to terminate the Agreement and/or any Development Orders and/or Purchase Orders with immediate effect by providing written notice to Shire in case that

- (a) subject to Section 15.4, Shire commits a material breach or default of any of its obligations hereunder, which shall include Shire's failure to meet Its payment obligations after appropriate written reminders by Centogene by more than sixty (60) days in three (3) consecutive calendar months; or
- (b) Shire's financial situation substantially deteriorates.

15.4 Material Breach. In the event that either Party commits a material breach or default of any of its obligations hereunder, the other Party shall give the breaching Party written notice of such material breach or default, and shall request that such material breach or default be cured as soon as reasonably practicable. In the event the breaching Party fails to cure such breach or default within thirty (30) calendar days after the date of the non-breaching Party's notice thereof, the non-breaching Party may terminate this Agreement and/or any Development Order and/or Purchase Order pursuant to Section 15.2(b) or 15.3(a), as the case may be. In case the breach is incapable of cure, the non-breaching party is entitled to terminate this Agreement and/or any Development Orders and/or Purchase Orders with immediate effect without the need to grant a cure period. Termination of this Agreement in accordance with Section 15.2(b) or 15.3(a), as the case may be, shall not affect or impair the non-breaching Party's right to pursue any legal remedy, Including, but not limited to, the right to recover damages, for any harm suffered or incurred by the non-breaching Party as a result of such breach or default.

15.5 Additional Termination by Shire.

15.6 Consequences of Termination. Any Development Orders. and/or Purchase Orders which are still on-going at the time of termination shall continue to be effective in accordance with the terms of this Agreement and the relevant Development Orders and/or Purchase Orders until fulfillment of such Development Order and/or Purchase Order, unless Shire has terminated the Development Order and/or Purchase Order in accordance with Section 15.2 or 15.5.

15.7 Survival. Termination of this Agreement for whatever reason shall not affect the accrued rights of the Parties under or out of this Agreement, and Sections 1, 2.7, 6.1, 7.1, 7.2, 7.3, 7.5; 11, 12.1, 13.4, 14, 15.6, 16.1, 16.3 to 16.7 shall survive the termination and remain in full force and effect. Any expiration or termination of this Agreement shall be without prejudice to the rights or payment claims of either Party against the other accrued or accruing under this Agreement prior to expiration or termination.

**16. Miscellaneous**

- 16.1 Governing Laws; Dispute Resolution. This Agreement shall be governed and construed in accordance with the laws of Germany, without reference to conflict of laws principles. If there is a dispute between the Parties relating to this Agreement, the Parties shall in the first instance attempt to solve the dispute amicably. If they cannot do so, the dispute shall be referred to the JSC which shall meet to resolve the matter. If the JSC is unable to agree upon a resolution within sixty (60) calendar days of the referral of the dispute to them, the dispute shall be finally settled in accordance with the Arbitration Rules of the German Institution of Arbitration (DIS) without recourse to the ordinary courts of law. The place of arbitration shall be Berlin. The number of arbitrators shall be three (3). The language of the arbitral proceedings shall be English. Nothing in this Section shall prevent or delay a Party from seeking interim relief in any court of competent jurisdiction.
- 16.2 Assignment. This Agreement may not be assigned by either Party in whole or in part without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, provided, however, that the prior written consent of Centogene shall not be required for Shire to assign this Agreement to an Affiliate. The Parties agree that it would be unreasonable for Shire to withhold or delay its consent for Centogene AG to assign this Agreement to an Affiliate if (i) the assignment is part of a larger restructuring project as already envisaged prior to the Effective Date; if (ii) the assignee is and continues to be after the assignment a wholly held (100%) subsidiary of Centogene AG; and if (iii) Centogene AG guarantees to Shire in writing the fulfillment of all obligations under this Agreement for the duration of such obligations and in accordance with this Agreement.
- 16.3 Severability. The invalidity of any provision or provisions of this Term Sheet shall not affect the other provisions contained therein. Any invalid provision shall be deemed to have been replaced by a provision which achieves as closely as legally permissible what the invalid provision was intended to achieve for commercial purposes.
- 16.4 No Authority. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party or its Affiliates, without the prior written consent of the other Party.
- 16.5 Written Form; Amendments. Upon being signed by both Parties and the exchange of the signed versions in the form of PDF files, this Agreement shall become effective and binding and the signed document being available in the form of the exchanged PDF files shall constitute evidence of the existence of this Agreement. The signed original copies of this Agreement shall later be exchanged by the Parties. Any amendment to this Agreement shall be effective only if made in writing and signed by the Parties. This also applies to a waiver of the written form requirement.
- 16.6 Interpretation. In this Agreement the headings are used for convenience only and shall not affect its interpretation. Where the word 'including' is used it shall be understood as meaning 'including without limitation'.
- 16.7 Entire Agreement. This Agreement including its Exhibits, sets out the entire agreement between the Parties relating to its subject matter and is intended to eventually supersede all existing agreements between Centogene and Shire relating to such subject matter.
- 16.8 Costs. Each Party shall bear the costs of its own accountants, attorneys, consultants and other professional advisors in connection with the negotiation and execution of this Agreement.

Exhibits:

- |           |                            |
|-----------|----------------------------|
| Exhibit 1 | Existing Countries         |
| Exhibit 2 | Planned/targeted countries |
| Exhibit 3 | Prices                     |

- Exhibit 4: Sample Development Order
- Exhibit 5: Kit Component Aging Studies
- Exhibit 6: Format for Status of Yearly Review

*[signature page follows]*



Place: Dublin

Date: 23-12-2015

for and on behalf of

**Shire Pharmaceuticals Ireland Ltd.**

/s/ Vincent Dunne

Name: Vincent Dunne

Title: Director

Place: Berlin

Date: 22-12-2015

For and on behalf of

**Centogene AG**

**CENTOGENE AG**

Schillingallee 68

18057 Rostock

**Germany**

/s/ Prof. Dr. Arndt Rolfs

Name: Prof. Dr. Arndt Rolfs

Title: CEO

## Exhibit 1

### Existing Countries

Legend:

- General = Centogene kits in English language that support selection / testing for multiple diseases
- LSD = Lysosomal Storage Disorders = Centogene DBS Kits in English language that only support selection I testing on one specific disease.
- BSI = External regulatory advisors; <http://www.bsigroup.com/>
- Emerge: External regulatory advisors; <http://www.emerg.ogroup.com/>

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Contract DBS Kits based on the Existing DBS Kits have so far already been developed by Centogene for Shire for use in:

. [\*\*\*\*\*]

. [\*\*\*\*\*]

**Exhibit 2**

Planned or targeted countries and potential bundling for Kit Development projects as of the Effective Date:

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**Exhibit 3****Prices****Development**

Kit Development: [\*\*\*\*\*] € per language and/or layout specific Kit Development project (design fee, incl. translation, QM control and documentation during the entire process and excluding Regulatory Approval for all countries in which such individual Contract DBS Test Kit can be used).

Kit Development projects requiring a fee of [\*\*\*\*\*]€ will be defined by one or a combination of the following (all compared to Centogene's Existing DBS Test Kit):

1. change to filter paper material and/or physical dimensions specifications;
2. change to outer card material and/or physical dimensions specifications;
3. changes to art work layout impacting where the information will be presented on the Centogene card;
4. translations into local languages not currently offered by Centogene for all related kit components;
5. changes to art work layout and or language content specific to the instructions for use or, to the extent solely requested by Shire and unrelated from requirements resulting from an initial review or a Yearly Review, the informed consent form.

A Kit Development project can include the development of one or more newly designed country-specific kits in a bundle, e.g. because the agreed countries are supported by the same language(s) or because no further regulatory filing/approval is necessary.

Kit Development projects NOT requiring a fee of [\*\*\*\*\*]€ will be such where an Existing DBS Test Kit or another Contract DBS Test Kit without any amendments as listed above under 1. to 5. can be used in a certain country without regulatory filings in such country.

**Regulatory - Legal**

- 1.) Actual and documented expenditures by Centogene for use of certain Third Party consultants as described in Section 8.4 of the Agreement.
- 2.) Centogene will present copies of the Third Party invoices.

**Supply**

- 1.) Minimum production numbers: [\*\*\*\*\*] Contract DBS Test Kits for each Contract DBS Kit per language, provided that Shire will order at least [\*\*\*\*\*] Contract DBS Test Kits in a single order, such order to contain [\*\*\*\*\*] or less language-specific Contract DBS Test Kits.
- 2.) Price per Contract DBS Test Kits (finally assembled filter card, incl. protective covering, envelope, instructions and consent): [\*\*\*\*\*] €.
- 3.) Storage gross fee, sending documentation etc.: lump sum payment of [\*\*\*\*\*] €

per year irrespective of the number of Contract DBS Test Kits supplied.

- 4.) General QM fee (covering the entire documentation process, external audits, maintaining Contract DBS Test Kit specific CE mark and Regulatory Approvals, external proficiency testing schemes (specific for blood spots), maintenance of quality systems, fulfilling medical device reporting requirements, etc., monitoring Applicable Laws or Standards pursuant to the provisions hereunder in accordance with Centogene's internal quality system): lump sum payment of [\*\*\*\*\*] € per year irrespective of the number of Contract DBS Test Kits supplied.
- 5.) If the Diagnostic Testing Services under the Global Master Services Agreement are suspended in its entirety any general fees (e.g. general QM fee, storage gross fee) shall also be suspended.
- 6.) Quality Control Step: once per each language and/or layout individual DBS Contract Kit production course: long-term storage (verification, meeting regulatory requirements (1 percent of total lot produced, but at least 20 randomized filter cards); incl. enzyme, lyso, genetics) per each separated production course as follows:
  - Purchase Orders above [\*\*\*\*\*] and more Contract DBS Test Kits: [\*\*\*\*\*] €;
  - Purchase Orders of [\*\*\*\*\*] Contract DBS Test Kits: a flat fee of [\*\*\*\*\*] €

#### **Services**

- 1.) Additional services will be charged separately, provided that such activities and the costs have been pre-approved by Shire or Shire International GmbH, as the case may be, in writing.

Sample Development Order

This Development Order dated 20[—] is between:

- (1) Shire International GmbH, a Swiss limited liability company having its registered office at Zahlerweg 10, 6301 Zug, Switzerland, (“Shire”); and
- (2) Centogene AG, a German stock corporation incorporated under the laws of the Federal Republic of Germany with principal office in Restock registered with the district court (‘Amtsgericht’) in Rostock under HRB 13225 and having a business address at Schillingallee 68, 18057 Restock, German, y

**Preamble**

(“Centogene”).

This Development Order is made subject to the provisions of the Supply Agreement entered into by Shire Pharmaceuticals Ireland Ltd. and Centogene entered into as of 1 January 2016 (“Agreement”).

**The Parties agree as follows:**

**1. Definitions**

Capitalized terms shall have the meaning set forth in the Agreement. unless specifically defined otherwise in this Development Order.

**2. Countries**

Centogene shall modify Existing DBS Test Kits and develop Contract DBS Test Kits for distribution in the following countries in accordance with Applicable Laws:

*[list countries]*

**3. Development Plan**

*[Include/add a development project plan for the development of, specific kits, including, development steps for each of the countries ,requested by Shire, detailed timelines design and matrix for the filter cards. instructions and informed consents]*

**4. Project Managers**

*[specify project managers]*

**5. Specifications**

*[Include a description of the Specifications]*

**6. Payments**

Invoices shall be addressed and sent to Shire Inc., 300 Shire Way, Lexington, MA 02421, USA.

*[Include a schedule of payments here]*

**7. Other**

*[Include other terms where appropriate]*



Place:

Place:

Date:

Date:

**for and on behalf of**

**For and on behalf of**

**Shire Pharmaceuticals Ireland Ltd.**

**Centogene AG**

\_\_\_\_\_  
Name: \_\_\_\_\_

\_\_\_\_\_  
Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Kit Component Aging Studies

1. Study Design

As described in Section 1 of the Aging Study Proposal.

2. Study I: Real Time Testing with concurrent shelf life extension

2.1 Test Material/Volume: [\*\*\*\*\*] DBS Kits from three different manufacturer lots ([\*\*\*\*\*] DBS Kits) per time point

2.2 [\*\*\*\*\*]

2.3 Storage and temperature requirements: AU Kits will be stored directly after spotting and the mandatory drying period of [\*\*\*\*\*]

2.4 Testing Intervals: [\*\*\*\*\*]. All results will be recorded and reported. Appendix A of the Aging Study Proposal contains a description of the QC criteria that will be used to review and report the results.

2.5 Shelf Life Extension: The shelf life for new batches will be extended only after new data becomes available, [\*\*\*\*\*]

2.6 Reporting: Shire will be notified in writing-via study report-within [\*\*\*\*\*] days of the completion of each time point.

2.7 Study Termination: Failure In biochemical activity is defined when the measured value at a certain time point deviates in the mean [\*\*\*\*\*]% from the original value measured at time (t=0). Failure of [\*\*\*\*\*]% of the kits with respect to the testing criteria, will lead to the study termination and the prior point will become the shelf life. Centogene and Shire upon review and agreement of the results will accept the limitations supported by these studies.

2.8 Total DBS Kit Requirement for Study I

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3. Study IV: Accelerated shelf life study under combined conditions of extreme temperature and humidity:

3.1 Test Material/Volume: [\*\*\*\*\*] DBS Kits from three different manufacturer lots ([\*\*\*\*\*] OBS Kits) per time point

3.2 Blood spotting: All 10 spots per filtercard will be spotted in the standard way with 3 drops of EDTA blood from one sample. The study records will be maintained to meet compliance with GLP/GMP and ISO 13485 requirements (standards).

- 3.3 Storage and temperature requirements: All kits will be spotted and stored at 40°C +/- 2°C & 80% relative humidity(+/- 2%) before final testing.
- 3.4 Testing Intervals: [\*\*\*\*\*] kits will be QC'd at time point of [\*\*\*\*\*] months. Time point O will used from Study I. Appendix A of the Aging Study Proposal lists the QC criteria that will be used to review and report the results.
- 3.5 Data Utilization: The data generated from the study will be used to predict the impact of high humidity in case of atypical events, i.e. tropical costal countries, acclimatized storage, extreme shipping conditions (hot/cold/long deliveries). This data will also be used in a manner to support risk associated with improper handling, storage and shipping.
- 3.6 Reporting: Shire will be notified in writing-via study report-within [\*\*\*\*\*] days of the completion of each time point.
- 3.7 Study Termination: Failure in biochemical activity is defined when the measured value at a certain time point deviates [\*\*\*\*\*]% from the original value measured at time (t=0.) Failure of [\*\*\*\*\*]% of the kits with respect to the testing criteria mentioned above, will lead to the study termination and the prior point will become the shelf life. Centogene and Shire upon review and agreement of the results will accept the limitations supported by these studies.

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## 4. Cost

Description	Cost per unit	Cost
[*****] DBS kits(Study I-IV)	[*****] €per filtercard	[*****]€
Physical characterization and compatibility of each filtercard with the robotic system	[*****] €per filtercard	[*****]€
Enzyme activity combined	[*****]€per enzyme/3 enzymes per time point and filtercard	[*****]€
I. Alpha galactosidase A		
II. Glucocerebrosidase	I	
III. Iduronate-2-sulfatase		
Administrative costs (storage, daily monitoring/recording, maintenance, etc)	[*****]€/month	[*****]€
Report preparation (total [*****] reports plus final report)	[*****]€/ report	[*****]€
<b>Total cost for Study I-IV ([*****] DBS/study)</b>		<b>[*****]€</b>

**Exhibit 6**

**Format for Status of Yearly Review**

<b>Country</b>	<b>Completion date of latest annual review</b>	<b>Target completion date of next annual review</b>

CONFIDENTIAL TREATMENT REQUESTED UNDER RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

[\*\*\*\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

**2017 AMENDMENT**  
**TO GLOBAL MASTER SERVICES AGREEMENT AND**  
**TO SUPPLY AGREEMENT**

This Amendment (“**2017 Amendment**”) to the Global Master Services Agreement dated 1 January 2015 (“**MSA**”) and the Supply Agreement dated 1 January 2016 (“**Supply Agreement**”) is entered into as of 3 May, 2017 (“**2017 Amendment Effective Date**”) by and between

- (1) **Shire International GmbH**, a Swiss limited liability company having its registered office at Zählerweg 10, 6301 Zug, Switzerland (“**Shire International**”);
- (2) **Shire Pharmaceuticals Ireland Ltd.**, an Irish limited liability company having its registered office at 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland, Eircode D24TW13 (“**SPIL**”); and
- (3) **Centogene AG**, a German stock corporation incorporated under the laws of the Federal Republic of Germany with principal office in Rostock, registered with the district court (‘Amtsgericht’) in Rostock under HRB 13225 and having a business address at Schillingallee 68, 18057 Rostock, Germany (“**Centogene**”).

**PREAMBLE**

- (A) Shire International and Centogene have entered into the MSA under which Centogene provides certain diagnostic testing services on the basis of dried-blood-spot (DBS) cards for the purpose of identifying patients suffering from lysosomal storage and other rare diseases to Shire International and its affiliates.
- (B) In addition to the MSA, SPIL and Centogene have entered into the Supply Agreement under which Centogene (i) develops DBS test kits for the use in certain countries as required by SPIL on the basis of Centogene’s existing DBS test kits, (ii) manufactures such DBS test kits and (iii) supplies SPIL and its affiliates with such DBS test kits.
- (C) On 8 March 2016, Shire International and Centogene entered into an amendment of the MSA under which Shire International and Centogene agreed, inter alia, on a flat fee for the performance of diagnostic services for the year 2016 (“**2016 Amendment**”). In a side letter to the MSA dated 24 November 2016, Shire International and Centogene agreed on certain additional commercial aspects with respect to the year 2016.
- (D) Shire International, SPIL and Centogene now wish to agree on certain financial and other aspects of their cooperation going forward.

**Now, therefore, Shire International, SPIL and Centogene, intending to be legally bound, hereby agree to amend the MSA and the Supply Agreement as follows:**

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## DEFINITIONS

In this 2017 Amendment any capitalized terms shall have the meaning set forth in the MSA (as amended by the 2016 Amendment) and the Supply Agreement, unless a term is specifically defined under this 2017 Amendment.

### 1. ANNUAL FLAT FEE

1.1. Annual Flat Fee. The Parties agree to amend Section 3.6 of the MSA with respect to the calendar years 2017 and 2018 as follows:

Subject to the below, Shire International will make an annual lump sum payment of € [\*\*\*\*\*] ([\*\*\*\*\*] Euro) to Centogene for the performance of [\*\*\*\*\*] of Diagnostic Tests for Morbus Fabry, Morbus Gaucher, Morbus Hunter, MPS1, MPS2, MPS3, MPS4 and MPS6 in the calendar years 2017 and 2018 (“**Annual Flat Fee**”). The financial terms of the Annual Flat Fee as well as other financial assumptions under the MSA and Supply Agreement are set forth in more detail in Appendix 1 to this 2017 Amendment. Centogene hereby expressly waives any payment claims for Excess Diagnostic Tests under Section 3.6(c) of the MSA; provided, however, that only the first [\*\*\*\*\*] Diagnostic Tests for MPS1, MPS3, MPS4 and MPS6 performed in each of 2017 and 2018 will be included in the Annual Flat Fee. Any additional Diagnostic Tests for MPS1, MPS3, MPS4 and MPS6 will be invoiced and paid in accordance with Sec. 3.6 (c) of the MSA.

1.2. Diagnostic Test and Prices. The Parties agree to replace Exhibit 1 of the MSA (Diagnostic Tests and Prices) in its entirety with a new Exhibit 1 attached to this 2017 Amendment as Appendix 2.

1.3. Reporting. The payment of the Annual Flat Fee does not relieve Centogene from its obligation under Section 3.4 of the MSA to provide Shire International with detailed monthly summaries of Diagnostic Services actually rendered in the previous month, in the form as attached to this 2017 Amendment as Appendix 3.

1.4. Upfront Payments. Centogene will issue at the beginning of each calendar month, a preliminary invoice for a prorated amount of the Annual Flat Fee, i.e. an amount equal to 1/12 of each Annual Flat Fee. Shire International shall make payment within seven (7) Business Days upon receipt of a proper invoice.

### 2. ACCESS TO DIAGNOSTIC TEST RESULTS

2.1. Electronic Access through CentoPortal®. As of 1 June 2017 Diagnostic Test Results will be available through electronic means exclusively via the CentoPortal®. Centogene shall ensure a smooth transition so that Physicians will continue to be able to receive Diagnostic Test Results through electronic means via the currently existing ways (including via pdf attached to email) until 31 May 2017.

2.2. Mail and Fax Access. Notwithstanding Section 2.1, Centogene guarantees that those Physicians that clearly indicate that they cannot use CentoPortal® for technical or IT- infrastructure reasons or because of local legal concerns, will have access to the Diagnostic Test Results via fax or postal mail and Centogene commits to inform physicians about the existence of this exception. Centogene represents and warrants that it will not challenge such statements made by physicians. Centogene will offer such access without additional charge during the entire term of the MSA. Centogene hereby further guarantees that the time frames set forth in Section 3.3 of the MSA will be fully complied with, also in case of access to

Diagnostic Test Results via fax or postal mail, provided that the necessary contact details have been duly and in full given by the physicians.

3. **REGULATORY REQUIREMENTS RE CONTRACT DBS TEST KITS**

3.1. Regulatory Responsibility. As set forth and subject to the provisions under the Supply Agreement, the Parties hereby reiterate that Centogene shall solely bear the responsibility that the regulatory requirements for importation and distribution of the Contract DBS Test Kits within the agreed countries of the Territory (as defined in the Supply Agreement) are met. Centogene will (continue to) indemnify the Shire Group Companies in the event of any Losses as defined in the Supply Agreement resulting from the activities and obligations referred to in the preceding sentence.

3.2. Regulatory Activities. The Parties agree to add the following clause as new Section 5.6 to the Supply Agreement:

Shire Notification. In case a Shire Group Company has serious concerns with Centogene’s approach related to registration or other regulatory approval activities regarding Contract DBS Test Kits in a specific country of the Territory, or a Shire Group Company reasonably believes a significant, country-related issue needs to be assessed by Centogene, each Shire Group Company has the right, but not the obligation, to notify Centogene, on a by exception basis, of this concern or issue. Centogene shall respond to Shire within two (2) business days. In case Shire does not receive a response or in case a Shire Group Company continues to have serious concerns, such a Shire Group Company shall have the right, but not the obligation, to escalate such concerns or issue to the Joint Steering Committee, which shall discuss such concerns or issue as soon as possible, provided that the Shire Group Company provides detailed information, naming the respective and possibly infringed regulatory or legal terms and provisions in writing, with respect to the concerns or issue raised. Shire and Centogene will each designate an employee who will act as a single contact person for each Party and who will coordinate with the other Party’s dedicated employee to resolve any discussions under the provision of this Section 5.6.

4. **AUDIT RIGHTS**

The Parties agree to amend Section 3.7 of the MSA and replace it in its entirety with the following:

Maintenance of Records: Audits. Centogene shall maintain accurate and complete records of all Testing Request Forms, Samples received, correspondence, invoices, and/or other information in Centogene’s possession relating to all activities under this Agreement (collectively, “**General Records**”). The General Records shall be maintained in accordance with recognized commercial accounting practices and retained during the term of the MSA and thereafter for a period of three (3) years or such longer period required by Applicable Laws. Not more than once per calendar year during the term and not more than once within three (3) years after the end of the term, upon reasonable prior written notification and during normal business hours, Centogene agrees to permit representatives of Shire International or mutually agreed Third Parties to examine and audit the General Records and to inspect the facilities on which the Services are being rendered at no charge to Shire International by Centogene with the sole purpose of confirming Centogene’s compliance with the terms of the MSA, as amended from time to time. Shire International may also conduct ‘for cause’ audits at shorter notice to address serious or on-going quality issues with respect to the Services. Any such inspection (or failure to inspect) shall not relieve Centogene of its obligation to comply with Applicable Laws and the provisions of the MSA and does not constitute a waiver of any right otherwise available to Shire International.



5. **GOVERNANCE**

The Parties hereby agree to replace the definition of Alliance Managers in Section 1 of the MSA and Section 6.1 of the MSA in its entirety with the following:

Section 1:

“**Project Manager**” shall have the meaning set forth in Section 6.1.

Section 6.1:

Project Managers: Project Team. Promptly following the Effective Date, each Party shall designate two (2) individuals (“**Project Managers**”) and form a project team (“**Project Team**”) to exchange information, facilitate communication and coordinate the Parties’ operational day-to-day activities under the MSA and the Supply Agreement. The Project Team shall meet as necessary to accomplish its objectives, at least once (1) every week during a teleconference or videoconference. In addition to this, the Project Team will meet face-to-face at least once (1) per calendar quarter. In the event either Party raises an operational issue, both Parties will seek to resolve this during the weekly calls and within the timelines agreed by the Parties. If no (timely) resolution or agreement can be found, the Parties commit to find a solution during the quarterly face-to-face meeting. If an issue is still not resolved or is deemed sufficiently serious by either Party, the matter can be escalated to the Joint Steering Committee.

6. **GENERAL TRANSPARENCY**

Assistance. Upon request of Shire International Centogene shall reasonably assist Shire International or any Shire Group Company in relation to any obligations to report the value of the Test performed by Centogene as a transfer of value as defined under the EFPIA HCP/HCO Disclosure Code. Centogene undertakes to provide the necessary information and assistance to Shire or the respective Shire Group Company, as the case may be, on a calendar quarterly basis within thirty (30) days after the end of a calendar quarter, provided that for the first calendar quarter of 2017 Centogene shall provide such information before 1 June 2017. A pro forma quarterly transparency report is attached to this 2017 Amendment in Appendix 4. As of the Amendment Effective Date, Centogene will cease to provide weekly reports to Shire and the monthly report format will be amended as agreed between the Parties in writing.

7. **TRANSPARENCY TO UNIVERSITY OF ROSTOCK**

Covenant. Centogene covenants (*sichert zu*) that the University of Rostock as employer of Prof. Rolfs has been provided with all relevant information related to the Shire- Centogene arrangements, acknowledged receipt of the information provided and stated in writing that the University of Rostock does not see any legal mandate and necessity to explicitly approve any arrangements between Shire and Centogene. Shire accepts this as sufficient for concluding this 2017 Amendment.

8. **BUSINESS CONTINUITY PLAN**

Finalization of BCP. Within sixty (60) days of the Amendment Effective Date, the Parties will complete the joint review and modification of the existing Business Continuity Plan.

9. **2016 AMENDMENT**

Deletion. Parties agree to delete Sections 4.1 and 6 of the 2016 Amendment.

10. **OTHER TERMS**

Other. All other terms and conditions as set forth in the MSA (as amended by 2016 Amendment} and the Supply Agreement shall remain In full force and effect.

*[signature page follows]*

Place: Zug

Date: May 8, 2017

**for and on behalf of**

**Shire International GmbH**

/s/ Tim Stow

Name: Tim Stow

Title: Director, SIG

Place: Dublin

Date: 05 May 2017

**for and on behalf of**

**Shire Pharmaceuticals Ireland Ltd.**

/s/ Michael Garry

Name: Michael Garry

Title: Director

Place: Berlin

Date: 3 May 2017

**for and on behalf of**

**Centogene AG**

/s/ Frank Volpers & Prof. Peter Bauer

Name: Frank Volpers & Prof. Peter Bauer

Title: Senior Director Legal & CSO

## Appendix 1

### Annual Flat Fee

Annual flat fee of € [\*\*\*\*\*] for 2017 and 2018, respectively, subject to following assumptions and clarifications as set out below:

Notwithstanding the concept of the flat fee, it is hereby clarified that if Centogene performs less than [\*\*\*\*\*] Diagnostic Tests in 2017 and/or 2018, reconciliation will take place in the subsequent calendar year (respectively 2018 or 2019). In the beginning of such subsequent calendar year, Centogene will issue a credit note, against which future Shire International invoices will be offset, for an amount equal to the difference between the annual flat fee and the value of actual tests performed invoiced at the prices set forth in Exhibit 1 of the MSA (Diagnostic Tests and Prices). Additionally, if less than [\*\*\*\*\*] Diagnostic Tests are performed in 2017, the Parties will negotiate and agree on revised terms of the flat fee for 2018.

### Further financial Details

1. Manual Processing Fee according to the MSA:

The manual processing fee is estimated by Shire to amount to € [\*\*\*\*\*] for 2017 under the assumption that [\*\*\*\*\*]% of the total kits are non-Centogene kits.

The pricing structure for the manual processing fee (€ [\*\*\*\*\*] for the first [\*\*\*\*\*] non-Centogene cards excluding EDTA samples and € [\*\*\*\*\*] for all other non-Centogene cards) is included in the current MSA and shall be invoiced separately to the flat fee in accordance with the payment provisions of the MSA.

2. Kit Supply Fee according to the Supply Agreement:

The Kit Supply Fee according to the Supply Agreement is estimated at € [\*\*\*\*\*] for 2017 under the assumption that [\*\*\*\*\*] DBS-kits are ordered pursuant to the pricing principles in the Supply Agreement.

3. Regulatory and Development Fee according to the Supply Agreement:

The Regulatory and Development Fee according to the Supply Agreement is estimated at € [\*\*\*\*\*] for 2017, pursuant to the pricing principles in the Supply Agreement, under the assumption that:

- kits are launched in [\*\*\*\*\*] new countries;
- yearly ICF legal review is performed in all countries in scope;
- the new version of the kit is rolled out in [\*\*\*\*\*] countries;
- an ageing study is performed.

## Appendix 2

### Exhibit 1 (Diagnostic Tests and Prices)

The below prices include (where Indicated) an additional technology access fee of € [\*\*\*\*\*] per tested sample.

Test	Costs In €
<b>Gaucher</b>	
[*****]	[*****] technology access fee
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
If a mutation in a family is found there will be an additional charge	[*****] sample processing fee + [*****] per exon (Total [*****] for a homozygous mutation and [*****] for an heterozygous mutation)
For a prenatal analysis there is an additional charge	[*****] for sample analysis + [*****] for contamination control with maternal material
<b>Fabry</b>	
[*****]	[*****] technology access fee
[*****]	[*****]
[*****]	[*****]
[*****]	[*****]
If a mutation in a family is found there will be an additional charge	[*****] sample processing fee + [*****] per exon
For a prenatal analysis there is an additional charge	[*****] for sample analysis + [*****] for contamination control with maternal material
<b>MPS II (Hunter Disease)</b>	
[*****]	[*****] technology access fee
[*****]	[*****]
<b>MPS IIIa (SGSH)</b>	
[*****]	[*****] technology access fee
[*****]	[*****]
<b>MPS IIIb (NAGLU)</b>	
[*****]	[*****] technology access fee
[*****]	[*****]

**MPS IIIc (HGSNAT)**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**MPS III d (GNS)**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**MLD (SGSH)**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**MPS I and VI**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee each  
[\*\*\*\*\*] [\*\*\*\*\*] each

**MPS IV**

[\*\*\*\*\*] [\*\*\*\*\*] technology access fee  
[\*\*\*\*\*] [\*\*\*\*\*]

**Appendix 3**

**Proforma Monthly Report**

[\*\*\*\*\*]

**Appendix 4**

**Proforma Quarterly Transparency Report**

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CONFIDENTIAL TREATMENT REQUESTED UNDER RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.

[\*\*\*\*\*] = Portions of this exhibit have been omitted pursuant to a confidential treatment request. An unredacted version of this exhibit has been filed separately with the Commission.

**2019 AMENDMENT**  
**TO GLOBAL MASTER SERVICES AGREEMENT AND**  
**TO SUPPLY AGREEMENT**

This Amendment (“**2019 Amendment**”) to the Global Master Services Agreement dated 1 January 2015 (“**MSA**”) and the Supply Agreement dated 1 January 2016 (“**Supply Agreement**”) is entered into as of 2 July, 2018 by and between

- (1) **Shire International GmbH**, a Swiss limited liability company having its registered office at Zählerweg 10, 6301 Zug, Switzerland (“**Shire International**”);
- (2) **Shire Pharmaceuticals Ireland Ltd.**, an Irish limited liability company having its registered office at Block 2 & 3 Miesian Plaza, 50 – 58 Baggot Street Lower, Dublin 2, Ireland (“**SPIL**”); and
- (3) **Centogene AG**, a German stock corporation incorporated under the laws of the Federal Republic of Germany with principal office in Restock, registered with the district court (‘Amtsgericht’) in Rostock under HRB 13225 and having a business address at Am Strande 7, 18055 Restock, Germany (“**Centogene**”).

**PREAMBLE**

- (A) Shire International and Centogene have entered into the MSA under which Centogene provides certain diagnostic testing services on the basis of dried-blood-spot (DBS) cards for the purpose of identifying patients suffering from lysosomal storage and other rare diseases to Shire International and its affiliates.
  - (B) In addition to the MSA, SPIL and Centogene have entered into the Supply Agreement under which Centogene (i) develops DBS test kits for the use in certain countries as required by SPIL on the basis of Centogene’s existing DBS test kits, (ii) manufactures such DBS test kits and (iii) supplies SPIL and its affiliates with such DBS test kits.
  - (C) On 8 March 2016, Shire International and Centogene entered into an amendment of the MSA under which Shire International and Centogene agreed, *inter alia*, on a flat fee for the performance of diagnostic services for the year 2016 (“**2016 Amendment**”). In a side letter to the MSA dated 24 November 2016, Shire International and Centogene agreed on certain additional commercial aspects with respect to the year 2016. On 3 May 2017, Shire International, SPIL and Centogene entered into an amendment of the MSA under which Shire International, SPIL and Centogene agreed, *inter alia*, on a flat fee for the performance of diagnostic services for the years 2017 and 2018 (“**2017 Amendment**”).
-

(D) Shire International, SPIL and Centogene now wish to agree on certain financial and other aspects of their cooperation going forward.

**Now, therefore, Shire International, SPIL and Centogene, intending to be legally bound, hereby agree to amend the MSA and the Supply Agreement as follows:**

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## DEFINITIONS

In this 2019 Amendment any capitalized terms shall have the meaning set forth in the MSA and the Supply Agreement (both as amended from time to time), unless a term is specifically defined under this 2019 Amendment.

### 1. ANNUAL FLAT FEE

1.1. Annual Flat Fee. The Parties agree to amend Section 3.6 of the MSA with respect to the calendar year 2019 as follows:

Subject to the below, Shire International will make an annual lump sum payment of € [\*\*\*\*\*] ([\*\*\*\*\*] Euro) to Centogene for the performance of [\*\*\*\*\*] of Diagnostic Tests for Morbus Fabry, Morbus Gaucher, Morbus Hunter, MPS1, MPS2, MPS3, MPS4, MPS6 and MPS7 in the calendar year 2019 (“**Annual Flat Fee**”). The financial terms of the Annual Flat Fee as well as other financial assumptions under the MSA and Supply Agreement are set forth in more detail in Appendix 1 to this 2019 Amendment. Centogene hereby expressly waives any payment claims for Excess Diagnostic Tests under Section 3.6(c) of the MSA; provided, however, that only the first [\*\*\*\*\*] Diagnostic Tests for MPS1, MPS3, MPS4, MPS6 and MPS7 performed in 2019 will be included in the Annual Flat Fee. Any additional Diagnostic Tests for MPS1, MPS3, MPS4, MPS6 and MPS7 will be invoiced and paid in accordance with Sec. 3.6 (c) of the MSA.

1.2. Diagnostic Test and Prices. The Parties agree to replace Exhibit 1 of the MSA (Diagnostic Tests and Prices) in its entirety with a new Exhibit 1 attached to this 2019 Amendment as Appendix 2. Parties acknowledge that the prices reflected therein have been increased as per Section 3.6(g) of the MSA.

1.3. Reporting. The payment of the Annual Flat Fee does not relieve Centogene from its obligation under Section 3.4 of the MSA to provide Shire International with detailed monthly summaries of Diagnostic Services actually rendered in the previous month, in the form as attached as Appendix 3 to this 2019 Amendment, including the information on the testing of expired Contract DBS Test Kits as further detailed in the Side Letter between Shire International and Centogene dated 2 July 2018.

1.4. Upfront Payments. Centogene will issue at the beginning of each calendar month, a preliminary invoice for a prorated amount of the Annual Flat Fee, i.e. an amount equal to 1/12 of each Annual Flat Fee. Shire International shall make payment within ten (10) Business Days upon receipt of a proper invoice.

### 2. BUSINESS CONTINUITY PLAN

Finalization of BCP, the parties hereby attach the latest agreed version of the Business Continuity Plan in Appendix 4.

### 3. OTHER TERMS

Other. All other terms and conditions as set forth in the MSA and the Supply Agreement (as amended from time to time) shall remain in full force and effect.

*[signature page follows]*

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Place: Zug, Switzerland

Date: 2 July 2018

**for and on behalf of**

**Shire International GmbH**

/s/ Renco Lenarca

Name: Renco Lenarca

Title: Proxy Holder

Place: Dublin, Ireland

Date: 2/7/2018

**for and on behalf of**

**Shire Pharmaceuticals Ireland Ltd.**

/s/ Denis Ahern

Name: Denis Ahern

Title: Director

Date: 2/7/2018

Place: Berlin

Date: 06.07.2018

**for and on behalf of**

**Centogene AG**

/s/ Richard Stoffelen

/s/ Frank Volpers

Name:

Title: CFO

VP Legal

CENTOGENE AG  
Zimmerstraße 69  
10117 Berlin / Germany  
Tel. +49 (0)30 213000-323  
Tel. +49 (0)30 213000-328  
Email: office@centogene.com  
Web: www.centogene.com

## Appendix 1

### Annual Flat Fee

Annual flat fee of € [\*\*\*\*\*] for 2019, respectively, subject to following assumptions and clarifications as set out below:

Notwithstanding the concept of the flat fee, it is hereby clarified that if Centogene performs less than [\*\*\*\*\*] Diagnostic Tests in 2019, reconciliation will take place in the subsequent calendar year (2020). In the beginning of such subsequent calendar year, Centogene will issue a credit note, against which future Shire International invoices will be offset, for an amount equal to the difference between the annual flat fee and the value of actual tests performed invoiced at the prices set forth in Exhibit 1 of the MSA (*Diagnostic Tests and Prices*).

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## Appendix 2

### Exhibit 1 (Diagnostic Tests and Prices)

The below prices include (where indicated) an additional technology access fee of € [\*\*\*\*\*] per tested sample.

Test/procedure	Price In € (net)	Technology Access Fee in € (net)
<b>Gaucher</b>		
[*****]	[*****] €	[*****] €
[*****]	[*****] €	
[*****]	[*****] €	
[*****]	[*****] €	
If a mutation in a family is found there will be an additional charge		
- sample processing	[*****] €	
- per exon	[*****] €	
- in total for homozygous mutation	[*****] €	
- in total for an heterozygous mutation	[*****] €	
For a prenatal analysis there is an additional charge		
- sample processing	[*****] €	
- for contamination control with maternal material	[*****] €	
<b>Fabry</b>		
[*****]	[*****] €	[*****] €
[*****]	[*****] €	
[*****]	[*****] €	
[*****]	[*****] €	
If a mutation In a family is found them will be an additional charge		
- sample processing	[*****] €	
- per exon	[*****] €	
For a prenatal analysis there is an additional charge		
- sample processing	[*****] €	
- for contamination control with maternal material	[*****] €	
<b>MPS II (Hunter Disease)</b>		
[*****]	[*****] €	[*****] €
[*****]	[*****] €	
<b>MPS IIIa (SGSH)</b>		
[*****]	[*****] €	[*****] €
[*****]	[*****] €	

**MPS IIIb (NAGLU)**

[\*\*\*\*\*] [\*\*\*\*\*] € [\*\*\*\*\*] €  
[\*\*\*\*\*] [\*\*\*\*\*] €

**MPS IIIc (HGSNAT)**

[\*\*\*\*\*] [\*\*\*\*\*] €

**MPS IIIId (GNS)**

[\*\*\*\*\*] [\*\*\*\*\*] € [\*\*\*\*\*] €  
[\*\*\*\*\*] [\*\*\*\*\*] €

**MLD(SGSH)**

[\*\*\*\*\*] [\*\*\*\*\*] €

**MPS I and VI (prices for each)**

[\*\*\*\*\*] [\*\*\*\*\*] € [\*\*\*\*\*] €  
[\*\*\*\*\*] [\*\*\*\*\*] €

**MPS IV**

[\*\*\*\*\*] [\*\*\*\*\*] € [\*\*\*\*\*] €  
[\*\*\*\*\*] [\*\*\*\*\*] €

**MPS VII**

[\*\*\*\*\*] [\*\*\*\*\*] € [\*\*\*\*\*] €  
[\*\*\*\*\*] [\*\*\*\*\*] €

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**Appendix 3****Proforma Monthly Report**

1. Monthly diagnostic test report (one line per test performed)

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Execution version

2. Monthly Expired Contract DBS Test Kit report (one line per country and disease on expired cards received)

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**Appendix 4****Business Continuity Plan**

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