

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[INDEX TO FINANCIAL STATEMENTS](#)

[Table of Contents](#)

Filed Pursuant to 424(b)(4)
Registration No. 333-234177

Prospectus

4,000,000 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 4,000,000 common shares, €0.12 par value per share. The initial public offering price is \$14.00 per common share.

Our common shares have been approved for listing 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 12 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	\$ 14.00	\$ 56,000,000
Underwriting discounts and commissions	\$ 0.98	\$ 3,920,000
Proceeds, before expenses, to us	\$ 13.02	\$ 52,080,000

(1) We refer you to "Underwriting" beginning on page 203 for additional information regarding underwriting compensation.

Certain of our existing institutional or other investors or their affiliates have committed to, or indicated an interest in, purchasing common shares in this offering in an aggregate amount of up to \$30 million. See "Summary—The Offering."

We have granted the underwriters the right for 30 days from the date of this prospectus to purchase up to an additional 600,000 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 November 12, 2019.

SVB Leerink

Evercore ISI

Baird

BTIG

November 6, 2019

TABLE OF CONTENTS

	<u>Page</u>
Summary	1
The Offering	8
Summary Financial Information	10
Risk Factors	12
Cautionary Statement Regarding Forward-Looking Statements	68
Use of Proceeds	70
Dividends and Dividend Policy	71
Corporate Reorganization	72
Capitalization	74
Dilution	75
Selected Financial Information	77
Management's Discussion and Analysis of Financial Condition and Results of Operations	79
Business	111
Management	152
Principal Shareholders	162
Certain Relationships and Related Party Transactions	164
Description of Share Capital and Articles of Association	166
Common Shares Eligible for Future Sale	184
Taxation	186
Underwriting	203
Expenses of the Offering	209
Legal Matters	210
Experts	210
Enforcement of Judgments	211
Where You Can Find More Information	213
Index to Financial Statements	F-1

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.

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 \$1.1129 to €1.00, the official exchange rate quoted as of October 17, 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

We are a commercial-stage company focused on rare diseases that transforms real-world clinical and genetic data into actionable information for patients, physicians and pharmaceutical companies. Our goal is to bring rationality to treatment decisions and to accelerate the development of new orphan drugs by using our knowledge of the global rare disease market, including epidemiological and clinical data and innovative biomarkers. We have developed a global proprietary rare disease platform based on our real-world data repository with over 2.0 billion weighted data points from over 450,000 patients representing 115 different countries as of August 31, 2019, or an average of over 500 data points per patient. Our platform includes epidemiologic, phenotypic and genetic data that reflects a global population, and also a biobank of these patients' blood samples.

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. As of August 31, 2019, we collaborated with over 35 pharmaceutical partners for over 30 different rare diseases.

A rare disease, by definition in the United States, is a disease that affects 200,000 or fewer people. However, with over 7,000 currently identified rare diseases, they in aggregate affect over 350 million people globally. Rare diseases can be severe and often take years to diagnosis—on average it takes five to seven years for a patient with a rare disease to be diagnosed. This underscores 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 rare hereditary diseases, only approximately 230 rare hereditary 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 epidemiology.

We have an integrated approach with a detailed, global understanding of the genetic basis and the clinical phenotype of rare hereditary diseases, which we believe will unlock the ability to target rare diseases and provide critical knowledge that will guide drug development and monitoring, and ultimately improve patient care. Our business is comprised of complementary solutions for both physicians and their patients, as well as pharmaceutical companies. Our diagnostics solution typically starts with specialist physicians requesting diagnostic information to identify or confirm a rare disease by sending us their patients' blood samples on our proprietary dried blood spot collection kit that bears the European Conformity Marking (the "CE Mark")—the CentoCard. With highly advanced technology, our proprietary database and our team of medical experts, we then deliver reports back to the physicians that contain what we believe is critical information containing genetic, proteomic, metabolomic information, or some combination, depending on what is most salient for each case. We also input this data to our CentoMD platform, which enriches our understanding of rare diseases broadly.

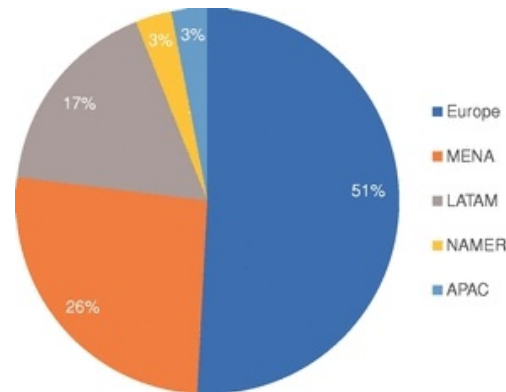
For our pharmaceutical partners, we are able to provide various valuable information using our platform. For instance, with the access to the data in our repository and biomaterials in our biobank, we have successfully developed biomarkers by applying highly sophisticated tools, including mass spectrometry technologies, together with artificial intelligence capabilities in an efficient and cost effective manner. Biomarkers are important in orphan drug development as well as post-commercialization monitoring, by demonstrating the efficacy of the drugs, performing longitudinal monitoring and informing necessary titration for individual rare disease patients. As of August 31, 2019, we had over 30 biomarkers under development and had commercialized ten biomarkers covering eight rare diseases, including Aromatic L-amino acid decarboxylase ("AADC") deficiency, Cystic Fibrosis, Fabry disease, Faber disease, Gaucher disease, Hereditary Angioedema ("HAE"), Niemann-Pick Type A/B, and Niemann-Pick Type C.

Our database is also valuable beyond drug discovery as the biomarkers can be relevant for patient stratification and monitoring. Our database has multiple additional applications such as patient identification for therapeutic trials and treatment. For example, identifying patients with a specific rare disease that are eligible for a clinical trial, which can reduce the time of clinical trial patient enrollment for our pharmaceutical partners. Reducing this enrollment time is often critically important in rare diseases as the small number of patients of each disease can cause long enrollment periods.

We were founded in 2006 in Rostock, Germany and currently have more than 400 highly qualified personnel (including consultants) across offices in Austria, Germany, India, the United Arab Emirates and the United States, from over 55 nationalities. Since 2012, we have received more than 450,000 patient samples. We generated total revenue of €31.7 million and €40.5 million in the years ended December 31, 2017 and 2018, respectively, and of €17.0 million and €21.2 million in the six months ended June 30, 2018 and 2019, respectively. We also incurred net comprehensive losses of €5.5 million and €11.3 million in the years ended December 31, 2017 and 2018, respectively, and of €6.6 million and €11.6 million in the six months ended June 30, 2018 and 2019, respectively.

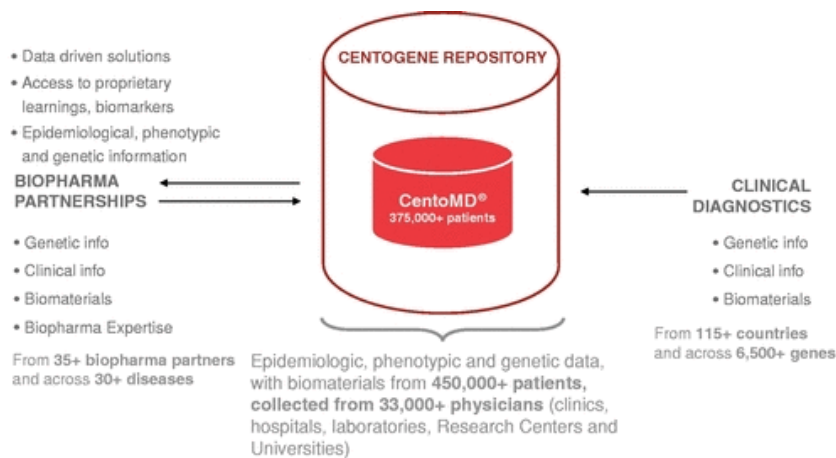
Our Platform—An Integrated, Knowledge-Based System

We have developed a global proprietary rare disease platform 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 real-world 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 CE-Marked dried blood spot collection kit, which captures blood samples of potential rare disease patients with a low cost of distribution, accompanied by the patients' medical histories and completed consent forms from the physicians. The data is then validated by professionals using a systematic and scientific approach prior to feeding it into our repository and our central CentoMD database, which we believe is the world's largest curated mutation database for rare diseases. As of September 30, 2019, our CentoMD 5.5 database included curated data from over 375,000 patients from over 120 countries. We received express consent from the majority of patients allowing us to retest their biomaterials in our biobank, with over 10 million unique variants and over 3,500 disease-associated phenotypes, with the following geographical distribution:



This systematic process results in information-based services that are beneficial for rare disease drug development by our biotech and pharmaceutical partners. These include providing epidemiological insights about rare diseases, further identification of rare disease patients as well as the ability to identify new biomarkers. 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. As of September 30, 2019, our repository included data from patients with metabolic (40%), neurologic (23%), malformation (10%), bone, skin and immunity (7%), liver and kidney and endocrinological (6%) and tumoral (5%) diseases, among others, covering over 3,000 diseases.

A graphical description of our platform is shown below:



**Genetics + Proteomics + Metabolomics = More Comprehensive View of Biology
> 2.0 billion data points (or > 500 data points per patient)**

The strengths of our platform include the following:

- Extensive repository to identify rare disease patients, containing phenotypic, genomic and epidemiological data from over 450,000 patients and a biobank which holds biomaterials from the blood samples of these patients;
- Ethnically diverse datasets with patients from over 115 countries;
- Highest level of quality through data curation and process standardization; and

- Enhancement of biomarker discovery.

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 are 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. For the six-months ended June 30, 2019, €8.7 million, or 39.7%, 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 August 31, 2019, we believe we offer the broadest diagnostic testing portfolio for rare diseases, covering over 6,500 genes using over 10,000 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. For the six-months ended June 30, 2019, €13.2 million, or 60.3%, 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 drug development and patient stratification, identification and monitoring. To achieve this objective our strategy is to:

- Transform the rare diseases landscape by applying precision medicine more comprehensively.
- Further our leadership position in rare diseases and continue to build upon the largest, most comprehensive repository for rare diseases patient data.
- Accelerate the discovery and development of orphan drugs for new and existing pharmaceutical partners.
- Evolve our business to share in more of the value we provide to 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.

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 to 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 4,000,000 common shares.
Underwriters' option to purchase additional common shares	We have granted the underwriters the right to purchase up to an additional 600,000 common shares from us within 30 days of the date of this prospectus.
Common shares to be outstanding after this offering	19,861,340 common shares (20,461,340 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	Our common shares have been approved for listing 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 \$47,080,000 (\$54,892,000 if the underwriters' option to purchase additional common shares is exercised in full) after deducting underwriting discounts and commissions and estimated offering expenses payable by us.</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	<p>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.</p>

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.
Indications of interest	Certain of our existing institutional or other investors or their affiliates have committed to, or indicated an interest in, purchasing common shares in this offering in an aggregate amount of up to \$30 million. The underwriters will receive the same underwriting discounts on any common shares purchased by these investors as they will on any other common shares sold to the public in this offering.
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.

The above number of common shares to be outstanding after this offering is based on 322,007 common and Series A preferred shares of Centogene AG outstanding as of June 30, 2019 (or 15,861,340 common shares of Centogene N.V. after giving effect to the corporate reorganization) and excludes:

- 16,349 common shares of Centogene AG issuable upon the exercise of 16,374 virtual share options outstanding under our 2017 Virtual Share Option Plan as of June 30, 2019, which options will be converted into awards exercisable for common shares of Centogene N.V. on a 1.00 to 49.2578 basis, upon consummation of this offering; and
- Any common shares to be issued pursuant to our 2019 Equity Incentive Plan, which will become effective prior to the completion of this offering and includes provisions that automatically adjust the number of common shares reserved for issuance thereunder each year (See "Management—Compensation of Managing Directors, Supervisory Directors and Officers—2019 Equity Incentive Plan").

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

- no common shares issuable upon the exercise of outstanding virtual share options after June 30, 2019;
- the completion, prior to the closing of this offering, of our corporate reorganization, as further described under the section titled "Corporate Reorganization"; and
- no exercise of the option granted to the underwriters to purchase up to 600,000 additional common shares in connection with the offering.

SUMMARY FINANCIAL INFORMATION

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

The following summary interim condensed consolidated statement of financial position as of June 30, 2019 and the summary interim condensed consolidated statement of comprehensive loss for the six-months ended June 30, 2018 and 2019 of Centogene AG are derived from the unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements referred to above except as disclosed therein for the adoption of new accounting standards as of January 1, 2019 and, in the opinion of management, reflect all adjustments necessary to state fairly our financial position as of June 30, 2019 and our results of operations for the six-months ended June 30, 2018 and 2019. Our historical results for the six-months ended June 30, 2018 and 2019 are not necessarily indicative of results to be expected for a full year or any other interim period. 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			For the Six-Months	
	December 31,			Ended June 30,	
	2016	2017	2018	2018	2019
	(€ in thousands)			(unaudited)	
Consolidated statement of comprehensive loss:					
Revenue	27,669	31,689	40,478	17,012	21,921
Cost of sales	12,856	14,939	19,941	9,126	12,858
Gross profit	14,813	16,750	20,537	7,886	9,063
Research and development expenses	5,885	6,396	6,300	2,356	4,108
General administrative expenses	8,888	9,498	18,610	9,030	11,603
Selling expenses	5,364	5,897	7,474	2,848	4,356
Other operating income	1,295	1,043	2,306	953	1,688
Other operating expenses	908	457	1,065	665	464
Real estate transfer tax expenses	—	—	—	—	1,200
Operating loss	(4,937)	(4,455)	(10,606)	(6,060)	(10,980)
Interest and similar income	26	14	33	14	12
Interest and similar expense	856	1,021	1,075	686	431
Finance costs, net	(830)	(1,007)	(1,042)	(672)	(419)
Loss before taxes	(5,767)	(5,462)	(11,648)	(6,732)	(11,399)
Income tax (benefits)/expenses	(408)	14	(310)	(110)	163
Loss for the period	(5,359)	(5,476)	(11,338)	(6,622)	(11,562)
Other comprehensive income/(loss)	9	10	(8)	44	10
Total comprehensive loss for the period	(5,350)	(5,466)	(11,346)	(6,578)	(11,552)

	As of June 30, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted ⁽¹⁾⁽²⁾
	(€ in thousands)		
	(unaudited)		
Consolidated statement of financial position:			
Cash and cash equivalents	3,564	3,564	46,967
Total assets	75,309	75,309	115,824
Total liabilities	59,849	59,849	58,059
Total equity	15,460	15,460	57,765

- (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 initial public offering price of \$14.00 per common share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, assuming no exercise of the underwriters' option to purchase additional common shares.
- (2) U.S. dollar amounts have been translated into euros at a rate of USD1.1129 to €1.00, the exchange rate quoted as of October 17, 2019 by the U.S. Federal Reserve.

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;

[Table of Contents](#)

- 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

[Table of Contents](#)

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 six-months ended June 30, 2019 and year ended December 31, 2018, our top five pharmaceutical partners, in the aggregate, accounted for 35.1% and 39.0% of our revenues, respectively. 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 six-months ended June 30, 2019, our collaboration with Shire International GmbH ("Shire") represented 27.1% 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

[Table of Contents](#)

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 as well as our Cambridge, Massachusetts facility. 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 and the United States 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 data 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

[Table of Contents](#)

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 the majority of our diagnostic testing at our laboratory in Rostock, Germany, and 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

[Table of Contents](#)

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, our third-party datacenter solutions, our broadband connections 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

[Table of Contents](#)

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

[Table of Contents](#)

(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 primarily 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

[Table of Contents](#)

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 epidemiology and 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 Commission and European Medicines Agency ("EMA"), German Federal Institute for Medicinal Products and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*), or comparable authorities' or 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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 have limited resources to be expended on research programs and biomarker development. Our resource allocation decisions may lead us to focus on research programs and biomarkers which are not commercially viable, and as a result we may be unable to recover the costs incurred under these efforts.

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 relevant results that are helpful to our existing programs or assist in the creation of 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

[Table of Contents](#)

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 authorization or oversight of the conduct of clinical trials in other countries;
- inability to 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 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 European Commission and 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

[Table of Contents](#)

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 platform (including CentoMD), 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

[Table of Contents](#)

Portability and Accountability Act ("HIPAA"), the General Data Protection Regulation (EU 2016/679) ("GDPR") 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. 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 44.1%, 30.9% and 16.8% of our total revenues for the six-months ended June 30, 2019, 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

[Table of Contents](#)

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 and the six-months ended June 30, 2019, we derived 30.6% and 30.9%, respectively, 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

[Table of Contents](#)

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 the CLIA 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.

[Table of Contents](#)

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.

For samples tested in the U.S., 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 or pseudonymized in accordance with GDPR 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 or pseudonymized in accordance with applicable laws and regulations, pharmaceutical partners or academic researchers may use technology or other methods to link that de-identified or pseudonymized 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, GDPR 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.

[Table of Contents](#)

In the European Union, various regulations apply to genetic testing and the use of genomic information. In Germany, the Genetic Diagnosis Act (*Genodiagnostikgesetz*) (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, GDPR, 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.

On May 25, 2018, 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") went into effect. 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.

Further complicating compliance efforts, on June 23, 2016, the electorate in the United Kingdom voted in favor of the United Kingdom leaving the European Union, commonly referred to as "Brexit." Thereafter, on March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom's exit from the European

[Table of Contents](#)

Union is scheduled to occur on October 31, 2019. The withdrawal of the United Kingdom from the European Union will take effect either on the scheduled date of the withdrawal or an extended departure date as agreed between the United Kingdom and the European Union. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

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 im Gesundheitswesen*), 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.

[Table of Contents](#)

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, and for the six-months ended June 30, 2019, €1,041 thousand. In the year ended December 31, 2018 and the six-months ended June 30, 2019, 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 as of December 31, 2016, 2017 and 2018 amounted to €67 thousand, €77 thousand and €1,351 thousand, respectively, and as of June 30, 2019 amounted to €1,848 thousand. 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. Similar laws and regulations exist in other jurisdictions where we promote our products. 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, manufacturing, 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

[Table of Contents](#)

not entirely clear as the IVD-MDD lacks an explicit definition and there is no related case law. On May 26, 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) becomes applicable, 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.

In the EU, genetic tests on humans and prenatal tests for genetically caused disorders are regulated as Class C devices under the IVD Regulation. If our LDTs are subject to the IVD Regulation, our tests that qualify as Class C devices will be subject to conformity assessments performed by a notified body.

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

[Table of Contents](#)

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,

[Table of Contents](#)

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 has been certified by a notified body, 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. Moreover, patent applications that we have made in the past have

[Table of Contents](#)

been subject to comment and revision by the relevant patent offices, which have resulted in our withdrawal of certain patent applications. 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. Parties who have access to confidential or patentable aspects of our research and development output, such as our employees, advisors, and other third parties, and who are party to non-disclosure and confidentiality agreements with us, may breach such 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

[Table of Contents](#)

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

[Table of Contents](#)

determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office or nullity or entitlement proceedings, 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. In other jurisdictions, defendants have and/or may have comparable grounds for defending against such claims, especially with regard to claims that a patent is invalid. 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 or nullity or entitlement proceedings. 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

[Table of Contents](#)

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 or in courts in other jurisdictions, 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. The same applies to other jurisdictions. 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 and therefore may be unable to develop, sell or otherwise commercialize our products or solutions. 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.

[Table of Contents](#)

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 patent laws 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, the USPTO, or other foreign patent offices or courts 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.

[Table of Contents](#)

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

[Table of Contents](#)

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 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

[Table of Contents](#)

and which are or were made by personnel working in Germany (except for legal representatives of our respective legal entities, for example managing directors) 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' or owners' interest in such patents, such co-owners or 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 or 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 current and past German employee inventors have subsequently assigned to us their interest in inventions or patents they invented or co-invented, there can be no assurance that all such assignments are fully effective, which can lead to unexpected costs or economic disadvantages. Even if we lawfully own all inventions created by our employees who are subject to the German Inventions Act, we are required under German law to reasonably 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. Legal representatives of legal entities, for example managing directors, whose contractual relationships with the respective entity are subject to German law and that are not subject to the German Inventions Act as well as consultants must assign and transfer their interest in inventions and/or patents they invent or co-invent to us in order for us to have any rights to such inventions or patents. While we believe that all assignments have been made, there can be no assurance that all such assignments are fully effective, which may harm our business, prospects, financial condition and results of operations.

If any of our current or past employees, legal representatives of our legal entities or consultants obtain or retain ownership or co-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 or legal representatives of legal entities or consultants 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, legal representative's of legal entities or consultant'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 or solutions we may develop or may have developed. 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.

[Table of Contents](#)

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. Such claims could materially harm our business, prospects, financial condition and result of operations.

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 €11,552 thousand in the six-months ended June 30, 2019, €11,346 thousand in the year ended December 31, 2018, €5,466 thousand in the year ended December 31, 2017 and €5,350 thousand in the year ended December 31, 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 provides that we may not (i) assume further indebtedness or grant security interests or any guarantees above certain thresholds, (ii) dispose of 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 obtain the consent of the lenders prior to the sale of more than 10% of his shares in our Company. 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 June 30, 2019, we had €15,242 thousand of loans outstanding under our syndicated loan facility including bank overdrafts of €2,296 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 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 B and D. We repaid all outstanding amounts under tranche A in September 2019 upon completion of the sale and leaseback transaction of our headquarters building in Rostock.

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 the financial covenants of the facility 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

[Table of Contents](#)

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 was secured by a land charge in the amount of €19,910 thousand, a cash pledge in the amount of €2,500 thousand related to tranche D as of July 1, 2019 and assignments of certain laboratory equipment and trade and other receivables. In September 2019, the land charge was fully released upon repayment of the outstanding amounts under tranche A noted above.

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 €3,420 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.

[Table of Contents](#)

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.

[Table of Contents](#)

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 was 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;

[Table of Contents](#)

- 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 79,000,000 common shares, of which 19,861,340 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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

trainings are planned for our accounting and financial reporting personnel. Although we are working to remediate the material weakness as quickly and efficiently as possible, we cannot at this time estimate how long it will take, and our initiatives may not prove to be successful in remediating the material weakness. 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 69.7% of the outstanding common shares after this offering excluding any potential purchases as described in the paragraph below. 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.

In addition, certain of our existing institutional or other investors or their affiliates have committed to, or indicated an interest in, purchasing common shares in this offering in an aggregate amount of up to \$30 million. If these existing institutional or other investors or their affiliates are allocated all or a portion of the common shares in which they have committed to, or indicated an interest in, such purchases would reduce the available public float for our common shares because such shareholders would be restricted from selling the common shares by a lock-up agreement entered into by us with the underwriters and/or by restrictions under applicable securities laws. See "Underwriting—No Sales of Similar Securities" for additional information. As a result, any purchase of common shares by such existing institutional or other investors or their affiliates in this offering may reduce the liquidity of our common shares relative to what it would have been had these common shares been purchased by investors that were not previously associated with us. See "Principal Shareholders."

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

[Table of Contents](#)

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, any dividends distributed by us are subject to Dutch dividend withholding tax on the basis of Dutch domestic law. On the basis of the 2012 Convention between the Federal Republic of Germany and the Kingdom of the Netherlands for the avoidance of double taxation with respect to taxes on income (the "double tax treaty between Germany and the Netherlands"), however, the Netherlands will be restricted in imposing these taxes if the Company is also a tax resident of Germany and its effective management is located in Germany. See "Risk factors—We may become taxable in a jurisdiction other than Germany and this may increase the aggregate tax burden on us." Dutch dividend withholding tax is, however, still required to be withheld from dividends if and when paid to Dutch resident holders of our common shares (and non-Dutch resident holders of our common 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 in the Netherlands to which the common shares are attributable) in respect of which Dutch dividend tax has to be withheld. Such identification may not always be possible in practice. As the dividend withholding tax liability of a Dutch resident shareholder can generally be credited against such shareholder's (corporate) income tax liability, we may approach the Dutch tax authorities prior to a payment of dividends to apply for a tax ruling confirming that no withholding of any Dutch withholding tax is required. The outcome of such tax ruling request is, however, uncertain. 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 is substantially higher than the pro forma net tangible book value per share of the outstanding common shares immediately after the offering. Based on the initial public offering price of \$14.00 per share and our net tangible book value as of June 30, 2019, 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 \$11.39 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 805,308 outstanding share options to purchase common shares with exercise prices that are below the 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

[Table of Contents](#)

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 our incorporation we have had, on a continuous basis, our place of "effective management" in Germany. We will therefore qualify as a tax resident of Germany on the basis of German domestic law. As an entity incorporated under Dutch law, however, we also qualify as a tax resident of the Netherlands on the basis of Dutch domestic law. However, based on our current management structure and the current tax laws of the United States, Germany and the Netherlands, as well as applicable income tax treaties, and current interpretations thereof, we should qualify solely as a tax resident of Germany for the purposes of the double tax treaty between Germany and the Netherlands due to the "effective management" tie-breaker. The test of "effective management" is largely a question of fact and degree based on all the circumstances, rather than a question of law. Nevertheless, the relevant case law and OECD guidance suggest that the Company is likely to be regarded as having become German tax resident from incorporation and remaining so if, as the Company intends, (i) most meetings of its management board are held in Germany (and none will be held in the Netherlands) with a majority of directors present in Germany for those meetings; (ii) at those meetings there are full discussions of, and decisions are made regarding, the key strategic issues affecting the Company and its subsidiaries; (iii) those meetings are properly minuted; (iv) at least some of the directors of the Company, together with supporting staff, are based in Germany; and (v) the Company has permanent staffed office premises in Germany. We may, however, 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 in such other country.

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 reduced or avoided entirely.

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

[Table of Contents](#)

"KStG") and Section 10a of the German Trade Tax Act (*Gewerbesteuer*gesetz, 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 50% 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 expire in full. To the extent that the tax loss carryforwards do not 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. In case of a qualified ownership change, tax loss carryforwards will be preserved (in the form of a "*fortführungsgebundener Verlustvortrag*") if the business operations have not been changed and will not be changed within the meaning of Section 8d KStG.

According to another appeal filed by the fiscal court of Hamburg dated August 29, 2017, Section 8c, paragraph 1, sentence 1 KStG is not in line with the German constitution. 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 1 KStG is not in line with the German constitution.

As of December 31, 2018, we had unrecognized NOL carryforwards for German tax purposes of €21,728 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, and (iii) 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.

[Table of Contents](#)

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. 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 (*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

[Table of Contents](#)

- 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 with the approval of 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. Most 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

[Table of Contents](#)

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.

[Table of Contents](#)

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 4,000,000 common shares in this offering will be approximately \$47.1 million (or \$54.9 million if the underwriters exercise in full their option to purchase additional shares), at the initial public offering price of \$14.00 per common share, after deducting 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 \$22.5 million for research and development under our pharmaceutical segment, including the development and clinical validation of biomarkers, as well as for growth of our partnership opportunities through sales and marketing investments;
- approximately \$17.5 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.

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 1.00 to 89.6125 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 1.00 to 33.2238 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 15,861,340 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 June 30, 2019 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 4,000,000 common shares in this offering, at an initial public offering price of \$14.00 per common share, after deducting 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.

	June 30, 2019		
	Actual	Pro Forma (€ in thousands) (unaudited)	Pro Forma As Adjusted
Cash and cash equivalents	3,564	3,564	46,967
Liabilities			
Non-current loans	12,025	12,025	12,025
Current loans	5,524	5,524	5,524
Total debt	<u>17,549</u>	<u>17,549</u>	<u>17,549</u>
Equity			
Issued capital	322	1,903	2,383
Capital reserve	47,411	45,830	87,655
Retained earnings and other reserves	(31,390)	(31,390)	(31,390)
Non-controlling interests	(883)	(883)	(883)
Total shareholders' equity	<u>15,460</u>	<u>15,460</u>	<u>57,765</u>
Total capitalization	<u><u>33,009</u></u>	<u><u>33,009</u></u>	<u><u>75,314</u></u>

The above number of common shares to be outstanding after this offering is based on 322,007 common and Series A preferred shares of Centogene AG outstanding as of June 30, 2019 (or 15,861,340 common shares of Centogene N.V. after giving effect to the corporate reorganization) and excludes:

- 16,349 common shares of Centogene AG issuable upon the exercise of 16,374 virtual share options outstanding under our 2017 Virtual Share Option Plan as of June 30, 2019, which options will be converted into awards exercisable for common shares of Centogene N.V. on a 1.00 to 49.2578 basis, and after the consummation of this offering; and
- Any common shares to be issued pursuant to our 2019 Equity Incentive Plan, which will become effective prior to the completion of this offering and includes provisions that automatically adjust the number of common shares reserved for issuance thereunder each year (see "Management—Compensation of Managing Directors, Supervisory Directors and Officers—2019 Equity Incentive Plan").

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 June 30, 2019, we had a pro forma net tangible book value of \$1.6 million (€1.4 million), corresponding to a pro forma net tangible book value of \$0.10 per common share (€0.09 per common share). Pro forma net tangible book value represents the amount of our total assets less our total liabilities, excluding intangible assets and deferred offering costs, divided by 15,861,340, the number of common shares issued and outstanding, after giving effect to the corporate reorganization.

After giving further effect to the sale of the 4,000,000 common shares offered by us in the offering, at the initial offering price of \$14.00 per common share (€12.58 per common share), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value estimated at June 30, 2019 would have been \$51.8 million (€46.6 million), representing \$2.61 per common share (€2.35 per common share). This represents an immediate increase in pro forma net tangible book value of \$2.51 per common share (€2.26 per common share) to existing shareholders and an immediate dilution in net tangible book value of \$11.39 per common share (€10.23 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.

	\$	€
Initial public offering price per common share	14.00	12.58
Pro forma net tangible book value per common share at June 30, 2019 after giving effect to the corporate reorganization	0.10	0.09
Increase in net tangible book value per common share attributable to new investors	2.51	2.26
Pro forma as adjusted net tangible book value per common share at June 30, 2019 after giving effect to the corporate reorganization and the offering	2.61	2.35
Dilution per common share to new investors	11.39	10.23
Percentage of dilution per common share to new investors	81%	81%

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 \$2.92 per common share (€2.62 per common share), and the dilution per common share to new investors would be \$11.08 per common share (€9.96 per common share), in each case at the initial public offering price of \$14.00 per common share (€12.58 per common share).

The above number of common shares to be outstanding after this offering is based on 322,007 common and Series A preferred shares of Centogene AG outstanding as of June 30, 2019 (or 15,861,340 common shares of Centogene N.V. after giving effect to the corporate reorganization) and excludes:

- 16,349 common shares of Centogene AG issuable upon the exercise 16,374 of virtual share options outstanding under our 2017 Virtual Share Option Plan as of June 30, 2019, which options will be converted into awards exercisable for common shares of Centogene N.V. on a 1.00 to 49.2578 basis, and after the consummation of this offering; and

[Table of Contents](#)

- Any common shares to be issued pursuant to our 2019 Equity Incentive Plan, which will become effective prior to the completion of this offering and includes provisions that automatically adjust the number of common shares reserved for issuance thereunder each year (see "Management—Compensation of Managing Directors, Supervisory Directors and Officers—2019 Equity Incentive Plan").

Certain of our existing institutional or other investors or their affiliates have committed to, or indicated an interest in, purchasing common shares in this offering in an aggregate amount of up to \$30 million. The foregoing discussion and tables do not reflect any potential purchases by these investors to the extent any such investor is an existing investor or affiliate thereof.

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 interim condensed consolidated statement of financial position as of June 30, 2019 and the interim condensed consolidated statement of comprehensive loss for the six-months ended June 30, 2018 and 2019 of Centogene AG are derived from the unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements referred to above except as disclosed therein for the adoption of new accounting standards as of January 1, 2019 and, in the opinion of management, reflect all adjustments necessary to state fairly our financial position as of June 30, 2019 and our results of operations for the six-months ended June 30, 2018 and 2019. Our historical results for the six-months ended June 30, 2018 and 2019 are not necessarily indicative of results to be expected for a full year or any other interim period. 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.

[Table of Contents](#)

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,			For the Six-Months Ended June 30,	
	2016	2017	2018	2018	2019
	(€ in thousands)			(unaudited)	
Consolidated statement of comprehensive loss:					
Revenue	27,669	31,689	40,478	17,012	21,921
Cost of sales	12,856	14,939	19,941	9,126	12,858
Gross profit	14,813	16,750	20,537	7,886	9,063
Research and development expenses	5,885	6,396	6,300	2,356	4,108
General administrative expenses	8,888	9,498	18,610	9,030	11,603
Selling expenses	5,364	5,897	7,474	2,848	4,356
Other operating income	1,295	1,043	2,306	953	1,688
Other operating expenses	908	457	1,065	665	464
Real estate transfer tax expenses	—	—	—	—	1,200
Operating loss	(4,937)	(4,455)	(10,606)	(6,060)	(10,980)
Interest and similar income	26	14	33	14	12
Interest and similar expense	856	1,021	1,075	686	431
Finance costs, net	(830)	(1,007)	(1,042)	(672)	(419)
Loss before taxes	(5,767)	(5,462)	(11,648)	(6,732)	(11,399)
Income tax (benefits)/expenses	(408)	14	(310)	(110)	163
Loss for the period	(5,359)	(5,476)	(11,338)	(6,622)	(11,562)
Other comprehensive income/(loss)	9	10	(8)	44	10
Total comprehensive loss for the period	(5,350)	(5,466)	(11,346)	(6,578)	(11,552)
Loss per share—Basic and diluted	(25)	(22)	(40)	(25)	(36)

	As of December 31,		As of June 30,
	2017	2018	2019
	€ in thousand		
	(unaudited)		
Consolidated statement of financial position:			
Cash and cash equivalents	3,157	9,222	3,564
Total assets	55,486	76,674	75,309
Total current liabilities	23,808	24,283	35,509
Total non-current liabilities	15,324	25,867	24,340
Total equity	16,354	26,524	15,460

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 unaudited interim condensed consolidated financial statements as of June 30, 2019 and for the six-months ended June 30, 2018 and 2019, as well as the 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

We are a commercial-stage company focused on rare diseases that transforms real-world clinical and genetic data into actionable information for patients, physicians and pharmaceutical companies. Our goal is to bring rationality to treatment decisions and to accelerate the development of new orphan drugs by using our knowledge of the global rare disease market, including epidemiological and clinical data and innovative biomarkers. We have developed a global proprietary rare disease platform based on our real-world data repository with over 2.0 billion weighted data points from over 450,000 patients representing 115 different countries as of August 31, 2019, or an average of over 500 data points per patient. Our platform includes epidemiologic, phenotypic and genetic data that reflects a global population, and also a biobank of these patients' blood samples. 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, access to rare disease patients and their biomaterials, 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 August 31, 2019, we collaborated with over 35 pharmaceutical partners for over 30 different rare diseases. In addition, we had over 30 biomarkers under

development and had commercialized ten biomarkers for eight rare diseases as of August 31, 2019.

- **Diagnosics.** 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. As of August 31, 2019, we believe we offer the broadest diagnostic testing portfolio for rare diseases, covering over 6,500 genes using over 10,000 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 six-months ended June 30, 2019, we received approximately 62,500 test requests, representing an approximate 33.1% increase as compared to approximately 46,900 test requests received during the six-months ended June 30, 2018, and in the year ended December 31, 2018, we received over 105,300 test requests, representing an approximate 26.9% increase as compared to approximately 83,000 test requests received during the year ended December 31, 2017. Test requests received during the year ended December 31, 2017 represented an increase of approximately 1.7% as compared to approximately 81,600 test requests received during the year ended December 31, 2016.

Our revenue for the six-months ended June 30, 2019 was €21,921 thousand, an increase of €4,909 thousand, or 28.9%, from €17,012 thousand for the six-months ended June 30, 2018. Our pharmaceutical and diagnostics segments contributed 39.7% and 60.3%, respectively, of our total revenues for the six-months ended June 30, 2019, as compared to 36.9% and 63.1%, respectively, of our total revenues for the six-month ended June 30, 2018. Test requests received by our pharmaceutical and diagnostics segments for the six-months ended June 30, 2019 were approximately 29,800 and 32,700, respectively, representing increases of approximately 8.3% and 68.6%, respectively, as compared to approximately 27,500 and 19,400 test requests, respectively, received during the six-months ended June 30, 2018.

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. Test requests received by our pharmaceutical and diagnostics segments for the year ended December 31, 2018 were approximately 57,400 and 47,900, respectively, representing increases of approximately 1.4% and 82.6%, respectively, as compared to approximately 56,900 and 26,100 test requests, respectively, received for the year ended December 31, 2017. Test requests received by our pharmaceutical segment for the year ended December 31, 2017 represented a decrease of approximately 6.5% as compared to approximately 60,800 test requests received by our pharmaceutical segment for the year ended December 31, 2016. Test requests received by our diagnostics segment for the year ended December 31, 2017 represented an increase of approximately 25.9% as compared to approximately 20,800 test requests received by our diagnostics segment 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 six-months ended June 30, 2019, we incurred research and development expenses of €4,108 thousand, an increase of €1,752 thousand, or 74.4%, from €2,356 thousand for the six-months ended June 30, 2018. For the year ended December 31, 2018, we 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

[Table of Contents](#)

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.

For the six-months ended June 30, 2019, our loss before taxes was €11,399 thousand, an increase of €4,667 thousand, or 69.3%, from €6,732 thousand for the six-months ended June 30, 2018. The loss before tax for the six-months ended June 30, 2019 included share-based compensation expenses of €4,828 thousand, as compared to €2,272 thousand for the six-months ended June 30, 2018. Loss before tax for the six-months ended June 30, 2019 also reflected a real estate transfer tax of €1,200 thousand on the intercompany transfer of land and building in preparation for a sale and leaseback transaction, which transaction was then executed in September 2019.

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 share-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

[Table of Contents](#)

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 six-months ended June 30, 2019, we entered into agreements for further services with an existing pharmaceutical partner, in respect of which revenues of €430 thousand were recognized during the period representing the transaction price to be allocated in relation to the provision of epidemiological insights of the relevant rare diseases. 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"). Among the approximately 32,700 test requests received by our diagnostics segment for the six-months ended June 30, 2019, approximately 22.6% were WES and WGS, 20.9% were standard genetic testing (which includes our single gene, CNV and mutation quantification products), 16.0% were panel sequencing, 36.0% were non-invasive pre-natal testing ("NIPT") and 4.2% were biochemistry. Among the approximately 47,900 test requests received by our diagnostics segment for the year ended December 31, 2018, approximately 25.1% were WES and WGS, 22.6% were standard genetic testing, 15.9% panel sequencing, 33.0% were NIPT and 3.3% were biochemistry.

For the six-months ended June 30, 2019, our total diagnostic segment revenues were split amongst our primary testing products as follows: 33.4% WES, 21.4% standard genetic testing, 20.0% panel sequencing, 12.7% NIPT, 12.2% WGS and 0.3% biochemistry. 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% standard genetic testing (which includes our single gene, CNV and mutation quantification products), 14.3% NIPT, 10.5% WGS and 0.3% biochemistry.

We provide these services in over 115 countries either through third party distributors or directly to our diagnostics clients, who are typically physicians, labs or hospital facilities. 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 (sequencing, interpretation and reporting) 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, North America 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 maintenance 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.

[Table of Contents](#)

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. For the six-months ended June 30, 2019, our cost of sales represented 58.7% of our total revenue, as compared to 53.6% for the six-months ended June 30, 2018. 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 ("R&D") 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 six-months ended June 30, 2019, we spent €7,224 thousand on research and development, of which €3,116 thousand were capitalized as intangible assets. 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.

For the six-months ended June 30, 2019, our research and development expenses represented 18.7% of our total revenue, as compared to 13.8% for the six-months ended June 30, 2018. 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 share-based compensation, as well as professional services

[Table of Contents](#)

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 six-months ended June 30, 2019, our general administrative expenses represented 52.9% of our total revenue, as compared to 53.1% during the six-months ended June 30, 2018. 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 increases in general administrative expenses for the year ended December 31, 2018 as compared to the year ended December 31, 2017, as well as for the increase for the six-months ended June 30, 2019 as compared to the six-months ended June 30, 2018, was primarily attributable to an increase in share-based compensation expenses across each of the periods and the 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 six-months ended June 30, 2019, our selling expenses represented 19.9% of our total revenue, as compared to 16.7% during the six-months ended June 30, 2018. 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, expected credit loss allowances 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. For the six-months ended June 30, 2019, we received €341 thousand investment-related government grants that we used for the purchase of certain items of property, plant and equipment, including the development of our facilities in Rostock and €915 thousand in R&D-related grants, as compared to investment-related government grants of €1.2 million and €340 thousand in R&D-related grants received for the six-months ended June 30, 2018. During the year ended December 31, 2018, we

[Table of Contents](#)

received investment-related government grants of €3.0 million and €378 thousand in R&D-related grants of the same nature, as compared to €6.8 million and €224 thousand, respectively, for the year ended December 31, 2017 and €2.8 million and €473 thousand, respectively, for the year ended December 31, 2016. The investment-related grant amounts were included in other liabilities and will be recognized in other operating income throughout the useful life of the facilities. The R&D-related grant amounts are recognized in consolidated statements of comprehensive loss. The government grants which we receive can fluctuate from period to period.

Results of Operations

Six-Months Ended June 30, 2018 Compared to Six-Months Ended June 30, 2019

	For the Six-Months Ended June 30,	
	2018	2019
	(unaudited, € in thousands)	
Consolidated statement of comprehensive loss:		
Revenue	17,012	21,921
Cost of sales	9,126	12,858
Gross profit	7,886	9,063
Research and development expenses	2,356	4,108
General administrative expenses	9,030	11,603
Selling expenses	2,848	4,356
Other operating income	953	1,688
Other operating expenses	665	464
Real estate transfer tax expenses	—	1,200
Operating loss	(6,060)	(10,980)
Interest and similar income	14	12
Interest and similar expenses	686	431
Finance costs, net	(672)	(419)
Loss before taxes	(6,732)	(11,399)
Income tax (benefits)/expenses	(110)	163
Loss for the period	(6,622)	(11,562)
Other comprehensive income	44	10
Total comprehensive loss for the period	(6,578)	(11,552)

Revenue

Revenue increased by €4,909 thousand, or 28.9%, to €21,921 thousand for the six-months ended June 30, 2019 from €17,012 thousand for the six-months ended June 30, 2018, principally due to improvements in performance by both pharmaceutical and diagnostics businesses, with increases in both pharmaceutical services provided and test requests received from both new and existing partners and clients during the period. Test requests received from our pharmaceutical and diagnostics segments for the six-months ended June 30, 2019 were approximately 29,800 and 32,700, respectively, representing increases of approximately 8.3% and 68.6%, respectively, as compared to approximately 27,500 and 19,400 test requests, respectively, received during the six-months ended June 30, 2018.

[Table of Contents](#)

The breakdown of our revenue by segment was as follows:

	For the Six-Months Ended June 30,	
	2018	2019
	(unaudited, € in thousands)	
Revenue by segment:		
Pharmaceutical	6,270	8,698
Diagnostics	10,742	13,223
Total Revenue	<u>17,012</u>	<u>21,921</u>

Revenues from our pharmaceutical segment were €8,698 thousand for the six-months ended June 30, 2019, an increase of €2,428 thousand, or 38.7%, from €6,270 thousand for the six-months ended June 30, 2018. This increase was primarily attributable to the expansion of our collaborations with our existing pharmaceutical partners. As of June 30, 2019, we collaborated with over 30 pharmaceutical partners, as compared to over 20 pharmaceutical partners as of June 30, 2018. During the six-months ended June 30, 2019, the Company entered into over ten additional collaborations with existing and new pharmaceutical partners, among which, according to the terms of two collaborations with an existing pharmaceutical partner, upfront fees of €430 thousand were recognized as revenue representing the transaction price to be allocated in relation to the provision of epidemiological insights of the relevant rare diseases. During the six-months ended June 30, 2019, revenues from one pharmaceutical partner represented 27.1% of our total revenues, as compared to 32.6% for the six-months ended June 30, 2018.

Revenues from our diagnostics segment were €13,223 thousand for the six-months ended June 30, 2019, an increase of €2,481 thousand, or 23.1%, from €10,742 thousand for the six-months ended June 30, 2018. The increase in revenues was primarily attributable to the new NIPT contract entered into in June 2018, which brought in revenues of €810 thousand for the six-months ended June 30, 2019. The increase in revenues from our diagnostics segment was also attributable to an increase in revenues from sales of our standard genetic, WES and WGS products for the six-months ended June 30, 2019, mainly driven by growth in the number of test requests in the Middle East, Europe and Asia Pacific regions, growth in the number of WES test requests in the Europe and North America regions, and growth in the number of WGS test requests in the Middle East and North America regions.

Test requests received in the diagnostics segment for the six-months ended June 30, 2019 were approximately 32,700, representing an approximate 68.6% increase as compared to approximately 19,400 test requests received during the six-months ended June 30, 2018. The total number of NIPT test requests received for the six-months ended June 30, 2019 was approximately 11,700, an increase of approximately 7,000 requests as compared to approximately 4,700 requests for the six-months ended June 30, 2018. In addition, the total number of standard genetic, panel and WES test requests for the six-months ended June 30, 2019 were approximately 6,800, 5,200 and 6,600 requests, respectively, representing increases of approximately 52.3%, 38.8% and 25.3%, respectively, as compared to the six-months ended June 30, 2018.

[Table of Contents](#)

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

	For the Six-Months Ended June 30,	
	2018	2019
	(unaudited, € in thousands)	
Revenue by geographical region:		
Europe	3,226	3,691
<i>Of which: Germany</i>	234	328
Middle East	5,450	6,772
<i>of which: Saudi Arabia</i>	2,989	3,182
North America	6,764	9,678
<i>of which: United States</i>	6,274	9,329
Latin America	1,081	1,319
Asia Pacific	491	461
Total Revenue	<u>17,012</u>	<u>21,921</u>

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 €9,678 thousand to revenue for the six-months ended June 30, 2019, an increase of €2,914 thousand, or 43.1%, from €6,764 thousand for the six-months ended June 30, 2018, primarily driven by the increase in revenues from our pharmaceutical segment, of which almost all are allocated to the North America region. Revenues from the North America region represented 44.2% of our total revenues for the six-months ended June 30, 2019 as compared to 39.8% for the six-months ended June 30, 2018.

Our Middle East region contributed €6,772 thousand to revenue for the six-months ended June 30, 2019, an increase of €1,322 thousand, or 24.3%, from €5,450 thousand for the six-months ended June 30, 2018. This was primarily attributable to an increase in sales of NIPT tests, mainly due to an increase in test requests received under the NIPT contract entered into in June 2018, as well as an increase in sales of standard genetic tests and WGS, mainly due to expansion of business in the region through distributors.

Our Europe region contributed €3,691 thousand to revenue for the six-months ended June 30, 2019, an increase of €465 thousand, or 14.4%, from €3,226 thousand for the six-months ended June 30, 2018.

Cost of Sales

Cost of sales increased by €3,732 thousand, or 40.9%, to €12,858 thousand for the six-months ended June 30, 2019, from €9,126 thousand for the six-months ended June 30, 2018. This increase was primarily attributable to an increase in the volume of test requests processed for the diagnostics segment, resulting in an increase in costs incurred for consumables. The increase of 40.9% in total cost of sales for the six-months ended June 30, 2019 from six-months ended June 30, 2018 was lower than the 68.6% increase in test requests in the diagnostics segment for the same period. The increase in test requests for the six-months ended June 30, 2019 was driven primarily by an increase in sales of NIPT products, for which the consumables cost is relatively lower than our other diagnostics products. The consumable costs

[Table of Contents](#)

incurred for the tests processed in the pharmaceutical segment is comparatively low due to the use of different technology.

Share-based compensation expenses of €859 thousand, primarily related to options granted to an employee, were included in cost of sales for the six-months ended June 30, 2019, which also contributed to the increase in cost of sales. Share-based compensation expenses of €276 thousand, relating to the same employee, were included in cost of sales for the six-months ended June 30, 2018.

Gross Profit

Our gross profit increased by €1,177 thousand, or 14.9%, to €9,063 thousand for the six-months ended June 30, 2019, from €7,886 thousand for the six-months ended June 30, 2018. The gross profit margin decreased to 41.3% for the six-months ended June 30, 2019, from 46.4% for the six-months ended June 30, 2018, which was mainly due to increases in consumable and staff costs (including share-based compensation expenses) for the diagnostics segment.

Research and Development Expenses

Research and development expenses increased by €1,752 thousand, or 74.4%, to €4,108 thousand for the six-months ended June 30, 2019, from €2,356 thousand for the six-months ended June 30, 2018, primarily attributable to an increase in IT-related expenses and research that does not qualify for capitalization. The amount also 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 €2,573 thousand, or 28.5%, to €11,603 thousand for the six-months ended June 30, 2019, from €9,030 thousand for the six-months ended June 30, 2018, principally due to an increase in share-based compensation expenses. Share-based compensation expenses for the period were calculated based on the estimated fair values of the share-based awards at June 30, 2019 and 2018, as well as the estimated number of awards expected to vest. The share-based compensation expenses for the six-months ended June 30, 2019 included in general administrative expenses amounted to €3,969 thousand, an increase of €2,027 thousand as compared to €1,996 thousand for the six-months ended June 30, 2018.

Selling Expenses

Selling expenses increased by €1,508 thousand, or 52.9%, to €4,356 thousand for the six-months ended June 30, 2019, from €2,848 thousand for the six-months ended June 30, 2018, principally due to further expansion of the marketing and sales team in both of the pharmaceutical and diagnostic segments, in particular the hiring of our new Chief Business Officer in November 2018, as well as an increase in attendance at conferences and exhibitions.

Other Operating Income / (Expenses)

Other operating income increased by €735 thousand, or 77.1%, to €1,688 thousand for the six-months ended June 30, 2019, from €953 thousand for the six-months ended June 30, 2018, principally due to an increase in the recognition of grant income.

Other operating expenses decreased by €201 thousand, or 30.2%, to €464 thousand for the six-months ended June 30, 2019, from €665 thousand for the six-months ended June 30, 2018, mainly relating to credit loss allowances on trade receivables recognized in accordance with IFRS 9.

[Table of Contents](#)

Real estate transfer tax

During the six-months ended June 30, 2019, we sold our land and building, which had a carrying value of €22,778 thousand, to a subsidiary in preparation of a potential sale and leaseback transaction. As the sale and leaseback transaction with a third party was entered into in July 2019, the intercompany transaction was irreversible and a real estate transfer tax expense of €1,200 thousand related to the intercompany transaction was recognized accordingly.

Interest and Similar Income / (Expenses)

Interest and similar income decreased by €2 thousand, or 14.3%, to €12 thousand for the six-months ended June 30, from €14 thousand for the six-months ended June 30, 2018.

Interest and similar expenses decreased by €255 thousand, or 37.2%, to €431 thousand for the six-months ended June 30, 2019, from €686 thousand for the six-months ended June 30, 2018, principally due to interest expenses from loans related to the development of our new laboratory in Rostock, Germany, which was completed in 2018.

Loss Before Taxes for the Year

As a result of the factors described above, our loss before taxes for the six-months ended June 30, 2019 was €11,399 thousand, an increase of €4,667 thousand, or 69.3%, from a loss before taxes of €6,732 thousand for the six-months ended June 30, 2018.

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 Six-Months Ended June 30,	
	2018	2019
Segment Adjusted EBITDA:		
Pharmaceutical	4,757	6,161
Diagnostics	1,576	541

Adjusted EBITDA from our pharmaceutical segment was €6,161 thousand for the six-months ended June 30, 2019, an increase of €1,404 thousand, or 29.5%, from €4,757 thousand for the six-months ended June 30, 2018. This increase was primarily attributable to the increase in revenues from the pharmaceutical segment during the period, as a result of the increase in services provided to new or existing pharmaceutical partners described above.

Adjusted EBITDA from our diagnostics segment was €541 thousand for the six-months ended June 30, 2019, a decrease of €1,035 thousand, from €1,576 thousand for the six-months ended June 30, 2018. The decrease was primarily attributable to the increase in revenues during the period, offset by increase in cost of sales as a result of the increase in number of test requests, related in particular to test requests of NIPT products discussed above, of which the gross margin is relatively low (as the average sales price of NIPT is comparatively low) as compared to our other products in the diagnostics segment.

Year Ended December 31, 2017 Compared to Year Ended December 31, 2018

	For the Years Ended December 31,	
	2017	2018
	(€ in thousands)	
Consolidated statement of comprehensive loss:		
Revenue	31,689	40,478
Cost of sales	14,939	19,941
Gross profit	16,750	20,537
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
Operating loss	(4,455)	(10,606)
Interest and similar income	14	33
Interest and similar expenses	1,021	1,075
Finance costs, net	(1,007)	(1,042)
Loss before taxes	(5,462)	(11,648)
Income tax expenses/(benefits)	14	(310)
Loss for the period	(5,476)	(11,338)
Other comprehensive income/(loss)	10	(8)
Total comprehensive loss for the period	(5,466)	(11,346)

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)	
Revenue by segment:		
Pharmaceutical	13,931	17,307
Diagnostics	17,758	23,171
Total Revenue	31,689	40,478

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 thousand for the year ended December 31, 2017. This increase was primarily attributable to new pharmaceutical partnerships. As of December 31, 2018, we collaborated with over 30 pharmaceutical partners, as compared to 19 pharmaceutical partners

[Table of Contents](#)

as of December 31, 2017. During the year ended December 31, 2018, we 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 our 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 licenses, 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 our total revenues, as compared to 37.7% 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 requests 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 requests 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 requests 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
	(€ in thousands)	
Revenue by geographical region:		
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
Total Revenue	31,689	40,478

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.

[Table of Contents](#)

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 share-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.

[Table of Contents](#)

Other Operating Income / (Expenses)

Other operating income increased by €1,263 thousand, or 121.1%, to €2,306 thousand for 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

Our Segment Adjusted EBITDA was as follows:

	For the Years Ended December 31,	
	2017	2018
	(€ in thousands)	
Segment Adjusted EBITDA:		
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 to an increase in revenues during the year.

Adjusted EBITDA from our diagnostics segment was €2,285 thousand for the year ended December 31, 2018, a 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,	
	<u>2016</u>	<u>2017</u>
	(€ in thousands)	
Consolidated statement of comprehensive loss:		
Revenue	27,669	31,689
Cost of sales	<u>12,856</u>	<u>14,939</u>
Gross profit	<u>14,813</u>	<u>16,750</u>
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
Operating loss	<u>(4,937)</u>	<u>(4,455)</u>
Interest and similar income	26	14
Interest and similar expenses	856	1,021
Finance costs, net	<u>(830)</u>	<u>(1,007)</u>
Loss before taxes	(5,767)	(5,462)
Income tax (benefits)/expenses	<u>(408)</u>	<u>14</u>
Loss for the period	<u>(5,359)</u>	<u>(5,476)</u>
Other comprehensive income	9	10
Total comprehensive loss for the period	<u>(5,350)</u>	<u>(5,466)</u>

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

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 collaborated 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,

[Table of Contents](#)

revenues from one pharmaceutical partner represented 37.7% of our 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 requests 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 requests 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 requests 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
Revenue by geographical region:		
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
Total Revenue	27,669	31,689

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.

[Table of Contents](#)

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 requests 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 share-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

[Table of Contents](#)

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
	(€ in thousands)	
Segment Adjusted EBITDA:		
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 are 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 Six-Months Ended June 30, 2018 and 2019

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

	For the Six-Months Ended June 30,	
	2018	2019
	(unaudited, € in thousands)	
Consolidated statement of cash flows:		
Cash flow used in operating activities	(3,402)	(1,907)
Cash flow used in investing activities	(6,279)	(3,603)
Cash flow provided by/(used in) financing activities	9,119	(148)
Net decrease in cash and cash equivalents	(562)	(5,658)
Cash and cash equivalents at the beginning of the period	3,157	9,222
Cash and cash equivalents at the end of the period	2,595	3,564

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 payments made to our suppliers.

For the six-months ended June 30, 2019, cash used in operating activities was €1,907 thousand, a decrease of €1,495 thousand as compared to €3,402 thousand for the six-months ended June 30, 2018. This change was principally due to a reduction of payments to our suppliers as part of working capital management.

Investing Activities

Our cash flow used in investing activities for the six-months ended June 30, 2019 consisted of investments in intangible assets and plant, property and equipment. These mainly included 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. Cash flow used in investing activities for the six-months ended June 30, 2018 also included investments in the development of our new headquarters in Rostock, Germany and the grants received for such investments.

For the six-months ended June 30, 2019, cash flow used in investing activities was €3,603 thousand, a decrease of €2,676 thousand as compared to €6,279 thousand for the six-months ended June 30, 2018, mainly due to reduced property, plant and equipment capital expenditures as a result of the completion of the construction of our new headquarters in Rostock, Germany in 2018.

Financing Activities

Our cash flow used in financing activities for the six-months ended June 30, 2019 consisted of repayments of secured bank loans related to the development of our new headquarters in Rostock, Germany, drawing of overdrafts, proceeds and repayments of finance leases, as well as interest payments.

[Table of Contents](#)

For the six-months ended June 30, 2019, cash used in financing activities was €148 thousand, a change of €9,267 thousand as compared to €9,119 thousand generated from financing activities for the six-months ended June 30, 2018. Cash generated from financing activities for the six-months ended June 30, 2018 also included net proceeds received from an external private financing of €9,999 thousand, cash received from secured bank loans relating to the construction of our new headquarters, as well as cash received from overdrafts related thereto. Upon the completion of the construction of our headquarters in 2018, repayment of the secured bank loan commenced in the six-months ended June 30, 2019. Such repayment, together with the repayment of finance leases, offset the cash received from the overdraft and resulted in a cash outflow from financing activities for the period.

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)	
Consolidated statement of cash flows:		
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
Net increase in cash and cash equivalents	<u>2,192</u>	<u>6,065</u>
Cash and cash equivalents at the beginning of the period	965	3,157
Cash and cash equivalents at the end of the period	<u>3,157</u>	<u>9,222</u>

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 payments 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.

[Table of Contents](#)*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 a capital injection of €5,125 thousand from one of our shareholders and two current employees. In addition, in 2017, we completed an external private financing with a consortium of investors for an investment of €15,000 thousand, of which proceeds of €14,325 thousand were received net of transaction costs incurred by the investors and bank charges.

In 2018, an additional investment of €20,000 thousand (€19,974 thousand net of bank charges) was received from certain of the investors that had participated in the 2017 consortium referenced in the paragraph above (see "Certain Relationships and Related Party Transactions—Investment and Shareholder 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)	
Consolidated statement of cash flows:		
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
Net increase in cash and cash equivalents	<u>570</u>	<u>2,192</u>
Cash and cash equivalents at the beginning of the period	395	965
Cash and cash equivalents at the end of the period	<u>965</u>	<u>3,157</u>

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.

[Table of Contents](#)

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 net proceeds received from an external private financing of €14,325 thousand.

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.

[Table of Contents](#)

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 ⁽¹⁾	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 ⁽²⁾	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 June 30, 2019, we had secured bank loans outstanding under our Syndicated Loan Facility in an aggregate principal amount of €15,242 thousand, among which €12,946 thousand was outstanding under tranches A and B, and bank overdrafts of €2,296 thousand under the Tranche D Loan (defined below). In September 2019, the entire amount outstanding (€10,776 thousand) under the Tranche A Loan (defined below) was fully repaid upon the completion of a sale and leaseback transaction of our Rostock facility. 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. The Company repaid the entire amount outstanding (€10,776 thousand) under the Tranche A Loan in September 2019;

[Table of Contents](#)

- 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 of July 1, 2019, we had pledged €2,500 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 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 obtain the consent of the lenders prior to the sale of more than 10% of his shares in our company.

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 our 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 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."

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. €1,447 thousand was utilized as of June 30, 2019. 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

[Table of Contents](#)

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

[Table of Contents](#)

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 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

[Table of Contents](#)

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.

[Table of Contents](#)

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, 2017 and 2018 and June 30, 2019 by geographical region was as follows:

	As of December 31,		As of June 30,
	2017	2018	2019
	(€ in thousands)		
Europe	1,202	2,697	2,583
Middle East	2,982	6,348	7,288
North America	1,585	1,074	2,291
Latin America	306	595	701
Other Regions	917	187	132
Total	6,992	10,901	12,995

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

[Table of Contents](#)

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 €3,743 thousand was utilized as of June 30, 2019, €1,915 thousand was utilized as of December 31, 2018, and which 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 for the year ended December 31, 2018 and the six-months ended June 30, 2019 or equity as of December 31, 2018 and June 30, 2019 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 for the year ended December 31, 2018 and the six-months ended June 30, 2019 or equity as of December 31, 2018 and June 30, 2019 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.

[Table of Contents](#)

Since we identified the material weakness, we have taken steps to remediate the underlying control deficiencies. During the year ended December 31, 2018 and the six-months ended June 30, 2019, management hired additional qualified 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;

[Table of Contents](#)

- 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

We are a commercial-stage company focused on rare diseases that transforms real-world clinical and genetic data into actionable information for patients, physicians and pharmaceutical companies. Our goal is to bring rationality to treatment decisions and to accelerate the development of new orphan drugs by using our knowledge of the global rare disease market, including epidemiological and clinical data and innovative biomarkers. We have developed a global proprietary rare disease platform based on our real-world data repository with over 2.0 billion weighted data points from over 450,000 patients representing 115 different countries as of August 31, 2019, or an average of over 500 data points per patient. Our platform includes epidemiologic, phenotypic and genetic data that reflects a global population, and also a biobank of these patients' blood samples. 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. As of August 31, 2019, we collaborated with over 35 pharmaceutical partners for over 30 different rare diseases.

A rare disease, by definition in the United States, is a disease that affects 200,000 or fewer people. However, with over 7,000 currently identified rare diseases, they in aggregate affect over 350 million people globally. Rare diseases can be severe and often take years to diagnosis—on average it takes five to seven years for a patient with a rare disease to be diagnosed. This underscores 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 rare hereditary diseases, only approximately 230 rare hereditary 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 epidemiology.

Our business is comprised of complementary solutions for both physicians and their patients, as well as pharmaceutical companies. Our diagnostics solution typically starts with specialist physicians requesting diagnostic information to identify or confirm a rare disease by sending us their patients' blood samples on our proprietary dried blood spot collection kit that bears the CE Mark—the CentoCard. With highly advanced technology, our proprietary database and our team of medical experts, we then deliver reports back to the physicians that contain what we believe is critical information containing genetic, proteomic, metabolomic information, or some combination, depending on what is most salient for each case. We also input this data to our CentoMD platform, which enriches our understanding of rare diseases broadly.

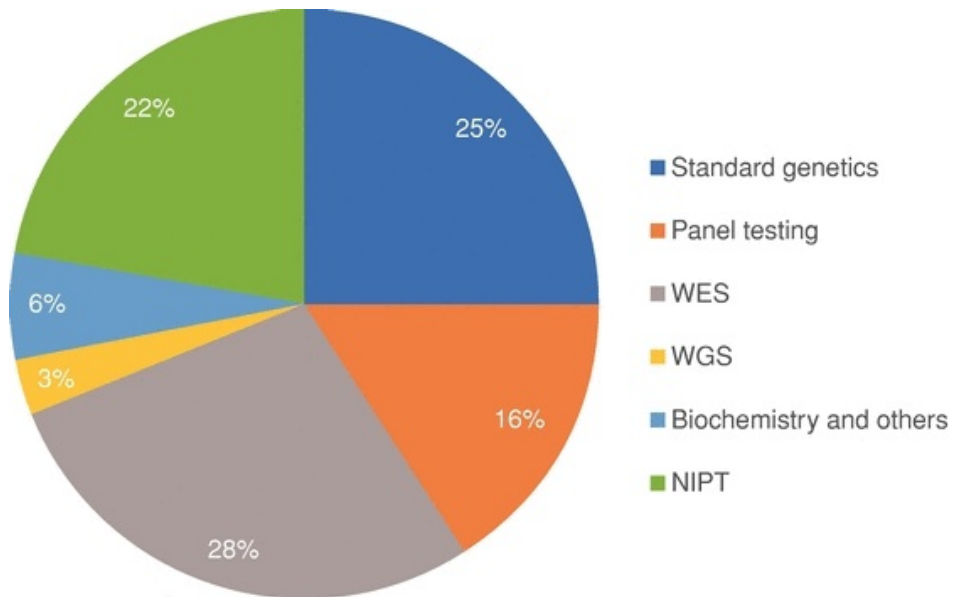
For our pharmaceutical partners, we are able to provide various valuable information using our platform. For instance, with the access to the data in our repository and biomaterials in our biobank, we have successfully developed biomarkers by applying highly sophisticated tools, including mass spectrometry technologies, together with artificial intelligence capabilities in an efficient and cost effective manner. Biomarkers are important in orphan drug development as well as post commercialization monitoring, by demonstrating the efficacy of the drugs, performing longitudinal monitoring and informing necessary titration for individual rare disease patients. As of August 31, 2019, we had over 30 biomarkers under development and had commercialized ten biomarkers covering eight rare diseases, including AADC deficiency, Cystic Fibrosis, Fabry disease, Faber disease, Gaucher disease, HAE, Niemann-Pick Type A/B, and Niemann-Pick Type C.

[Table of Contents](#)

In December 2018, the FDA issued a statement that supports the use of real-world evidence to accelerate drug development and to monitor the safety of drugs after they have been commercialized. Moreover, in February 2019, the FDA also issued a revised draft guidance for drug discovery in rare diseases, including a discussion of the benefits of using biomarkers as surrogate endpoints (the outcomes of which can be measured against therapy effectiveness in clinical trials). We believe that this new guidance from FDA, acknowledging the benefits of the use of both real-world evidence and biomarkers, further validates the value of our global proprietary rare disease platform and our biomarkers.

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 access to rare diseases patients and their biomaterials 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 are structured on a fee per sample basis, milestone basis, fixed fee basis, royalty basis or a combination of these. For the six-months ended June 30, 2019, €8.7 million, or 39.7%, of our total revenues were derived from our pharmaceutical segment. 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 August 31, 2019, we believe we offer the broadest diagnostic testing portfolio for rare diseases, covering over 6,500 genes using over 10,000 different tests. From January 1, 2016 to August 31, 2019, we received approximately 139,300 test requests from our diagnostics segment, split by the following type of 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 six-months ended June 30, 2019, €

[Table of Contents](#)

13.2 million, or 60.3%, of our total revenues were derived from our diagnostics segment. 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, as of August 31, 2019, together employ over 400 highly qualified personnel (including consultants) from over 55 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 drug development and patient stratification, identification and monitoring. To achieve this objective our strategy is to:

- **Transform the rare disease landscape by applying precision medicine more comprehensively.** 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 more comprehensively, 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.
- **Further our leadership position in rare diseases and continue to build upon the largest, most comprehensive repository for rare disease patient data.** Since our Company's founding in 2006, we have been focused on collecting clinical, phenotypic and genomic data for patients with rare hereditary diseases. As of August 31, 2019, our data repository included over 450,000 patient samples from over 115 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 new and existing pharmaceutical partners.** We are focused on leveraging our vast knowledge-base to support drug development for the rare disease industry in various ways. As of August 31, 2019, we collaborated with over 35 pharmaceutical partners for over 30 different rare diseases. We intend to continue expanding the scope of these collaborations as well as our network of partners, and we actively target new partners in the pharmaceutical industry on an ongoing basis. 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.

- **Evolve our business to share in more of the value we provide to our pharmaceutical partners.** Our database is also valuable beyond drug discovery as the biomarkers can be relevant for patient stratification and monitoring. Our database has multiple additional applications such as patient identification for therapeutic trials and treatment. For example, by identifying patients with a specific rare disease that are eligible for a clinical trial, which can reduce the time of clinical trial patient enrollment for our pharmaceutical partners. Reducing this enrollment time is often critically important in rare disease as the small number of patients of each disease can cause long enrollment periods.

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 β -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 subtypes. 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.

[Table of Contents](#)

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 granted over 4,700 orphan drug designations to December 31, 2018. Moreover, the FDA's Center for Drug Evaluation and Research ("CDER") approved 59 novel drugs in 2018, the highest number since 1996, representing an increase of 28% as compared to the number of novel drugs approved in 2017. Among the 59 novel drugs approved in 2018, 58% were orphan drugs, which is higher than the combined average of 40% over the prior five years. 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, with over 2,000 orphan drug designations granted from 2004 to 2018.

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 addition, more than \$400 million was provided by the FDA's Orphan Products Clinical Trials Grants Program over the last three decades and led to the approval of more than 60 different drugs for rare diseases. 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. In addition, as of April 30, 2019, there were approximately 610 non-oncology orphan designated products being developed worldwide. 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 12.3% from 2019 to 2024 to \$242 billion, capturing approximately 20% of worldwide prescription sales.

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 rare hereditary diseases, only approximately 230 rare hereditary 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 given the small patient population. The lack of sufficient understanding of the clinical manifestations of rare disease makes it even more challenging to derive accurate diagnoses. The ability to access relevant patients with a particular rare disease and to access appropriate expertise, a network and dataset via the biobank, 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. For example, patients suffering from Gaucher disease and Cystic Fibrosis can have average life expectancies of only eleven years and one year, respectively, if no treatments are available, leaving limited time for effective treatment if not diagnosed early. 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 have an integrated approach with a detailed, global understanding of the genetic basis and the clinical phenotype of rare hereditary diseases, which we believe will unlock the ability to target rare diseases and provide critical knowledge that will guide drug development and monitoring, and ultimately improve patient care. 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 founding in 2006 by our CEO and founder, Prof. Arndt Rolfs.

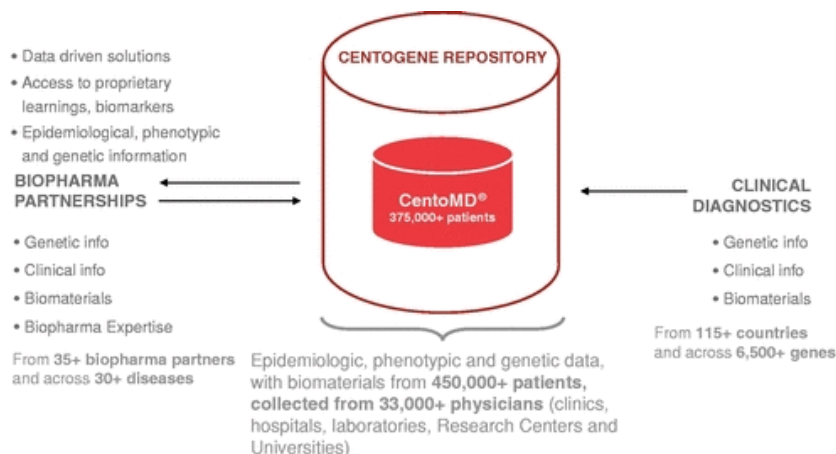
Our Platform—An Integrated, Knowledge-Based System

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

[Table of Contents](#)

At the core of our platform is our data repository, which included, as of August 31, 2019, epidemiologic, phenotypic and genetic data of over 450,000 patients representing over 115 countries, 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, accompanied by the patients' medical histories and completed consent forms from the physicians. The data is then validated by professionals using a systematic and scientific approach prior to feeding it into our repository and our central CentoMD database, which we believe is the world's largest curated mutation database for rare diseases. As of August 31, 2019, we had over 2.0 billion weighted data points, or an average of over 500 data points per patient, 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:



**Genetics + Proteomics + Metabolomics = More Comprehensive View of Biology
> 2.0 billion data points (or > 500 data points per patient)**

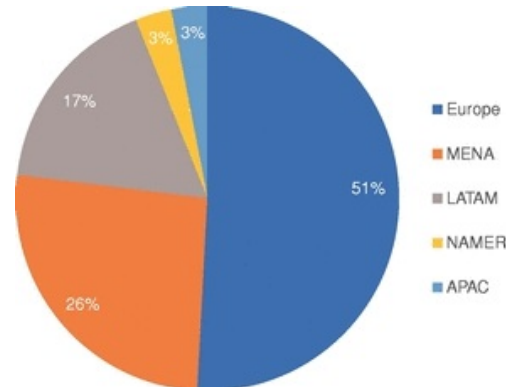
The Strengths of Our Platform

Access to these insights and knowledge through our platform 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:** Our platform includes epidemiologic, phenotypic and genetic data that reflects a global population from over 450,000 patients, and also a biobank of these patients' blood samples. 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 majority of patients in our CentoMD, which offers the ability to retest their biomaterials in our biobank. 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," including over 33,000 physicians worldwide. 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.

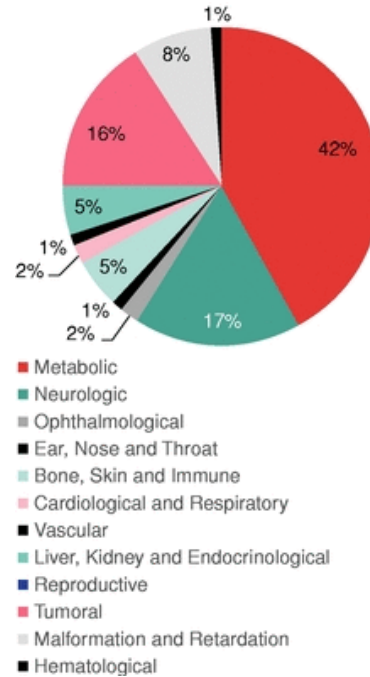
- **Ethnically diverse datasets:** Our repository has the advantage of holding samples from a broad range of ethnicities. Our repository covers a substantial majority of ethnicities, as we have performed diagnostic tests for patients in over 115 countries. Without the ability to recognize ethnicity-specific 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. For example, studies have shown that of the more than 1,893 Cystic Fibrosis mutations identified, patients of different ethnicities were subject to different types of genetic mutations. With access to data from a more diverse patient population, we are able to improve the interpretation of genetic variants, whether benign or causative. As of August 31, 2019, the patients from which we held data in our CentoMD 5.5 were located among different geographical regions as follows:



- **Curated information in CentoMD:** We focus on achieving the highest level of quality through data curation and process standardization. As of September 30, 2019, our CentoMD 5.5 database included curated data from over 375,000 patients with over 10 million unique variants. Whenever sufficient information is available, another layer of manual curation will be performed by our professional scientists with strong backgrounds in human genetics for genotype-phenotype association, supported by computer-based tools. 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.

[Table of Contents](#)

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. As of September 30, 2019, CentoMD 5.5 contained over 3,500 associated phenotypes and over 500,000 individual HPO associations, covering the following 12 therapeutic areas (which areas include over 3,000 diseases):



- **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, including 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 ten proprietary biomarkers for eight rare diseases and have over 30 additional biomarkers in research and development. Biomarkers further support the

[Table of Contents](#)

diagnosis and monitoring of patients in a cost-effective manner, which is important to our pharmaceutical partners during the drug development process, and also can be used to help physicians make informed predictions regarding the progression of a particular disease in order to optimize treatment.

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. As of September 30, 2019, we have identified over 6,200 Fabry patients.
- *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, has the potential to demonstrate 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. A paper published in June 2019 in the *International Journal of Molecular Sciences* reported a four-year study of 81 children suffering from Gaucher disease of varying severity. This paper suggested that Lyso-Gb1 has the potential to be used as an accurate biomarker for monitoring children suffering from Gaucher disease. In addition, the data generated from Gaucher disease has stimulated new research and treatment strategies for Parkinson's disease.
- *Niemann-Pick Type C.* Through our studies, we have been able to demonstrate that the majority of adult patients suffering from Niemann-Pick Type C also exhibit psychiatric symptoms. In addition, our preliminary data suggests our biomarker, Lyso-SM509, is a feasible biomarker for Niemann-Pick Type C. 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.

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.

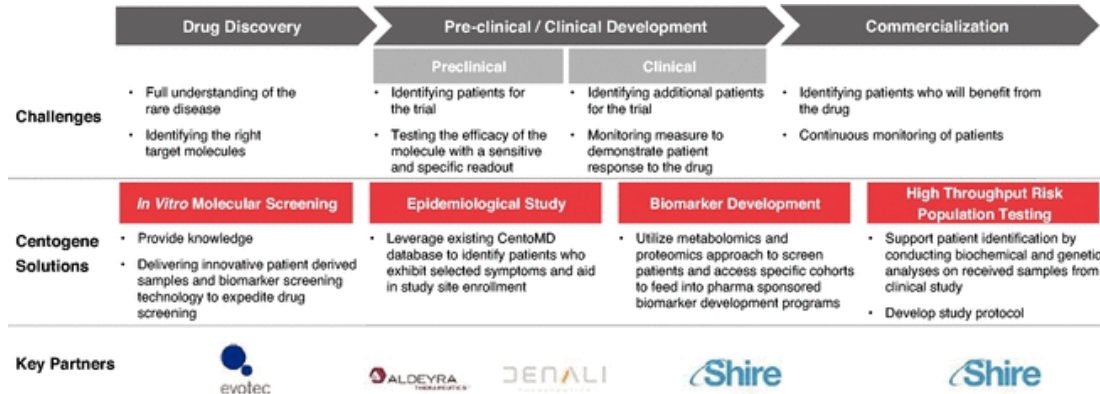
Our solutions are offered to our clients via two channels:

- **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 six-months ended June 30, 2019, €8.7 million, or 39.7%, of our total revenues were derived from our pharmaceutical segment. 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 August 31, 2019, we believe we offer the broadest diagnostic testing portfolio for rare diseases, covering over 6,500 genes using over 10,000 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 six-months ended June 30, 2019, €13.2 million, or 60.3%, of our total revenues were derived from our diagnostics segment. 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 August 31, 2019, we collaborated with over 35 pharmaceutical partners for over 30 different rare diseases, 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.

[Table of Contents](#)

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 mutation database for rare diseases, 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.

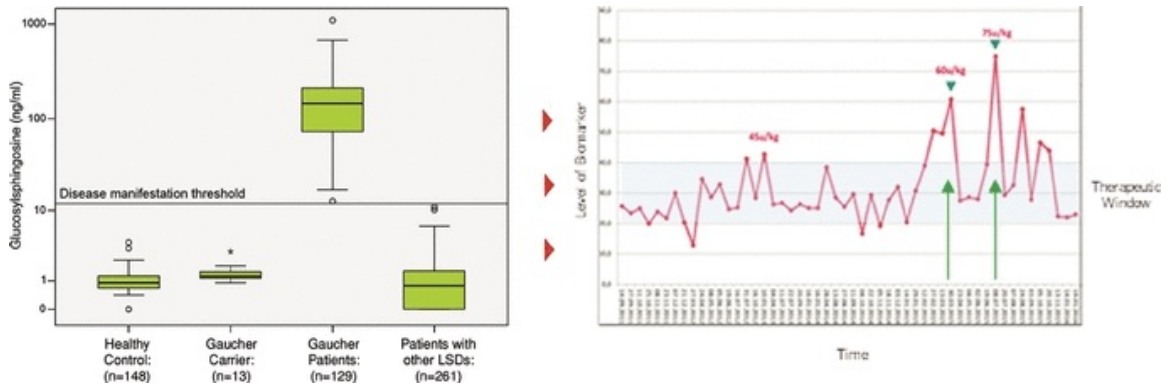
We have developed a suite of biomarkers, of which ten are already commercialized and over 30 are under development as of August 31, 2019. Our ten commercialized biomarkers, each of which is currently used in existing collaborations with our pharmaceutical partners, cover AADC deficiency,

[Table of Contents](#)

Cystic Fibrosis, Fabry disease, Farber disease, Gaucher disease, HAE, Niemann-Pick Type A/B and Niemann-Pick Type C. 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)	✓	✓	✓	✓	✓	✓	✓
Gaucher (Gb1 -GLucosylCeramides in DBS)	✓	✓	✓	✓	✓	✓	✓
Fabry Disease (Lyso-Gb3)	✓	✓	✓	✓	✓	✓	✓
Farber Disease	✓	✓	✓	✓	✓	✓	✓
Niemann-Pick Type C Disease (Lyso-509)	✓	✓	✓	✓	✓	✓	✓
Niemann Pick (Type A/B (Lyso-509 & Lyso-465)	✓	✓	✓	✓	✓	✓	✓
Cystic fibrosis (C26)	✓	✓	✓	✓	✓	✓	✓
Hereditary Angioedema (HAE) – Proteomics	✓	✓	✓	✓	✓	✓	✓
HAE – high molecular weight kininogen	✓	✓	✓	✓	✓	✓	✓
AADC (3-OMD)	✓	✓	✓	✓	✓	✓	✓
Hunter (MPS II)	✓	✓	✓	✓	✓	✓	✓
Morquio A (MPS IVA)	✓	✓	✓	✓	✓	✓	✓
Hereditary Angioedema (metabolite)	✓	✓	✓	✓	✓	✓	✓
Duchenne Muscular (Dystrophy)	✓	✓	✓	✓	✓	✓	✓
MLD (ARSA biomarker)	✓	✓	✓	✓	✓	✓	✓
Pompe	✓	✓	✓	✓	✓	✓	✓
Amyloidosis (TTR-FAP)	✓	✓	✓	✓	✓	✓	✓
Alpha-mannosidase	✓	✓	✓	✓	✓	✓	✓
Trosemia type 1	✓	✓	✓	✓	✓	✓	✓
NCL 2	✓	✓	✓	✓	✓	✓	✓

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

(Rolf's 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,

[Table of Contents](#)

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 in 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 Sjogren-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

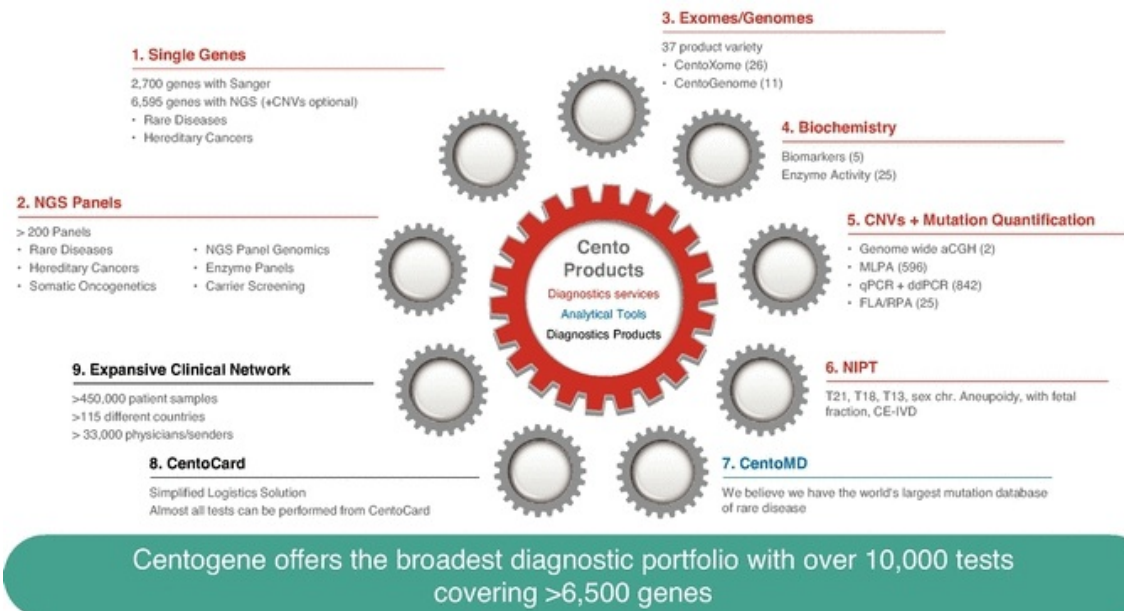
Overview and Product Offering

Our diagnostic solutions channel provides diagnostic testing services to patients exclusively through our network of distribution partners and our diagnostics clients, who are typically physicians, labs or hospital facilities. Our patient outreach includes over 115 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 place orders and 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 whenever

[Table of Contents](#)

necessary, sample preparation, sequencing using NGS technology, medical interpretation using our manual and automated bioinformatics pipelines and medical reporting by our specialists.

Of the more than 5,600 identified rare hereditary diseases, in many cases not only is there no treatment available but even the natural course of the disease and the relevant tests to diagnose the disease are unknown or underdeveloped. In order to further improve the understanding of rare hereditary diseases and to provide a better and earlier diagnosis for rare disease patients, in 2018 we instituted a program with the aim of characterizing at least 50 new genes per year. In addition, we continuously develop new testing products to provide the most effective diagnosis products to our physician clients, leveraging insights from our platform and our deep medical expertise. For example, in 2018 we launched CentoDx, one of the largest panels currently available for rare hereditary disease diagnosis, based on next-generation sequencing technology and covering over 6,500 clinically relevant genes and more than 3,200 rare diseases. In 2019, we launched CentoMetabolic, a panel product covering 166 genes and over 150 metabolic disorders, developed specifically for patients suspected to have a metabolic disorder or presenting complex, overlapping symptoms, a metabolic crisis or neurological conditions of unknown etiology. The panel also includes enzyme-activity testing where applicable, and a selection of biomarker testing offerings. As of August 31, 2019, we offered a comprehensive testing portfolio of over 10,000 genetic sequencing tests covering more than 6,500 genes, from single gene WGS-based products, using Sanger, MLPA, qPCR, array and NGS technologies. Of this total, we offer over 9,000 standard genetic sequencing products, over 200 panel products, 26 WES products and 11 WGS products. We also offer differentiated comprehensive testing solutions including 30 biochemistry testing products, over 1,460 copy number variation tests ("CNVs") and 5 NIPT products (single and twin). The graphic below outlines the scope of the diagnostics products that we currently offer.



Overview of the Diagnostic Process

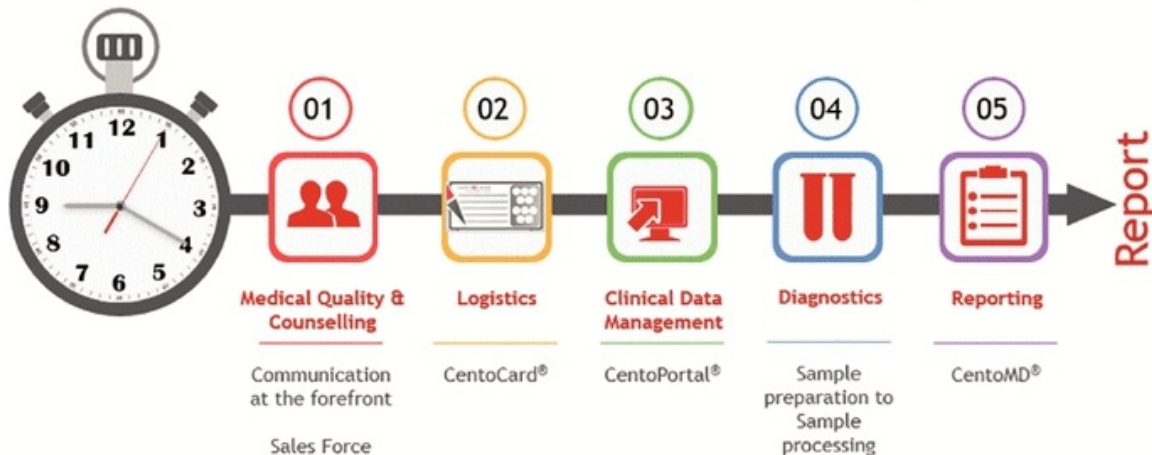
Our diagnostics processes are designed with the aim of providing the highest-quality diagnosis within the shortest turnaround time. We currently perform a majority of the diagnostic services for our diagnostics and pharmaceutical businesses in our clinical laboratory located in Rostock, Germany,

[Table of Contents](#)

which is certified under CLIA and accredited by the CAP. Additionally, we perform certain of these services in our Cambridge, Massachusetts facility, which is also certified under CLIA, accredited by the CAP and permitted by the Massachusetts Clinical Laboratory Program.

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

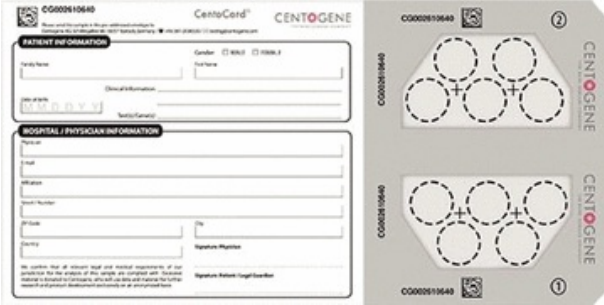
Our sample collection method is a CE-Marked dried blood spot collection kit, the CentoCard (as shown below), which is translated into more than 30 languages and registered in more than 50 countries. The CentoCard is sent to physicians as part of a five-component kit: (1) the CentoCard, (2) a genetic 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

[Table of Contents](#)

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, provide 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 on a regular basis, offering the most complete and up-to-date information possible. The patient data we have collected in CentoMD cover 12 therapeutic areas with over 3,100 diseases. Our CentoMD 5.5 includes curated data from over 375,000 patients with over 10 million unique variants and over 3,500 associated phenotypes.

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 free and accessible via our website and allows for researchers, pharmaceutical partners and clinicians to access a comprehensive database of genetic variants classified through 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.

MyLSD app

In parallel with CentoLSD, we are also developing MyLSDapp, a smartphone application, which is currently in its pilot testing phase. MyLSDapp is designed to drive the management of personalized treatment for Gaucher disease patients and to support Gaucher specialists around the world. For patients, MyLSDapp is designed to provide an overview of their personal treatment plan and their biomarker (Lyso-Gb1) monitoring results, and allows them to share treatment and result information with physicians. The app is designed to help physicians monitor the treatment of their patients and to develop insights into new treatments.

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.

We then use artificial intelligence to facilitate the biomarker development process. Artificial intelligence helps us to identify correlations between different data in an efficient and more accurate manner, and discover patterns that would not be discovered manually. Artificial intelligence also allows us to perform fully automated pattern recognition on multidimensional data (e.g., retention time, collision cross section, monoisotopic ion mass, fragmentation pattern) obtained from mass spectrometry.

[Table of Contents](#)

While it may take weeks to months of manual data comparisons, biomarker candidates can be found in just a few minutes with our in-house artificial intelligence 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.

Research and Development

We are dedicated to scientific research and development in order to continuously improve the industry's understanding of epidemiology and its analysis of clinical heterogeneity as an aid to the diagnosis of rare diseases. We have organized various conferences with experts and patient advocacy groups in the rare disease field from all over the world to exchange and promote knowledge related to rare diseases, such as our "Recent Advances in Rare Diseases (RARD)" conference which we hold annually. In addition, we also undertake scientific research and clinical studies, both independently and together with our pharmaceutical partners, with the aim of positively contributing to the global understanding of rare diseases, as well as to improve the accuracy of diagnosis and to support the development of effective treatments for rare diseases.

We published 20 scientific papers in 2018 and 25 scientific papers in the current year as of September 30, 2019. Our major on-going clinical studies, other than those related to biomarker development, are as follows as of June 2019:

Two Year Global Study on Colon- and Pancreas-Carcinoma (PICOP-Global)

In June 2019, we announced the initiation of a 24-month global proof-of-concept study focusing on the identification of tumor-specific neoantigens, which we anticipate will be used by our partners as the basis for developing a personalized, immune-based therapy to trigger patients' own immune responses against tumors.

The study aims to enroll approximately 100 participants with pancreas or colorectal carcinoma in order to analyze the molecular characteristics of tumors and to subsequently identify tumor-specific antigens (neoepitopes). In addition, the tumor and normal samples will be tested genetically to identify tumor associated mutations and MS/MS-based mutations, which will be used to develop neoepitopes and biomarkers. We believe that the collected data can be used in a multi-omics approach to potentially predict neoepitopes suitable for use in vaccines.

The PICOP-GLOBAL Study will be conducted without a treatment arm and in collaboration with the Surgical Oncology Society Pakistan. We are also partnering on this study with the University of

Rostock, Germany and University of Greifswald, Germany. After this study is completed, a follow-up Phase I study will be conducted by Miltenyi Biotec.

Induced pluripotent stem cells (iPSC) program

Since early 2019, we have independently conducted an iPSC program (the "iPSC Program") with the aim of supporting orphan drug development in a more cost-effective and efficient manner, in particular for the development of orphan drugs related to rare neurodegenerative, metabolic, and cardiovascular diseases. Human iPSCs, first reported in 2007, are reprogrammed from somatic cells and are self-renewal cells that can produce different types of cells. In the drug discovery process for rare diseases, iPSC technology is particularly important in providing information on the clinical spectrum of such diseases by generating disease-specific cells.

As of September 30, 2019, we had collected approximately 700 skin biopsies from patients with rare diseases from around the world. As part of our iPSC Program, we are currently in the process of reprogramming these biopsies into iPSC for a number of metabolic rare diseases such as Gaucher, Niemann Pick Type A and C, Polycystic kidney disease, Fabry disease, Glycogenosis, Sanfilippo (MPS III), Maroteaux-Lamy Disease (MPS VI), Morquio (MPS IV) Pompe and Wilson diseases. Once completed, the iPSC Program will also further support orthogonal target validation as well as further biomarker discovery that we undertake.

Rostock International Parkinson's Disease Study (ROPAD)

In May 2019, we initiated a 24-month global study (the "ROPAD Study") to investigate the genetic factors in Parkinson's disease ("PD"), one of the most common neurodegenerative disorders that affects approximately 1% of individuals globally over the age of 60. The ROPAD Study, which is being conducted in cooperation with the University of Lübeck, Germany, aims to enroll approximately 10,000 participants worldwide in order to provide a study cohort with a broad genetic background that mirrors the global population. The objective of the ROPAD Study is to gain a comprehensive understanding of how many and which genetic mutations in PD-associated genes are linked to the development of the disease. We plan to utilize our CentoCard product to identify participants with a mutation in LRRK2, GBA and other PD-associated genes.

ROPAD Study participants that display mutations in PD genes will have the option to undergo further clinical assessment in a supplementary study, "LRRK2 International Parkinson's Disease Project (LIPAD)", conducted at the University of Lübeck, where a detailed phenotyping of participants will be performed in order to describe the frequency of all important clinical PD signs and symptoms. Patients enrolled in ROPAD with a LRRK2 mutation may also be offered participation in future clinical studies with one of our major collaboration partners, Denali.

Epidemiological Analysis for Hereditary Angioedema Disease (EHA)

In September 2018, we commenced the EHA study, which is a prospective, multicenter study in Germany, Poland, Turkey and the United Kingdom. The study focuses on patients with Hereditary Angioedema Disease ("HAE"), or patients with high-grade suspicion of suffering from HAE. The aim of the study is to estimate the epidemiological prevalence of disease in a population of 5,000 patients with repetitive abdominal pain attacks of unknown origin, as well as other clinical symptoms that could indicate the presence of HAE. HAE is a rare autosomal dominant disease resulting from mutations in the SERPING1 gene, leading to the deficient (type 1) or nonfunctional (type 2) C1 inhibitor protein. Clinical manifestations in all HAE types include acute attacks of non-urticarial edemas affecting the upper airway, face, extremities, genitals, and gastrointestinal system. As of September 30, 2019, over 500 patients were enrolled in the study.

European Alpha-Mannosidosis Patient Epidemiological Program (EUMAP)

In August 2018, we commenced the EUMAP study, which is an international, multicenter, epidemiological study. The study aims to further explore and analyse the prevalence of Alpha-Mannosidosis disease in a clinical study cohort of 1,000 patients that are potentially suffering from Alpha-Mannosidosis disease, based on the patient's clinical symptoms. Alpha-Mannosidosis is a very rare, hereditary lysosomal storage disorder, closely related to Mucopolysaccharidoses, which is estimated to occur in approximately 1 in 500,000 people worldwide. The disease is caused by mutations in the MAN2B1 gene, which interferes with the activity of the alpha-mannosidase enzyme and results in accumulation mannose-containing oligosaccharides in the lysosomes. The course of the disease is progressive in general, although symptoms can vary significantly between individual patients. It has been categorized into "mild", "moderate" and "severe" depending on the severity of the symptoms and age of onset.

Hereditary Transthyretin-Related Amyloidosis Study (TRAM2)

In April 2018, we commenced TRAM2 study, which is a prospective, multicenter study in Germany, Austria and Switzerland, focusing on patients with polyneuropathy or cardiomyopathy of undetermined etiology. The study is a continuance of TRAM1 and aims to estimate the prevalence of hereditary transthyretin-Related Amyloidosis ("hATTR") in a study cohort of 5,000 patients with polyneuropathy or cardiomyopathy of unknown etiology. As of August 31, 2019, over 2,800 patients were enrolled in the study. hATTR is an autosomal dominant inherited variable penetrance disease that we believe is often under- or misdiagnosed, and it is caused by mutations in the receptor gene TTR. The clinical spectrum of hATTR varies greatly from exclusive neurological involvement to predominant cardiac manifestations, and without treatment hATTR can lead to heart failure. This disease typically affects people in their 30s to 50s and may lead to death within 10 years if left untreated.

Screening for the Transthyretin-Related Familial Amyloidotic Small Fiber Polyneuropathy (TRAP)

In December 2016 we commenced the TRAP study, an international, multicentre, epidemiological study. The study aims to determine the prevalence of patients with transthyretin-related familial amyloidotic-polyneuropathy ("TTR-FAP") in a clinical study cohort of 500 patients with a polyneuropathy of undetermined etiology, based on medical history (no anamnesis for carcinoma, no continuous alcohol consumption, no anamnesis for heavy metal exposure, no significant comorbidities), and the normal results of laboratory data. As of August 31, 2019, over 180 patients were enrolled in the study.

TTR-FAP is an autosomal dominant rare disease, the exact prevalence of which is unknown but is estimated to occur in around 1 in 100,000 people to 1 in 1,000,000 people. The TTR-FAP has a very heterogeneous phenotype which can manifest starting at the age of 18 and may lead to death within 10 years.

Our Operations

Sales and Marketing

As of August 31, 2019, our CBO led a team of six 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 August 31, 2019, we had a sales force of approximately 29 employees and 26 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 and our distribution network 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 in separate, protected server rooms;
- 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, data encryption (in storage and in transit) 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

Since 2018, we have been using artificial intelligence to further automate our processes, 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 in our phenotypic, genomic, transcriptomic, proteomic and metabolomic datasets. We also use artificial intelligence to automate our curation process and the identification of genetic and/or metabolic modifiers. We currently have five employees dedicated to this artificial intelligence effort.

We believe that our data repository provides us with a competitive advantage for driving the development of new and effective artificial intelligence tools, as the foundation of any successful artificial intelligence program is high quality data in a volume that can effectively generate results. The higher quality the data and the more data that are available, the better chance we have of building a machine learning model with high predictive power and accuracy.

In June 2019, we announced the deployment of a new variant prioritization tool based on our in-house artificial intelligence capability. This tool identifies the most likely disease-causing genes based on our repository, in order to further accelerate our and our partners' diagnostics processes, and is in particular aimed to enhance the diagnostics process for whole exome and clinical exome sequencings.

With our clinical exome panel, which covers over 6,500 genes with known associated clinical phenotypes and covers over 3,200 diseases, the result of the sequencing process usually discovers between 70,000 and 150,000 variants per individual. However, the majority of these variants are benign or unrelated to the observed disease phenotype of the patient. With our huge data repository built up from the last 12 years, and a curated database with standardized HPO terms, our tool is able to rank the variants from most to least relevant. Based on such "ranked" variants, we can then compare the HPO terms of a new patient with the results of prior, anonymized patients included in our repository with variants in the same gene. This allows us provide a diagnosis in a more rapid, comprehensive and accurate manner, especially for patients with very rare or as yet undescribed diseases.

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 six-months ended June 30, 2019 and for 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 six-months ended June 30, 2019 and for 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.

[Table of Contents](#)

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 written off 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 on a regular basis, 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");

[Table of Contents](#)

- 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. Based on the variants in CentoMD 5.5 (released in September 2019), a comparison against the list of variants in other industry databases such as ClinVar (version ClinVar 2019, September 2019) and HGMD Pro (version HGMD Pro 2019.1, January 2019) shows that of the shared variants among CentoMD 5.5, ClinVar and HGMD Pro, approximately 9% and approximately 13% 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,

[Table of Contents](#)

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 on a regular basis, 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 September 30, 2019, this number had grown to over 375,000 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

[Table of Contents](#)

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 October 6, 2019, our patent portfolio was 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 seven pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, Europe, Israel, India, and Russia. The issued European patent is currently being validated in one or more contracting states of the European Patent Convention. 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 three pending patent applications in the following foreign jurisdictions: Australia, Brazil 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 three issued U.S. patents, two pending U.S. non-provisional patent applications, issued patents in Europe, Japan and Mexico, and pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, Europe, Israel, India, Japan, Mexico and Saudi Arabia. The issued European patent is currently being validated in one or more contracting states of the European Patent Convention. 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 nine pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, China, Europe, Hong Kong, Mexico, Saudi Arabia and the United Arab Emirates. Any patents granted from such applications are expected to expire in 2036, without taking potential patent term extensions or adjustments into account.
- With regard to our biomarker for Cystic Fibrosis, we own one pending U.S. non-provisional patent application and six pending patent applications in the following foreign jurisdictions: Australia, Brazil, Canada, Europe, Israel and India. Any patents granted from such

[Table of Contents](#)

applications are expected to expire in 2037, without taking potential patent term extensions or adjustments into account.

- We have also filed European priority applications for our biomarkers for dystrophinopathy, transthyretin amyloidosis, Krabbe disease and HAE. 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 businesses are 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 were 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, 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

[Table of Contents](#)

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.

[Table of Contents](#)

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.

[Table of Contents](#)

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. These civil penalties are also adjusted for inflation periodically.

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.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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

[Table of Contents](#)

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, CentoNPC, CentoFarber, 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 EU MDR, which will replace the EU MDD, was adopted on May 25, 2017 and will become applicable in its main part on May 26, 2020. Additionally, a new version of ISO 13485 was recently published, effective March 31, 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 26, 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 a majority 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 becomes applicable, diagnostic tests manufactured "on an industrial scale" qualify as IVDs with a need for a conformity assessment. Additionally, U.S. regulation applies to our laboratory-developed tests (see "Regulation—Regulation States Regulation—Laboratory-developed tests" for more information).

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 in the medical and research fields. For example, it is not yet clear if such authorities will conduct random audits of companies subject to the GDPR or will only respond to complaints filed by

[Table of Contents](#)

individuals who claim their rights have been violated. Enforcement actions to date in other industries has resulted in significant fines and other penalties. 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 August 31, 2019, we employed over 400 highly qualified personnel (including consultants) from over 55 nationalities, of which 25% had M.D. or Ph.D. 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 July 2019, the Company entered into a sale and leaseback transaction, pursuant to which the Company sold our Rostock headquarters building to a third party for €24,000 thousand, which was the approximate fair value of the building as of June 30, 2019. Following the sale, we lease the building from the third party for a period of 12 years at a fixed rate per month with the option to extend.

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. We filed our response to Sanofi's opposition in February 2019, and an oral hearing has been scheduled for early 2020. 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 Regional Court of Rostock of our intention to defend against the claim. On January 3, 2019 we filed a motion to dismiss in which we denied the merits of the claim. UMCU and Neon Underwriting Limited responded to this motion on March 15, 2019 with a statement of reply, and the parties made several court filings setting out their arguments since. By order dated June 3, 2019, the Regional Court of Rostock provided a first set of questions to be answered by an expert witness. Following a request by the Court, the Director of the Institute of Genetics at the University of Bonn recommended a professor for human genetics from the University of Aachen to be appointed as such expert witness in this case. We agreed to such recommendation. 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, as well as the year of expiration of their terms as management board members of Centogene N.V.:

Name	Position	Age	Year of Expiration of Term
Prof. Arndt Rolfs, M.D.	Chief Executive Officer	60	2022
Dirk H. Ehlers, Ph.D.	Chief Operating Officer	59	2020
Richard Stoffelen	Chief Financial Officer	52	2021
Volkmar Weckesser, Ph.D.	Chief Information Officer	52	2022

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, M.D. 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

[Table of Contents](#)

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, Ph.D. 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 Ph.D. 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, Ph.D. 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 Ph.D. 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	54	—
Prof. Peter Bauer, M.D.	Chief Scientific Officer	50	—
Sun Kim	Chief Strategy & Investor Relations Officer	48	—

Oved Amitay. Mr. Amitay has served as our chief business officer since November 2018, prior to which he held the position of president and chief operating officer of Arrett Neuroscience from 2016 to 2018, having led 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

[Table of Contents](#)

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, M.D. Prof. Bauer has served as our chief scientific officer since January 2017, prior to which he served as chief operating officer since joining us in 2016. Prof. 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. Prof. Bauer has been vice president of the German Society of Neurogenetics since 2004. Prof. 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.

Sun Kim. Mr. Kim has served as our chief strategy and investor relations officer since May 2019. Prior to his appointment, Mr. Kim was Head of Corporate Strategy at Shire Plc from August 2018 to April 2019, where he also oversaw Shire Plc's investor relations activities in the US and, from October 2017 to August 2018, he was Vice President, Investor Relations. Prior to joining Shire Plc, he served as Global Head of Business Service Excellence at Novartis from March 2015 to September 2017, as General Manager at Alcon Singapore from July 2013 to March 2015, and as Global Head of Strategy for Alcon from September of 2011 to July 2013. Mr. Kim also worked at Bausch & Lomb from August 2009 to September 2011, heading up its strategy function for the pharmaceutical business unit. Prior to his experience in the pharmaceutical industry, Mr. Kim spent seven years as a Management Consultant at McKinsey & Company and A.T. Kearney. Mr. Kim holds a Ph.D. and M.S. in chemical engineering from Stanford University, and B.S. in chemical engineering from Seoul National University.

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.

[Table of Contents](#)

The following table presents the names of the current members of our supervisory board, as well as the year of expiration of their terms as supervisory board members of Centogene N.V.:

Name	Position	Age	Year of Expiration of Term
Flemming Ornskov	Chairman of the Supervisory Board	61	2022
Hubert Birner, Ph.D.	Vice-Chairman of the Supervisory Board	53	2022
Christoph Ehlers	Member of the Supervisory Board	61	2022
Holger Friedrich	Member of the Supervisory Board	53	2022
Jacob Kaluski	Member of the Supervisory Board	69	2022
Guido Prehn	Member of the Supervisory Board	41	2022
Eric Sou�tre	Member of the Supervisory Board	63	2022
Berndt Modig	Member of the Supervisory Board	61	2022

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, M.D., MPH, MBA. Dr. Ornskov has served as the Chairman of our Supervisory Board since April 2019. He has served as the Chief Executive Officer of Galderma S.A. since October 2019. He served as Chief Executive Officer and Executive Director of Shire Plc from April 2013 to January 2019, when Shire was acquired by Takeda. 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 has been a Non-Executive Director for the Waters Corporation since 2017. Previously, 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 A/S, now Veloxis Pharma A/S; President and Chief Executive Officer of Ikaria; and various roles at Merck and Novartis. Dr. Ornskov received his M.D. from the University of Copenhagen, MBA from INSEAD, and Masters of Public Health from Harvard University.

Hubert Birner, Ph.D. 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., Biocell SA, Evotec AG, Probiobdrug 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

[Table of Contents](#)

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, Kohlspitz 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, M.D. 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 Ph.D. in neurosciences by the Marseille University, an M.D. 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

[Table of Contents](#)

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 member of the audit committee of Axovant Sciences Ltd, supervisory board director and member of the audit committee of Affimed N.V., and vice-chairman of the supervisory board and chairman 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, Jacob Kaluski 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 Berndt Modig and Jacob Kaluski each satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act and Berndt Modig 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

[Table of Contents](#)

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.

The compensation, including benefits in kind, accrued or paid to our managing directors and supervisory directors with respect to the year ended December 31, 2018, for services in all capacities is shown below on an individual basis. Further details for the compensation for our managing directors and supervisory directors are given in note 19 to our consolidated financial statements as of and for the year ended December 31, 2018.

Directors Compensation 2018

Supervisory Directors

	<u>E. Ornskov</u>	<u>H. Birner</u>	<u>C. Ehlers</u>	<u>H. Friedrich</u>	<u>J. Kaluski</u>	<u>G. Prehn</u>	<u>E. Souetre</u>	<u>R. Modig</u>	<u>D. Parera⁽¹⁾</u>	<u>M. Schlenk⁽²⁾</u>
Periodically paid compensation	—	47	45	23	24	44	28	52	27	12
Total cash compensation	—	47	45	23	24	44	28	52	27	12

(1) No longer a member of the Supervisory Board, effective March 2019.

(2) No longer a member of the Supervisory Board, effective April 2018.

Managing Directors

	<u>A. Rolfs</u>	<u>D. Ehlers</u>	<u>R. Stoffelen</u>	<u>V. Weckesser</u>
	(in € thousands)			
Periodically paid compensation	544	261	474	358
Bonuses	197	127	95	95
Total cash compensation	741	388	569	453
2016 Virtual Share Option Plan	—	—	478	333
2017 Virtual Share Option Plan	672	646	448	374
Total share-based payment expense	672	646	926	707

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 of Centogene AG 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.

<u>Beneficiary</u>	<u>Grant Date</u>	<u>Number of Options</u>	<u>Strike Price EUR</u>	<u>Expiration Date</u>
Richard Stoffelen	November 1, 2016	46,200	100	October 31, 2025
Richard Stoffelen	November 1, 2016	272,683	400	October 31, 2025
Volkmar Weckesser	November 1, 2016	138,600	200	October 31, 2025
Total		457,483		

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 16,349 common shares of Centogene AG derived from 16,374 virtual share options.

In conjunction with the corporate reorganization, common shares of Centogene AG issuable upon the exercise of all outstanding awards granted under the 2017 Plan will be converted into awards

[Table of Contents](#)

exercisable for common shares of Centogene N.V. on a 1.00 to 49.2578 basis, and after the consummation of this offering, we do not intend to issue any additional awards under the 2017 Plan.

<u>Beneficiary</u>	<u>Grant Date</u>	<u>Number of Options</u>	<u>Strike Price EUR</u>	<u>Expiration Date</u>
Arndt Rolfs ⁽¹⁾	January 1, 2017	900	1	December 31, 2026
Arndt Rolfs ⁽¹⁾	January 1, 2018	900	1	December 31, 2026
Richard Stoffelen	January 1, 2017	600	1	December 31, 2026
Richard Stoffelen	January 1, 2018	600	1	December 31, 2026
Volkmar Weckesser	January 1, 2017	500	1	December 31, 2026
Volkmar Weckesser	January 1, 2018	500	1	December 31, 2026
Dirk Ehlers	April 1, 2018	1,478	1	December 31, 2026
Total		5,178		

- (1) As approved by our supervisory board in October 2019, 350 options in each of these tranches will be transferred without consideration to Richard Stoffelen upon consummation of the offering.

2019 Equity Incentive Plan

In conjunction with the consummation of this offering, we intend to establish a new long-term incentive plan (our "2019 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 2019 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 2019 Plan (other than replacement awards under the 2019 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 or supervisory board, where appropriate on the basis of a recommendation of the compensation committee (as the case may be, as prescribed by the 2019 Plan and, collectively, the "Committee").

Upon consummation of this offering, Flemming Ornskov will receive options for 396,522 common shares with an expiration date 10 years following issuance and a strike price consistent with the price at this offering.

Plan Administration. The 2019 Plan will be administered by the Committee.

Eligibility. Awards under the 2019 Plan may be granted to our employees, the members of our management board and supervisory boards, consultants or other advisors.

Awards. Awards under the 2019 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 2019 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 2019 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

[Table of Contents](#)

unless decided otherwise by the Committee. In the event of a bad leaver's (as defined in the 2019 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 2019 Plan), outstanding awards that will be substituted or exchanged for equivalent replacement awards, will be cancelled. If outstanding rewards 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 €9,480,000, consisting of 79,000,000 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 June 1, 2019 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 preferred shares of Centogene AG will be exchanged for common shares of Centogene B.V. on a 1.00 to 89.6125 basis and all of the outstanding common shares of Centogene AG will be exchanged for common shares of Centogene B.V. on a 1.00 to 33.2238 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.

Certain of our existing institutional or other investors or their affiliates have committed to, or indicated an interest in, purchasing common shares in this offering in an aggregate of up to \$30 million. The following existing institutional or other investors or their affiliates have committed to, or indicated an interest in, purchasing up to the respective amount in and number of shares of our common stock at the initial public offering price of \$14.00 per share: DPE has indicated an interest in purchasing up to \$15 million or 1,071,428 common shares; TVM Life Science Innovation II SCSp. (an affiliate of TVM Life Science Innovation I, L.P.) has indicated an interest in purchasing up to \$12 million or 857,142 common shares; Careventures Fund II ScSP has indicated an interest in purchasing up to \$2 million or 142,857 common shares; and Arndt Rolfs has indicated an interest in purchasing up to \$1 million or 71,428 common shares. The foregoing discussion and table below do not reflect any potential purchases by these investors to the extent any such investor is an existing investor or affiliate thereof.

Shareholder	Common shares and Series A Preference Shares beneficially owned prior to the corporate reorganization and the Offering		Common shares beneficially owned after giving effect to the corporate reorganization and the Offering			
	Number	Percentage	No exercise of underwriter's option		Full exercise of underwriter's option	
			Number	Percentage	Number	Percentage
>5% Shareholders:						
Entities affiliated with DPE ⁽¹⁾	64,197	19.94%	4,124,289	20.77%	4,124,289	20.16%
Equicore Beteiligungs GmbH ⁽²⁾	55,748	17.31%	1,852,161	9.33%	1,852,161	9.05%
Careventures Fund II S.C.Sp ⁽³⁾	34,663	10.76%	3,106,236	15.64%	3,106,236	15.18%
TVM Life Science Innovation I, L.P ⁽⁴⁾	21,583	6.70%	1,934,105	9.74%	1,934,105	9.45%
Michael Schlenk	16,711	5.19%	555,203	2.80%	555,203	2.71%

Shareholder	Common shares and Series A Preference Shares beneficially owned prior to the corporate reorganization and the Offering		Common shares beneficially owned after giving effect to the corporate reorganization and the Offering			
	Number	Percentage	No exercise of underwriter's option		Full exercise of underwriter's option	
			Number	Percentage	Number	Percentage
Management Board Members and Key Officers:						
Arndt Rolfs ⁽⁵⁾	71,725	22.27%	2,382,978	12.00%	2,382,978	11.65%
Dirk Ehlers	250	*	8,305	*	8,305	*
Richard Stoffelen	500	*	16,611	*	16,611	*
Volkmar Weckesser	200	*	6,644	*	6,644	*
Peter Bauer	100	*	3,322	*	3,322	*
Oved Amitay	—	—	—	—	—	—
Sun Kim	—	—	—	—	—	—
Supervisory Board Members:						
Hubert Birner ⁽⁶⁾	21,583	6.70%	1,934,105	9.74%	1,934,105	9.45%
Christoph Ehlers ⁽⁷⁾	55,748	17.31%	1,852,161	9.33%	1,852,161	9.05%
Holger Friedrich ⁽⁸⁾	10,539	3.27%	350,145	1.76%	350,145	1.71%
Jacob Kaluski	1,462	*	48,573	*	48,573	*
Guido Prehn ⁽⁹⁾	64,197	19.94%	4,124,289	20.77%	4,124,289	20.16%
Eric Sou�tre ⁽¹⁰⁾	34,663	10.76%	3,106,236	15.64%	3,106,236	15.18%
Flemming Ornskov	—	—	—	—	—	—
Berndt Modig	—	—	—	—	—	—

* Less than 1% ownership.

- (1) Prior to the consummation of this offering, the 64,197 Centogene AG shares held by entities affiliated with DPE consist of (a) 42,187 common and preference shares held by DPE Deutschland II A GmbH & Co. KG ("DPE II A") and (b) 22,010 common and preference 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 Thierry 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. Guido Prehn has decision-making power over the common shares beneficially owned by DPE Deutsche Private Equity GmbH but disclaims beneficial ownership of such shares. The address for DPE Deutsche Private Equity GmbH, DPE II A and DPE II B is Ludwigstrasse 7, 80539 Munich, Germany.
- (2) Prior to the consummation of this offering, Centogene AG common shares held by Equicore Beteiligungs GmbH consist of 55,748 shares which Christoph Ehlers may be deemed to beneficially own. The address for Equicore Beteiligungs GmbH is Weiherhofstra e 5, 79104 Freiburg im Breisgau, Germany.
- (3) Careventures Fund II S.C.Sp ("Careventures II") is managed by Careventures Fund II GP Sarl ("Careventures Fund"), and Eric Sou tre, the founder of Careventures Fund, may be deemed to have voting and investment power over the shares held by Careventures II. The address for Careventures II is 42-44, Avenue de la Gare, 1610 Luxembourg, Luxembourg.
- (4) The governance, investment strategy and decision-making process with respect to investments held by TVM Life Science Innovation I, L.P. is directed by TVM Life Science Innovation I (GP) Limited, whose directors are Reshenthla Beeby, Hubert Birner, Gary Leatt and Luc Marengere and who have shared power to vote the common shares beneficially owned by TVM Life Science Innovation I, L.P. As a result, each may be deemed to beneficially own the shares beneficially owned by TVM Life Science Innovation I, L.P. The address for TVM Life Science Innovation I, L.P. is 204 Notre Dame ouest, suite 350, Montr al (Qu bec) H2Y 1Z3, Canada.
- (5) 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.
- (6) Hubert Birner beneficially owns common shares through his indirect ownership of interests in TVM Life Science Innovation I, L.P.
- (7) Christoph Ehlers beneficially owns common shares through his direct ownership of interests in Equicore Beteiligungs GmbH.
- (8) Common shares are held by CCG-Commercial Coordination Germany GmbH and are beneficially owned by Holger Friedrich. The address for CCG-Commercial Coordination Germany GmbH is Mauerstra e 78, 10117 Berlin, Germany.
- (9) Guido Prehn has decision-making power over the common shares beneficially owned by DPE Deutsche Private Equity GmbH but disclaims beneficial ownership of such shares.
- (10) Eric Sou tre beneficially owns common shares through his indirect ownership of interests in Careventures Fund.

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., DPE Deutschland II A GmbH & Co. KG, DPE 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 €15.0 million from such investors and increased the authorized 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 €10.0 million 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 €10.0 million 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 Ehlers, our Chief Operating Officer and member of our management board. In addition to the nominal value of such shares (€250), Mr. Ehlers 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

[Table of Contents](#)

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. In April 2019, we signed a consulting contract with Flemming Ornskov, the chairman of our supervisory board, for corporate strategy services outside the scope of his services as the chairman of our supervisory board to be provided to us. For the six-months ended June 30, 2019, total costs incurred in respect of this contract were €63 thousand.

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. We intend to enter into indemnification agreements with all members of our supervisory and management board.

Service Agreements

None of our managing or supervisory directors have currently entered into service agreements with the Company. We intend to enter into service agreements with all members of our management board, all of which will provide for notice of termination periods after certain minimum appointment periods and all of which will include restrictive covenants. We also intend to enter into service agreements with all members of our supervisory board.

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 €9,480,000, divided into 79,000,000 common shares, each with a nominal value of €0.12, and our issued share capital will amount to €1,903,349.4. Our common shares have been approved for listing 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

[Table of Contents](#)

- 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

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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 2019 Plan allows us to set the terms and conditions of equity awards granted thereunder. Under the 2019 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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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);

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

(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 November 6, 2019, upon completion of this offering, 19,861,340 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 198,613 common shares immediately after the completion of this offering based on the number of common shares outstanding as of November 6, 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 SVB Leerink LLC and Evercore Group L.L.C. See "Underwriting—No Sales of Similar Securities" 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, the tax laws of Germany and regulations thereunder and 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 common 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 (*deelnemning*) 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 (*verbonden lichaam*) has a participation or if the company in which the shares are held is a related entity (*verbonden lichaam*);
- 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 effective 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 corporate income 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 case the following paragraph 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 (corporate) income 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.

[Table of Contents](#)

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 (*formaal, 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, 2019) 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).

[Table of Contents](#)

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

[Table of Contents](#)

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 (*Solidaritätszuschlag*) 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 (*inländisches Wertpapierhandelsunternehmen*) or a domestic securities trading bank (*inländische 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

[Table of Contents](#)

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.

[Table of Contents](#)

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

[Table of Contents](#)

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 (*Mitunternehmenschaften*), 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

[Table of Contents](#)

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 (*Gewerbesteuer*gesetz), 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 administers 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

[Table of Contents](#)

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

[Table of Contents](#)

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 a Financial Transaction Tax ("FTT") within the framework of enhanced cooperation. On February 14, 2013, the European Commission published a proposal for a Council Directive implementing enhanced cooperation in the area of financial transaction tax. The plan focuses on levying a 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.

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

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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, and (iii) 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.

[Table of Contents](#)

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

SVB Leerink LLC and Evercore Group L.L.C. are acting as representatives of each of the underwriters named below and as joint book running managers for this offering. Subject to the terms and conditions set forth in the underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of common shares set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
SVB Leerink LLC	1,860,000
Evercore Group L.L.C.	1,340,000
Robert W. Baird & Co. Incorporated	440,000
BTIG, LLC	360,000
Total	<u>4,000,000</u>

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the common shares sold under the underwriting agreement if any of the common shares are purchased. 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 certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

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, including the validity of the common shares, and subject to other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. 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 SVB Leerink LLC is One Federal Street, 37th Floor, Boston, Massachusetts 02110 and the address of Evercore Group L.L.C. is 55 East 52nd Street, New York, New York 10055.

Certain existing institutional or other investors or their affiliates have committed to, or indicated an interest in, purchasing common shares in this offering in an aggregate amount of up to \$30 million.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the common shares to the public at the initial public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$0.588 per share. After the initial offering of the common shares, the public offering price, concession or any other term of this offering may be changed by the representatives.

[Table of Contents](#)

The following table shows the initial public offering price, underwriting discounts and commissions and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Total	
		Without Option	With Option
Initial public offering price	\$ 14.00	\$ 56,000,000	\$ 64,400,000
Underwriting discounts and commissions	\$ 0.98	\$ 3,920,000	\$ 4,508,000
Proceeds, before expenses, to us	\$ 13.02	\$ 52,080,000	\$ 59,892,000

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$5,000,000. We also have agreed to reimburse the underwriters for up to \$25,000 for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 600,000 additional common shares at the initial public offering price, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to the conditions contained in the underwriting agreement, to purchase a number of additional common shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our management board members, our supervisory board members and certain of our other existing shareholders have agreed not to sell or transfer any common shares or securities convertible into or exchangeable or exercisable for common shares, for 180 days after the date of this prospectus without first obtaining the written consent of SVB Leerink LLC and Evercore Group L.L.C. on behalf of the underwriters. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly, 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.

The lock-up provisions apply to common shares and to securities convertible into or exchangeable or exercisable for common shares.

Nasdaq Global Market Listing

Our common shares have been approved for listing on the Nasdaq Global Market, or Nasdaq, under the symbol "CNTG".

Determination of Offering Price

Prior to this offering, there has been no public market for our common shares. The initial public offering price for our common shares was determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us;

[Table of Contents](#)

- our financial information;
- the history of, and the prospects for, our company and the industry in which we compete;
- 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. It is also possible that after this offering, our common shares will not trade in the public market at or above the initial public offering price.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the common shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common shares. However, the representatives may engage in transactions that stabilize the price of the common shares, such as bids or purchases to peg, fix or maintain that price.

In connection with this offering, the underwriters may purchase and sell common shares in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in this offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option described above. The underwriters may close out any covered short position by either exercising their option or purchasing common shares in the open market.

In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them under the underwriting agreement described above. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing common shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common shares in the open market after pricing that could adversely affect investors who purchase in this offering. Stabilizing transactions consist of various bids for or purchases of common shares made by the underwriters in the open market prior to the closing of this offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common shares or preventing or retarding a decline in the market price of our common shares. As a result, the price of our common shares may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common

[Table of Contents](#)

shares. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with this offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a "Member State"), no shares have been offered or will be offered pursuant to the offering to the public in that Member State, except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- A. to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- B. to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or
- C. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require the Company or the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have

[Table of Contents](#)

they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and each of our and the representatives' affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Member State will be made pursuant to an exemption under the Prospectus Regulation from the requirement to publish a prospectus for offers of shares. Accordingly, any person making or intending to make an offer in that Relevant Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation in relation to such offer. Neither we nor the underwriters have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the company or the underwriters to publish a prospectus for such offer.

For the purpose of the above provisions, the expression "an offer to the public" in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

MiFID II Product Governance

Any person offering, selling or recommending the shares (a "distributor") should take into consideration the manufacturers' target market assessment; however, a distributor subject to MiFID II is responsible for undertaking its own target market assessment in respect of the shares (by either adopting or refining the manufacturers' target market assessment) and determining appropriate distribution channels.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) 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, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons") or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to Prospective Investors in Canada

The shares 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

[Table of Contents](#)

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 shares 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.

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	9,553
Nasdaq listing fee	150,000
FINRA filing fee	11,540
Printing and engraving expenses	163,267
Legal fees and expenses	3,079,030
Accounting fees and expenses	723,385
Miscellaneous costs	863,225
Total	<u>5,000,000</u>

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.

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

[Table of Contents](#)

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.

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.

INDEX TO FINANCIAL STATEMENTS

Unaudited Interim Condensed Consolidated Financial Statements—Centogene AG

Interim condensed consolidated statements of comprehensive loss for the six-months ended June 30, 2018 and 2019	F-3
Interim condensed consolidated statements of financial position as at December 31, 2018 and June 30, 2019	F-4
Interim condensed consolidated statements of cash flows for the six-months ended June 30, 2018 and 2019	F-5
Interim condensed consolidated statements of changes in equity for the six-months ended June 30, 2018 and 2019	F-6
Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019	F-7

Audited Consolidated Financial Statements—Centogene AG

Report of independent registered public accounting firm	F-23
Consolidated statements of comprehensive loss for the years ended December 31, 2016, 2017 and 2018	F-25
Consolidated statements of financial position as at December 31, 2017 and 2018	F-26
Consolidated statements of cash flows for the years ended December 31, 2016, 2017 and 2018	F-27
Consolidated statements of changes in equity for the years ended December 31, 2016, 2017 and 2018	F-28
Notes to the consolidated financial statements as of December 31, 2017 and 2018 and for the three years ended December 31, 2018	F-29

Unaudited Interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 for Centogene AG

[rest of this page intentionally left blank]

Centogene AG
Unaudited Interim condensed consolidated statements of comprehensive loss
for the six-months ended June 30, 2018 and 2019
(in EUR thousand)

	<u>Note</u>	<u>2018</u>	<u>2019</u>
Revenue	4	17,012	21,921
Cost of Sales		9,126	12,858
Gross profit		7,886	9,063
Research and development expenses		2,356	4,108
General administrative expenses		9,030	11,603
Selling expenses		2,848	4,356
Other operating income	5.1	953	1,688
Other operating expenses	5.2	665	464
Real estate transfer tax expenses	6	—	1,200
Operating loss		(6,060)	(10,980)
Interest and similar income		14	12
Interest and similar expense		686	431
Financial costs, net		(672)	(419)
Loss before taxes		(6,732)	(11,399)
Income taxes (benefits)/expenses		(110)	163
Loss for the period		(6,622)	(11,562)
Other comprehensive income, all attributable to equity holders of the parent		44	10
Total comprehensive loss		(6,578)	(11,552)
Equity holders of the parent		(6,434)	(11,426)
Non-controlling interests		(144)	(126)
		(6,578)	(11,552)
Loss per share—Basic and diluted		(25)	(36)

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements

Centogene AG
Unaudited Interim condensed consolidated statements of financial position
as at December 31, 2018 and June 30, 2019
(in EUR thousand)

<u>Assets</u>	<u>Note</u>	<u>Dec 31, 2018</u>	<u>June 30, 2019</u>
Non-current assets			
Intangible assets		8,795	11,179
Property, plant and equipment	3	39,115	32,265
Right-of-use assets	3	—	5,573
		47,910	49,017
Current assets			
Inventories		1,346	1,706
Trade receivables	7	10,901	12,995
Other assets	7	7,295	8,027
Cash and cash equivalents	8	9,222	3,564
		28,764	26,292
		76,674	75,309
Equity and liabilities			
Equity			
Issued capital		322	322
Capital reserve		46,923	47,411
Retained earnings and other reserves		(19,964)	(31,390)
Non-controlling interests		(757)	(883)
		26,524	15,460
Non-current liabilities			
Non-current loans	10	12,915	12,025
Lease liabilities	3, 10.1	1,712	1,425
Other liabilities	10.3	11,240	10,890
		25,867	24,340
Current liabilities			
Investment subsidies	10.3	794	925
Current loans	10.1	3,702	5,524
Lease liabilities	3, 10.1	1,350	1,391
Liabilities from income taxes	10.3	10	173
Trade payables	10.3	5,429	7,524
Other liabilities	10.3	12,998	19,972
		24,283	35,509
		76,674	75,309

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements

Centogene AG
Unaudited Interim condensed consolidated statements of cash flows
for the six-months ended June 30, 2018 and 2019
(in EUR thousand)

	Note	2018	2019
Loss before taxes		(6,732)	(11,399)
Amortization and depreciation	4	2,202	2,849
Interest income		(14)	(12)
Interest expense		686	431
Share-based payment expenses		2,272	4,828
Real Estate transfer tax expenses	6	—	1,200
Other non-cash items		(322)	(147)
Inventories		(729)	(360)
Trade receivables	7	(2,213)	(2,094)
Other assets	7	(1,840)	(244)
Trade payables	10.3	(3,732)	2,095
Other liabilities	10.3	7,020	946
Cash flow used in operating activities		(3,402)	(1,907)
Cash paid for investments in intangible assets		(1,535)	(3,116)
Cash paid for investments in property, plant and equipment		(5,965)	840
Grant received for investment in property, plant and equipment	10.3	1,207	341
Interest received		14	12
Cash flow used in investing activities		(6,279)	(3,603)
Cash received from equity contributions, net		9,999	—
Cash received from loans	10.1	3,393	1,828
Cash repayment of loans	10.1	(2,090)	(896)
Cash received from finance leases	3, 10.1	—	470
Cash repayments of financial leases/lease liabilities	3, 10.1	(1,497)	(1,119)
Interest paid		(686)	(431)
Cash flow generated from/(used) in financing activities		9,119	(148)
Changes in cash and cash equivalents		(562)	(5,658)
Cash and cash equivalents at the beginning of the period		3,157	9,222
Cash and cash equivalents at the end of the period		<u>2,595</u>	<u>3,564</u>

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements

Centogene AG
Unaudited Interim condensed consolidated statements of changes in equity
for the six-months ended June 30, 2018 and 2019

in EUR thousand	Note	Attributable to the owners of the parent						Non-controlling interests	Total equity
		Issued capital	Capital reserve	Currency translation reserve	Retained earnings	Total			
As of January 1, 2018		262	25,467	(8)	(8,985)	16,736	(382)	16,354	
Loss for the period		—	—	—	(6,478)	(6,478)	(144)	(6,622)	
Other comprehensive loss		—	—	44	—	44	—	44	
Total comprehensive loss		—	—	44	(6,478)	(6,434)	(144)	(6,578)	
Share-based payments	11	—	623	—	—	623	—	623	
Issuance of shares	9	34	9,965	—	—	9,999	—	9,999	
As of June 30, 2018		296	36,055	36	(15,463)	20,924	(526)	20,398	

in EUR thousand	Note	Attributable to the owners of the parent						Non-controlling interests	Total equity
		Issued capital	Capital reserve	Currency translation reserve	Retained earnings	Total			
As of January 1, 2019		322	46,923	(16)	(19,948)	27,281	(757)	26,524	
Loss for the period		—	—	—	(11,436)	(11,436)	(126)	(11,562)	
Other comprehensive loss		—	—	10	—	10	—	10	
Total comprehensive loss		—	—	10	(11,436)	(11,426)	(126)	(11,552)	
Share-based payments	11	—	488	—	—	488	—	488	
As of June 30, 2019		322	47,411	(6)	(31,384)	16,343	(883)	15,460	

The accompanying notes form an integral part of these unaudited interim condensed consolidated financial statements

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019

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 interim condensed consolidated financial statements for the six months ended June 30, 2018 and 2019 have been prepared in accordance with IAS 34 Interim Financial Reporting.

The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual consolidated financial statements as of December 31, 2017 and 2018 and for the three years ended December 31, 2018.

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group's annual consolidated financial statements for the year ended December 31, 2018, except for the adoption of new standards effective as of January 1, 2019 (see note 3). The Group has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

Several other amendments and interpretations apply for the first time in 2019, but do not have an impact on the interim condensed consolidated financial statements of the Group.

These interim condensed 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

IFRS 16 Leases

IFRS 16 supersedes 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. The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for most leases under a single on-balance sheet model.

The Group adopted IFRS 16 as of January 1, 2019, using the modified retrospective method of adoption. The Group elected to use the transition practical expedient allowing the standard to be applied only to contracts that were previously identified as leases applying IAS 17 and IFRIC 4 at the date of initial application. The Group also elected to use the recognition exemptions for lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

3 Effects of new accounting standards (Continued)

option ('short-term leases'), and lease contracts for which the underlying asset is of low value ('low-value assets').

The effect of adoption of IFRS 16 is as follows:

<u>Impact on the statement of financial position (increase/(decrease)) as at January 1, 2019:</u>	<u>In EUR k</u>
Assets	
Property, plant and equipment	(5,364)
Right-of-use assets	5,767
Total assets	403
Liabilities	
Lease liabilities—Current	93
Lease liabilities—Non-Current	310
Total liabilities	403

Based on the foregoing, as at 1 January 2019:

- Right-of-use assets of EUR 5,767k, were recognised and presented separately in the consolidated statement of financial position. This includes the lease assets recognised previously under finance leases of EUR 5,364k, that were reclassified from property, plant and equipment.
- Additional lease liabilities of EUR 403k, were recognised.

a) *Nature of the effect of the adoption of IFRS 16*

The Group has lease contracts for offices as well as various items of plant, machinery, motor vehicles and other equipment. Prior to the adoption of IFRS 16, the Group classified each of its leases (as lessee) at the inception date as either a finance lease or an operating lease. A lease was classified as a finance lease if it transferred substantially all of the risks and rewards incidental to ownership of the leased asset to the Group; otherwise it was classified as an operating lease. Finance leases were capitalised at the commencement of the lease at the inception date fair value of the leased property or, if lower, at the present value of the minimum lease payments. Lease payments were apportioned between interest (recognised as finance costs) and reduction of the lease liability. For operating leases, the leased property was not capitalised and the lease payments were recognised as rent expense in the statement of profit or loss on a straight-line basis over the lease term. Any prepaid rent and accrued rent were recognised under Prepayments and Trade and other payables, respectively.

Upon adoption of IFRS 16, the Group applied a single recognition and measurement approach for all leases under which it is the lessee, except for short-term leases and leases of low-value assets. The Group recognised lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

- Leases previously classified as finance leases

The Group did not change the initial carrying amounts of recognised assets and liabilities at the date of initial application for leases previously classified as finance leases (i.e., the right-of-use assets)

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

3 Effects of new accounting standards (Continued)

and lease liabilities equal the lease assets and liabilities recognised under IAS 17). The requirements of IFRS 16 was applied to these leases from January 1, 2019.

In accordance with the modified retrospective method of adoption, the Group does not restate its comparative figures but recognises the cumulative effect of adopting IFRS 16 as an adjustment to equity at the beginning of the current period.

b) Summary of new accounting policies

Set out below are the new accounting policies of the Group upon adoption of IFRS 16:

- Right-of-use assets

The Group recognises right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognised right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment.

- Lease liabilities

At the commencement date of the lease, the Group recognises lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for leases reasonably certain to be terminated. The variable lease payments that do not depend on an index or a rate are recognised as expenses in the period during which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

- Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered of low value (i.e., below EUR 5k). Lease payments on short-term leases and leases of low-value assets are recognised as expenses on a straight-line basis over the lease term.

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

3 Effects of new accounting standards (Continued)

The adoption of IFRS 16 did not have any impact to the equity as of January 1, 2019, while total assets and total liabilities as of January 1, 2019 have been increased by EUR 403k, in relation to the right-of-use assets and lease liabilities related to leasing of vehicles and office space in the United States.

c) *Amounts recognised in the statement of financial position and profit or loss*

Set out below, are the carrying amounts of the Group's right-of-use assets and lease liabilities and the movements during the period:

In EUR k	Right-of-use assets				Lease liabilities
	Plant and equipment	Motor vehicles	Offices	Total	
As at January 1, 2019	5,364	12	391	5,767	3,465
Additions	470	—	—	470	405
Depreciation expenses	(605)	(3)	(56)	(664)	—
Interest expenses	—	—	—	—	65
Payments	—	—	—	—	(1,119)
As at June 30, 2019	5,229	9	335	5,573	2,816

Set out below, are the amounts recognised in profit or loss:

in EUR k	For the six months ended June 30, 2019
Depreciation expense of right-of-use assets	664
Interest expenses on -/lease liabilities under IFRS 16	65
Rent expenses—short-term leases	110
Rent expense—leases of low-value assets	10
Total amounts recognized in profit or loss	849

IFRIC Interpretation 23 Uncertainty over Income Tax Treatment (the "Interpretation")

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; and
- 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 then be followed.

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

3 Effects of new accounting standards (Continued)

The Group applies the Interpretation for the reporting period beginning on or after 1 January 2019. The Interpretation did not have an impact 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 Segment information

in EUR k	2018			
	Pharmaceutical	Diagnostics	Corporate	Total
Rendering of services	5,655	10,742	—	16,397
Sales of goods	615	—	—	615
Revenues from external customers	6,270	10,742	—	17,012
Recognized over time	5,250	10,742	—	15,992
Recognized at a point in time	1,020	—	—	1,020
Revenues from external customers	6,270	10,742	—	17,012
Adjusted EBITDA	4,757	1,576	(7,919)	(1,586)
Capital Expenditures				
Additions to property, plant and equipment	—	1,312	4,653	5,965
Additions to intangible assets	880	—	655	1,535
Other segment information				
Depreciation and amortization	495	993	714	2,202
Research and development expenses	—	—	2,356	2,356

in EUR k	2019			
	Pharmaceutical	Diagnostics	Corporate	Total
Rendering of services	8,033	13,223	—	21,256
Sales of goods	665	—	—	665
Revenues from external customers	8,698	13,223	—	21,921
Recognized over time	7,452	13,223	—	20,675
Recognized at a point in time	1,246	—	—	1,246
Revenues from external customers	8,698	13,223	—	21,921
Adjusted EBITDA	6,161	541	(10,005)	(3,303)
Capital Expenditures				
Additions to property, plant and equipment	179	269	392	840
Additions to intangible assets	1,786	—	1,330	3,116
Other segment information				
Depreciation and amortization	513	1,085	1,252	2,849
Research and development expenses	—	—	4,108	4,108

Adjustments

Corporate expenses, depreciation and amortization, interest and similar income and expenses as well as share-based payment expenses are not allocated to individual segments as the underlying instruments are managed on a group basis. Current taxes and deferred taxes are allocated to Corporate as they are also managed on a group basis.

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

4 Segment information (Continued)

Corporate expenses for the six months ended June 30, 2019 also included real estate transfer tax of EUR 1,200k (the six months ended June 30, 2018: EUR nil) related to an intercompany sale of land and building. See note 6 for further details.

Capital expenditure consists of additions of property, plant and equipment, intangible assets and right-of-use assets.

Reconciliation of segment Adjusted EBITDA to Group loss for the period

	2018	2019
Reported segment Adjusted EBITDA	6,333	6,702
Corporate expenses	(7,919)	(10,005)
	(1,586)	(3,303)
Share-based payment expenses	(2,272)	(4,828)
Depreciation and amortization	(2,202)	(2,849)
Operating loss	(6,060)	(10,980)
Financial costs, net	(672)	(419)
Income taxes benefits/(expenses)	110	(163)
Loss for the six months ended June 30	(6,622)	(11,562)

Geographical information

in EUR k	2018		
	Pharmaceutical	Diagnostics	Total
Revenues			
Europe	190	3,036	3,226
— <i>Germany</i> *	—	234	234
Middle East	—	5,450	5,450
— <i>Saudi Arabia</i> #	—	2,989	2,989
North America	6,080	684	6,764
— <i>United States</i> #	6,080	194	6,274
Latin America	—	1,081	1,081
Asia Pacific	—	491	491
Total	6,270	10,742	17,012

* country of the incorporation of the Company

countries contributing more than 10% of the Group's total consolidated revenues for the six months ended June 30, 2018

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

4 Segment information (Continued)

in EUR k	2019		
	Pharmaceutical	Diagnostics	Total
Revenues			
Europe	280	3,411	3,691
— <i>Germany*</i>	195	133	328
Middle East	61	6,711	6,772
— <i>Saudi Arabia#</i>	—	3,182	3,182
North America	8,357	1,321	9,678
— <i>United States#</i>	8,357	972	9,329
Latin America	—	1,319	1,319
Asia Pacific	—	461	461
Total	8,698	13,223	21,921

* country of the incorporation of the Company

countries contributing more than 10% of the Group's total consolidated revenues for the six months ended June 30, 2019

We collaborated with the majority of our pharmaceutical partners on a worldwide basis in 2018 and 2019. 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 the pharmaceutical segment by geographical region are allocated 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 the diagnostics segment is based on the location of each customer.

During the six months ended June 30, 2019, revenues from one pharmaceutical partner represented 27.1% of the Group's total revenues (the six months ended June 30, 2018: 32.6%).

Non-current assets of the Group consist of property, plant and equipment, intangible assets as well as right-of-use 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 350k (December 31, 2018: EUR 718k) and right-of-use assets of EUR 720k (December 31, 2018: EUR nil), which is located in the United States.

5 Other income and expenses

5.1 Other operating income

in EUR k	2018	2019
Government grants	854	1,470
Income from the reversal of provisions	5	89
Others	94	129
Total other operating income	953	1,688

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

5 Other income and expenses (Continued)

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.

5.2 Other operating expenses

<u>in EUR k</u>	<u>2018</u>	<u>2019</u>
Currency losses	195	2
Expected credit loss allowances on trade receivables	470	462
Total other operating expenses	<u>665</u>	<u>464</u>

6 Real Estate transfer tax expenses

During the six months ended June 30, 2019, the Company sold its land and building with a carrying value of EUR 22.8 million to its subsidiary in preparation for a potential sale and leaseback transaction. As the subsequent sale and leaseback transaction with a third party was entered in July 2019 (refer to note 14), the intercompany transaction was irreversible and a real estate transfer tax expense of EUR 1.2 million related to the intercompany transaction was recognized accordingly.

7 Trade receivables and other assets

<u>in EUR k</u>	<u>Dec 31, 2018</u>	<u>Jun 30, 2019</u>
Current		
Trade receivables	8,572	10,045
Contract assets	2,329	2,950
Receivables due from shareholders	2,170	2,658
Other assets	5,125	5,369
	<u>18,196</u>	<u>21,022</u>

Trade receivables are non-interest bearing and generally portfolio-based expected credit loss allowances are recognized on trade receivables.

The Group's trade receivables and contract assets were designated as collateral in respect of existing loan agreements (see note 10).

Other assets

Other assets include VAT receivables of EUR 745k (December 31, 2018: EUR 1,317k), prepaid expenses of EUR 460k (December 31, 2018: EUR 476k) as well as receivables from grants of EUR 584k (December 31, 2018: EUR 489k). Other assets also include costs relating to anticipated initial public offering of EUR 2,888k (December 31, 2018: EUR 2,591k).

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

8 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 2,500k. See note 10 for further details. The restriction applying to the collateral in the amount of EUR 1,500k may be terminated at any time subject to the full amount of the overdraft being repaid. The collateral increased to EUR 2,500k since July 2019.

9 Equity

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.

As a result of the above, a share premium of EUR 9,965k was received for the six months ended June 30, 2018.

10 Financial liabilities

10.1 Interest-bearing liabilities

in EUR k	Dec 31, 2018	Jun 30, 2019
Non-current liabilities		
Non-current portion of secured bank loans	12,055	11,165
Municipal loans	860	860
Total non-current loans	12,915	12,025
Liabilities from leases	1,712	1,425
Total non-current liabilities	14,627	13,450
Current liabilities		
Current portion of secured bank loans	1,787	1,781
Bank overdrafts	1,915	3,743
Total current loans	3,702	5,524
Current portion of liabilities from leases	1,350	1,391
Total current liabilities	5,052	6,915
Total non-current and current liabilities	19,679	20,365

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 that are reset annually. The Group obtained formal waiver from the lenders for such covenants for the year ended December 31, 2018, as well as for the year ending December 31, 2019. Therefore the secured bank loans were disclosed as current and non-current liabilities based on the contractual maturity of such loans.

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

10 Financial liabilities (Continued)

The following table is based on the original terms and conditions:

Conditions and statement of liabilities

The outstanding interest-bearing liabilities as of June 30, 2019 and December 31, 2018 have the following conditions:

in EUR k	Currency	Nominal interest rate	Maturity	Dec 31, 2018		Jun 30, 2019	
				Nominal amount	Carrying amount	Nominal amount	Carrying amount
Secured bank loan	EUR	3.50%	2016-19	6	6	—	—
Secured bank loan	EUR	2.50%	2018-25	5,633	5,633	5,388	5,388
Secured bank loan	EUR	2.50%	2018-25	5,633	5,633	5,388	5,388
Secured bank loan	EUR	2.950%	2018-25	2,570	2,570	2,170	2,170
Finance lease liabilities	EUR	5.4%-8.9%	2018-23	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	8%; plus 1.5% profit-related; 0.75% on losses	2022	360	360	360	360
Bank overdrafts	EUR	4.46%	Rollover	—	—	472	472
Bank overdrafts	EUR	3.75%	Rollover	1,915	1,915	2,296	2,296
Bank overdrafts	EUR	3.59%	Rollover	—	—	975	975
IFRS 16 lease liabilities	EUR	3.5%*, 5.4%-8.9%	2018-22	—	—	2,816	2,816
Total interest-bearing financial liabilities				19,679	19,679	20,365	20,365

* represents the incremental borrowing rate of the Group at the commencement of the leases

The secured bank loans are secured by trade and other receivables, including contract assets, with a carrying amount of EUR 12,995k (December 31, 2018: EUR 10,901k) (see note 7), as well as secured by a land charge in the amount of EUR 19,910k and by the assignment of certain laboratory equipment.

Bank overdrafts of EUR 2,296k as of June 30, 2019 (December 31, 2018: EUR 1,915k) were secured by short-term deposits with a carrying amount of EUR 1,500k (December 31, 2018: EUR 1,500k) (see note 8), and was further increased to EUR 2,500k since July 2019.

The municipal loan due to MBMV (Mittelständische Bürgschaftsbank Mecklenburg-Vorpommern) of EUR 860k (December 31, 2018: EUR 860k) with a remaining term between 4 to 6 years and an interest rate of 8.25%/8% is secured by guarantees provided by the Group's shareholders.

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

10 Financial liabilities (Continued)

10.2 Lease liabilities

Liabilities from lease liabilities from IFRS 16 and, for 2018, financial leases have the following maturities:

in EUR k	Future minimum lease payments		Interest payments	
	Dec 31, 2018	Jun 30, 2019	Dec 31, 2018	Jun 30, 2019
Less than one year	1,350	1,391	104	119
Between one and five years	1,712	1,425	76	86

New leases entered into for the six months ended June 30, 2019 amounted to EUR 405k (financial leases: in the six months ended June 30, 2018: EUR 178k).

10.3 Trade payables and other liabilities

in EUR k	Dec 31, 2018	Jun 30, 2019
Trade payables	5,429	7,524
Government grants (deferred income)	12,034	11,815
Liability for Virtual Stock Option Program	7,093	11,921
Deferred income	297	664
Amounts to be refunded to customers	111	116
Others	5,507	7,434
Trade payables and other liabilities	30,471	39,484
Non-current	11,240	10,890
Current	19,231	28,594

The investment-related government grants were received for the purchase 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. Additional grants of EUR 341k were received in the six months ended June 30, 2019 relating to construction of the Rostock facility in 2018 (in the six months ended June 30, 2018: EUR 1,207k).

In addition, other liabilities include personnel-related liabilities for vacation and bonuses totaling EUR 2,011k (December 31, 2018: EUR 1,955k) as well as liabilities for wage and church tax of EUR 273k (December 31, 2018: EUR 307k). Other liabilities also include real estate transfer tax related to an intercompany sale of land and building of EUR 1,200k (December 31, 2018: EUR nil) (see note 6) and costs relating to the anticipated initial public offering of EUR 1,790k (December 31, 2018: EUR 1,695k).

11 Share-based payments

At June 30, 2019, the Group had the following share-based payment arrangements.

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

11 Share-based payments (Continued)

(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 7). As this is a shareholder transaction, the respective receivable against shareholders was recorded against equity (capital reserve).

No options were granted or forfeited during the six months ended June 30, 2019 (the six months ended June 30, 2018: nil).

The weighted average remaining contractual life for the share options outstanding as at June 30, 2019 was 6.5 years (December 31, 2018: 7 years).

The weighted average fair value of options outstanding as of June 30, 2019 was EUR 3.32 (December 31, 2018: EUR 2.74). The range of exercise prices for options outstanding at the end of the period was EUR 1.0 to EUR 6.0 (as at December 31, 2018: EUR 1.0 to EUR 6.0).

The intrinsic value of the options vested as of June 30, 2019 was EUR 2,585k (December 31, 2018: EUR 2,169k)

(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 29,560 virtual options, representing approximately 10% 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

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

11 Share-based payments (Continued)

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.

5,878 options with weighted average exercise price of EUR 1.0 were granted during the six month period ended June 30, 2019 (the six month period ended June 30, 2018: 5,328 options granted with weighted average exercise price of EUR 1.0).

The weighted average remaining contractual life for the share options outstanding as at June 30, 2019 was 7.5 years (December 31, 2018: 8 years).

The weighted average fair value of options outstanding as of June 30, 2019 was EUR 621.4 (December 31, 2018: EUR 540.3). The exercise price for options outstanding at the end of the period was EUR 1.0 (December 31, 2018: EUR 1.0).

The intrinsic value of the options vested as of June 30, 2019 was EUR 3,295k (December 31, 2018: EUR 2,722k).

Valuation of Options

The fair values of the virtual 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.

<u>in percent</u>	<u>June 30, 2018</u>	<u>June 30, 2019</u>
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 0%—5% (2018: 0%—5%) at a market interest rate of 6% (2018: 6%).

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

11 Share-based payments (Continued)

The key assumptions used to derive the option value are set out below:

	June 30, 2018	June 30, 2019
Volatility (%)	60	60
Risk-free interest rate (%)	(0.7)	(0.7)
Dividend yield (%)	0	0
Option term (years)	0.69	0.13

Exit events were reflected in measurement based on the likelihood of their occurrence.

For the six months ended June 30, 2019, the Group recognised EUR 4,828k of share-based payment expense in the statement of comprehensive income (six months ended June 30, 2018: EUR 2,272k).

12 Future payment obligations

The Group concluded agreements with suppliers, for goods and services to be provided subsequent to June 30, 2019 with a total payment obligation of EUR 475k (December 31, 2018: EUR 1,013k).

13 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 880k.

On November 12, 2018, the Company submitted a notice to the Regional Court of Rostock of the intention to defend against the claim. On January 3, 2019, the Company filed a motion to dismiss in which the Company denied the merits of the claim. UMCU and Neon Underwriting Limited responded to this motion on March 15, 2019 with a statement of reply, and the parties made several court filings setting out their arguments since. By order dated June 3, 2019, the Regional Court of Rostock provided a first set of questions to be answered by an expert witness. Following a request by the Court, the Director of the Institute of Genetics at the University of Bonn recommended a professor for human genetics from the university of Aachen be appointed as an expert witness in this case. The Company agreed to such recommendation.

The Company intends to continue 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 June 30, 2019. In addition, in case a settlement would be required, the Company believes that the corresponding liability will be fully covered by the respective existing insurance policies.

Notes to the unaudited interim condensed consolidated financial statements as of December 31, 2018 and June 30, 2019 and for the six-months ended June 30, 2018 and 2019 (Continued)

14 Subsequent Event

The Company entered into a sale and leaseback transaction in July 2019, according to which, the Company will sell the Rostock headquarters building to a third party for EUR 24 million, which approximated the fair value of the building as of June 30, 2019. The Company will then lease the building from the third party for a period of 12 years at a fixed rate per month with the option to extend. The consideration received will be used to repay the loans related to the construction of the building of EUR 11 million outstanding as of June 30, 2019 plus additional interest of approximately EUR 1.2 million, while the remaining amount will be used to finance the development and working capital of the Group. The transaction was effective in September 2019 and will be recorded according to IFRS 16, resulting in a gain on disposal of fixed assets of EUR 0.5 million, a decrease in property, plant and equipment of approximately EUR 23 million, an increase of right-of-use assets of approximately EUR 13 million and increases in lease liabilities of approximately EUR 14 million.

These condensed interim consolidated financial statements were approved by management on October 11, 2019.

[This page is intentionally left blank]

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

/s/ CHRISTIAN PATZELT

Wirtschaftsprüfer
(German Public Auditor)

Wirtschaftsprüfer
(German Public Auditor)

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2010.
Berlin, Germany
March 28, 2019

[rest of this page intentionally left blank]

Centogene AG
Consolidated statements of comprehensive loss 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>
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)

<u>Assets</u>	<u>Note</u>	<u>Dec 31, 2017</u>	<u>Dec 31, 2018</u>
Non-current assets			
Intangible assets	12	7,480	8,795
Property, plant and equipment	11	33,837	39,115
Other assets	14	729	—
		42,046	47,910
Current assets			
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
		13,440	28,764
		55,486	76,674
Equity and liabilities			
Equity			
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)
		16,354	26,524
Non-current liabilities			
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
		15,324	25,867
Current liabilities			
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
		23,808	24,283
		55,486	76,674

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)

	Note	2016	2017	2018
Operating activities				
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
Cash flow used in operating activities		1,390	(4,336)	(4,577)
Investing activities				
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
Cash flow used in investing activities		(8,687)	(11,154)	(8,694)
Financing activities				
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)
Cash flow from financing activities		7,867	17,682	19,336
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
As of January 1, 2016		212	3,254	(27)	1,606	5,045	(138)	4,907
Loss for the period		—	—	—	(5,230)	(5,230)	(129)	(5,359)
Other comprehensive income		—	—	9	—	9	—	9
Total comprehensive loss		—	—	9	(5,230)	(5,221)	(129)	(5,350)
Share-based payments		—	964	—	—	964	—	964
Issuance of shares	16	4	2,210	—	—	2,214	—	2,214
As of December 31, 2016		216	6,428	(18)	(3,624)	3,002	(267)	2,735
	Attributable to the owners of the parent					Non-controlling interests	Total equity	
Note	Issued capital	Capital reserve	Currency translation reserve	Retained earnings in EUR k	Total			
As of January 1, 2017		216	6,428	(18)	(3,624)	3,002	(267)	2,735
Loss for the period		—	—	—	(5,361)	(5,361)	(115)	(5,476)
Other comprehensive income		—	—	10	—	10	—	10
Total comprehensive loss		—	—	10	(5,361)	(5,351)	(115)	(5,466)
Share-based payments	19	—	51	—	—	51	—	51
Issuance of shares	16	46	19,404	—	—	19,450	—	19,450
Transaction cost		—	(416)	—	—	(416)	—	(416)
As of December 31, 2017		262	25,467	(8)	(8,985)	16,736	(382)	16,354
	Attributable to the owners of the parent					Non-controlling interests	Total equity	
Note	Issued capital	Capital reserve	Currency translation reserve	Retained earnings in EUR k	Total			
As of January 1, 2018		262	25,467	(8)	(8,985)	16,736	(382)	16,354
Loss for the period		—	—	—	(10,963)	(10,963)	(375)	(11,338)
Other comprehensive loss		—	—	(8)	—	(8)	—	(8)
Total comprehensive loss		—	—	(8)	(10,963)	(10,971)	(375)	(11,346)
Share-based payments	19	—	1,443	—	—	1,443	—	1,443
Issuance of shares	16	60	20,013	—	—	20,073	—	20,073
As of December 31, 2018		322	46,923	(16)	(19,948)	27,281	(757)	26,524

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.

IFRS 9 changed the way financial instruments are classified. Financial assets are classified at initial recognition, and then subsequently measured, at i) amortized 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.

**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)

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 amortized 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 amortized 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.

(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

**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)

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 recognize 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 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

**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)**

4 Basis of consolidation (Continued)

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.

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.

**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)

(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.

- (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.

**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)

(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".

(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.

**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)

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 amortized 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.

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.

**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)

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.

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 .

**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)

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 realizable 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.

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

**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 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.

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.

**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)

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.

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 recognizes 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.

**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 Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognizes 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.

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

**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)

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).

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

**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)

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 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.

**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 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.

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
Revenues from external customers	12,348	15,321	—	27,669
Adjusted EBITDA	10,865	(122)	(12,631)	(1,888)
Capital Expenditures	2,147	5,945	7,683	15,775
Additions to property, plant and equipment	410	5,945	5,692	12,047
Additions to intangible assets	1,737	—	1,991	3,728
Other segment information				
Depreciation and amortization	944	667	474	2,085
Research and development expenses	28	—	5,857	5,885

**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	2017			
	Pharmaceutical	Diagnostics	Corporate	Total
Rendering of services	12,326	17,758	—	30,084
Sales of goods	1,605	—	—	1,605
Revenues from external customers	13,931	17,758	—	31,689
Adjusted EBITDA	10,870	2,552	(13,746)	(324)
Capital Expenditures	1,464	607	15,964	18,035
Additions to property, plant and equipment	241	607	14,716	15,564
Additions to intangible assets	1,223	—	1,248	2,471
Other segment information				
Depreciation and amortization	793	1,311	1,133	3,237
Research and development expenses	35	—	6,361	6,396

in EUR k	2018			
	Pharmaceutical	Diagnostics	Corporate	Total
Rendering of services	16,077	23,171	—	39,248
Sales of goods	1,230	—	—	1,230
Revenues from external customers	17,307	23,171	—	40,478
Recognized over time	12,077	23,171	—	35,248
Recognized at a point in time	5,230	—	—	5,230
Revenues from external customers	17,307	23,171	—	40,478
Adjusted EBITDA	13,641	2,285	(15,836)	90
Capital Expenditures				
Additions to property, plant and equipment	1,225	1,917	5,568	8,710
Additions to intangible assets	1,948	—	1,111	3,059
Other segment information				
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.

**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)

Reconciliation of segment Adjusted EBITDA to Group Loss for the Period

	2016	2017	2018
Reportable segment Adjusted EBITDA	10,743	13,422	15,926
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)
Operating loss	(4,937)	(4,455)	(10,606)
Financial costs, net	(830)	(1,007)	(1,042)
Income taxes	408	(14)	310
Loss for the year	(5,359)	(5,476)	(11,338)

Geographical information

in EUR k	For the year ended December 31, 2016		
	Pharmaceutical	Diagnostics	Total
Revenues			
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
Total	12,348	15,321	27,669

in EUR k	For the year ended December 31, 2017		
	Pharmaceutical	Diagnostics	Total
Revenues			
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
Total	13,931	17,758	31,689

**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	For the year ended December 31, 2018		
	Pharmaceutical	Diagnostics	Total
Revenues			
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
Total	17,307	23,171	40,478

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 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

in EUR k	2016	2017	2018
Government grants	787	637	1,611
Exchange rate gains	95	159	147
Income from the reversal of provisions	277	—	309
Others	136	247	239
Total other operating income	1,295	1,043	2,306

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.

**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)**8.2 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
Total other operating expenses	908	457	1,065

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
Total	(830)	(1,007)	(1,042)

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
Total	15,603	16,578	26,034

Social security contributions include contributions to state pension scheme of EUR 1,046k (2017: EUR 987k; 2016: EUR 875k) 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>
Current tax expenses	(35)	(23)	(87)
Current year	(77)	(27)	(87)
Adjustments for prior periods	42	4	—
Deferred tax income/(expense)	443	(9)	397
Temporary differences	(368)	31	527
Tax losses	811	(22)	(130)
Total income tax benefit/(expenses)	408	(14)	310

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.

<u>in EUR k</u>	<u>2016</u>	<u>2017</u>	<u>2018</u>
Loss before tax	(5,767)	(5,462)	(11,648)
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)
Income tax benefit/(expenses)	408	(14)	310

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
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

9 Income taxes (Continued)

The below table shows a breakdown of deferred taxes in the Group's statement of financial position.

in EUR k	December 31, 2017		December 31, 2018	
	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities
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	1,375	(1,772)	2,178	(2,985)
Offset	(1,375)	1,375	(2,985)	2,985
Deferred Taxes	—	(397)	—	—

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
Acquisition and production cost						
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)
As of Dec 31, 2017	2,149	—	12,869	3,501	20,678	39,197
Additions	—	—	3,142	1,154	4,414	8,710
Reclass	—	24,891	—	201	(25,092)	—
As of Dec 31, 2018	2,149	24,891	16,011	4,856	—	47,907
Accumulated depreciation and impairment						
As of Jan 1, 2017	—	—	2,417	958	—	3,375
Depreciation	—	—	1,672	313	—	1,985
As of Dec 31, 2017	—	—	4,089	1,271	—	5,360
Depreciation	—	612	2,089	731	—	3,432
As of Dec 31, 2018	—	612	6,178	2,002	—	8,792
Carrying amounts						
As of Dec 31, 2017	2,149	—	8,780	2,230	20,678	33,837
As of Dec 31, 2018	2,149	24,279	9,833	2,854	—	39,115

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
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

12 Intangible assets

Reconciliation of carrying amounts

in EUR k	Internally generated /acquired biomarkers	Internally developed database	Purchased rights, licenses, software	Total
Acquisition and production cost				
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
Accumulated amortization and impairment				
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
Carrying amounts				
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
Inventories	779	1,346

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).

**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)**

14 Trade and other receivables and other assets

in EUR k	Dec 31, 2017	Dec 31, 2018
Non-current		
Receivables against shareholders	729	—
	729	—
Current		
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
	9,504	18,196

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
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

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	—
Authorized Capital	34	30

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
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

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 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.

**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)**

17 Capital management (Continued)

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	Dec 31, 2017	Dec 31, 2018
Non-current liabilities		
Non-current portion of secured bank loans	—	12,055
Municipal loans	2,000	860
Total non-current loans	2,000	12,915
Finance lease liabilities	1,851	1,712
Total non-current liabilities	3,851	14,627
Current liabilities		
Current portion of secured bank loans	13,837	1,787
Bank overdrafts	—	1,915
Total current loans	13,837	3,702
Current portion of liabilities from finance leases	1,653	1,350
Total current liabilities	15,490	5,052
Total non-current and current liabilities	19,341	19,679

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
as of December 31, 2017 and 2018 and for the three years ended December 31, 2018 (Continued)**

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	—	—	—	—
Total interest-bearing financial liabilities				19,341	19,341	19,679	19,679

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
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	
Long-term financial liabilities	3,851	(1,373)	—	856	—	11,293	14,627
Long-term bank loans	2,000	(1,140)	—	—	—	12,055	12,915
Long-term financial leases	1,851	(233)	—	856	—	(762)	1,712
Current financial liabilities	15,490	267	—	588	—	(11,293)	5,052
Current bank loans	13,837	1,920	—	—	—	(12,055)	3,702
Current financial leases	1,653	(1,653)	—	588	—	762	1,350
Total	19,341	(1,106)	—	1,444	—	—	19,679

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
Trade payables and other liabilities	19,394	30,471
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	WAEF	Number	WAEF
Outstanding at January 1	842,283	3.36	802,283	3.22
Forfeited during the year	(40,000)	6.15	—	—
Outstanding at December 31	802,283	3.22	802,283	3.22
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	4,318	1.0	10,496	1.0
Vested at December 31	1,478	1.0	5,040	1.0
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 Company.

**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)

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.

<u>in percent</u>	<u>2017</u>	<u>2018</u>
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:

	<u>2017</u>	<u>2018</u>
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.

	<u>2017</u>	<u>2018</u>
Expenses arising from equity-settled share-based payment transactions	286	—
Expenses arising from cash-settled share-based payment transactions	608	5,521
Total expenses arising from share-based payment transactions	894	5,521

**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.

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,

**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)

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	—
Total	7,833	4,172	1,179	1,170	1,312

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
Total	12,534	6,435	1,078	1,953	3,068
Expected credit loss rate	13.0%	0.1%	0.5%	2%	51.6%
Expected credit loss	1,633	6	5	39	1,583

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
As of Jan 1, 2017	626	80
Recognized impairment	367	—
Utilized	(152)	(80)
As of Jan 1, 2018	841	—
Recognized impairment	692	100
As of Dec 31, 2018	1,533	100

**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	—	—
	24,629	28,132	3,978	4,244	9,478	10,432

**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	—	—
	25,108	27,836	6,310	4,670	7,607	9,249

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	—	—	—
Net exposure	636	70	—	16

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
Net exposure	-519	13	63	-1

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%
Total	85.04%

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
Total compensation paid to key management	2,237	2,383	5,257

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.

4,000,000 Shares

CENTOGENE

CENTOGENE B.V.

Common Shares

PROSPECTUS

SVB Leerink

Evercore ISI

Baird

BTIG

November 6, 2019

Through and including December 1, 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.
