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

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-40627

SOPHiA GENETICS SA

(Exact name of Registrant as specified in its charter)

Switzerland
(Jurisdiction of incorporation or organization)

Rue du Centre 172
CH-1025 Saint-Sulpice
Switzerland
+41 21 694 10 60
(Address of principal executive offices)

Ross Muken
SOPHiA GENETICS, Inc.
185 Dartmouth Street Floor 5
Boston, MA 02116
(617) 982-1210
(Name, telephone, e-mail and/or facsimile number and address of company contact person)

Securities registered or to be registered, pursuant to Section 12(b) of the Act.

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Ordinary shares, par value CHF 0.05 per share	**SOPH**	**The Nasdaq Stock Market LLC**

Securities registered or to be registered pursuant to Section 12(g) of the Act: None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None
Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of business covered by the annual report. Ordinary shares, nominal value CHF 0.05 per share: 63,857,604

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No
If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐
Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐
† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐
Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐
If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

TABLE OF CONTENTS

ABOUT THIS ANNUAL REPORT

Unless otherwise indicated or the context otherwise requires, all references in this Annual Report to "SOPHiA GENETICS," "SOPH," the "Company," "we," "our," "ours," "us" or similar terms refer to SOPHiA GENETICS SA and its consolidated subsidiaries.

Trademarks

We own various trademark registrations and applications, and unregistered trademarks, including for "SOPHiA GENETICS," "SOPHiA DDM," "Alamut," "SOPHiA Trial Match," "SOPHiA Insights," "SOPHiA CDx," "SOPHiA Awareness" and our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Presentation of Financial Information

Our consolidated financial statements are presented in U.S. dollars and have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). None of the consolidated financial statements were prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The terms "dollar," "USD" and "$" refer to U.S. dollars and the terms "Swiss franc" and "CHF" refer to the legal currency of Switzerland, unless otherwise indicated. We have made rounding adjustments to some of the figures included in this Annual Report. Accordingly, any numerical discrepancies in any table between totals and sums of the amounts listed are due to rounding.

Our fiscal year ends on December 31. References in this Annual Report to a fiscal year relate to our fiscal year ended on December 31 of that calendar year.

Market and Industry Data

This Annual Report contains industry, market and competitive position data that are based on general and industry publications, surveys and studies conducted by third parties, some of which may not be publicly available, and our own internal estimates and research. Third-party publications, surveys and studies generally state that they have obtained information from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. While we are not aware of any misstatements regarding the industry, market and competitive position data presented herein, these data involve a number of assumptions and limitations and contain projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains statements that constitute forward-looking statements. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, technology, collaborations and partnerships, as well as plans and objectives of management for future operations are forward-looking statements. Many of the forward-looking statements contained in this Annual Report can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate,” “will” and “potential,” among others.

Forward-looking statements appear in a number of places in this Annual Report and include, but are not limited to, statements regarding our intent, belief or current expectations. 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 in the section titled “Item 3. Key Information—D. Risk Factors” in this Annual Report. These forward-looking statements include, among others:

- our expectations regarding our revenue, gross margin, expenses and other operating results;
- our plans regarding further development of our SOPHiA platform and its expansion into additional features, applications and data modalities;
- future investments in our business, our anticipated capital expenditures and our estimates regarding our capital requirements, future revenues, expenses, reimbursement rates and needs for additional financing;
- our expectations regarding the market size for our platform, services and products and the market acceptance they will be able to achieve;
- our expectations regarding changes in the healthcare systems in different jurisdictions, in particular with respect to the manner in which electronic health records are collected, distributed and accessed by various stakeholders;
- the timing or outcome of any domestic and international regulatory submissions;
- impact from future regulatory, judicial, and legislative changes or developments in the United States and foreign countries;
- our ability to acquire new customers and successfully engage and retain customers;
- the costs and success of our marketing efforts, and our ability to promote our brand;
- our ability to increase demand for our products and services, obtain favorable coverage and reimbursement determinations from third-party payors and expand geographically;
- our expectations of the reliability, accuracy and performance of our products and services, as well as expectations of the benefits to patients, medical personnel and providers of our products and services;
- our expectations regarding our ability, and that of our manufacturers, to manufacture our products;
- our efforts to successfully develop and commercialize our products and services;
- our competitive position and the development of and projections relating to our competitors or our industry;
- our ability to identify and successfully enter into strategic collaborations in the future, and our assumptions regarding any potential revenue that we may generate thereunder;
- our ability to obtain, maintain, protect and enforce intellectual property protection for our technology, products and services, and the scope of such protection;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of third parties;

- our expectations regarding the impact of the COVID-19 pandemic;
- our plans with respect to use of proceeds from our initial public offering;
- our ability to enter into additional statement of works and other related agreements to support the Master Alliance Agreement with GE Precision Healthcare LLC ("GE Healthcare") and our expectations with respect to the terms and the effect on us and our business of our current and any future statements of work and other related agreements;
- our ability to attract and retain qualified key management and technical personnel; and
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart our Business Startups Act of 2012 ("JOBS Act") and a foreign private issuer.

These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the sections in this Annual Report titled "Item 3. Key Information—D. Risk Factors" and "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Item 3. Key Information

D. Risk Factors

Our business faces significant risks and uncertainties. You should carefully consider all of the information set forth in this Annual Report and in other documents we file with or furnish to the SEC, including the following risk factors, before deciding to invest in or to maintain an investment in our securities. If any of the events or developments described below were to occur, our business, results of operations, financial condition and prospects could suffer materially and the trading price of our ordinary shares could decline. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

- We may not be successful in expanding features, applications and data modalities of our SOPHiA platform and related solutions, products and services.
- We may experience challenges with the acquisition, development, enhancement and deployment of technology necessary for our data analytics platform technologies.
- If we are unable to expand our sales and marketing capabilities, including through additional strategic relationships, in a cost-effective manner, we may not be able to grow our revenue.
- The coverage and reimbursement status of newly developed products, such as data analytics platforms and related solutions, products and services, particularly in a new category of diagnostics and therapeutics, is uncertain. An inability to obtain or maintain adequate coverage and reimbursement could limit the commercial potential of our SOPHiA platform and related solutions, products and services.
- If we cannot maintain our current relationships and enter into new relationships with hospitals, reference and specialty laboratories and biopharmaceutical companies, our revenue prospects could be reduced.
- We are highly dependent on our senior management team and other key personnel, and our business could be harmed if we are unable to retain and attract such personnel.
- Our industry is subject to rapid change, which could make our SOPHiA platform and related solutions, products and services obsolete. If we are unable to continue to innovate and improve our SOPHiA platform and related solutions, products and services, we could fail to attract new customers and expand our market share and we could lose existing customers and market share.
- We face competition from many sources and we may be unable to compete successfully.
- Cyber security or data privacy breaches, other unauthorized or improper access, or (distributed) denial service lack of access (e.g., ransomware, persistent DoS/DDoS) could result in additional costs, loss of revenue, significant liabilities, harm to our brand and decreased use of our SOPHiA platform and related solutions, products or services.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and the price of our ordinary shares.
- Our internal controls over financial reporting and our disclosure controls and procedures in the past have not prevented all errors and fraud and in the future may not prevent all errors and fraud.
- If we are not able to obtain, maintain, defend and enforce patent and other intellectual property protection or if the scope of such patent and other intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products, services and technology similar or identical to ours.
- We license patent rights from third-party owners. If such owners do not properly or successfully obtain, maintain, defend and enforce the patents underlying such licenses, or if they retain or license to others any competing rights, our competitive position and business prospects may be adversely affected. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our relationships with any of our licensors, we could lose license rights that are important to our business.

- We have incurred net losses since our inception and expect to continue to incur losses for the foreseeable future. We may never achieve or sustain profitability.
- A limited number of distributors collectively account for a substantial portion of sales of our SOPHiA platform and related solutions, products and services.

Risks Related to the Development of Our SOPHiA Platform and Related Solutions, Products and Services

We may not be successful in expanding features, applications and data modalities of our SOPHiA platform and related solutions, products and services.

Our SOPHiA platform offers a broad range of genomics applications across oncology, rare diseases, infectious diseases, cardiology, neurology, metabolism and other disease areas. A major part of our long-term strategy is bringing new high-impact content to our customers through updates to our platform, which may include expanding our platform with additional features, applications and data modalities and related solutions, products and services. We expect to make significant investments to advance these efforts.

Enhancing our platform and developing new related solutions, products and services is a speculative and risky endeavor. Features, applications, data modalities and services that initially show promise may fail to achieve the desired results or may not achieve acceptable levels of analytical accuracy or utility. We may need to alter our platform, solutions, products or services in development and repeat studies before we identify a potentially successful feature, application, data modality, product or service. Platform, solution, service and product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the development. Even if we confirm that our platform can be successfully employed for additional features, applications and data modalities, those features, applications and data modalities may be limited in scope to only some diseases, disease segments, patient markets or geographies. If, after development, a new feature, application, data modality, solution, service or product appears successful, we or our collaborators may, depending on the nature of the feature, application, data modality, service or product, need to obtain U.S. Food and Drug Administration (the "FDA"), European Medicines Agency (the "EMA"), United Kingdom (the "UK") Medicines and Healthcare products Regulatory Agency (the "MHRA") and other regulatory clearances, authorizations or approvals before we can market the feature, application, data modality, solution, service or product. The FDA's, EMA's and MHRA's clearance, authorization or approval pathways are likely to require significant time and expenditures. The FDA, EMA, MHRA or other applicable regulatory authority may not clear, authorize or approve any feature, application, data modality, solution, service or product we develop. Even if we develop a feature, application, data modality, solution, service or product that receives regulatory clearance, authorization or approval, we or our collaborators would need to commit substantial resources to commercialize, sell and market the feature, application, data modality, solution, service or product and the feature, application, data modality, solution, service or product may never achieve significant market acceptance among various stakeholders and be commercially successful. Furthermore, we purposefully built our SOPHiA platform in a decentralized manner and strategically positioned it as a "universal operating-system" for multiomics and multimodal data analytics in order to provide for a broad range of product and service expansion opportunities. However, certain jurisdictions, such as the Netherlands, have implemented centralized services architectures for electronic healthcare records ("EHR") where all patient data passes through a single, often government-run, entity rather than being shared directly between the healthcare providers. Such centralized systems, if widely implemented, may limit the development of our platform in a decentralized manner across different data modalities. Any of the foregoing could adversely affect our business, revenue growth and results of operations.

In addition, we generally sell our platform, solutions, products and services in industries that are characterized by rapid technological changes, frequent new product introductions and changing industry standards. If we do not develop platform enhancements based on technological innovation on a timely basis, our platform may become obsolete over time and our financial and competitive position may suffer. Our success will depend on several factors, including but not limited to our ability to:

- correctly identify customer needs and preferences and predict future needs and preferences;
- allocate our research and development funding to areas with higher growth prospects;
- anticipate and respond to our competitors' development of new solutions, products, services and technological innovations;
- innovate and develop new technologies and applications, and acquire or obtain rights to third-party technologies that may have valuable applications in the markets we serve;

- successfully develop and commercialize new technologies and applications in a timely manner; and
- convince customers to adopt new technologies and applications.

The expenses or losses associated with unsuccessful platform innovation or expansion could adversely affect our business revenue growth and results of operations.

Strong platform, product and service performance, security and reliability are necessary to maintain and grow our business.

We need to maintain and continuously improve the performance, security and reliability of our SOPHiA platform and related solutions, products and services. Our platform, solutions and other products may contain errors or defects, and while we have made efforts to test them and are not aware of any widespread material errors, defects or other performance-related issues, there can be no assurance that our platform, solutions, products and services do not or will not have performance problems. As we continue to launch more platform features, applications, data modalities, solutions, products and services, these risks may increase. Poor performance, security and reliability could adversely impact our customers and lead to customer dissatisfaction, adversely affect our reputation and revenues and increase our service, product care, and distribution costs and working capital requirements.

We may experience challenges with the acquisition, development, enhancement and deployment of technology necessary for our data analytics platform technologies.

Our business requires sophisticated computer systems and software in order to accurately and efficiently capture, service and process increasing volumes of health data, in particular a growing number of genomic profiles generated by our customers through various NGS test kits, sequencers and sample materials from different manufacturers. Some of the technologies are changing rapidly and we must continue to adapt to these changes in a timely and effective manner at an acceptable cost. There can be no assurance that we will be able to develop, acquire, enhance, deploy or integrate new technologies, including technologies needed to integrate new genomics test kits into our data analytics platform, that these new technologies will be effective and efficient, will meet our needs or achieve our expected goals or that we will be able to do so as quickly or cost-effectively as our competitors. Significant technological change could render our data analytics platform and technologies obsolete and incompatible with new or improved genomics test kits. In addition, we may face challenges in expanding into markets without suitable cloud infrastructure compatible with our SOPHiA platform. Our continued success will depend on our ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance features of our data analytics platform technologies in response to an ever-changing patient population. We may experience difficulties that could delay or prevent the successful design, development, testing and introduction of new versions of our data analytics platform technologies, limiting our ability to identify new solutions, products and services. Any of these challenges could have a material adverse effect on our operating results and financial condition.

Any failure to offer high-quality support for our products and services may adversely affect our relationships with customers and collaborators and negatively impact our reputation and our business, financial condition and results of operations.

In implementing and using our SOPHiA platform and related solutions, products and services, our customers and collaborators depend on our support to resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short-term increases in demand for customer support. Increased customer demand for support could increase costs and adversely affect our financial condition and results of operations. In addition, we need highly trained technical support personnel. Hiring technical support personnel is very competitive in our industry due to the limited number of people available with the necessary scientific and technical backgrounds and ability to understand our technology at a technical level. Our sales are highly dependent on our reputation and on positive recommendations from our customers, users, care collaborators, providers, laboratories, hospitals and clinics. If we do not maintain high-quality customer support, or if the market perceives that we do not maintain high-quality customer support, our reputation and our business, financial condition and results of operations could be adversely affected.

Delays in the commencement and successful completion of multimodal clinical studies, and negative or ambiguous data generated from such studies, could increase costs and delay or prevent regulatory approval of our SOPHiA platform and related solutions and products.

To further improve our SOPHiA platform and its capabilities, for example by developing new predictive algorithmic models that we can deploy on our platform, we are sponsoring, and in the future intend to sponsor, observational multimodal clinical studies in various disease areas. There can be no assurance that any multimodal clinical study that we sponsor will be conducted as planned or be completed on schedule, if at all. These clinical studies are subject to numerous risks, and a failure, delay or termination of one or more such studies can occur at any stage of the process. Events that may prevent successful or timely commencement and completion of multimodal clinical studies include:

- delays in receiving the required regulatory clearance from the appropriate regulatory authorities to commence the studies;
- delays in reaching, or a failure to reach, an agreement on acceptable terms with prospective clinical research organizations ("CROs") and participating sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and participating sites;
- difficulties in obtaining required Institutional Review Board ("IRB") or ethics committee approval at each participating site;
- challenges in recruiting and enrolling suitable patients that meet the study criteria to participate in the studies;
- the inability to enroll a sufficient number of patients in the studies;
- our CROs or participating sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;
- lower than anticipated patient retention rates;
- difficulties in maintaining contact with patients, resulting in incomplete data;
- ambiguous or negative interim or final results;
- changes in regulatory requirements and guidance that require amending or submitting new protocols;
- lack of adequate funding to continue the study; or
- delays and disruptions as a result of unforeseen external events, such as the COVID-19 pandemic.

The commencement and successful and timely completion of a multimodal clinical study will require us to enroll a sufficient number of eligible patients to participate in such study. Any delay or difficulty in patient enrollment could significantly delay or otherwise hinder our research and development efforts, including potential regulatory submissions and approvals and commercialization efforts. Patient enrollment is affected by many factors, including the size and nature of the patient population; the severity of the disease under investigation; the eligibility criteria for the study in question, including any misjudgment of, and resultant adjustment to, the appropriate ranges applicable to the exclusion and inclusion criteria; the number of participating sites and the proximity of patients to those sites; the commitment of participating sites to identify eligible patients; competing studies with similar eligibility criteria; and other disruptions, such as due to the COVID-19 pandemic. The risks related to patient enrollment may be heightened for any clinical study that seeks to enroll patients with characteristics that are found in a small population. In addition, patients may also be unwilling to participate in our studies because of data security and privacy concerns.

Furthermore, there can be no assurance that any multimodal clinical study will produce the data necessary to support further development of our platform in a particular disease area or to support any potential regulatory submission. Even if a study is completed, the data generated may be negative, ambiguous or otherwise insufficient. To obtain sufficient data, we may be required to conduct additional studies beyond those that we current plan for, which would increase our costs and delay potential regulatory submissions and commercialization activities.

If we do not have the support of key opinion leaders or clinical data using our products is not published in peer-reviewed journals, it may be difficult to drive adoption of our products.

We have established relationships with leading thought leaders. If these key opinion leaders determine that our SOPHiA platform and related solutions, products and services are not accurate or that alternative technologies, products and services are more accurate or more cost-effective, or if we fail to establish new relationships with key opinion leaders in different markets, geographies and among various stakeholders, we may see lower demand for our SOPHiA platform and related solutions, products and services, which would limit our revenue growth and our ability to achieve profitability.

The publication of clinical data using our products in peer-reviewed journals is also crucial to our success. For instance, as of December 31, 2021, our SOPHiA platform and related solutions, products and services have been utilized in clinical trials and research projects discussed in more than 330 peer-reviewed publications. We are unable to control when, if ever, results of current or future trials and projects are published, which may delay or limit adoption of our SOPHiA platform and related solutions, products and services. Such peer-reviewed publications may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from, clinical studies, as well as delays in the review, acceptance and publication process. If our SOPHiA platform and related solutions, products and services do not receive sufficient favorable exposure in peer-reviewed publications, the rate of adoption of our SOPHiA platform and related solutions, products and services among medical personnel and positive reimbursement coverage determinations for them could be adversely affected.

Risks Related to Commercialization

If we are unable to expand our sales and marketing capabilities, including through additional strategic relationships, in a cost-effective manner, we may not be able to grow our revenue.

Our future sales will depend in large part on our ability to develop, train, retain and substantially expand, our sales force, to increase the scope of our marketing efforts, including into markets and geographies where our presence is currently limited, and to maintain our current strategic relationships and enter into new strategic relationships. Our current target market of hospitals, reference and specialty laboratories, and biopharmaceutical companies is a large and diverse market. As a result, we believe it is necessary to continue to develop a sales force that includes sales representatives with specific technical backgrounds and industry expertise. Competition for such personnel is intense. We may not be able to retain and attract personnel or be able to continue to build and maintain an efficient and effective sales and marketing force, which could adversely impact sales of our SOPHiA platform and related solutions, products and services and their market acceptance and limit our revenue growth and potential profitability.

We currently have multiple strategic relationships with third-party providers of solutions, products and services that can be bundled with our SOPHiA platform, including Integrated DNA Technologies, Inc. (“IDT”), Twist Biosciences Corporation (“Twist”), Agilent Technologies, Inc. (“Agilent”) and New England Biolabs (“NEB”), Inc., as well as additional strategic relationships to develop and commercialize solutions, products and services. See “Item 10. Additional Information—C. Material Contracts.” We also offer our SOPHiA platform and related solutions, products and services through various global and local distributors. See “—Risks Related to Our Relationships with Third Parties—Our operating results depend on the performance of third-party distributors” and “—Risks Related to Our Relationships with Third Parties—We intend to rely on third-party distributors to realize our expansion strategy.” In addition, we have a direct sales force to market and sell our SOPHiA platform and related solutions, products and services, including a dedicated BioPharma Business Development and Operations team, focusing on expanding our collaborations with biopharmaceutical companies, both advanced and early stage. Sales and marketing activities in the healthcare space are subject to various rules and regulations. In addition, our marketing messaging can be complex and nuanced, and there may be errors or misunderstandings in our sales force’s communication of such messaging. As we continue to grow our sales and marketing efforts, we face an increased need to continuously monitor and improve our policies, processes and procedures to maintain compliance with a growing number and variety of laws and regulations. To the extent that there is any violation, whether actual, perceived or alleged, of our policies or applicable laws and regulations, we could incur additional training and compliance costs, receive inquiries from third parties or be held liable or otherwise responsible for such acts of noncompliance. Any of the foregoing could adversely affect our business, reputation and results of operations.

We intend to continue to expand and leverage our sales and marketing infrastructure. Identifying, recruiting and training qualified sales and marketing personnel requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive, depending on the target market or geographies. Our sales force may subject us to higher fixed costs than that incurred by our competitors that utilize independent third parties, which could place us at a competitive disadvantage.

Our ability to increase our customer base and achieve broader market acceptance of our SOPHiA platform and related solutions, products and services will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. However, marketing activities may not generate medical personnel awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the market acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad use of our SOPHiA platform and related solutions, products and services.

The commercial success of our SOPHiA platform and current and future products and services depends on attaining significant market acceptance.

Our commercial success depends, in part, on market acceptance of our SOPHiA platform and our products and services. We cannot predict how quickly, if at all, our SOPHiA platform and related solutions, products and services will attain significant market acceptance or, if accepted, how frequently they will be used. These constituents must believe that our SOPHiA platform and related solutions, products and services offer benefits over other available alternatives. The degree of market acceptance of our SOPHiA platform and related solutions, products and services depends on a number of factors, including:

- whether there is adequate utilization of our SOPHiA platform and related solutions, products and services based on their potential and perceived advantages over those of our competitors;
- the safety, accuracy and ease of use of our SOPHiA platform and related solutions, products and services relative to those currently on the market;
- our ability to develop, commercialize and obtain regulatory clearance or approval for *in vitro* device (“IVD”) products for diagnostic use and our compliance with the FDA’s “Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only” (the “RUO Guidance”) and other laws and regulations governing Research Use Only (“RUO”) and IVD products in the United States, the European Union (the “EU”) and other geographies;
- the clinical flexibility, operational versatility and technology agnostic nature of our SOPHiA platform and related solutions, products and services;
- the prices at which we and our distributors offer our SOPHiA platform and related solutions, products and services;
- the effectiveness of our sales and marketing efforts;
- our ability to provide incremental data that show the clinical benefits and cost-effectiveness, and operational benefits, of our SOPHiA platform and related solutions, products and services;
- our ability to build and maintain robust data sets with respect to patient populations, both in geographic regions that we have historically served and in geographic regions that we may seek to enter or further penetrate in the future;
- the coverage and reimbursement acceptance of our products and services;
- pricing pressure, including from group purchasing organizations (“GPOs”), seeking to obtain discounts on our SOPHiA platform and related solutions, products and services based on the collective bargaining power of the GPO members;
- negative publicity regarding our or our competitors’ platforms, products and services; and
- the accuracy of our SOPHiA platform and related solutions, products and services relative to those of our competitors.

Additionally, even if our SOPHiA platform and related solutions, products and services achieve widespread market acceptance, they may not maintain that market acceptance over time if more cost-effective or more favorably received platforms, products, services or technologies are introduced. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue.

In addition, our customer base includes hospitals, reference and specialty laboratories, and biopharmaceutical companies. In the years ended December 31, 2021 and December 31, 2020, most of our revenue came from sales to our customers in Europe, the Middle East and Africa ("EMEA"). Our success will depend on our ability to increase our market penetration among these customers, including our ability to provide additional applications of our platform and additional products and services to our existing customers, and expand our customer base across various markets and geographies by developing and marketing new applications of our data analytics platform and new solutions, products and services. In particular, we intend to focus our efforts on geographic and biopharma expansion, for example by capitalizing on increasing NGS testing and expanding our offerings to biopharmaceutical companies with new and improved pre- and post-market solutions. As we continue to scale our business, we may find that certain applications of our SOPHiA platform, certain of our solutions, products and services, certain customers or certain markets may require a dedicated sales force or sales personnel with different experience than those we currently employ. For instance, we have a dedicated BioPharma Business Development and Operations team, focusing on expanding our collaborations with biopharmaceutical companies, both advanced and early stage. Identifying, recruiting and training additional qualified personnel would require significant time, expense and attention.

There can be no assurance that we will be able to further penetrate our existing markets, that our existing markets will be able to sustain our current and future solutions, products and services offerings and that we will be able to expand into new markets. Any failure to increase penetration in our existing markets or expand into new ones would adversely affect our revenues and results of operations.

The market opportunities for our SOPHiA platform and related solutions, products and services may be smaller than we estimate.

Our estimates of the addressable market for our SOPHiA platform and related solutions, products and services are derived from a variety of sources, including scientific literature, surveys of clinicians, medical personnel and healthcare professionals and other forms of market research. These estimates may be inaccurate or based on imprecise data. Further, these estimates are based on various assumptions, including the outcomes of clinical studies, and whether the clinical studies will achieve objectives needed to meet clinical and payor expectations, the number of people who have a particular disease or condition, our expansion into other features, applications and data modality opportunities and disease areas, maintenance and expansion of our clinical and multimodal data sets for patient populations in specific geographic regions, the prices at which we and our distributors provide or sell our SOPHiA platform and related solutions, products and services in the market, the regulatory framework governing the development, sale and use of our SOPHiA platform and related solutions, products and services, including the laws and regulations governing RUO and IVD products, the degree of coverage and reimbursement, the cost-containment efforts by payors, customers and collaborators as well as obtaining necessary clearance or regulatory approvals. Further, while we currently offer germline and somatic oncology testing across both solid and liquid tumors, our solid tumor offering is more nascent and, as a result, our ability to penetrate our total addressable market for oncology may depend on expansion of our solid tumor offering, among other factors. While we believe our assumptions and estimates are reasonable, these assumptions and estimates may prove to be incorrect and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. The future growth of the market for our current and future products and services depends on many factors beyond our control, including recognition and acceptance of our products by the scientific community and the growth, prevalence and costs of competing products and solutions. Such recognition and acceptance may not occur in the near term, or at all. If the addressable market for our SOPHiA platform and related solutions, products and services is smaller than our estimates, or if the prices at which we can sell our SOPHiA platform and related solutions, products and services are lower than our estimates, our business, financial condition and results of operations could be negatively impacted.

The coverage and reimbursement status of newly developed products, such as data analytics platforms and related solutions, products and services, particularly in a new category of diagnostics and therapeutics, is uncertain. An inability to obtain or maintain adequate coverage and reimbursement could limit the commercial potential of our SOPHiA platform and related solutions, products and services.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford our current and future platforms, solutions, products and services, if approved for IVD use. In addition, because our SOPHiA platform and related solutions, products and services represent new approaches to the research, diagnosis, detection and treatment of diseases, we cannot accurately estimate how they would be priced, whether reimbursement could be obtained or any potential revenue generated. Sales of our SOPHiA platform and related solutions, products and services, if approved for IVD use, may depend substantially on the extent to which they are covered by health maintenance, managed care and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our SOPHiA platform and related solutions, products and services. Even if coverage is provided, the available reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our research and development and sales and marketing costs.

Coverage and reimbursement are ever changing, and we are not in control of how our competitors' coverage and pricing strategies are established. Some of our competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that payors and healthcare professionals could view as functionally equivalent to our products, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve and maintain profitability. Payors may compare our products to our competitors and utilize them as precedents, which may impact our coverage and reimbursement. In addition, technological innovations that result in the creation of enhanced diagnostic tools that are more effective than ours may enable other clinical laboratories, hospitals, medical personnel or medical providers to provide specialized diagnostic tests similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible.

In the United States, many significant decisions about reimbursement for new diagnostics and medicines are made by the Centers for Medicare & Medicaid Services ("CMS"), which decides whether and to what extent a new diagnostic or medicine will be covered and reimbursed under Medicare, although it frequently delegates this authority to local Medicare Administrative Contractors ("MACs"). Private payors tend to follow Medicare to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel platforms, solutions, products and services such as ours. Outside the United States, the reimbursement process and timelines vary significantly. Certain countries, including a number of member states of the EU, set prices and make reimbursement decisions for diagnostics and pharmaceutical products, or medicinal products, as they are commonly referred to in the EU, with limited participation from the marketing authorization or CE mark holders, or may take decisions that are unfavorable to the authorization or CE mark holder where they have participated in the process. There can be no assurance that we can achieve acceptable prices and reimbursement decisions.

Cost-containment efforts of our customers and third-party payors could have a material adverse effect on our sales and profitability.

Increasing efforts by governmental and third-party payors to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly cleared, authorized or approved devices and medicines and, as a result, they may not cover or provide adequate payment for our platform and related solutions, products and services. Such efforts include legislation and regulations designed to control pharmaceutical and biological pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, which are, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, such organizations may decide to divert or reallocate their available funding to other services, products or uses, for instance to limit the effects of the COVID-19 pandemic. Additionally, some countries require approval of the sale price of a product before it can be marketed or mandatory discounts or profit caps may be applied.

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system to contain costs, improve quality, and expand access to care. There have been executive and judicial challenges to certain aspects of the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act of 2010 (the "ACA"), as well as efforts to repeal, replace or alter the implementation of certain aspects of the ACA. It is unclear how any such efforts as well as the healthcare reform measures of the U.S. presidential administration will affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020 through December 31, 2021. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

Further, we expect that additional state and federal healthcare reform measures will be adopted in the future. Because of that, we expect to experience pricing pressures on our SOPHiA platform and related solutions, products and services due to the trend toward value-based pricing and coverage, the increasing influence of health maintenance organizations and legislative changes.

In an effort to reduce costs, many hospitals in the United States have become members of GPOs and Integrated Delivery Networks (the "IDNs"), which negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain and maintain contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our SOPHiA platform and related solutions, products and services, thereby reducing our revenue and margins.

We expect that a significant portion of our revenue will be derived from sales to customers for research and development applications, including for CROs. The demand for our SOPHiA platform and related solutions, products and services will depend in part upon the research and development budgets of these customers, which are impacted by factors beyond our control. In addition, academic, governmental and other research institutions that fund research and development activities may be subject to stringent budgetary constraints that could results in spending reductions, reduced allocations or budget cutbacks, which could jeopardize the ability of these customers to purchase our products.

Risks Related to Our Business Strategy

We may encounter difficulties in managing our growth, which could disrupt our operations and make it difficult to execute our business strategy.

As of December 31, 2021, we had 518 employees. We anticipate continued growth in our business operations, particularly in the areas of research and development, sales and marketing, regulatory affairs and other functional areas such as finance, accounting, quality and legal. Additionally, we expect to expand our testing, analytics and manufacturing capacities as we develop and commercialize additional platforms, products and services and expand our presence in existing markets and enter new markets, including North America. To manage our anticipated growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue to recruit, train and retain additional qualified personnel. This growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management, in particular during the COVID-19 pandemic. Our management may also have to divert its attention away from day-to-day activities in order to manage growth. Difficulties managing our growth could disrupt our operations and make it difficult to execute our business strategy.

If we are unable to manage our growth, we may not be able to maintain the quality or expected turnaround times of our SOPHiA platform and related solutions, products and services, or satisfy customer demand. Our ability to manage our growth will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely and efficient manner could materially adversely affect our operations.

Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for, and utilization of, our SOPHiA platform and related solutions, products and services and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and assemble products related to our SOPHiA platform and services based on our estimates of future demand. Our ability to accurately forecast demand could be negatively affected by various factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, change in customer demand, changes in customer acceptance, changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would adversely affect our gross margin and impair the strength of our brand. Conversely, if we underestimate customer demand for our SOPHiA platform and related solutions, products and services, our supply chain, manufacturing collaborators and/or internal manufacturing team may not be able to deliver components to meet our requirements, which could damage our reputation, sales growth and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, if at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which could adversely affect our business, reputation and results of operations.

We have in the past and may in the future acquire other businesses, which could require significant management attention, disrupt our business, dilute shareholder value and adversely affect our results of operations.

As part of our business strategy, we have in the past and may in the future acquire complementary companies, platforms, products or technologies that we believe fit within our business model and can address the needs of our current and potential customers. There can be no assurance that we can acquire or successfully integrate such companies, platforms, products or technologies into our business, in particular that we can successfully integrate any acquired technology into our SOPHiA platform. We may not be able to find suitable acquisition candidates, and we may not be able to complete such acquisitions on favorable terms, if at all. In addition, the pursuit of potential acquisitions may divert the attention of management and cause us to incur additional expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. If we do complete acquisitions, we may not ultimately strengthen our competitive position or achieve our strategic goals and any acquisitions we complete could be viewed negatively by our customers, investors and industry analysts. We may not be aware of all of the risks associated with the acquired business. In addition, an acquisition may result in unforeseen operating difficulties and expenditures, such as:

- difficulties integrating businesses, services, personnel, operations and financial and other controls and systems and retaining key employees;
- assumption of unknown liabilities, known contingent liabilities, that become realized or known liabilities that prove greater than anticipated;
- difficulties retaining the customers or employees of any acquired business;
- incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill;
- entry into a new market or business line in which we have no prior experience and in which we may not successfully compete;
- integration of an acquired company, which may disrupt ongoing operations and require management resources that would otherwise be used in developing our existing business; and
- divergent interests from those of our collaborators.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Any such acquisitions may reduce cash available for operations and other uses and could result in amortization expense related to identifiable assets acquired. We may have to pay cash, incur debt or issue equity securities to pay for any such acquisition, each of which could adversely affect our financial condition and the value of our ordinary shares. The sale or issuance of equity securities to finance any such acquisitions would result in dilution to our shareholders. The incurrence of indebtedness to finance any such acquisition would result in fixed obligations and could also include restrictive covenants that impede our ability to manage our operations. In addition, our results of operations may be adversely affected by the dilutive effect of an acquisition, performance earn-outs or contingent bonuses associated with an acquisition.

Risks Related to Our Relationships with Third Parties

If we cannot maintain our current relationships and enter into new relationships with hospitals, reference and specialty laboratories and biopharmaceutical companies, our revenue prospects could be reduced.

We collaborate with various constituents in the healthcare ecosystem, such as hospitals, reference and specialty laboratories, and biopharmaceutical companies to analyze patient samples for multiple applications, strategic partners with whom we combine our SOPHiA platform with their offerings and with whom we jointly develop product and service offerings, and manufacturers, suppliers and distributors of our products and offerings. See “Item 10. Additional Information—Material Contracts.” There can be no assurance that these collaborations will be successful or provide benefits to us as we expect. The revenue attributable to such relationships may fluctuate from period to period, which could adversely affect our financial condition and results of operations. In addition, the termination of these relationships could result in a temporary or permanent loss of revenue and could negatively impact our reputation.

Our future success depends in part on our ability to maintain these relationships and to establish new relationships, including with additional partners and collaborators and with governmental and third-party payors and patients. Many factors have the potential to impact such relationships, including our customers’ and collaborators’ satisfaction with our SOPHiA platform and related solutions, products and services and our ability to respond to the evolving needs of our customers. Furthermore, our customers may decide to decrease or discontinue their use of our SOPHiA platform and related solutions, products and services due to changes in clinical routine, research and product development plans, financial constraints or utilization of internal testing resources or tests. In addition, our collaborators may decide to discontinue providing services or manufacturing products, for instance testing kits, complementary to or compatible with our SOPHiA platform and related solutions, products and services, in particular products offered as part of “bundle” solutions together with our SOPHiA platform. Furthermore, our collaborators with whom we entered into both manufacturing and distribution agreements may be disincentivized from adequately performing their obligations under the applicable distribution agreement if we substantially decrease the quantities of products purchased from them under the manufacturing agreement or terminate the manufacturing agreement. In addition to reducing our revenue, the loss of one or more of these relationships may reduce our exposure to clinical routine and research that facilitate the collection and incorporation of new data, including new genomics profiles, into our SOPHiA platform.

We engage in conversations with potential collaborators regarding commercial opportunities on an ongoing basis. There can be no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the resulting relationship will be successful or that clinical or research studies conducted as part of the engagement will produce successful outcomes.

Our operating results depend on the performance of third-party distributors.

A portion of our sales is made through independent global and regional distributors that are not under our control. We rely on distributors to grow and develop our customer base and anticipate customer needs, and any lack of such actions by our distributors may adversely affect our results of operations. If the business relationship with such distributor is terminated, whether through industry consolidation or otherwise, and we are unable to find a suitable replacement, our operations and operating results could be materially adversely affected. These independent distributors also generally represent products offered by several companies and are not subject to any minimum sales requirements or obligation to market our products to their customers. In turn, distributors could reduce their sales efforts for our products or choose to terminate their representation of us. They may also fail to perform their obligations under the agreements with us, including their obligations to ensure that end users of our SOPHiA platform are aware that informed consent is required from patients prior to obtaining access to our SOPHiA platform. Additionally, we rely on our distributors to provide accurate and timely sales reports in order for us to be able to generate financial reports that accurately represent distributor sales of our products during any given period. Any inaccuracies or untimely reports could adversely affect our ability to produce accurate and timely financial reports and recognize revenue.

We rely on third-party service providers to host and deliver our SOPHiA platform and related services, and any interruptions or delays in these services could harm our business.

We currently serve our customers from third-party data center hosting facilities located in the United States, Canada, Brazil, Europe, Turkey and Australia. Our operations depend, in part, on our third-party facility providers' ability to protect these facilities against damage or interruption from natural disasters, power or telecommunications failures, criminal acts, and similar events. In the event that our data center arrangements are terminated, or if there are any lapses of service or damage to a center, we could experience lengthy interruptions in providing our SOPHiA platform and related solutions, products and services as well as delays and additional expenses in making new arrangements.

We designed our system infrastructure and procure and own or lease the computer hardware used for our services. Design and mechanical errors, spikes in usage volume and failure to follow system protocols and procedures could cause our systems to fail and result in interruptions in our SOPHiA platform and related services. Any interruptions or delays in our service, whether as a result of third-party error, our own error, natural disasters or security breaches could harm our relationships with our customers, reduce our revenue and increase our expenses. In such events, our insurance policies may not adequately compensate us for losses that we may incur but such events could subject us to liability and cause us to issue credits or cause customers to abandon our SOPHiA platform and related services.

In addition, we currently use Microsoft Corporation ("Microsoft") and Microsoft Azure Services for a substantial portion of our computing, storage, data processing, networking and other services. In addition, our platform can be deployed onto other platforms, including Amazon Web Services ("AWS") or Google Cloud Platform ("Google Cloud"). Any significant disruption of, or interference with, our use of Microsoft Azure Services, AWS, Google Cloud or other similar cloud platforms, could adversely affect our business, financial condition and results of operations. Cloud providers have broad discretion to change and interpret the terms of service and other policies with respect to us, and those actions may be unfavorable to our business operations. Cloud providers may also take actions beyond our control that could seriously harm our business, including discontinuing or limiting our access to one or more services, increasing pricing terms, terminating or seeking to terminate our contractual relationship altogether or altering how we are able to process data in a way that is unfavorable or costly to us. If our arrangements with cloud providers were terminated, we could experience interruptions on our platform and in our ability to make our content available to users, as well as delays and additional expenses in arranging for alternative cloud infrastructure services. Any transition to new cloud providers would be difficult to implement and would cause us to incur significant delays and expense.

Additionally, we are vulnerable to service interruptions experienced by Microsoft Azure Services, Microsoft, AWS, Google Cloud and other providers, and we expect to experience interruptions, delays or outages in service availability in the future due to a variety of factors, including infrastructure changes, human, hardware or software errors, hosting disruptions and capacity constraints. Outages and capacity constraints could arise from a number of causes such as technical failures, natural disasters, fraud or security attacks. The level of service provided by these providers, or regular or prolonged interruptions in that service, could also affect the use of, and our users' satisfaction with, our products and services and could harm our business and reputation. In addition, hosting costs will increase as user engagement grows, which could harm our business if we are unable to grow our revenue faster than the cost of using these services or the services of other providers. Any of these factors could further reduce our revenue or subject us to liability, any of which could adversely affect our business, financial condition and results of operations.

We rely on third-party manufacturers for the supply, manufacture and production of our products. Our reliance on these third parties may impair the advancement and commercialization of our products.

We rely, and expect that we will continue to rely, on third parties for the manufacturing and supply of our products offered with our SOPHiA platform, and such reliance on third-party manufacturers may expose us to different risks than if we were to manufacture products ourselves. If our agreements with these third parties expire or are terminated, there can be no assurance that we would be able to negotiate new agreements with them or other third parties on equally favorable terms as the current agreements, or at all. For example, we rely on our manufacturing and supply agreements with multiple parties, including IDT, Twist, Qiagen GmbH ("Qiagen") and NEB, for the manufacture of our DNA enrichments kits, which we offer to our clients as part of "bundle" solutions together with our SOPHiA platform.

Reliance on third-party providers exposes us to different risks than if we were to manufacture and supply products ourselves. If our third-party manufacturers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have a material adverse effect on our business, financial condition and results of operations. Further, although we have auditing rights with all our manufacturing counterparties and we have the right under our agreements both with IDT and Twist to submit our own product design specifications, we do not have control over a manufacturer's compliance with applicable manufacturing standards and other laws and regulations, such as those related to environmental health and safety matters. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our products and that obtained regulatory clearance could be revoked, which would adversely affect our business and reputation. In addition, we have encountered and may in the future encounter quality issues with our products if our third-party manufacturers fail to deliver the required materials for, or components of, our products free of defects and contaminants and/or in conformity with applicable specifications, warranties and statutory or regulatory requirements. For example, in June 2021, we detected cross-contamination of index plates used in some of the DNA enrichment kits sold as part of our "bundle" solutions, which resulted from a defect in index plates supplied by one of our third-party manufacturers, and notified certain of our customers of this. Though in this instance, the cross-contamination to date has not led to detection rates inconsistent with our claimed limits of detection for the DNA enrichment kits or given rise to any pending or threatened claims, we cannot guarantee that quality issues resulting from one of our third-party manufacturer's failure to deliver compliant materials or components free of defects and contaminants will not lead to product recalls, marketing or promotional restrictions, litigation, customer loss or reputational harm or otherwise negatively affect our business, financial condition and results of operations. Further, our manufacturing collaborators may be unable to successfully increase the manufacturing capacity for our products in a timely or cost-effective manner, or at all, as needed for our development efforts or, if our additional products are developed and approved, our commercialization efforts. Quality issues may also arise during scale-up activities, some of which may not be readily apparent to us or our collaborators.

Establishing additional or replacement manufacturers could take a substantial amount of time and be expensive, which may result in interruptions in our operations and product delivery, negatively affect the quality and performance of our products or require that modifications be made to our products' designs. Even if we are able to find replacement manufacturers, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. If we are unable to find an adequate replacement or another acceptable solution in time, our research and development and commercial activities could be harmed.

We rely on third parties to conduct multimodal clinical studies. If they do not properly and successfully perform their obligations to us, we may not be able to gather data necessary to support further development of our SOPHiA platform in a particular disease area or to support potential regulatory submissions and commercial activities.

We rely, and we expect that we will continue to rely, on third parties to assist in managing, monitoring and otherwise carrying out multimodal clinical studies of our SOPHiA platform and related solutions and products. For example, we rely on participating sites and their staff, such as clinical research assistants, to gather and enter data and on clinical research organizations and their staff to gather, enter and monitor data. As a result of our reliance on these third parties, we have less direct control over the conduct, timing and completion of these studies than we would otherwise have if we relied entirely upon our own staff. These third parties are not our employees and we have limited control over the amount of time and resources that they dedicate to our studies, but we nevertheless are responsible for ensuring that each of our clinical studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards. In addition, communications with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, fail to comply with contractual obligations, experience regulatory compliance issues, undergo changes in priorities or become financially distressed, or form relationships with other entities, some of which may be our competitors.

If these third parties do not successfully carry out their duties under their agreements, or if the quality or accuracy of the data they obtain is compromised, or if they fail to comply with study protocols or meet expected deadlines, the multimodal clinical studies of our SOPHiA platform and related solutions and products may fail to generate data necessary to support further development of our platform in a particular disease area or to support potential regulatory submissions and commercial activities and could subject us to liability claims. If third parties fail to comply with applicable regulatory requirements, the data generated in the multimodal clinical studies may be unreliable and these studies may be extended, delayed, suspended or terminated and we could be subject to liability claims.

We compete with many other companies for the resources of these third parties. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources away from our studies. If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or to do so on commercially reasonable terms. As a result, delays may occur in our studies, which can materially impact our ability to meet our desired development, regulatory and commercialization timelines. There can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, results of operations, financial condition and prospects.

Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business, reputation and ability to provide our products on a timely basis.

Expedited, reliable shipping and delivery services and secure warehousing are essential to our operations. We rely on providers of transport services for reliable and secure point-to-point transport of our research and diagnostic products and for tracking of these shipments, and from time to time require warehousing for our products. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation, reduce demand for our SOPHiA platform and related solutions, products and services and increase costs and expenses to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, civil unrest and disturbances or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for our products on a timely basis.

We rely on commercial courier delivery services to transport samples to our laboratory facility in a timely and cost-efficient manner and if these delivery services are disrupted, our business will be harmed. Disruptions in delivery service, whether due to labor disruptions, bad weather, natural disaster, civil unrest or disturbances, terrorist acts or threats or other reasons could adversely affect specimen integrity and our ability to process samples in a timely manner and to service our customers, and ultimately our reputation and our business. In addition, if we are unable to continue to obtain expedited delivery services on commercially reasonable terms, our operating results may be adversely affected.

We intend to rely on third-party distributors to realize our expansion strategy.

We offer our SOPHiA platform and related solutions, products and services through third-party distributors in various geographies. We intend to extend our presence into new geographies and further penetrate existing geographies, particularly geographies that represent largely underpenetrated opportunities such as North America, and to do so we must attract additional distributors and retain existing distributors to maximize the commercial opportunity for our platform, services and products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution collaborators or that we will be able to enter into such arrangements on favorable terms. Most of our distribution relationships are non-exclusive and permit such distributors to distribute competing products. As such, our distributors may not commit the necessary resources to market our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately or we are unable to enter into effective arrangements with distributors in particular geographies, we may not achieve revenue growth and realize our expansion strategy.

Risks Related to Our Business and Industry

We are highly dependent on our senior management team and other key personnel, and our business could be harmed if we are unable to retain and attract such personnel.

We are highly dependent on our senior management, including our Chief Executive Officer Dr. Jurgi Camblong. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists and other highly skilled personnel. The loss of members of our senior management, sales and marketing professionals, scientists, IT and data experts or clinical and regulatory specialists could result in delays in product development and commercialization and harm our business.

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 due to the competition for such personnel among life science businesses, particularly near our headquarters in Saint-Sulpice, Switzerland, our facility and laboratory in Rolle, Switzerland and our locations in Boston, Massachusetts and Bidart and Bordeaux, France. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific and technical personnel. We may also have difficulties locating, recruiting or retaining qualified sales people. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have granted and intend to continue to grant share-based compensation awards that vest over time. The value to employees of such awards is significantly affected by movements in our share price, and such awards may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. We do not maintain “key person” insurance policies.

Our industry is subject to rapid change, which could make our SOPHiA platform and related solutions, products and services obsolete. If we are unable to continue to innovate and improve our SOPHiA platform and related solutions, products and services, we could fail to attract new customers and expand our market share and we could lose existing customers and market share.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product or service introductions and enhancements and evolving industry standards, all of which could make our SOPHiA platform and related solutions, products and services and others we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances.

In recent years, there have been numerous advancements in genomics and our understanding of cancer, rare diseases, cardiology, neurology, metabolism and infectious diseases. There have also been advancements in methods used to analyze very large amounts of molecular information. New technologies, including new AI/ML-powered technologies, and evolving business models in the field of precision medicine continue to develop rapidly. We must continuously enhance our offerings and develop new and improved features, applications and data modalities of our SOPHiA platform and related solutions, products and services to keep pace with scientific and industry developments. If we do not leverage or scale our database of genomic profiles or update our data analytics platform and improve our services and research and diagnostic products to reflect new scientific knowledge, including in the fields of oncology and hereditary disorders, our SOPHiA platform and related solutions, products and services could become obsolete and sales of our SOPHiA platform and related solutions, products and services could decline or fail to grow as expected. A failure to make continuous improvements to our SOPHiA platform and related solutions, products and services to keep ahead of those of our competitors could result in the loss of customers or market share.

We face competition from many sources and we may be unable to compete successfully.

There are a number of healthcare technology companies providing bioinformatics analysis solutions, services and products in North and South America, Europe and Asia. See “Item 4. Information on the Company—Business Overview—Competition.” These competitors provide AI-driven precision medicine platforms, services and research and diagnostic products to hospitals, researchers, medical personnel, laboratories and other medical facilities. Many of these organizations, particularly in the United States, are more established, possess regulatory clearances and approval, have broader or deeper relations with healthcare professionals, customers and third-party payors, have greater ability to price their platforms, solutions, products and services competitively and have significantly greater financial and personnel resources and market share than we do. As a consequence, they may be able to spend more on product development, marketing, sales and other product initiatives than we can. Our continued success depends on our ability to:

- further penetrate the disease diagnostic solutions market and increase utilization of our SOPHiA platform and related solutions, products and services;
- maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis;
- cost-effectively develop and improve our SOPHiA platform and related solutions, products and services;
- add new clinically relevant features, applications and data modalities to our SOPHiA platform and related solutions, products and services, such as anatomical pathology and proteomics, and generate suitable evidence supporting the research and clinical utility of our multimodal analytical approach ahead of our competitors; and
- maintain existing and establish additional research and development, manufacturing, distribution and commercialization collaborations and partnerships.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, development of our SOPHiA platform and related solutions, products and services. Because of the complex and technical nature of data-driven healthcare analysis and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our SOPHiA platform and related solutions, products and services, which would have a material adverse effect on our business, financial condition and results of operations.

As we attain greater commercial success, our competitors are likely to develop technology, platforms, products and services that offer features and functionality similar to ours. Improvements in existing competitive technology, platforms, products and services or the introduction of new competitive technology, platforms, products and services may make it more difficult for us to compete for sales, particularly if competitors demonstrate better accuracy, reliability, convenience or effectiveness or price their platforms, products and services less expensively.

Our competitors may develop data analytics platforms and products or adopt and implement standards or technologies not compatible with our SOPHiA platform and our other services and products. This may inhibit our efforts to develop our platform, services and products in a technology-agnostic manner, which could narrow the addressable market for our SOPHiA platform and our other services and products, adversely impact their sales and market acceptance, and limit our revenue growth and potential profitability.

In addition, we operate in an ecosystem where we and our customers have multiple offerings and our own customers may become our competitors or may view us as potential competitors. This could disincentivize our customers or potential customers from adopting our offerings and sharing data with us, which would adversely impact sales and market acceptance and limit our revenue growth and potential profitability.

Cyber security or data privacy breaches, other unauthorized or improper access, or (distributed) denial service lack of access (e.g., ransomware, persistent DoS/DDoS) could result in additional costs, loss of revenue, significant liabilities, harm to our brand and decreased use of our SOPHiA platform and related solutions, products or services.

In connection with various facets of our business, we collect and use a variety of personal data related to different data subjects (e.g., patients, users, agents, employees, representatives, etc.), such as identity data, contact data, profile data, technical data, health data, and genomic data. In addition, in connection with the performance of our contractual obligations and upon request from our customers and collaborators, we may access additional data, such as data available in the accounts of customers for support operations or data provided for research and development projects. Any failure to prevent or mitigate cyber security incidents or improper access to, use, disclosure or other misappropriation of our data or customers' personal data or the inability to rightfully access any such data could result in significant liability under state (e.g., state breach notification and privacy laws such as the California Consumer Privacy Act ("CCPA")), federal (e.g., the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), collectively "HIPAA") and international laws (e.g., the General Data Protection Regulation ("GDPR")). Such an incident may also cause a material loss of revenue from the potential adverse impact to our reputation and brand, affect our ability to retain or attract new users and customers of our products and services and potentially disrupt our business.

Unauthorized disclosure (loss, leakage, exfiltration) of sensitive or confidential patient or employee data, including personally identifiable information, whether through a breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security incident resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our products or services could be delayed.

As we become more dependent on information technologies, to conduct our operations, cyber security incidents, including deliberate cyber security attacks and attempts to gain unauthorized access to computer systems and cloud/hybrid networks, may increase in frequency and sophistication. These cyber security threats pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data, and these risks apply both to us (including via our corporate systems and any employees that may be working remotely) and to third parties on whose systems we rely for the conduct of our business. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently and often are not recognized until launched against a target, we and our collaborators may be unable to anticipate these techniques or to implement adequate preventative measures. We may in the future experience security incidents. In particular, we may be subject to cyber security incidents as we continue to adapt and upgrade our platform architecture. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, data loss or the loss of or damage to intellectual property or other proprietary information. While no security incidents in the past have had a material adverse effect on our business, financial condition and results of operations, we cannot predict the impact of any such future events. Further, although we are obligated under certain laws and regulations to ensure that our platform, systems and servers and those of our service providers remain compliant with the relevant legal requirements with respect to data privacy and cyber security, we do not have any control over the operations of the facilities or technology of such providers, including any third-party vendors that collect, process and store personal data on our behalf. Our platform, systems and servers and those of our service providers may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect, including via supply chain attacks. Individuals able to circumvent such security measures may misappropriate our confidential or proprietary information, disrupt our operations, damage our computers or otherwise impair our reputation and business. We may need to expend significant resources and make significant capital investments to protect against cyber security breaches or to mitigate (compensating controls) the impact of any such breaches. In addition, to the extent that our platform, systems and servers and those of our service providers experience security breaches that result in the unauthorized or improper use of confidential data, employee data or personal data, we may not be indemnified for any losses resulting from such breaches. There can be no assurance that we or our third-party providers will be successful in preventing cyberattacks or successfully mitigating their effects. If we are unable to prevent or mitigate the impact of such security breaches, our ability to attract and retain new customers, patients and other collaborators could be harmed as they may be reluctant to entrust their data to us, and we could be exposed to litigation and governmental investigations, proceedings and regulatory actions by federal, state and local regulatory entities in the United States and by international regulatory entities, and we could breach our contractual obligations, all of which could result in significant legal and financial exposure and reputational damages and lead to a potential disruption to our business or other adverse consequences.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including the performance, distribution and maintenance of our SOPHiA platform and related solutions, products and services, as well as for accounting, data storage, compliance, purchasing and inventory management, and our continued growth is dependent on our ability to adapt and upgrade our platform architecture without suffering significant business disruption, data loss or the loss of or damage to intellectual property or other proprietary information. Our information technology systems may fail and are vulnerable to breakdown, cyber security breach, interruption or damage from computer viruses, ransomware, DoS/DDoS attacks or other malware, attacks by computer hackers, including sophisticated nation-state and nation-state-supported actors, employee error or malfeasance, theft or misuse, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We could be subject to an unintentional event that involves a third party gaining unauthorized access to our systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions would disrupt our operations, including our ability to timely ship and track diagnostic test orders and results, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability to use our products and services. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition and results of operations.

Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount and by the relevant policy's terms and conditions and there can be no assurance that such potential losses will not exceed our policy limits. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage, or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, financial condition and results of operations. Further, such insurance may not cover all potential claims to which we are exposed. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition and results of operations.

A pandemic, epidemic or outbreak of an infectious disease in Switzerland, the United States or worldwide, including the novel strain of coronavirus disease, COVID-19, could adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in Switzerland, the United States or worldwide, our business may be adversely affected. In response to the COVID-19 pandemic, various measures such as "shelter-in-place" orders, quarantines, executive orders and similar government orders have been imposed, which have resulted in reduced operations at our headquarters, work stoppages, slowdowns and delays, travel restrictions and cancellation of events. Other disruptions or potential disruptions include the inability of our suppliers and manufacturers to manufacture and deliver components and products on a timely basis; disruptions in our research and development schedules; disruptions in our ability to provide customer support; delays in actions of regulatory bodies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business; business adjustments or disruptions of medical institutions and clinical investigators with whom we conduct business; and additional government requirements or other incremental mitigation efforts that may further impact the supply, manufacture and delivery of our products. In addition, the COVID-19 pandemic may result in restricted access to reference and specialty laboratories, prioritization of COVID-19-related testing at the expense of non-COVID-19 analysis and potential supply bottlenecks, in particular with respect to consumables, reagents and other products shared between NGS and COVID-19 testing or COVID-19 vaccination. For example, we may face a shortage of dry ice and other materials which are essential to delivering our products to our customers due to the increased demand for such products because of the COVID-19 vaccination distribution, COVID-19 testing and COVID-19 antibody development.

The COVID-19 pandemic has negatively affected our non-COVID-19 analysis-related revenue in 2020. Certain of our customers have experienced, and may in the future experience, operational disruptions within their organizations, economic disruptions and delays in clinical trial enrollment and have prioritized combating COVID-19, which have resulted in delayed or canceled orders of our solutions, products and services. As a result, we observed a significant decrease in analysis volume generated on our SOPHiA platform in the second quarter of 2020 and we believe that we experienced lower customer acquisition and revenue growth in 2020 as a result of the COVID-19 pandemic than we otherwise would have achieved. With the loosening of COVID-19-related restrictions in 2021, we have seen a general recovery in our business with the resumption of our customer acquisition initiatives and as customers returned to their labs and reallocated resources and focus to non-COVID-19-related operations. However, we are still subject to periodic disruptions resulting from the implementation and loosening of variant-related restrictions, such as what has been transpiring with the progression of the Omicron variant.

The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and spread of COVID-19 and the actions to contain COVID-19. While the potential impact brought by, and the duration of, any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets and a reduction in our ability to access capital, which could adversely affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

If our laboratory facility becomes damaged or inoperable or we are required to vacate our existing facilities, our ability to conduct our laboratory processes and analysis and pursue our research and development efforts may be jeopardized.

We operate a laboratory facility located in Rolle, Switzerland. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure or terrorism, which may render it difficult or impossible for us to operate our platform for some period of time or result in damages to our inventory that require sensitive storage conditions. The inability to perform our laboratory processes or to reduce the backlog that could develop if our facilities are inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. In the past, we have incurred write-offs for damaged inventory that were deemed unusable.

Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace, which may increase backlog. It would be difficult, time-consuming and expensive to rebuild our facility, to locate new facilities or license or transfer our proprietary technologies to a third party.

We carry business continuity insurance and insurance for damage to our property in amounts and pursuant to terms that we believe are reasonable, but this insurance may not cover all of the risks associated with damage, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our SOPHiA platform and related solutions, products and services.

We face an inherent risk of product liability as a result of the marketing and sale of our SOPHiA platform and related solutions, products and services and the testing of our SOPHiA platform in clinical studies. For example, we may be sued if our NGS test kits cause or are perceived to cause injury, provide inaccurate or incomplete information or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the preexisting health of the patient. If medical personnel, care collaborators or patients who operate our research and diagnostic products are not properly trained, are negligent or use our research and diagnostic products incorrectly, the capabilities of such products may be diminished or the patient may suffer injury. If we sponsor interventional clinical studies of our SOPHiA platform in the future, our risk of being subject to product liability lawsuits may be heightened.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delays in obtaining necessary regulatory clearances or approvals;
- decreased demand for our SOPHiA platform and related solutions, products and services;
- harm to our reputation;
- initiation of investigations by regulators;
- delays or abandonment of clinical studies;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- adverse impact on the market price of our ordinary shares; and
- exhaustion of any available insurance and our capital resources.

We believe that we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of our products and services. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in our industry, significantly increase our expenses and reduce sales.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and the price of our ordinary shares.

We have identified material weaknesses in our internal control over financial reporting. A company's internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with IFRS. 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 the annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of our consolidated financial statements and audit process for the years ended December 31, 2020 and December 31, 2019, we and our independent registered public accounting firm have identified material weaknesses in our internal controls related to financial reporting. For each of the fiscal years ended December 31, 2020 and 2019, we have determined that we did not:

- design or maintain an effective control environment commensurate with our financial reporting requirements due to lack of sufficient accounting professionals with the appropriate level of skill, experience and training. Specifically, we lack sufficient financial reporting and accounting personnel with appropriate knowledge of IFRS to address complex technical accounting issues and to prepare consolidated financial statements and related disclosures;

- design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, year-end reporting and disclosures, including controls over the preparation and review of account reconciliations, journal entries and period end financial reporting; and

- design and maintain effective controls over certain information technology general controls for IT systems that are relevant to the preparation of our consolidated financial statements. Specifically, we did not design and maintain: (a) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate personnel, (b) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, and (c) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These material weaknesses resulted in adjustments to our consolidated financial statements during the audit process.

Since our IPO, we have taken and continue to take steps to remediate the aforementioned material weaknesses and to enhance our overall control environment. Regarding the material weakness related to the lack of sufficient accounting professionals with the appropriate level of skill, experience and training, we have hired a number of key employees in our accounting department, including a new Controller and Assistant Controller, to support our Chief Financial Officer and retaining accounting consultants to provide additional support to our technical accounting and financial reporting capabilities and support our finance department in the design and implementation of an improved internal controls system. We have also begun the process of reviewing and documenting our accounting and financial processes and internal controls, improving and formalizing accounting and reporting policies, and building out the appropriate technical, financial management and reporting systems infrastructure to automate and standardize such policies.

We believe that the professionals that we have hired to date have the appropriate level of skills, experience, and training to put us in the position to remediate the first aforementioned material weakness once they have been fully integrated into our control environment and operated those controls across a sufficient number of reporting periods. To address the other two aforementioned material weaknesses, we also are continuing to improve our process of reviewing and documenting our accounting and financial processes and internal controls, to improve and formalize accounting and reporting policies, and to build out the appropriate technical, financial management and reporting systems infrastructure to automate and standardize such policies.

In addition, as an emerging growth company, we currently are not required to comply with Section 404 of the Sarbanes-Oxley Act. As a result, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses.

Our internal controls over financial reporting and our disclosure controls and procedures in the past have not prevented all errors and fraud and in the future may not prevent all errors and fraud.

A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of a control system reflects resource constraints, which requires management to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Further, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management's override of the control. The design of our system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

For example, in August 2020, we received a whistleblower complaint that certain members of our finance team were requested to increase revenues by recording uncollected revenues of $2.0 million in the aggregate for unused minimum volume commitments for two contracts with customers of our U.S. subsidiary for the years ended December 31, 2020 and 2019. The whistleblower complaint raised concerns as to whether these minimum volume commitments could be contractually enforced and collected. We commissioned an independent external forensic review of this whistleblower complaint. In light of the findings of this review, the chair of our audit committee recommended to our chief executive officer to reverse all revenues related to those two contracts for uncollected minimum volume commitments recorded in our U.S. subsidiary's financial statements for the years ended December 31, 2020 and 2019, which recommendation was implemented. The revenue reversals were recorded prior to the finalization of our consolidated financial statements prepared in accordance with IFRS that are included in this Annual Report. Our then-chief financial officer left the company in February 2021.

We have undertaken steps to strengthen our internal controls over financial reporting, including (i) the hiring of a new chief financial officer, (ii) the hiring of additional personnel and external advisors to support our finance function and improve internal controls over financial reporting, (iii) formalization of revenue recognition policy to clarify the accounting treatment for minimum volume commitments and (iv) enhanced training on our systems, policies and procedures and our whistleblower policy. However, there can be no assurance that our control systems can prevent all errors or fraud.

Litigation and other legal proceedings may adversely affect our business.

From time to time, we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated judgements and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our solutions, products and services, even if the regulatory or legal action is unfounded or not material to our operations.

Our business is subject to economic, political, regulatory and other risks associated with international operations.

Our results could be adversely affected by a variety of risks associated with our international operations, including economic weakness, such as inflation, or political instability in economies and markets; global trends towards pharmaceutical pricing; differing regulatory requirements for bioinformatics analysis services and research and diagnostic products approvals; differing reimbursement, pricing and insurance regimes; potentially reduced protection for, and complexities and difficulties in obtaining, maintaining, protecting and enforcing, intellectual property rights; difficulties in compliance with U.S. and non-U.S. laws and regulations, including data security and data protection laws, which may result in increased compliance costs to us, and anti-corruption and anti-bribery laws; changes in regulations and customs, tariffs and trade barriers; changes in currency exchange rates and currency controls; changes in a specific country's or region's political or economic environment; trade protection measures, economic sanctions and embargoes on certain countries and persons, import or export licensing requirements or other restrictive actions by governments, including with respect to our products and services, in particular IT solutions, services and technologies on which our operations rely; changes in tax laws; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; workforce uncertainty in countries where labor unrest is more common than in Switzerland and the United States; difficulties associated with staffing and managing international operations, including differing labor relations; production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and the impact of public health epidemics on employees and the global economy, such as the COVID-19 pandemic. Certain of our suppliers and service providers are located in geopolitically sensitive regions, including Ukraine and other eastern European countries, and may be negatively impacted in their ability to conduct their operations and perform services for us as a result of war, hostilities, and other conflict in such regions. As a result, we may experience supply chain disruptions and interruptions in our operations. We are continuously assessing the ongoing geopolitical risks in Europe, and globally in general, and are prepared to adjust our business operations accordingly. In addition, as a result of the UK's exit from the EU, we may increasingly face divergent regulations in the UK and the EU. Any of these factors could require us to modify our business plans and strategy and significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

Risks Related to Governmental Regulation

Currently our products in the United States are labeled as RUO. We intend to seek regulatory clearance or approval to offer our products as IVD products for diagnostic use. We cannot guarantee when, if at all, we will apply for regulatory clearance or approval or that we will be successful in obtaining such clearances or approvals.

While we have several CE-IVD products, our currently available products in the United States are labeled as RUO products and are not intended for diagnostic use. Although we have focused initially on the RUO products only, our strategy is to expand our product line to encompass products that are intended to be used as IVDs. Such IVD products will be subject to regulation by the FDA as medical devices, including requirements for regulatory clearance or approval of such products before they can be marketed. Accordingly, we will be required to obtain FDA 510(k) clearance or premarket approval ("PMA") in order to sell our products in a manner consistent with FDA laws and regulations. Such regulatory approval processes or clearances are expensive, time-consuming and uncertain; our efforts may never result in any premarket approval or 510(k) approval or clearance for our products; and failure by us to obtain or comply with such approvals and clearances could have an adverse effect on our business, financial condition or operating results.

Regulatory authorities have substantial discretion in the approval process. They may refuse to accept any application or may decide that our data are insufficient for approval and require additional studies. Therefore, even if we believe the data collected from studies of our platform are promising, such data may not be sufficient to support approval by any regulatory authority. If we are required to conduct additional studies or other testing of any of our platform beyond those we contemplate, we may incur significant additional costs and regulatory approval may be delayed or prevented. Furthermore, approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions, and we may be required to undertake additional studies to access particular markets.

If we successfully obtain such approvals, we will be subject to a substantial number of additional requirements for medical devices, including establishment registration, device listing, and Quality Systems Regulations ("QSRs") which cover the design, testing, production, control, quality assurance, labeling, packaging, servicing, sterilization (if required), and storage and shipping of medical devices (among other activities), advertising, record keeping, post-market surveillance, post-approval studies, adverse event reporting, and correction and removal (recall) regulations. We may be required to expend significant resources to ensure ongoing compliance with the FDA regulations and/or take satisfactory corrective action in response to enforcement action, which may have a material adverse effect on the ability to design, develop and commercialize products using our technology as planned. Failure to comply with these requirements may subject us to a range of enforcement actions, such as warning letters, injunctions, civil monetary penalties, criminal prosecution, recall and/or seizure of products, and revocation of marketing authorization, as well as significant adverse publicity. If we fail to obtain, or experience significant delays in obtaining, regulatory approvals for IVD or other products, such products may not be able to be launched or successfully commercialized in a timely manner, or at all.

Laboratory developed tests ("LDTs") are a subset of IVD tests that are designed, manufactured and used within a single laboratory. The FDA maintains that LDTs are medical devices and has for the most part exercised enforcement discretion for most LDTs. A significant change in the way that the FDA regulates any LDTs that our customers develop using our RUO components could affect our business. If the FDA requires laboratories to undergo premarket review and comply with other applicable FDA requirements in the future, the cost and time required to commercialize an LDT will increase substantially, and may reduce the financial incentive for laboratories to develop LDTs, which could reduce demand for our RUO products.

We develop products for clinical laboratories, which may be qualified as LDTs, as well as market RUO products. Our customer may decide to validate our products to use as an LDT, which will be covered under Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and CMS, although future developments may cause us to be subject to additional FDA requirements.

The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Pursuant to its authority under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), the FDA has jurisdiction over medical devices, including *in vitro* diagnostics and, therefore, potentially our diagnostic products.

Pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, record keeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. Although the FDA has asserted that it has authority to regulate the development and use of LDTs, such as our and many other laboratories' tests, as medical devices, it has generally exercised enforcement discretion and is not otherwise regulating most tests developed and performed within a single high-complexity CLIA-certified laboratory. The FDA could, at any time, change its policy with regard to this matter or the U.S. Congress could take action to amend the law to change the current regulatory framework for *in vitro* diagnostics and LDTs.

We currently do not offer any diagnostic products in the United States. We believe that our research products, as utilized in clinical laboratories by our customers, are and would be considered LDTs and that as a result, the FDA does not require that they obtain regulatory clearances or approvals for the LDTs or their components pursuant to the FDA's current policies and guidance. Although we believe that our products and test components delivered to our customers, when validated as LDTs, are either exempt from FDA medical device regulations or are subject to an enforcement discretion policy, it is possible that the FDA would not agree with these determinations or that the FDA will change its regulations and policies such that our products become regulated as medical devices.

In addition, changes in the current regulatory framework for diagnostic products and services can impose additional regulatory burdens on us. For example, the FDA's Center for Devices and Radiological Health is currently considering a total product lifecycle-based regulatory framework for AI/ML technologies. On January 12, 2021, the FDA released its Artificial Intelligence/Machine Learning-Based Software as a Medical Device Action Plan. As the regulatory framework evolves, we may incur substantial costs to ensure compliance with new or amended laws and regulations. Failure to comply with any of these laws and regulations could result in enforcement actions against us, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business.

Our operations, therefore, are or may become subject to extensive regulation by the FDA in the United States, the EMA in the EU, the MHRA in the UK and in other jurisdictions in which we conduct business. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- test design, development, manufacture, and release;
- laboratory and clinical testing, labeling, packaging, storage and distribution;
- product safety and efficacy;
- premarketing clearance or approval;
- service operations;
- record keeping;
- product marketing, promotion and advertising, sales and distribution;
- post-marketing surveillance, including reporting of deaths or serious injuries, recalls, correction and removals;
- post-market approval studies; and
- product import and export.

The FDA, the EMA, the MHRA and U.S. state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, "it has come to our attention" letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;

- denial of our requests for regulatory clearance or PMA of new products, new intended uses or modifications to existing products;
- withdrawal of regulatory clearance or PMA that have already been granted; or
- criminal prosecution.

As discussed above, although we believe that our current line of products and their components, as utilized in clinical laboratories by our customers, are LDTs, subject to state licensing requirements and federal regulation by CMS under CLIA, it is possible that the FDA or comparable regulatory authorities would not agree with our determinations. If our products become subject to 510(k) or other similar FDA regulations, we would need to comply with the applicable regulations or face significant civil and criminal penalties. Exposure to these additional regulatory requirements would also affect our business, financial condition and results of operations.

Failure to comply with federal, state, and foreign laboratory licensing requirements if we begin to provide diagnostic products in the United States could result in significant penalties and materially adversely affect our operations.

CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease, or impairment of, or the assessment of the health of, human beings. CLIA regulations require, among other things, clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, test management, and quality assurance. In addition to federal certification requirements of laboratories under CLIA, CLIA provides that states may adopt laboratory regulations and licensure requirements that are more stringent than those under federal law. A number of states have implemented their own licensure and more stringent laboratory regulatory requirements. Such laws, among other things, establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. Failure to comply with CLIA and applicable state clinical laboratory licensure requirements may result in a range of enforcement actions, including license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, and criminal sanctions as well as significant adverse publicity.

Based on our current scope of operations, we do not currently operate a CLIA-certified laboratory and our customers are responsible for their own CLIA certification. However, if we begin to provide diagnostic products in the United States, we will become subject to such requirements.

We may fail to obtain required clearances or approvals in additional jurisdictions for any of our products or services and, even if we do, we may never be able to commercialize them in additional jurisdictions, which would limit our ability to realize their full market potential.

In order to eventually market any of our current or future products and services in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding quality, safety, performance and efficacy. In addition, regulatory clearance, authorization or approval in one country does not guarantee regulatory clearance, authorization or approval in any other country. For example, the performance characteristics of our products and services may need to be validated separately in specific ethnic and genetic populations. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory clearance, authorization or approval could result in difficulties and costs. Regulatory requirements and ethical approval obligations can vary widely from country to country and could delay or prevent the introduction of our products and services in those countries. We have no experience in obtaining regulatory clearance, authorization or approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required regulatory clearances, authorizations or approvals in international markets, or if those approvals are delayed, our target market will be reduced and our ability to realize the full market potential of our products and services will be unrealized.

Our products or services may be subject to product or service recalls in the future. A recall of products or services, either voluntarily or at the direction of a regulatory authority, or the discovery of serious safety issues with our products or services, could have a significant adverse impact on us.

Regulatory authorities can require the recall of commercialized products or services that are subject to its regulation. Manufacturers may, under their own initiative, recall a product or service if any deficiency is found. For reportable corrections and removals, companies are required to make additional periodic submissions to the regulatory authorities after initiating the recall, and often engage with the regulatory authorities on their recall strategy prior to initiating the recall. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable health risk, component failures, failures in laboratory processes, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products or services would divert managerial and financial resources and adversely affect our business, results of operations, financial condition and reputation. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the regulatory authorities. We may initiate voluntary recalls involving our commercialized products or services, including kits offered as part of “bundle” solutions. A recall announcement by us could harm our reputation with customers and negatively affect our business, financial condition and results of operations. In addition, the FDA or another agency could take enforcement action for failing to report the recalls when they were conducted.

If we initiate a recall, including a correction or removal, for one of our commercialized products or services, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our products and services, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

We are subject to stringent privacy and, information security laws and regulations and changes in such laws and regulations could adversely affect our business.

We are subject to numerous state, federal and foreign laws and regulations that govern the collection, transmission, storage, dissemination, use, privacy, confidentiality, security, availability, integrity and processing of individually identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement actions against us, including fines, imprisonment of company officials, public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business.

There is ongoing concern from privacy advocates, regulators and others regarding data privacy and security issues, and the number of jurisdictions with data privacy and security laws has been increasing. Also, there are ongoing public policy debates regarding whether the standards for de-identification, anonymization or pseudonymization of health information are sufficient, and whether the risk of re-identification is sufficiently small, to adequately protect patient privacy. In particular, there are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. These laws and regulations include HIPAA, which establishes a set of national privacy and security standards for the protection of protected health information ("PHI") by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services as well as their covered subcontractors. HIPAA requires covered entities and business associates to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information and ensure the confidentiality, integrity and availability of electronic PHI. For instance, we offer private cloud-based software to help medical personnel and laboratories more efficiently use our products. The software maintains security safeguards that are designed to be consistent with HIPAA, but we cannot guarantee that these safeguards will not fail or that they will not be deemed inadequate in the future. In addition, we could be subject to periodic audits for compliance with the HIPAA Privacy and Security Standards by the HHS and our customers. HIPAA also implemented the use of standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including activities associated with the billing and collection of healthcare claims. The United States Office of Civil Rights may impose penalties for HIPAA violations. 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. These penalties include civil monetary penalties per violation, up to an annual cap. However, a single breach incident can result in violations of multiple standards. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty and imprisonment up to one year. The criminal penalties are greater and up to five years' imprisonment if the wrongful conduct involves false pretenses, and even higher 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. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. Furthermore, in the event of a breach as defined by HIPAA, the covered entity has specific reporting requirements under HIPAA. In the event of a significant breach, the reporting requirements could include notification to the general public. Enforcement activity can result in reputational harm, and responses to such enforcement activity can consume significant internal resources. Additionally, if we are unable to properly protect the privacy and security of PHI, we could be found to have breached our contracts. Determining whether PHI has been handled in compliance with applicable privacy standards and our contractual obligations can be complex, and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations.

In addition, many states in which we operate have laws that protect the privacy and security of sensitive and personal information. Certain state laws may be more stringent or broader in scope, or offer greater rights to individuals, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the CCPA, among other things, requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt out of certain sales of personal information and imposes new operational requirements for covered businesses. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. On November 3, 2020, California voters approved a new privacy law, the California Privacy Rights Act (the "CPRA"), which significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. Many of the CPRA's provisions will become effective on January 1, 2023. In addition, new legislation or constitutional amendments proposed or enacted in various states impose, or have the potential to impose, additional obligations on companies that collect, store, use, retain, disclose, transfer and otherwise process confidential, sensitive and personal information, and will continue to shape the data privacy environment nationally. For example, Virginia enacted the Consumer Data Privacy Act (the "CDPA"), which has general similarities to the CPRA and goes into effect on January 1, 2023. State laws are changing rapidly and there is discussion in the U.S. Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which may have a material and adverse impact on our business, financial condition and results of operations.

Outside of the United States, laws, regulations and standards in many jurisdictions, including data localization and storage requirements, apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information, which impose significant compliance obligations. For example, in the EU and the European Economic Area (the "EEA"), the collection, use and other processing of personal data, is governed by the GDPR, which became effective in May 2018. The GDPR greatly increased the European Commission's jurisdictional reach of its laws and imposed more stringent data privacy and security requirements on companies in relation to the processing of personal data of EU data subjects, including, for example, requirements to establish a legal basis for processing, higher standards for obtaining consent from individuals to process their personal data, including sensitive data such as health or genomic information, more robust disclosures to individuals and a strengthened individual data rights regime, requirements to implement safeguards to protect the security and confidentiality of personal data that requires the adoption of administrative, physical and technical safeguards, shortened timelines for data breach notifications to appropriate data protection authorities or data subjects, limitations on retention and secondary use of information, increased requirements pertaining to health data and additional obligations when we contract third-party processors in connection with the processing of the personal data. EU and EEA member states are tasked under the GDPR to enact, and have enacted, certain implementing legislation that adds to and/or further interprets the GDPR requirements and potentially extends our obligations and potential liability for failing to meet such obligations. The GDPR, together with national legislation, regulations and guidelines of the EU and EEA member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal data. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the EEA, security breach notifications and the security and confidentiality of personal data. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater, and other administrative penalties.

Further, the exit of the UK from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. The UK has transposed the GDPR into domestic law, with its version of the GDPR that took effect on January 1, 2021, which could expose us to two parallel regimes, each of which potentially authorizes similar fines for certain violations. In Switzerland, the collection and processing of personal data is governed by the Swiss Federal Act on Data Protection (the "FADP"). The revised FADP is expected to enter into force in 2022. The FADP provides for data protection principles that are substantially similar to those applied under the GDPR, and the FADP also applies to collection and processing of personal data outside of Switzerland. While the current FADP authorizes certain criminal fines of up to CHF 10,000, the revised FADP will authorize criminal fines for certain violations of up to CHF 250,000. Such fines are mainly imposed upon the individual responsible for the violation. However, the revised FADP also authorizes fines of up to CHF 50,000 on the responsible data controller or processor. Fines under the FADP may be imposed in addition to fines under other data protection regimes. For more information on the FADP, see "Item 4. Information the Company—B. Business Overview—Government Regulation—Data Privacy and Security—General Data Protection Regulation and Other Foreign Laws and Regulations."

Although there are legal mechanisms to allow for the transfer of personal data from the EEA, Switzerland and the UK to the United States, uncertainty remains about such mechanisms. For example, legal challenges in the EU and EEA to the mechanisms that allow companies to transfer personal data from the EU and EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers. Specifically, on July 16, 2020, in a case known as *Schrems II*, the Court of Justice of the European Union, invalidated the European Commission's Decision 2016/1250 on the adequacy of the protection provided by the EU-U.S. Privacy Shield. Although we rely on the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, for cross-border data transfers from the EU to the United States and other jurisdictions, *Schrems II* also raised questions about whether the Standard Contractual Clauses can lawfully be used for such data transfers. Use of the Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred data. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Inability to transfer personal data from the EU, EEA, Switzerland or the UK to the United States may restrict our research and development activities in these territories and limit our ability to offer products and services we may develop. Similar restrictions of cross-border data transfer apply to Switzerland, where the Swiss Federal Data Protection and Information Commissioner (the "FDPIC") considers that the CH-U.S. Privacy Shield does not provide an adequate level of data protection.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or reinterpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of health-related and data protection laws, regulations, standards and other obligations are still uncertain, and often contradictory and in flux, it is possible that the scope and requirements of these laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. 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, and our operations or business practices may not comply with these regulations in each country.

In addition to the possibility of fines, sanctions, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. 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. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material and adverse impact on our business.

Any failure to comply with our privacy policies or contractual or statutory notification obligations could result in significant liability or reputational harm.

We make public statements about our use and disclosure of personal information through our privacy policy, information provided on our internet platform and press statements. Although we endeavor to comply with our public statements and documentation, we may be alleged to have failed to do so. The publication of our privacy policy and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unlawful, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our posted privacy policies or with any legal or regulatory requirements, standards, certifications or orders or other privacy or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our products and services and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for noncompliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products, services or processes compromise the privacy of customers and others. Concerns about our practices with regard to the collection, use and reuse, retention, security, disclosure, transfer and other processing of personal information or other privacy-related or security-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, jurisdictions have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

Our operations may subject us to various healthcare laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

Our operations may subject us to health care regulation and enforcement by both the federal government and the states and foreign jurisdictions in which we conduct our business. Various federal and state laws, as well as the laws of foreign countries, prohibit payments to induce the referral, purchase, order or use of healthcare products or services and require medical device companies to limit, prevent, and/or monitor and report certain payments to third-party payors, healthcare professionals and other individuals. These healthcare fraud and abuse anti-kickback, public reporting and aggregate spend laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with providers, hospitals, medical personnel or other potential purchasers or users, including patients, of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales offerings, including discount practices, customer support, education and training programs, and physician consulting and other service arrangements. These laws prohibit certain marketing initiatives that are commonplace in other industries. If we were to offer or pay inappropriate inducements for the purchase, order or use of our SOPHiA platform and related solutions, products and services or our services, or our arrangements are perceived as inappropriate inducements, we could be subject to claims under various healthcare fraud and abuse laws. Restrictions under applicable U.S. federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute (the “AKS”), which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for, or to induce, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs;

- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of “designated health services” with whom the physician or a member of the physician’s immediate family has an ownership interest or compensation arrangements, unless a statutory or regulatory exception applies;

- the federal Eliminating Kickbacks in Recovery Act of 2018 (the “EKRA”) prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA’s reach extends beyond federal health care programs to include private insurance (i.e., it is an “all payor” statute). The full scope of such law is uncertain and is subject to a variety of interpretations;

- HIPAA, which established additional federal civil and criminal liability for, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by HITECH and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- federal false claims and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the federal government;

- the federal Physician Payments Sunshine Act requirements under the ACA, which require certain manufacturers of drugs, devices, biologics and medical supplies to report to CMS information related to payments and other transfers of value made to or at the request of physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the ACA, among other things, amended the intent requirement of the federal AKS and certain criminal healthcare fraud statutes. Where the intent requirement has been lowered, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may now assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the false claims statutes. Moreover, these laws may change significantly and adversely in the future.

Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including, among others, significant administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, integrity oversight and reporting obligations, and exclusion from participation in government-funded healthcare programs such as Medicare and Medicaid. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business, financial condition and results of operations.

Our employees, collaborators, distributors, agents, contractors and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, collaborators, distributors, agents, contractors or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, anti-corruption, environmental, competition, and patient privacy and other privacy laws and regulations. Misconduct by these parties could include intentional failures to comply with FDA, EMA, MHRA or other applicable regulations, including, without limitation, regulations governing the marketing, sale, labeling and use of RUO and IVD products, provide accurate information to the FDA, the EMA, the MHRA and comparable regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Such improper actions could subject us to civil, criminal and regulatory investigations, monetary and injunctive penalties, regulatory enforcement actions, fines and penalties, including regulatory prohibitions on offering our SOPHiA platform and related solutions, products and services in one or more countries or markets, and could adversely impact our ability to conduct business, operating results and reputation.

In addition, we are subject to the Foreign Corrupt Practices Act (the "FCPA") and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act 2010 and the French Law n° 2016-1691 (*Sapin II*). The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments, government purchasers and healthcare providers who are employed by governments. There is no certainty that all of our employees, collaborators, distributors, agents, contractors and collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. We have provisions in our Code of Business Conduct and Ethics (the "Code of Ethics"), an anti-corruption policy, certain provisions in some of our agreements with third parties, including our collaborators and distributors, and certain controls and procedures in place that are designed to mitigate the risk of noncompliance with anti-corruption and anti-bribery laws. However, it is not always possible to identify and deter misconduct by employees and agents, and the 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 government investigations or other actions stemming from a failure to comply with these laws or regulations. Violations of these laws and regulations could result in, among other things, significant administrative, civil and criminal fines and sanctions against us, our officers, or our employees, the closing down of our facilities, exclusion from participation in federal healthcare programs, implementation of compliance programs, integrity oversight and reporting obligations and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our SOPHiA platform and related solutions, products and services in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

We face risks related to handling of hazardous materials and other regulations governing environmental safety.

Our activities currently require and may in the future continue to require the use of hazardous chemicals and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples, and other human tissue. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to laws and regulations governing the use, storage, handling and disposal of these materials and specified waste services that both public officials and private individuals may seek to enforce. We could discover that we, an acquired business or our suppliers are not in material compliance with these regulations. The cost of compliance with these laws and regulations may become significant and could negatively affect our business, financial condition and results of operations. We do not carry specific biological waste or hazardous waste insurance coverage, workers' compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

If a clinical trial subject's or a clinical research study participant's informed consent is challenged or proven invalid, unlawful, or otherwise inadequate for our purposes, our product development efforts may be hindered and we could become involved in legal challenges.

We seek to ensure that all data and biological samples that we receive from our collaborators and customers have been collected from subjects or participants who have provided appropriate informed consent for purposes that extend to our development activities. We also strive to make sure such data and samples are provided to us in a subject de-identified manner. Our collaborators currently conduct clinical trials and clinical research studies in a number of different countries. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genomic material under a large number of different legal systems. Therefore, we rely on our collaborators and customers to comply with the informed consent requirements and with applicable local law and international regulation. The subject's or participant's informed consent obtained in any particular country could be challenged in the future, and those could prove invalid, unlawful or otherwise inadequate for our purposes. Any findings against us, or our collaborators and customers, could deny us access to or force us to stop using some of our data and clinical samples, which would hinder our product development efforts, potentially involve us in costly and prolonged litigation, result in reputational harm and adversely affect our business, financial condition and results of operations.

Healthcare reform measures could hinder or prevent the commercial success of our SOPHiA platform and related solutions, products and services.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system to contain costs, improve quality, and expand access to care, any of which may harm our future revenues and profitability and the demand for our SOPHiA platform and related solutions, products and services. In the United States, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of, or lower reimbursement for, the procedures associated with the use of our SOPHiA platform and related solutions, products and services.

For example, the ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. There have been executive and judicial challenges to certain aspects of the ACA, as well as efforts to repeal, replace or alter the implementation of certain aspects of the ACA. Further, the Biden administration has taken executive action relating to the ACA and access to healthcare. It is unclear how any such efforts as well as the healthcare reform measures of the current U.S. presidential administration will affect our business, financial condition and results of operations. In addition, other legislative changes have been adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020 through December 31, 2021. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

We expect that additional foreign and U.S. state and federal healthcare reform measures will be adopted in the future. The impact of those changes on us and potential effect on our industry as a whole is currently unknown, as we cannot predict what healthcare programs and regulations will ultimately be implemented or the effect of any future legislation or regulation on our business, financial condition and results of operations.

If we or our suppliers fail to comply with ongoing FDA or comparable regulatory authority requirements, or if we experience unanticipated problems with our research and diagnostic, they could be subject to restrictions or withdrawal from the market.

Any medical device that we manufacture, including those for which we obtain regulatory clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such diagnostic test, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and comparable regulatory authorities. In particular, we and our suppliers may be required to comply with the FDA's QSR for medical devices, the International Standards Organization ("ISO") 13485 standards for the manufacture of our diagnostic products and other regulations that cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any diagnostic test for which we obtain clearance or approval. Regulatory authorities enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and comparable regulatory authorities, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, one or more of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our diagnostics products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA of new diagnostics products or modified versions of such products currently manufactured;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted; and
- criminal prosecution.

In addition, we are required to conduct surveillance to monitor the safety or effectiveness of our research and diagnostic products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our research and diagnostic products. Later discovery of previously unknown problems with our diagnostic products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling restrictions on such products or manufacturing processes, withdrawal of the research and diagnostic products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties, which would adversely affect our business, operating results and prospects.

Risks Related to Intellectual Property

If we are not able to obtain, maintain, defend and enforce patent and other intellectual property protection or if the scope of such patent and other intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products, services and technology similar or identical to ours.

Our success depends in part on our ability to obtain, maintain, defend and enforce patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, as well as our ability to preserve our trade secrets and to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property and proprietary rights. Our ability to protect our products or services from unauthorized use by third parties depends on the extent to which valid and enforceable patents cover them or they are effectively protected as trade secrets. Although we have filed a number of patents, our patent portfolio is in an earlier stage of prosecution, and we own a limited number of issued patents related to our products and technology. For information regarding our patent portfolio, see "Item 4. Information on the Company—B. Business Overview—Intellectual Property."

The patent position of biotechnology and information technology companies generally is highly uncertain, 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. There can be no assurance that our patent rights will not be invalidated or held to be unenforceable, will adequately protect our technology, products or services or provide any competitive advantage, or that any of our pending or future patent applications will issue as valid and enforceable patents. Our ability to obtain and maintain patent protection for our methods and related solutions, products or services is uncertain due to a number of factors, including that:

- we or our licensors may not have been the first to invent the technology covered by our pending patent applications or issued patents;
- we or our licensors may not be the first to file all patent applications, as patent applications in the United States and most other countries are confidential for a period of time after filing;
- our methods and related solutions, products may not be patentable;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- others may independently develop identical, similar or alternative technologies;
- others may design around our patent claims to produce competitive technologies or methods or products that fall outside of the scope of our patents;
- we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable methods or products, may not provide any competitive advantages or may be successfully challenged by third parties;
- a third party may challenge our patents in court and, upon such a challenge, a court may not hold that our patents are valid, enforceable and non-infringing;
- a third party may challenge our patents in various patent offices and, if challenged, we may be compelled to limit the scope of our pending, allowed or granted claims or lose some or all of the pending, allowed or granted claims altogether;
- the patents of others could harm our business; and
- our competitors could conduct research and development activities in countries where we will not have enforceable patent rights and then use the information learned from such activities to develop competitive methods or products for sale in our major commercial markets.

While we will endeavor to protect our technology with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable, 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. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations or manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, we cannot guarantee that any patents will be issued from any of our pending or future patent applications. The standards applied by the U.S. Patent and Trademark Office (“the USPTO”) and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology or information technology patents. 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. As such, we do not know the degree of future protection that we will have on our proprietary products, services and technology. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

Even if we have or obtain patents, we may still be barred from making, using and selling such methods, products, or services because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop our technology or to successfully commercialize any approved assays alone or with collaborators. Patent applications in the United States and elsewhere are generally published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications could have been filed by others without our knowledge. Additionally, pending claims in patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies or related solutions, products and services. These patent applications may have priority over patent applications filed by us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to third party pre-issuance submissions of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our products, services and technology and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products or provide services without infringing third-party patent rights. Moreover, we, or our licensors, may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge priority of invention or other features of patentability. Such challenges may result in loss of patent rights, loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products, services and technology, or limit the duration of the patent protection of our products, services and technology. Such proceedings also may result in substantial cost and require significant time from our employees and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technology.

In addition, third parties may be able to develop technology that is similar to, or better than, ours in a way that is not covered by the claims of our patents or may have blocking patents that could prevent us from marketing our products or practicing our own patented technology. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed and the life of a patent, and the protection it affords, is limited. Without patent protection for current or future methods and related solutions, products and services, we may face competing technology. Given the amount of time required for the development and testing, and regulatory review where necessary, patents protecting such technology might expire before or shortly after such technology is commercialized. At the same time, given the rapid pace of technological advancement and innovation in the information technology field, the time needed to obtain patents for novel information technology solutions often renders the protection, once obtained, ineffective if the protected solution has become obsolete or widely-adopted while the patent protection was pending. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology similar or identical to that we or our collaborators may develop.

Moreover, certain of our patents and patent applications may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third party co-owners' interest in such patents or patent applications, such co-owners may be able to use or license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We may in the future be involved in lawsuits to defend or enforce our patents and proprietary rights. Such disputes could result in substantial costs or loss of productivity, delay or prevent the development and commercialization of our technology, products and services, prohibit our use of proprietary technology or put our patents and other proprietary rights at risk.

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and intellectual property rights or the patents and intellectual property rights of our licensors. The enforcement of such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent owned or in-licensed by us is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our owned and in-licensed patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly. In addition, our ability to enforce our patent or other intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service.

If we were to initiate legal proceedings against any other third party to enforce a patent covering our technology, the defendant could assert that our patent is invalid or unenforceable. In patent litigation in the United States and Europe, defendants alleging invalidity or unenforceability are common in response to a claim of infringement. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, overbreadth or lack of utility. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information or made a misleading statement. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to, our patents in such a way that they no longer cover our technology or products. The outcome of proceedings involving assertions of invalidity and unenforceability, including during patent litigation, is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution, but that an adverse third party may identify and submit in support of such assertions of invalidity. If a defendant 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 technology. Such a loss of patent protection could have a material adverse effect on our business. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

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. There can be no assurance that we will have sufficient financial or other resources to file and pursue infringement claims, which typically last for years before they are concluded. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or have used them without authorization, due to the associated expense and time commitment of monitoring these activities. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information could be compromised by disclosure during this type of litigation. There could also 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 material adverse effect on the price of our ordinary 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 commercialization activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Uncertainties resulting from patent and other intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace, our ability to raise additional funds, and could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

We may in the future be subject to claims against us alleging that we are infringing, misappropriating or otherwise violating the intellectual property rights of third parties, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our commercial success depends in part upon our ability to develop, manufacture, market and sell our products and services and use our proprietary technology without infringing, misappropriating or otherwise violating the patents or other intellectual property or proprietary rights of third parties. Litigation relating to infringement, misappropriation or other violations of patents and other intellectual property rights in the biotechnology industry is common, including patent infringement lawsuits, trade secret lawsuits, interferences, oppositions, and *inter partes* review, post-grant review and reexamination proceedings before the the USPTO, and corresponding international patent offices.

In the future, we may be subject to third-party claims and similar adversarial proceedings or litigation regarding any infringement, misappropriation or other violation by us of patent or other intellectual property rights of third parties. If any such claim or proceeding is brought against us, our collaborators or our third-party service providers, our development, manufacturing, marketing, sales and other commercialization activities could be similarly adversely affected. Even if we believe 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 third-party patents asserted against us are valid, enforceable and infringed, which could materially and adversely affect our ability to develop, manufacture, market, sell and commercialize any of our products or services. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe any third party's patents or other intellectual property rights, and we are unsuccessful in demonstrating that such patents or other intellectual property are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, marketing, selling and commercializing our products and services. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, which would give 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. We also could be forced, including by court order, to cease developing, manufacturing, marketing, selling and commercializing the infringing product or technology. 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. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. It is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may be unable to develop, manufacture, market, sell and commercialize products or services or perform research and development or other activities covered by these patents. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, many companies in intellectual property-dependent industries, including the biotechnology industry, have employed intellectual property litigation as a means to gain an advantage over their competitors. Furthermore, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology industry expands and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our products, services and technology may be subject to intellectual property-related claims by third parties.

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, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays or prohibit us from manufacturing, marketing, selling or otherwise commercializing our products, services and technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that our confidential information could be compromised by disclosure during this type of litigation. There could also 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 material adverse effect on the price of our ordinary 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 commercialization activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Uncertainties resulting from patent and other intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace, our ability to raise additional funds, and could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

We license patent rights from third-party owners. If such owners do not properly or successfully obtain, maintain, defend and enforce the patents underlying such licenses, or if they retain or license to others any competing rights, our competitive position and business prospects may be adversely affected. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our relationships with any of our licensors, we could lose license rights that are important to our business.

Even though we actively file patent applications, we also rely on intellectual property rights licensed from third parties to protect our technology, including licenses that give us rights to third-party intellectual property that is necessary or useful for our business. For example, we are dependent on licenses from Normandie Valorisation for certain products we commercialize. If one or both of our license agreements with Normandie Valorisation were to terminate for any reason, we may be required to cease the manufacturing, marketing, selling and commercialization of certain products. For more information regarding these license agreements, please see "Item 10. Additional Information —C. Material Contracts."

We also may license additional third-party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain, protect and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive rights. These licenses, and other licenses we may enter into in the future, may not provide adequate rights to use such intellectual property and proprietary technologies in all relevant fields of use or in all territories in which we may wish to develop or commercialize technology, products and services in the future. In some cases, patent prosecution of our licensed technology is controlled by the licensor. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, and maintained in a manner consistent with the best interests of our business. For example, under our license agreements with Normandie Valorisation, Normandie Valorisation controls the prosecution, maintenance and defense of the patents licensed to us pursuant to the agreements. Our licensors may not successfully prosecute the patent applications licensed to us, by failing to draft or prosecute the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. Even if patents issue or are granted, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue litigation less aggressively than we would. Further, we may not obtain exclusive rights, which would allow for third parties to develop competing products. In addition, our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If our licensors fail to obtain and maintain a patent or other protection for the proprietary intellectual property we license from such licensor, we could lose our rights to such intellectual property or the exclusivity of such rights, and our competitors could market competing technology using such intellectual property. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we or our collaborators may be unable to develop or commercialize the affected technology, which could adversely affect our competitive business position and harm our business prospects.

Our existing license agreements impose, and we expect that future license agreements will impose, various development, commercialization, royalty, diligence, patent prosecution and enforcement, and other obligations on us. If we breach any of these obligations, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in our being unable to commercialize related solutions, products or services that are covered by these agreements, which could materially adversely affect the value of any such technology and our business. In spite of our efforts, our licensors might conclude that we have breached our obligations under such license agreements, and might therefore terminate the license agreements. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in the products and services that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products and services, we may be unable to achieve or maintain profitability.

In addition, disputes may arise under our license agreements, including regarding the payment of the royalties or other payments due to licensors in connection with our exploitation of the rights we license from them. For example, licensors may contest the basis of royalties we retained and claim that we are obligated to make payments under a broader basis. In addition to the costs of any litigation we may face as a result, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors.

Disputes may arise regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- the amounts of royalties due under the license agreement;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the sublicensing of patent and other rights under the license agreements;
- the inventorship and ownership of inventions and know-how resulting from the creation or use of intellectual property by our licensors and by us and our collaborators; and
- the priority of invention of patented technology.

The agreements under which we currently license intellectual property or technology from third parties are 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. Such disputes may be costly to resolve and may divert management's attention away from day-to-day activities. If disputes over intellectual property that we have licensed from third parties prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we or our collaborators may be unable to successfully develop and commercialize the affected technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 noncompliance with these requirements.

Obtaining and maintaining a patent portfolio entails significant expense, including periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications, which must be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing collaborators to pay these fees due to U.S. and non-U.S. patent agencies. 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 are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. We may or may not choose to pursue or maintain protection for particular intellectual property in our portfolio. If we choose to forgo patent protection or to allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Furthermore, we employ reputable law firms and other professionals to help us comply with the various procedural, documentary, fee payment and other similar provisions we are subject to and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, 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 a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be successful in obtaining necessary rights to any products or services we may develop through acquisitions and in-licenses.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop certain products, services and technology. Many pharmaceutical companies, biotechnology companies and academic institutions are competing with us and filing patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses from such third-party intellectual property holders.

However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our business. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In-licensing patents covering our technology in all countries throughout the world may similarly be prohibitively expensive, if such opportunities are available at all. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection, or from selling or importing our technology in and into the United States or other jurisdictions.

We generally apply for patents in those countries where we intend to make, have made, use or offer for sale our products or services and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we may not seek protection in all countries where we will commercialize our products and services and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technology in jurisdictions where we do not pursue and obtain patent protection to develop their own assays and products and may export otherwise infringing assays and products to territories where we have patent protection, but where our ability to enforce our patent rights is not as strong as in the United States. These products and services may compete with technologies that we or our collaborators may develop, and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition.

The laws of some other countries do not protect intellectual property rights to the same extent as the laws of the United States. 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. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals or biotechnologies. As a result, many companies have encountered significant difficulties in protecting and defending intellectual property rights in certain jurisdictions outside the United States. Such issues may make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation or other violation of our other intellectual property rights. For example, many other countries, including countries in the EU, have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents and could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Furthermore, proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, subject our patents to the risk of being invalidated or interpreted narrowly, subject our patent applications to the risk of not issuing 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 to us, if any, may not be commercially meaningful, while the damages and other remedies we may be ordered to pay such third parties may be significant.

If we are unable to execute invention assignment agreements with our employees and consultants or protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our technology, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations or manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us.

We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that the assignment agreements that have been entered into are self-executing. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned by us. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets.

Moreover, our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets or seek to reverse-engineer our technology for which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We are also subject both in the United States and outside the United States to various regulatory schemes regarding requests for the information we provide to regulatory authorities, which may include, in whole or in part, trade secrets or confidential commercial information. While we are likely to be notified in advance of any disclosure of such information and would likely object to such disclosure, there can be no assurance that our challenge to the request would be successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We have in the past and may in the future be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed trade secrets or other confidential information of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

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

In addition, while it is our policy to require our employees and contractors 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 have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, cancelled or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may refuse to stop the other party from using the trademark at issue. We may not be able to protect our rights to these and other trademarks and trade names or may be forced to stop using these names, which we may need to build name recognition with potential collaborators or customers in our markets of interest.

We have certain trademark applications pending in the United States and abroad, but there can be no assurance that these applications will be allowed and not opposed. Any denial of our trademark applications or adverse ruling in any opposition proceedings could prevent us from differentiating our products and/or services and maintaining consistency across our brand. Even if these applications proceed to registration, third parties may challenge our use or registration of these trademarks in the future. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Other biotechnology companies may be using trademarks that are similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, they may infringe our trademarks and we may not have adequate resources to enforce our trademarks. If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Furthermore, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect our trademarks and impede our marketing efforts in the countries in which we operate. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Our use of “open-source” software could subject our proprietary software to general release, adversely affect our ability to sell our products or provide our services, and subject us to possible litigation.

A portion of the products or technologies licensed, developed or distributed by us incorporate so-called “open-source” software, and we may incorporate open-source software into other products or technologies in the future. Such open-source software is generally licensed by its authors or other third parties under open-source licenses. Some open-source licenses may contain requirements that we disclose source code for modifications we make to the open-source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open-source software could require that we disclose and license some or all of our proprietary code in that software as well as distribute our products that use particular open-source software at no cost to the user.

We monitor our use of open-source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open-source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of certain of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies.

Companies that incorporate open-source software into their products have, in the past, faced claims seeking enforcement of open-source license provisions and claims asserting ownership of open-source software incorporated into their product. If an author or other third party that distributes such open-source software were to allege that we had not complied with the conditions of an open-source license, we could incur significant legal costs from defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open-source software in certain ways, under some open-source licenses we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products and services that are similar to or better than ours and otherwise have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect their products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. 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 a 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. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our products or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications are 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. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of healthcare technology 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, recent U.S. Supreme Court decisions have served to curtail the scope of subject matter eligible for patent protection in the United States, and many software patents have since been invalidated on the basis that they are directed to abstract ideas. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, federal courts, and USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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 provide services that are similar to ours but that are not protected by our intellectual property;
- we or our licensors might not have been the first to make the inventions covered by our patents;
- we or our licensors might not have been the first to file patent applications covering certain of our or their inventions;
- others may seek to file provisional applications in the United States, thereby securing an earlier priority date that would prevent us from securing intellectual property rights in the same market space;

- others, including inventors or developers of our owned or in-licensed patented technologies who may become involved with competitors, 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 in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents;
- issued patents for which we have rights may not provide us with any competitive advantage and may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors might conduct research and development activities in countries where we do not have patent rights or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products and services in our commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents or pending or future applications of third parties, if issued, may harm our business; and
- we or our licensors 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 have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Financial Position and Capital Requirements

We have incurred net losses since our inception and expect to continue to incur losses for the foreseeable future. We may never achieve or sustain profitability.

We have incurred losses since our inception and expect to continue to incur losses for the foreseeable future. For the years ended December 31, 2021 and 2020, we reported net losses of $73.7 million and $39.3 million, respectively. As of December 31, 2021, we had an accumulated deficit of $211.4 million.

We expect to continue to incur net losses for the foreseeable future as we continue to devote substantial resources to (i) research and development, in particular to further expand the features, applications and data modalities of our SOPHiA platform in order to accommodate multimodal data analytics capabilities across a wide range of disease areas; (ii) expanding selling and marketing efforts for our SOPHiA platform, in particular to drive new customer adoption with clinical customers and biopharmaceutical companies; (iii) establishing and maintaining relationships with our collaborators and customers across the healthcare system; and (iv) obtaining regulatory clearance or approval to offer our products as IVD products for diagnostic use. We may encounter unforeseen expenses, difficulties, complications, delays and unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of growth of our expenses and of our revenue. In addition, we have incurred and expect to continue to incur increased general and administrative expenses associated with operating as a public company. Our net losses may fluctuate significantly from quarter to quarter and from year to year.

Because of the numerous risks and uncertainties associated with our research and development and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve or sustain profitability would depress our market value and could impair our ability to execute our business plan, raise capital, develop additional products and services and continue our operations. A decline in the value of our company could cause our shareholders to lose all or part of their investment.

We may need to raise additional capital to fund our existing operations, further develop our SOPHiA platform and products, commercialize our products and services and expand our operations.

Since our inception, we have used substantial amounts of cash. The research and development process as well as selling and marketing efforts are capital intensive and we expect that we will continue to expend substantial resources for the foreseeable future to develop, commercialize and market additional features, applications and data modalities of our SOPHiA platform and related solutions, products and services. In addition, we may also raise capital to expand our business and pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- fund research and development efforts of our SOPHiA platform and related solutions, products and services or any other future platforms, products and services, in particular biopharma services;
- increase our sales and marketing efforts to drive market adoption of our SOPHiA platform and related solutions, products and services and to address competitive developments;
- acquire, license or invest in complementary technologies and platforms;
- 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;
- our ability to secure any required regulatory clearance or approval for additional features, applications and data modalities of our SOPHiA platform and related solutions, products and services;
- the ability of our customers and collaborators to secure any required regulatory clearance or approval for their product candidates, other products and services the development of which they rely on our SOPHiA platform and related solutions, products and services;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our SOPHiA platform and related solutions, products and services;
- the rate of progress in establishing payor coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors by us with respect to our products, if approved for IVD use, and by our customers and collaborators, with respect to their product candidates, other products and services;
- the cost of expanding our research and development, manufacturing and laboratory operations and products and services offerings;
- our ability to maintain and expand our collaborations with biopharmaceutical companies, both advanced and early stage, and reference and specialist laboratories;
- our rate of progress in, and cost of research and development activities associated with, early research and development efforts;
- the effect of competing technological and market developments;
- market acceptance of our platform, solutions, products and services;
- costs related to international expansion; and
- the potential cost of, and delays in, product development as a result of regulatory oversight.

We do not have any committed external source of funds and additional funds may not be available when we need them or on terms that are acceptable to us. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from the COVID-19 pandemic and other factors could adversely impact our ability to access capital as and when needed. Further, as a Swiss company, we have less flexibility to raise capital, particularly in a quick and efficient manner, as compared to U.S. companies. See "—Risks Related to Our Securities—Our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs." If adequate funds are not available to us on a timely basis or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our research and development, commercialization and growth efforts.

We may seek additional capital through a variety of means, including through public and private equity offerings and debt financings, credit and loan facilities and collaborations. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such equity or convertible debt securities may include liquidation or other preferences that are senior to or otherwise adversely affect your rights as a shareholder. If we raise additional capital through the sale of debt securities or through entering into credit or loan facilities, we may be restricted in our ability to take certain actions, such as incurring additional debt, making capital expenditures, acquiring or licensing intellectual property rights, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. If we raise additional capital through collaborations with third parties, we may be required to relinquish valuable rights to our intellectual property, technology and products or we may be required to grant licenses for our intellectual property, technology and products on unfavorable terms.

Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause the price of our ordinary shares to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly. This fluctuation may be as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, including:

- the level of demand for our SOPHiA platform and related solutions, products and services;
- the timing and cost of development, enhancement and manufacturing, as applicable, of our SOPHiA platform and related solutions, products and services;
- expenditures that we may incur to acquire, develop or commercialize additional technologies, platforms, products and services;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- the length of time of the sales cycle for purchases of our SOPHiA platform and related solutions, products and services, which can last up to six months;
- the timing of customer billing and collection;
- any defaults on large contracts by our customers;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future collaborators;
- coverage and reimbursement policies with respect to our SOPHiA platform and related solutions, products and services;
- positive or negative coverage, or public perception, of our SOPHiA platform and related solutions, products and services or those of our competitors or broader industry trends;
- the impact of the COVID-19 pandemic, and the resulting effects on the demand for our COVID-19 research and surveillance platform;

- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our SOPHiA platform and related solutions, products and services;
- changes in governmental regulations or in the status of regulatory approvals or applications;
- pricing discounts and incentives for our research and diagnostic products; and
- general market and economic conditions.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual financial results. Because a substantial portion of our expenses are relatively fixed in the short-term and require time to adjust, our results of operations and liquidity would suffer if revenue falls below our expectations in a particular period. In addition, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of future performance.

If our operating results fall below the expectations of investors or securities analysts, the price of our ordinary shares could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our ordinary shares to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

A limited number of distributors collectively account for a substantial portion of sales of our SOPHiA platform and related solutions, products and services.

For the years ended December 31, 2021 and 2020, 48 and 38 distributors collectively accounted for 34% and 23% of revenue, respectively. We expect that a relatively small number of our distributors will continue to account for significant portion of our revenues in the foreseeable future. Our reliance on a few distributors may expose us to the risk of substantial losses if a single large distributor stops offering access to our platform, services and products, purchases lower quantities of our products or goes out of business and we cannot find substitute distributors on equivalent terms. Most of our distribution relationships are non-exclusive and permit such distributors to distribute competing products. As such, our distributors may not commit the necessary resources to market our products to the level of our expectations or may choose to favor marketing the products of our competitors. If any of our significant distributors reduces the quantity of the research and diagnostic products they purchase from us or stops purchasing from us, our revenue would be materially and adversely affected.

We may not be able to sufficiently reduce our costs to achieve sustainable gross margins.

Operating our business is costly, and we expect our expenses to continue to increase in the future as we broaden our customer base and expand our platform, services and product offerings. In particular, a significant portion of our business, including our SOPHiA platform, is provided through a cloud-based SaaS platform and computational and storage-related costs and fees constitute a significant portion of our cost of revenue. While we seek to negotiate favorable economic arrangements with respect to computational and storage-related costs and fees, in the near term, we expect that our gross profit margin will be adversely impacted by such fees and costs as we have purchased, and may be required to continue to purchase, increased capacity at less favorable rates in order to address increased demand for our SOPHiA platform and related solutions, products and services. Further, these hosting services depend on the uninterrupted operation of data centers as well as high-quality customer support. In addition, we collaborate with manufacturers in the assembly and development of our research and diagnostic products, in particular DNA enrichments kits. For example, we rely on our manufacturing and supply agreements with third parties, including IDT, Twist and Qiagen, for the manufacture of the DNA enrichments kits, which we assemble and offer to our clients as part of “bundle” solutions together with our SOPHiA platform. While we are undertaking a number of initiatives designed to reduce our costs, including provisions in our manufacturing and supply agreements that limit our counterparty’s ability to increase prices for the manufactured products if certain conditions are met by us, and expect that our gross margin will increase as we broaden our customer base and increase customer engagement, there can be no assurance that we will be able to achieve planned cost reductions. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our products, increased costs of hosting and consumer support services, changes to labor costs or less favorable terms with third-party suppliers, service providers or manufacturing collaborators. In addition, if our platform, services and product mix becomes more customer-specific and diversified, our costs may increase. If we are unable to

reduce our costs, or if cost reductions are less significant or less timely than those we project, we will not be able to achieve sustainable gross margins, which would adversely affect our ability to invest in and grow our business.

We customize a substantial portion of our research and diagnostic products to address the needs of individual customers and collaborators. If we cannot sell our customized products in the event an order is cancelled, we may be unable to cover our costs and may be left with substantial unsaleable inventory, which could have a material adverse effect on our financial condition and results of operations.

We assemble a substantial portion of our products to address the needs of individual customers. Some of the agreements with our customers require us to cover the initial manufacturing and assembly costs of such products, which means that we will be paid only upon delivery of such products to our customers. If our customers fail to purchase these customized products from us in sufficient quantities, do not purchase such products from us at all or otherwise fail to perform their obligations under the agreements with us, we may bear the full cost of manufacturing and assembling of such products, fail to cover our costs and have substantial unsaleable inventory, each of which could have a material adverse effect on our financial condition and results of operations.

Our ability to use tax loss carryforwards in Switzerland, the United States and other jurisdictions may be limited.

We are entitled to carry forward losses incurred in Switzerland, the United States and other jurisdictions in which we conduct business, which could be used to offset future taxable income. Due to our limited income, there is a significant risk that our tax loss carryforwards will expire in part or in their entirety and cannot be used to offset future taxable income for corporate income tax purposes. Furthermore, any tax loss carryforwards that we report on our tax returns are subject to review and confirmation by the competent tax authorities in their tax assessment of the tax year for which the tax loss carryforwards are used to offset taxable income. Consequently, we are exposed to the risk that the competent tax authorities may not accept the reported tax loss carryforwards in part or in their entirety.

Changes in tax laws or the interpretation of tax laws could have a material impact on our financial condition.

We are subject to standard corporate income taxation. The standard effective corporate tax rates in Saint-Sulpice, Canton of Vaud, Switzerland, can change from time to time. However, we expect that the standard combined (federal, cantonal, communal) effective corporate income tax rate, except for dividend income for which we could claim a participation exemption, for 2022 in Saint-Sulpice will be approximately 13%. We are also subject to corporate income taxation in other jurisdictions in which currently operate, including France, the United States, the UK, Brazil and Australia.

In addition, in view of the ongoing implementation of the OECD G20 Base Erosion and Profit Shifting Project and the EU anti-avoidance tax package, the existing transfer pricing system and our intercompany relationships could be challenged by the competent tax authorities, resulting in additional taxes, interest and penalties in case of profit add-backs, non-deductible expenses or objections to the transfer pricing documentation. A focus area is the taxation and allocation of profits generated from intangibles where the DEMPE (Development, Enhancement, Maintenance, Protection and Exploitation) functions will become more relevant compared to the pure bearing of costs. This may impact the taxation of our group profits and may impact our effective tax rate. These and other changes in tax laws or the interpretation of tax laws in Switzerland, France, the United States, the UK, Brazil, Australia and other jurisdictions in which we currently operate or will operate in the future, could have a material adverse effect on our financial condition.

We are subject to risks related to taxation in multiple jurisdictions.

We are subject to income taxes in Swiss and foreign jurisdictions. Significant judgments based on interpretations of existing tax laws or regulations may be required in determining our provision for income taxes. Our effective income tax rate could be adversely affected by various factors, including, but not limited to, changes in the mix of earnings in tax jurisdictions with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in existing tax policies, laws, regulations or rates, changes in the level of non-deductible expenses (including share-based compensation), changes in the location of our operations, changes in our future levels of research and development spending, mergers and acquisitions or the result of examinations by various tax authorities. Although we believe our tax estimates are reasonable, if taxing authorities disagree with the positions taken on our tax returns, we could have additional tax liability, including interest and penalties.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

We operate internationally and a meaningful portion of our revenue, expenses, assets and liabilities are denominated in currencies other than the U.S. dollar, our presentation currency, and the Swiss franc, SOPHiA GENETICS SA's functional currency. In preparing our consolidated financial statements, those revenues, expenses, assets and liabilities are translated into U.S. dollars at applicable exchange rates. Increases or decreases in exchange rates between the U.S. dollar and other currencies affect the U.S. dollar value of those items, as reflected in the consolidated financial statements. We expect that a significant part of our revenues and expenses will continue to be denominated in currencies

other than the U.S. dollar, including the euro and Swiss franc, and to a lesser extent, British pound, Australian dollar, Brazilian real, Turkish lira and Canadian dollar. Therefore, unfavorable developments in the value of the U.S. dollar relative to other relevant currencies could adversely affect our results of operations, financial condition and liquidity.

The exchange rates of the U.S. dollar and other currencies are affected by many factors, including forces of supply and demand in the foreign exchange markets and global economic events. These rates are also affected by the international balance of payments and other economic and financial conditions, government intervention, speculation and other factors. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar and even if we engage in hedging operations in the future, there can be no assurance as to the success of any hedging operations that we may implement. Foreign currency fluctuations may adversely affect our results of operations, financial condition and liquidity.

We are subject to risks related to the accounting treatment of our pension and other post-employment benefit plans.

We provide retirement benefits to our employees as required by Swiss law by means of a pension fund that is maintained by a life insurance company. The life insurance company operates a pension plan for all of our employees as a defined benefit plan under International Accounting Standard ("IAS") 19, *Employee Benefits* ("IAS 19"). As of December 31, 2021, we reported an employee benefit obligation, before deduction of plan assets, of $17.9 million in accordance with IAS 19. The obligation represents our projected obligations towards current and future pensioners discounted at an annual rate of 0.40%. Under Swiss statutory rules and pursuant to our contract with the group life assurance provider, all risks including investment risk are fully covered. That said, no underfunding exists under Swiss law. The variance between Swiss statutory rules and IFRS is apparent in many Swiss companies, and the IFRS obligation of our pension plan does not necessarily reflect a true payment obligation under Swiss law because Swiss law allows us to maintain flexibility to adjust benefit levels under the plans and we could use this flexibility to mitigate any liability. For more information, see Note 22—"Post-employment benefits" to the audited consolidated financial statements included elsewhere in this Annual Report. However, should the Swiss statutory rules at any time require a determination that our pension plan is significantly underfunded, we could be obliged to make additional contributions to the pension plan in addition to our obligation to make regular contributions as defined in the pension plan regulation. If such risk materializes, this could have a material adverse effect on our financial position or results of operations.

As a result of being a public company, we have incurred and expect to continue to incur additional costs, and we may not manage to comply with our internal control procedures and corporate governance structures.

To comply with the requirements imposed on us as a public company, we have incurred and expect to continue to incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. The increased costs may require us to reduce costs in other areas of our business. In addition, our board of directors, management and administrative staff are required to perform additional tasks. We have invested and intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment has resulted and will continue to result in increased general and administrative expenses and may divert management's time and attention from research and development activities. These laws, regulations and standards are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters, enforcement proceedings and higher costs necessitated by ongoing revisions to disclosure and governing practices, which could have a material adverse impact on our business, financial condition, results of operations and prospects.

We have elected to reserve capital under our directors and officers insurance policy to reduce the associated premiums. Our use of such designated capital for other purposes could increase our premiums.

We currently hold $30.0 million in a separate bank account to be used exclusively to settle potential liabilities arising from claims against our directors and officers. Our use of such a designated account reduces our directors and officers insurance premiums below those that we would pay absent such a designated account. Therefore, our current insurance premiums may not reflect those that we will incur in the future. Although we expect to continue to hold cash in a separate bank account for such purposes, we are under no obligation to do so and may withdraw the funds at any time, in which case we expect our insurance premiums to increase significantly. In addition, our practice diverts capital that can be used for other purposes, and there can be no assurance that the benefits of our practice (in the form of lower insurance premiums) outweigh the costs of such practice (in the form of benefits foregone by not deploying the reserved capital for other purposes). Moreover, our insurance provider may require additional capital to be reserved in the future in order to maintain our insurance premiums at current levels or reduce the rate of increases in our insurance premiums, and we may

be unable to meet such requirements or we may find it disadvantageous to do so, which would increase our insurance premiums.

Risks Related to Our Securities

The market price of our ordinary shares may be volatile and may fluctuate due to factors beyond our control.

The market price of our ordinary shares could be subject to wide fluctuations in response to many risk factors listed in this “Risk Factors” section, some of which are beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- effectiveness, accuracy and efficiency of our SOPHiA platform and related solutions, products and services;
- public concern relating to the commercial value or safety of any of our SOPHiA platform and related solutions, products and services;
- the timing and results of multimodal clinical studies of our SOPHiA platform;
- our inability to adequately protect our proprietary and intellectual property rights, including patents, trademarks and trade secrets;
- our inability to raise additional capital and the terms on which we raise it;
- our ability to enter into strategic collaboration or licensing agreements and the commencement, termination and terms of such agreements;
- regulatory developments, including actions with respect to our and our competitors’ platforms, products and services;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts’ projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our ordinary shares by us, our insiders or our other shareholders;
- changes in market conditions for our industry, including changes in the structure of healthcare payment systems; and
- changes in general market and economic conditions.

In addition, the stock market has historically experienced significant volatility, particularly with respect to healthcare technology company stocks. As we operate in a single industry, we are particularly vulnerable to these factors to the extent that they affect our industry, or to a lesser extent, our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This risk is particularly relevant for healthcare technology companies, which have experienced significant stock price volatility in recent years. Securities litigation could result in substantial costs and divert our management’s attention and resources and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Future sales, or the possibility of future sales, of a substantial number of our ordinary shares could adversely affect the price of our ordinary shares.

Future sales of a substantial number of our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ordinary shares. Ordinary shares that were issued prior to our initial public offering can be sold pursuant to Rule 144 under the Securities Act, subject to current public information and volume and manner of sale limitations applicable to affiliates. In addition, we have registered under the Securities Act all ordinary shares that we may issue under our share-based compensation plans, such that they can be freely sold in the public market upon

issuance, subject to volume limitations applicable to affiliates. If our shareholders sell substantial numbers of ordinary shares in the public market or if the market perceives that such sales may occur, the market price of our ordinary shares and our ability to raise capital through the issuance and sale of equity or equity-linked securities in the future could be adversely affected.

Under Swiss law, shareholders benefit from pre-emptive rights to subscribe on a pro rata basis for issuances of equity or other securities that are convertible into equity, unless such pre-emptive rights are excluded in accordance with Swiss law and our articles of association. However, due to the laws and regulations in certain jurisdictions, shareholders in certain jurisdictions may not be able to exercise such rights, unless the company registers or otherwise qualifies the rights offering, including by complying with Annual Report requirements under the laws of that jurisdiction. There can be no assurance that we will take any action to register or otherwise qualify an offering of subscription rights or shares under the laws of any jurisdiction where the offering of such rights is restricted, other than the United States. If shareholders in such jurisdictions are unable to exercise their subscription rights, their ownership interest will be diluted.

We have never paid dividends and do not expect to pay any dividends in the foreseeable future.

Since inception, we have not paid any dividends. Even if future operations lead to significant levels of distributable profits, we currently intend to reinvest any earnings in our business and do not anticipate declaring or paying any dividends until we have an established revenue stream to support dividend payments. In addition, any proposal for the payment of future dividends will be at the discretion of our board of directors after taking into account various factors including our business prospects, liquidity requirements, financial performance and new product development. Furthermore, payment of future dividends is subject to certain limitations pursuant to our current and future debt instruments, Swiss law and our articles of association. See “Item 10. Additional Information—Memorandum and Articles of Association.” Accordingly, investors cannot rely on dividend income from our ordinary shares, and any returns on an investment in our ordinary shares will likely depend entirely upon any future appreciation in the price of our ordinary shares.

If securities or industry analysts publish inaccurate or unfavorable research about our business or case to publish research about our business, the price of our ordinary shares and our trading volume could decline.

The trading market for our ordinary shares depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about us or our business, the price of our ordinary shares will likely decline. In addition, if our operating results fail to meet the forecast of analysts, the price of our ordinary shares will likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause the price of our ordinary shares and trading volume to decline.

The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

We are a Swiss corporation. Our corporate affairs are governed by our articles of association and by the laws governing companies, including listed companies, incorporated in Switzerland. The rights of our shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and directors of companies governed by the laws of U.S. jurisdictions.

In the performance of its duties, our board of directors is required by Swiss law to consider the interests of our company, our shareholders, our 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, shareholders’ interests. Swiss law limits the ability of our shareholders to challenge resolutions made or other actions taken by our board of directors in court. Our shareholders generally are not permitted to file a suit to reverse a decision or an action taken by our board of directors, but are instead only permitted to seek damages for breaches of fiduciary duty. As a matter of Swiss law, shareholder claims against a member of our board of directors for breach of fiduciary duty would have to be brought to the competent courts in Lausanne, Canton of Vaud, Switzerland, or where the relevant member of our board of directors is domiciled. In addition, under Swiss law, any claims by our shareholders against us must be brought exclusively to the competent courts in Lausanne, Canton of Vaud, Switzerland. For a further summary of applicable Swiss company law contained in this Annual Report, see “Item 10. Additional Information—Memorandum and Articles of Association.” However, there can be no assurance that Swiss law will not change in the future, which could adversely affect the rights of our shareholders, or that Swiss law will protect our shareholders in a similar fashion as under U.S. corporate law principles.

Our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs.

Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, the payment of dividends and cancellation of treasury shares must be approved by shareholders. Swiss law also requires that our shareholders themselves resolve to, or authorize our board of directors to, increase our share capital. While our shareholders may authorize share capital that can be issued by our board of directors without additional shareholder approval, Swiss law limits this authorization to 50% of the issued share capital at the time of the authorization. The authorization, furthermore, has a limited duration of up to two years and must be renewed by the shareholders from time to time thereafter in order to be available for raising capital. Additionally, subject to specified exceptions, including exceptions explicitly described in our articles of association, Swiss law grants pre-emptive subscription rights to existing shareholders to subscribe for new issuances of shares. Swiss law also does not provide as much flexibility in the various rights and regulations that can attach to different categories of shares as do the laws of some other jurisdictions. These Swiss law requirements relating to our capital management may limit our flexibility, and situations may arise where greater flexibility would have provided benefits to our shareholders. See “Item 10. Additional Information—Memorandum and Articles of Association.”

Our ordinary shares are not listed in Switzerland, our home jurisdiction. As a result, our shareholders will not benefit from certain provisions of Swiss law that are designed to protect shareholders in a public takeover offer or a change-of-control transaction.

Because our ordinary shares will be listed exclusively on Nasdaq and not in Switzerland, our shareholders will not benefit from the protection afforded by certain provisions of Swiss law that are designed to protect shareholders in the event of a public takeover offer or a change-of-control transaction. For example, Article 120 of the Swiss Financial Market Infrastructure Act and its implementing provisions require investors to disclose their interest in our company if they reach, exceed or fall below certain ownership thresholds. Similarly, the Swiss takeover regime imposes a duty on any person or group of persons who acquires more than one-third of a company’s voting rights to make a mandatory offer for all of the company’s outstanding listed equity securities. In addition, the Swiss takeover regime imposes certain restrictions and obligations on bidders in a voluntary public takeover offer that are designed to protect shareholders. However, these protections are applicable only to issuers that list their equity securities in Switzerland, and because our ordinary shares will be listed exclusively on Nasdaq, they will not be applicable to us. Furthermore, since Swiss law restricts our ability to implement rights plans or U.S.-style “poison pills,” our ability to resist an unsolicited takeover attempt or to protect minority shareholders in the event of a change-of-control transaction may be limited. Therefore, our shareholders may not be protected in the same degree in a public takeover offer or a change-of-control transaction as are shareholders in a Swiss company listed in Switzerland.

U.S. shareholders may not be able to obtain judgments or enforce civil liabilities against us or our executive officers or members of our board of directors.

We are organized under the laws of Switzerland and our registered office and domicile is located in Saint-Sulpice, Canton of Vaud, Switzerland. Moreover, a number of our directors and executive officers are not residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon us or upon such persons or to enforce against them judgments obtained in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our Swiss counsel that there is doubt as to the enforceability in Switzerland of original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent solely predicated upon the U.S. federal and state securities laws. Original actions against persons in Switzerland based solely upon the federal or state securities laws are governed, among other things, by the principles set forth in the Swiss Federal Act on Private International Law (the “PILA”). This statute provides that the application of provisions of non-Swiss law by the courts in Switzerland shall be precluded if the result is incompatible with Swiss public policy (*ordre public*). Also, certain mandatory provisions of Swiss law may be applicable regardless of any other law that would otherwise apply.

Switzerland and the United States do not have a treaty providing for reciprocal recognition and enforcement of judgments in civil and commercial matters. The recognition and enforcement of a judgment of the courts of the United States in Switzerland is governed by the principles set forth in the PILA. This statute provides in principle that a judgment rendered by a non-Swiss court may be enforced in Switzerland only if:

- the non-Swiss court had jurisdiction pursuant to the PILA;

- the judgment of such non-Swiss court has become final and non-appealable;
- the judgment does not contravene Swiss public policy;
- the court procedures and the service of documents leading to the judgment were in accordance with the due process of law; and
- no proceeding involving the same parties and the same subject matter was first brought in Switzerland, or adjudicated in Switzerland, or was earlier adjudicated in a third state, and this decision is recognizable in Switzerland.

Anti-takeover provisions in our articles of association could make an acquisition of us, which may be beneficial to our shareholders, more difficult.

Our articles of association contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us that shareholders may consider favorable, including transactions in which our shareholders may receive a premium for their shares. Our articles of association include provisions that:

- in certain cases, allow our board of directors to place up to 29,000,000 ordinary shares and rights to acquire an additional 29,000,000 ordinary shares (in aggregate, 45% of our share capital) with affiliates or third parties, without existing shareholders having statutory pre-emptive rights in relation to this share placement;
- allow our board of directors not to record any acquirer of ordinary shares, or several acquirers acting in concert, in our share register as a shareholder with voting rights with respect to more than 15% of our share capital as set forth in the commercial register;
- limit the exercise of voting rights by shareholders, acting alone or in concert with others, to a maximum of 15% of the share capital recorded in the commercial register;
- limit the size of our board of directors to seven members; and
- require two-thirds of the votes represented at a general meeting of the shareholders for amending or repealing most of the above-mentioned authorizations to place shares as well as the above-mentioned voting and recording restrictions, for amending the provision setting a maximum board size or providing for indemnification of our directors and members of our executive committee and for removing the chairman or any member of the board of directors before the end of his or her term of office.

These and other provisions, alone or together, could delay or prevent takeovers and changes in control. See “Item 10. Additional Information—Memorandum and Articles of Association.” These provisions could also limit the price that investors might be willing to pay in the future for our ordinary shares, thereby depressing the market price of our ordinary shares.

There can be no assurance that we will not be a passive foreign investment company for any taxable year, which could subject United States investors in our ordinary shares to significant adverse U.S. federal income tax consequences.

Under the Internal Revenue Code of 1986, as amended (the “Code”), we will be a passive foreign investment company (“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” (including cash). Passive income generally includes dividends, interest, certain non-active rents and royalties, and capital gains. We do not believe that we were a PFIC for our 2021 taxable year. However, there can be no assurance that the Internal Revenue Service (the “IRS”), will agree with our conclusion. In addition, whether we were a PFIC in 2021 or will be a PFIC in any future year is uncertain because, among other things, (i) we hold a substantial amount of cash, which is generally categorized as a passive asset; and (ii) our PFIC status for any taxable year will depend on the composition of our income and assets and the value of our assets from time to time (which may be determined, in part, by reference to the market price of our ordinary shares, which could be volatile). Accordingly, there can be no assurance that we will not be a PFIC for any taxable year.

If we are a PFIC for any taxable year during which a U.S. investor holds ordinary shares, we generally 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 ordinary shares, even if we ceased to meet the threshold requirements for PFIC status. 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. A "mark-to-market" election may be available that will alter the consequences of PFIC status if our ordinary shares are regularly traded on a qualified exchange. For further discussion, see "Item 10. Additional Information—E. Taxation—Material U.S. Federal Income Tax Consequences for U.S. Holders."

Risks Related to Our Status Under U.S. Securities Laws

We are a foreign private issuer, and, as a result, we are not subject to certain rules and obligations that are applicable to a U.S. domestic public company and are not subject to certain Nasdaq corporate governance listing standards that are applicable to a Nasdaq-listed U.S. domestic public company.

We 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 and although we intend to furnish quarterly financial information to the SEC, 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 stock 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 financial year, while U.S. domestic issuers are required to file their annual report on Form 10-K in less time. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information.

Furthermore, because we are a foreign private issuer, we comply with our home country governance requirements and certain exemptions thereunder, rather than complying with certain of the Nasdaq corporate governance listing standards that are applicable to U.S. companies listed on Nasdaq. For example, we are exempt from Nasdaq listing standards that require a listed U.S. company to have (i) a majority of the board of directors consist of independent directors, (ii) regularly scheduled executive sessions with only independent directors and (iii) a compensation committee and a nomination and corporate governance committee consisting entirely of independent directors. Furthermore, Nasdaq listing standards generally require Nasdaq-listed U.S. companies to, among other things, seek shareholder approval for the implementation of certain equity compensation plans and issuances of securities, which we are not required to follow as a foreign private issuer. Accordingly, our shareholders may not have the same protections afforded to shareholders of companies that are not foreign private issuers. For an overview of the material differences between our governance principles and Nasdaq corporate governance listing standards, see "Item 16G—Corporate Governance."

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 qualify as 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. We may no longer be a foreign private issuer as of June 30, 2022, which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers, as of January 1, 2023. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors 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 lose this status, we will 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 under U.S. securities laws, if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer, may be significantly higher than the cost 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. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would be more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to retain and attract qualified members of our board of directors.

We are an emerging growth company, and the reduced reporting requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements and (iii) exemptions from the requirements of holding a non-binding advisory vote on executive compensation.

We could be an emerging growth company for up to five years from our initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates equals or exceeds $700.0 million as of any June 30 (the end of our second fiscal quarter) before that time or if we have total annual gross revenues of $1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 (our fiscal year end); or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile. When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort towards ensuring compliance with them, and we cannot predict or estimate the amount or timing of such additional costs.

Item 4. Information on the Company

A. History and Development of the Company

SOPHiA GENETICS SA was incorporated as a Swiss stock corporation (*société anonyme*) under the laws of Switzerland on March 18, 2011. Our principal executive office is located at Rue du Centre 172, CH-1025 Saint-Sulpice, Switzerland and our telephone number is +41 21 694 10 60. Our agent for service of process in the United States is SOPHiA GENETICS, Inc., 185 Dartmouth Street, Suite 502, Boston, MA 02116, and its telephone number is (617) 982-1210.

Our website is www.sophiagenetics.com. The reference to our website is an inactive textual reference only and information contained therein or connected thereto are not incorporated into this Annual Report. We 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 site at www.sec.gov that contains reports, proxy and information statements and other information we have filed electronically with the SEC.

In July 2021, we completed our initial public offering on the Nasdaq Global Select Market ("Nasdaq") and our ordinary shares are listed under the ticker symbol "SOPH".

B. Business Overview

Our Mission

SOPHiA GENETICS was founded to generate clinically actionable insights from data to improve patient outcomes. Our mission is to provide equal access to knowledge and capabilities by democratizing data-driven medicine.

We observed that across the healthcare ecosystem, a vast amount of digital healthcare data was being generated, fueled by technologies such as NGS, and which held promise to accelerate the understanding of biology and disease. However, this data has been generated primarily using non-standardized methods and by clinicians and researchers across many healthcare institutions. As a result, the data remained siloed and complex and was not fully leveraged for the benefit of patients.

We founded SOPHiA GENETICS to change this. We are unlocking data silos, leveraging AI to generate actionable insights from data and helping healthcare professionals work together as a community and deploy their collective expertise for the benefit of patients around the world.

We refer to data-driven medicine as the practice of drawing insights from complex data sets to improve diagnosis, treatment and drug development. Using data-driven medicine, healthcare professionals supplement their own experience and intuition with data insights and shared knowledge from their peers to inform the best course of action for their patients or research. Our goal is to empower clinicians and researchers around the world to practice data-driven medicine and improve clinical and scientific outcomes.

Overview

We are a healthcare technology company dedicated to establishing the practice of data-driven medicine as the standard of care and for life sciences research. We purposefully built a cloud-based SaaS platform capable of analyzing data and generating insights from complex multimodal data sets and different diagnostic modalities. Our platform standardizes, computes and analyzes digital health data and is used across decentralized locations to break down data silos. This enables healthcare institutions to share knowledge and experiences and to build a collective intelligence. We envision a future in which all clinical diagnostic test data is channeled through a decentralized analytics platform that will provide insights powered by large real-world data sets and AI. We believe that a decentralized platform is the most powerful and effective solution to create the largest network, leverage data and bring the benefits of data-driven medicine to customers and patients globally. In doing so, we can both support and benefit from growth across the healthcare ecosystem.

In 2014, we launched the first application of our platform to analyze NGS data for cancer diagnosis. We offer a broad range of applications used by healthcare providers, clinical and life sciences research laboratories and biopharmaceutical companies for precision medicine across oncology, rare diseases, infectious diseases, cardiology, neurology, metabolism and other disease areas. In 2019, we launched our solution for radiomics data that enables longitudinal monitoring of cancer patients and tumor progression throughout their disease journey. Today, we believe that our SOPHiA platform, commercialized under the name "SOPHiA DDM," is one of the most widely used decentralized analytics platform globally for clinical genomics. As of December 31, 2021, we served more than 790 hospital, laboratory and biopharma customers globally through our SOPHiA platform and related solutions, products and services, and our SOPHiA platform has supported the analysis of more than 910,000 genomic profiles and has been utilized in clinical trials and research projects discussed in more than 330 peer-reviewed publications. As of December 31, 2021, we had approximately 380 recurring SOPHiA platform customers (defined as the number of customers who accessed our platform through the dry lab access and bundled access models and generated revenue during the specified time period, which, in this case, is the twelve months ended December 31, 2021). We commercialize our SOPHiA platform and related solutions, products and services as RUO and CE-IVD products.

In the United States, our products are labeled and sold for research use only. Because such products are not intended for use in clinical practice and diagnostics and cannot make clinical or diagnostic claims, the FDA regulations require that RUO products be labeled “For Research Use Only. Not for use in diagnostic procedures.” In the EU, we have self-certified our products without the intervention of a notified body in order to affix the CE marking.

Data-driven medicine has become possible through technological breakthroughs, like NGS, that have driven creation of digital healthcare data and an accelerated understanding of biology and disease. While genomics has played a large role in these advances, emerging technologies such as radiomics, digital pathology and proteomics are creating new data sets that add phenotypic context to genomic information. Additionally, the adoption of EHRs has enabled the matching of clinical outcome data to these data sets. The digital format of these data sets makes them ideal candidates for data exploration, analysis and interpretation by advanced algorithmic computing solutions. We believe that analytics approaches have traditionally primarily focused on analyzing data from a single modality and not on combining structured data from multiple modalities. Although some institutions and laboratories have created service-based business models designed to capture multimodal data, these approaches are typically centralized at a single institution, which we believe limits their ability to scale globally.

With our SOPHiA platform, we have the potential to serve and collaborate with all types of institutions in the global life sciences ecosystem, including healthcare providers, clinical and life sciences research laboratories and biopharmaceutical companies. Our platform is built on a decentralized model in which we push data analytics solutions to our customers’ sites, rather than a centralized model that requires samples to be sent to a central location. Our customers therefore generally perform testing on their own samples, retain custody of both their sample and data, and use our SOPHiA platform to analyze the pseudonymized data and share insights with other sites in our network. Through this process, we create and grow a global collective intelligence. Our platform is designed to improve as we analyze more data over time, leveraging AI and then sharing the benefits of this growing collective intelligence with our customers.

We believe that our global platform empowers better patient care through data-driven medicine by offering the following benefits for customers:

- high accuracy genomic analysis to support clinical diagnosis and life sciences research;
- rapid turnaround time for data analysis and insights;
- ability to lower cost of data analysis through higher efficiency;
- capacity to develop their own in-house precision medicine expertise and operations, retain custody of their samples and data and use their preferred instrument setup; and
- option to rapidly launch new precision medicine applications on our SOPHiA platform.

We believe that our strategic positioning as a universal healthcare analytics platform for multimodal data analytics offers us a broad range of product and service expansion opportunities and significant long-term growth in our total addressable market opportunity. We estimate the total addressable market opportunities in 2021 for our current commercial clinical applications and for our current biopharma applications were approximately $21 billion and $14 billion, respectively.

We offer a range of platform access models to meet our customers’ needs. Our primary pricing strategy is a pay-per-use model, in which customers can access our platform free of charge but pay for each analysis performed using our platform. To commercialize our products, we employ our direct sales force, use local distributors and form collaborations with other global product and service providers in the healthcare ecosystem to assemble solutions to address customer needs. For example, we combine our solution with other products used in the genomic testing process to provide customers integrated products in the testing workflow. We offer our SOPHiA platform and related solutions, products and services across 73 countries through our direct sales force and our distributor partners. As of December 31, 2021, our direct sales team consisted of more than 82 field-based commercial representatives with a direct presence in 61 countries. To supplement our direct salesforce, we offer our SOPHiA platform and related solutions, products and services in 12 additional countries through our distributor partners.

The Importance of Data-Driven Medicine

Over the last decade, there has been an explosion in the amount of healthcare data. This growth has been fueled by technologies that enable high throughput analysis and data generation at large scale, as well as the collection and digitization of real-world health data in EHRs. The ability to draw insights from this data has led to an acceleration in the understanding of biology and disease and paved the way for data-driven medicine.

Data-driven medicine aims to produce better clinical and scientific outcomes by drawing insights from complex data sets to improve diagnosis, treatment and drug development. Using data-driven medicine, healthcare professionals are able to supplement their own experience and intuition with shared knowledge and data insights from their peers and have the potential to select the best course of action for their patients or research.

Genomics is propelling data-driven medicine. The development of large-scale genomics data is advancing data-driven medicine. With broad access to NGS technologies, the life sciences field is beginning to successfully document the relationship between the genome and various diseases and is deploying this information to improve clinical and scientific outcomes. This has given rise to the field of precision medicine, which is having an increasing impact on a range of life sciences areas. In oncology, for example, advancements in genomics and the understanding of cancer have fueled the growth of a large precision oncology ecosystem, in which genomic information is critical to informing diagnostic, treatment and drug development decisions. In other areas such as rare diseases, cardiology, neurology, metabolism and infectious diseases, the adoption of data-driven medicine is just beginning and represents a significant opportunity for growth. For instance, in cardiology, clinical genomics is becoming more common for screening, diagnostic and therapy selection for certain inherited conditions, while in neurology, clinical genomics is helping direct treatment decisions for therapeutic intervention.

Multimodal data provides novel and deep insights to assess health and disease states. While the growing understanding of genomics has dramatically advanced the life sciences field and data-driven medicine, it is only one piece of the biological equation. Phenotypic information is also needed to put genomic information into context and provide a more complete picture of biology and disease. Driven by this need, innovation is accelerating across new health technologies, such as radiomics, digital pathology and proteomics, providing this phenotypic context. We believe that combining data from different instrument modalities, or a multimodal approach, will transform clinical and scientific outcomes by generating clinically actionable insights from combined relevant healthcare data sets. If leveraged properly, these data sets have the potential to provide a stronger “signal,” or window into biology and disease, than any single modality alone. In oncology, for example, oncologists can characterize the genetic determinants of a tumor at the time of diagnosis and complement this with phenotypic information through radiomics analysis of CT, MRI, SPECT and PET imaging, digital pathology analysis of histology slides and proteomics analysis of the tumor stroma and blood samples. Then, throughout a patient’s disease journey, the oncologist can collect longitudinal insights through imaging, liquid biopsies and proteomics assessment of repeat blood sampling. This information can be aggregated and linked to clinical outcome data to find associations between disease evolution and response to therapy. In addition, deep-learning algorithms applied to multimodal data sets now make it possible to predict the evolution of a disease or the response to a specific treatment with high accuracy, in order to inform the best treatment decisions for the patient. These unique insights are driving the opportunity and demand for analytics platforms that can draw clinically actionable insights from this information.

AI/ML produce novel insights from large and complex data sets. The output of these new health technologies is generated in a digital format, making data highly amenable to advanced algorithmic computing solutions for exploration, analysis and interpretation. AI approaches have enabled the ability to standardize, classify, analyze and interpret massive volumes of data, and separate the signal from the noise. Large volumes of digital information across modalities can then be mined using AI approaches to generate novel insights, enabling truly data-driven medicine.

Challenges to the Adoption of Data-Driven Medicine Today

While we believe that data-driven medicine has the potential to transform healthcare, currently, there are significant challenges that limit its democratization and adoption at scale. These challenges include:

- ***Lack of data harmonization and standardization across the healthcare ecosystem.*** Data is often produced with different approaches and methodologies, which can result in dramatic variability in data quality. In the clinical genomics field, for example, every experimental step, from using different technologies for nucleic acid extraction and DNA or RNA amplification to using different models of NGS instruments, could lead to inconsistent data across sites and experiments, or “noise” in the data. As a result, obtaining a comparable set of clinical genomics

data can be challenging, particularly in decentralized settings in which inter-laboratory variability can be considerable.

- ***Data silos and lack of knowledge sharing.*** Most healthcare data is produced by different healthcare institutions and by centralized laboratories that use different instrument modalities. As a result, data is created and remains in silos. In hospitals, for example, clinicians may struggle to collect and piece together data sets from clinical genomics to pathology to medical imaging for patients that have been produced in different, non-standardized ways. Pharmaceutical companies face similar challenges when reconciling their clinical trial data with disparate real-world data sources, resulting in highly variable quality of insights.

- ***Barriers to collaboration.*** Healthcare professionals and researchers may be limited in their ability to share their patients' healthcare data for various reasons, such as privacy or concerns over losing control of their data. In addition, they have difficulties collaborating with peers from different sites or different fields. As a result, collaborations among healthcare professionals and researchers across different sites and fields is suboptimal.

- ***Healthcare infrastructure is designed to facilitate healthcare delivery at a local or regional level, rather than on a global scale.*** Healthcare infrastructure is generally designed around centralized institutions, such as hospitals and laboratories, that generate data within their own facilities. This centralized design is not built to scale or to provide equal access to data-driven medicine globally.

- ***Existing software analytics approaches are limited in their ability to generate insights from multimodal data.*** Traditional approaches to software analytics solutions have primarily focused on analyzing data from a single modality and not on combining structured data from multiple modalities. Existing analytical software solutions thus have limited utility to generate insights from multimodal information.

Our SOPHiA Platform

We believe that a decentralized platform is necessary to create the largest network that will bring the benefits of big data to customers and to both support, and benefit from, growth across the healthcare ecosystem. We purposefully built a cloud-based SaaS platform capable of being used in decentralized locations and of analyzing data from multiple modalities and that can be scaled globally. With our SOPHiA platform, we have the potential to serve and collaborate with a variety of types of institutions in the healthcare ecosystem, including healthcare providers, centralized laboratories and biopharmaceutical companies.

Our SOPHiA platform is a global, cloud-based SaaS platform that we began building in 2011. It is powered by our SOPHiA AI that standardizes, computes and analyzes digital health data, generating insights from complex multimodal data sets that have the potential to improve diagnosis, therapy selection and drug development. Our customers generally perform testing on their own samples, retain custody of both their sample and data, and use our SOPHiA platform to analyze the pseudonymized data and share insights with each other. Through this process, we create and grow a collective intelligence. We offer multiple platform access models that enable customers to choose how they want to use our platform and customer network. These range from models in which customers produce their own data independently through their own testing operations to those in which customers produce the data through testing operations provided by our network of customer institutions. In all cases, customers access their data and our analytics through our SOPHiA platform. Our platform is designed to continually improve as we analyze more data over time, leveraging AI and then sharing the benefits of this growing collective intelligence with our customers.

We believe that our SOPHiA platform addresses key challenges to the adoption and democratization of data-driven medicine by:

- ***Enabling data harmonization and standardization across the healthcare ecosystem.*** The accuracy of our pattern-recognition AI/ML-based algorithms enables our platform to separate the signal from the noise and standardize data at high-quality levels.

- ***Breaking down data silos.*** We empower our customers to practice data-driven medicine through a decentralized model and support clinicians, laboratories and researchers across the healthcare ecosystem to improve clinical and scientific outcomes.

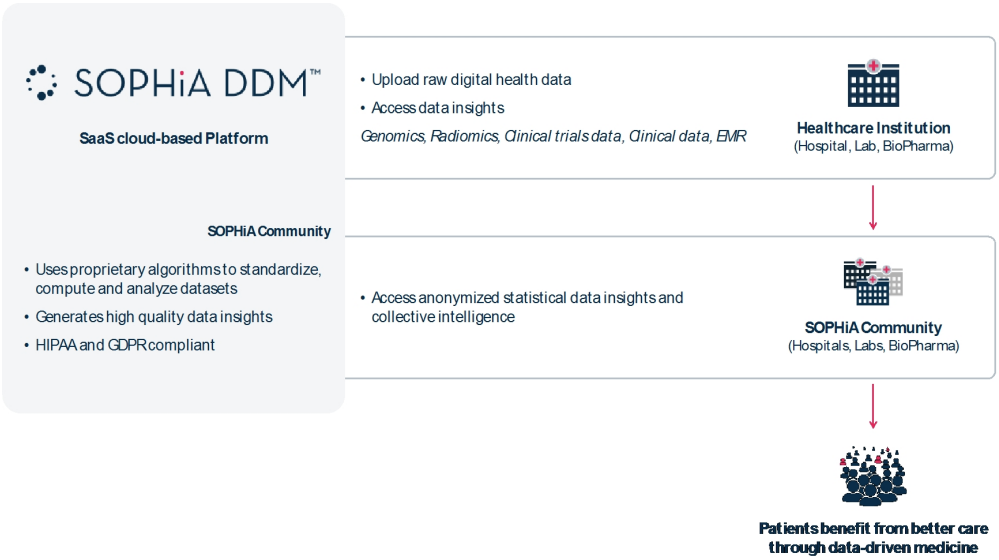
- ***Empowering clinicians and researchers to collaborate with peers from different sites or different fields.*** Our customers use our platform to share insights with each other across sites in our network. Our platform is designed to improve as we analyze more data over time, leveraging AI and then sharing the benefits of this growing collective intelligence with our customers.

- ***Offering a highly scalable platform.*** We designed our cloud-based SaaS platform to be capable of scaling globally and to use AI to leverage the data that this scale provides.

- ***Generating insights from complex multimodal data sets.*** We believe our platform is uniquely positioned to combine high-quality data at the patient level to generate multimodal insights, leveraging the power of advanced AI/ML models.

The following figure shows how our SOPHiA platform functions within the healthcare ecosystem.

Our SOPHiA Platform within the Healthcare Ecosystem

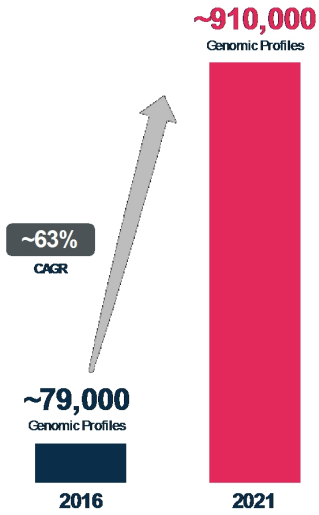


We launched the first commercial application of our platform in 2014 to analyze NGS data for cancer diagnosis. We offer a broad range of applications focused on precision medicine across oncology, rare diseases, infectious diseases, cardiology, neurology, metabolism and other disease areas. In 2019, we launched our solution for radiomics data that enables longitudinal monitoring of cancer patients and tumor progression throughout their disease journey.

Our Network and Data

Today, we believe that our SOPHiA platform, commercialized under the name “SOPHiA DDM,” is one of the most widely used decentralized analytics platform globally for clinical genomics. As of December 31, 2021, we served approximately 400 hospitals and laboratory customers globally through our SOPHiA platform who are part of our clinical genomics network. The establishment and creation of this network of customers has enabled us to capture and compute more than 910,000 raw clinical genomics profiles in oncology and other genetic-related disorders as of December 31, growing by more than 20,000 new profiles on a monthly basis. The following figure shows the growth in the aggregate number of genomics profiles analyzed by our SOPHiA platform from 2016 to 2021.

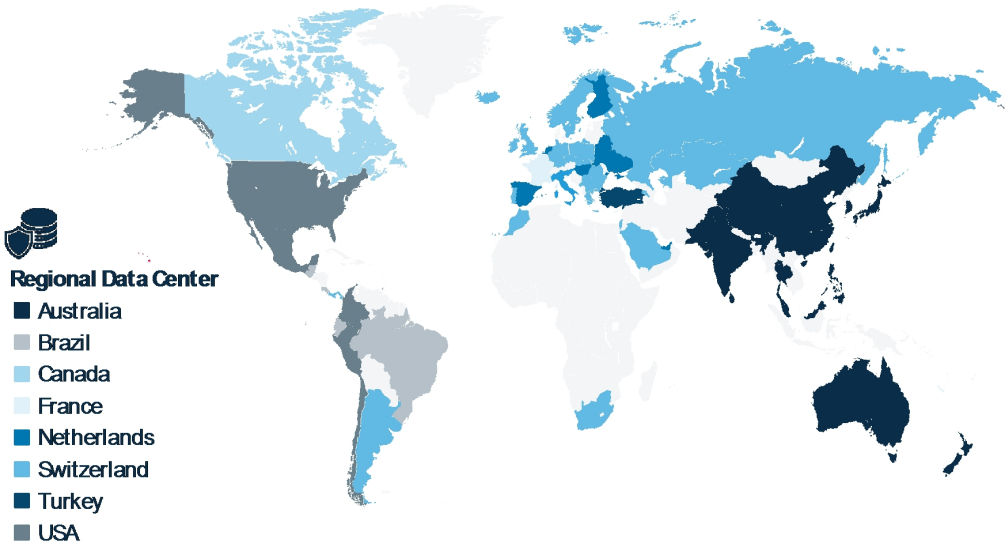
Growth in Total Number of Genomic Profiles Analyzed by Our SOPHiA Platform



Our SOPHiA Platform Architecture

We believe that our platform architecture allows our platform to be highly flexible and scalable in terms of analyzing larger volumes of data, supporting additional data modalities, expanding to new geographies and deploying new applications and functionalities. This flexibility and scalability comes from our platform's underlying architecture that is developed based on a deep understanding of our users' needs and a thorough domain model, allowing us to build re-useable User Interface ("UI") components and services to interact with the data. Our SOPHiA platform includes multiple tailored analytics engines, each tuned to specific domains and use cases. Each domain is responsible for its own data with a common shared data model that allows powerful Extract-Transform-Load (ETL) pipelines to process specific data sets, integrating data into a series of regional data warehouses that enable comprehensive and performant multimodal queries to be run across the entire global data set. The following figure shows our eight regional data centers and the countries they cover.

Country Platform Coverage through Regional Data Centers



As of December 31, 2021, this platform architecture was deployed in 73 countries through our cloud-based solution. We have developed significant operational experience by running such a large-scale cloud-based platform, which we believe enables us to deploy rapidly in new geographies. We have demonstrated that we can deploy in a new geography in approximately four weeks if appropriate cloud infrastructure exists such as Microsoft Azure, Amazon Web Services or Google Cloud Platform, or in approximately 12 weeks if such cloud infrastructure does not exist.

We regularly release platform updates. Through these updates, we offer our customers either new content, in the form of new applications, or improvements to existing applications, such as new functionalities. We believe the frequency of our updates is a competitive advantage in a rapidly evolving precision medicine ecosystem and allows our customers to benefit from new biological discoveries, such as genomic associations, that are reflected on the platform.

Cybersecurity

As part of our business, we collect, transmit, receive, process, use and store pseudonymized data provided by our customers. Our customers are required to obtain their patients' consent to our use of the data. We use security techniques designed to safeguard data received from our customers using a combination of data architecture, pseudonymization, anonymization, minimization and segregation, and process and store this data only in accordance with our agreements with customers and applicable data protection laws and regulations. This data is aggregated and analyzed by our proprietary algorithms and models in our SOPHiA platform to generate insights. These insights, which show aggregated and general trends without identifying specific patients and without providing personally identifiable information, form the growing collective intelligence that we provide to our customers.

Cybersecurity and data protection are core tenets of our company. We have processed hundreds of thousands of genomic profiles and continue to process more than 50 terabytes of data each month for our customers around the world, subject to applicable data protection laws and regulations, including HIPAA and the GDPR. We accomplish this through our global compliance framework that integrates specialized and dedicated personnel, procedures and controls and ISO/IEC 27001:2013 security infrastructure to protect data against damage, loss and unauthorized access, use, modification, disclosure or other misuse.

Applications of Our Platform

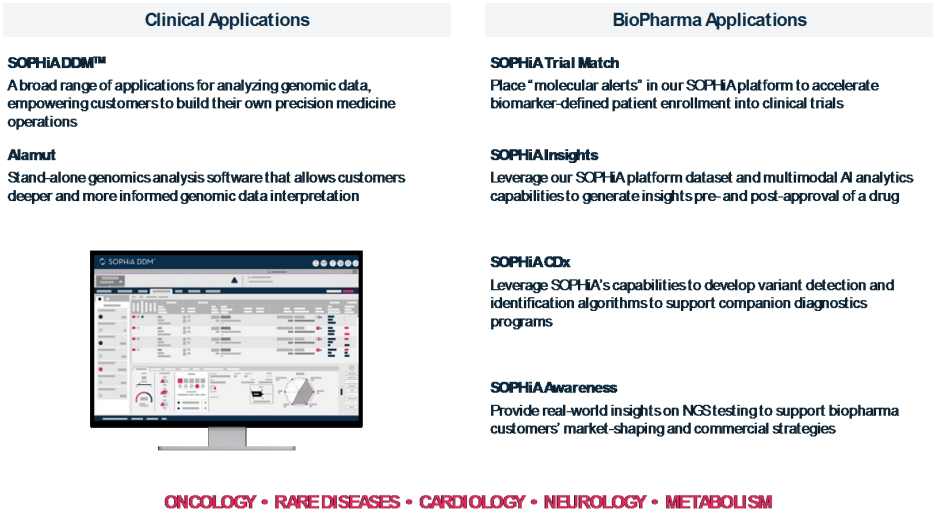
We currently have commercial applications targeting both clinical and biopharma markets. We serve our clinical market customers through two offerings of our SOPHiA platform. Our first offering is our SOPHiA DDM platform for clinical genomics, spanning a broad range of applications that we market for analyzing genomic data across oncology, rare diseases, infectious diseases, cardiology, neurology, metabolism and other disease areas. Our SOPHiA DDM platform empowers customers to build their own precision medicine operations, including testing, and then use our platform to generate insights from their data. Our second offering is our Alamut suite of genomics mutation interpretation software, which is connected to our SOPHiA DDM platform and gives our customers advanced analytics capabilities for a deeper and more informed genomic data interpretation.

For revenues generated from applications for which the disease end market is known, approximately 65% of our revenue from clinical customers in the year ended December 31, 2021 was attributable to oncology applications, while approximately 35% was attributable to other disease areas such as rare diseases, cardiology, neurology and metabolism, with applications ranging from targeted gene panels to whole-exome solutions. In the future, we intend to pursue additional IVD status and FDA approval for specific solutions. We also intend to support external collaborators in deploying their own IVD or FDA-approved solutions on our SOPHiA platform.

We serve our biopharma customers by leveraging the capabilities of our SOPHiA platform to help customers solve bottlenecks across the biopharma value chain, including throughout discovery, clinical development and commercialization stages. We currently have four applications for biopharma customers: SOPHiA Insights for generating insights pre- and post-approval of a drug based on our own proprietary SOPHiA platform data sets or on the biopharma customers' own data sets; SOPHiA Trial Match for clinical trial recruitment of biomarker-defined patient populations; SOPHiA CDx for companion diagnostics development and deployment in our decentralized network of customer institutions; and SOPHiA Awareness for providing real-world insights into NGS testing to inform market-shaping and commercialization strategies. We launched our initial applications for the biopharma market in 2019.

The following figure shows our applications that we currently commercialize across both clinical and biopharma markets.

Our SOPHiA Platform's Applications Currently in Market



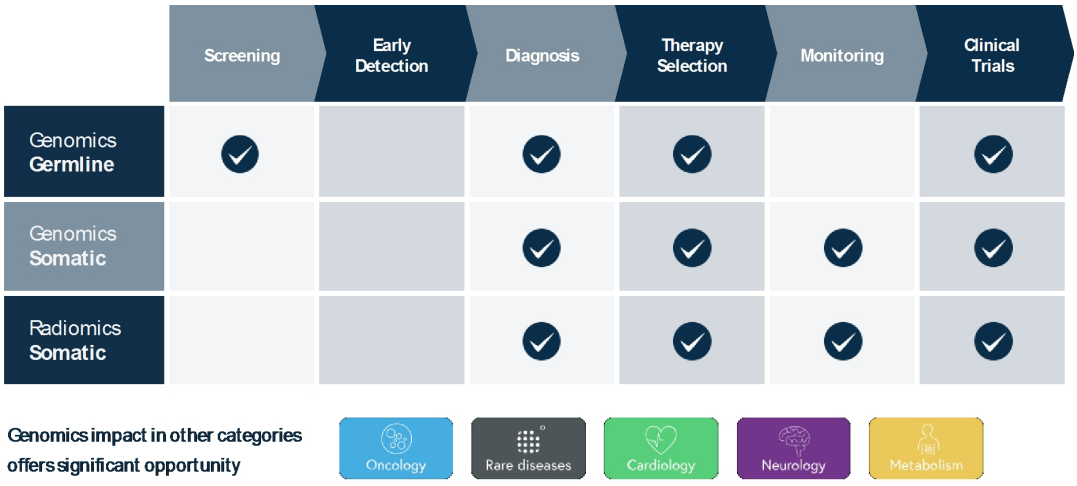
Clinical Applications

In the clinical market, we currently serve three main customer segments: academic and non-academic hospitals (including comprehensive cancer centers and children's hospitals), reference laboratories and specialty laboratories. We currently serve our clinical market customers through two offerings of our SOPHiA platform: our SOPHiA DDM platform for clinical genomics and our Alamut suite of genomics mutation interpretation software.

Oncology Applications

Our oncology applications support both germline and somatic oncology testing across both solid and liquid tumors. Our commercial oncology applications support diagnosis, therapy selection and disease monitoring. Our SOPHiA platform also supports the deployment of novel oncology testing applications. In genomics, this includes liquid biopsy-based early cancer screening as well as treatment response monitoring and minimal residual disease monitoring. In radiomics, this includes diagnosis, prediction of disease evolution and response to specific therapies, as well as longitudinal follow-up of the tumor for treatment response monitoring. The following figure shows our current applications in oncology.

Our SOPHiA Platforms' Oncology Applications



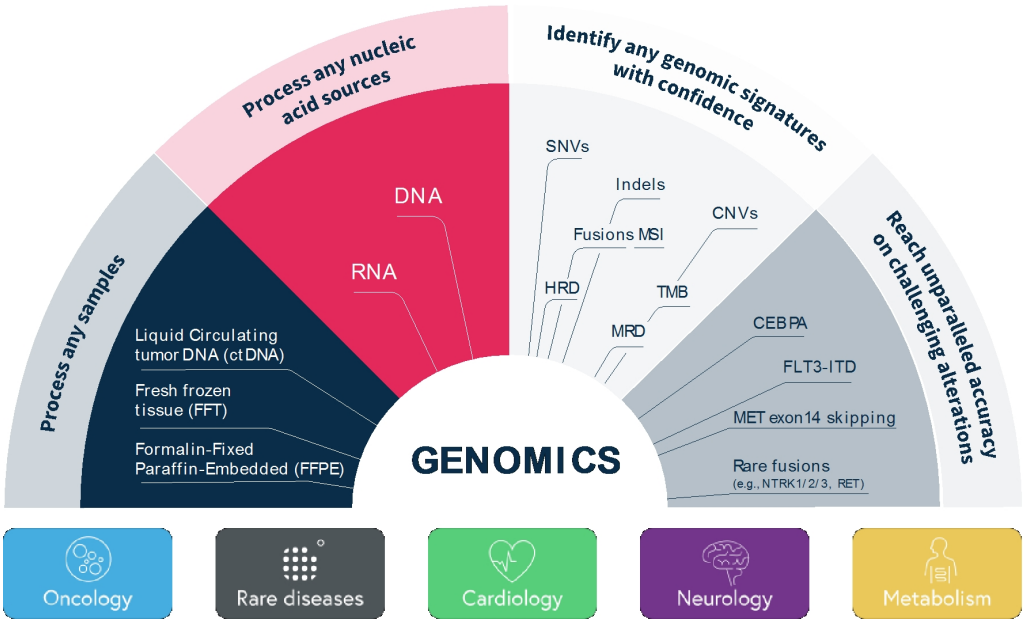
Non-Oncology Applications

Our non-oncology applications currently focus on disease areas such as rare diseases, cardiology, neurology and metabolism, with applications ranging from targeted gene panels to whole-exome solutions. While clinical genomics applications are still emerging in these disease areas, we expect significant opportunity as the life sciences field continues to establish the genetic determinants of high-profile diseases such as hereditary cardiovascular conditions, multiple sclerosis, Alzheimer's disease, autism and metabolic syndrome. We also see significant promise of multimodality in these other disease areas, for example, in cardiology by generating novel multimodal insights stemming from the joint analysis of genomics data, radiomics analysis of ultrasound images and analysis of electrocardiograms.

Our SOPHiA Platform in Genomics

We believe that our technical capabilities are cutting-edge in the genomics space. Our platform can process data from any type of biological sample, including fresh frozen tissue, formalin-fixed paraffin-embedded samples as well as liquid circulating tumor DNA samples. It can also process data from any nucleic acid source across DNA and RNA. We can identify with confidence any type of genomic alteration, including single nucleotid variants ("SNVs"), insertions-deletions ("indels"), copy-number variations ("CNVs") and gene fusions, as well as more complex mutational signatures such as microsatellite instability ("MSI"), tumor mutational burden ("TMB"), homologous recombination deficiency or minimal residual disease. Our smart algorithms allow us to reach high accuracy on the detection and identification of challenging genomic alterations, such as mutations in CEBPA or FLT3-ITD, MET exon14 skipping mutations, or rare gene fusions. The following figure shows our SOPHiA platform's capabilities in genomics.

Our SOPHiA Platform's Capabilities in Genomics



Our SOPHiA platform clinical genomics workflow involves CLIA-CAP and equivalent laboratories in academic hospitals, comprehensive cancer centers, children's hospitals and reference and specialty laboratories collecting patient samples and conducting the genetic sequencing on their premises. In doing so, they can use different NGS solutions on different NGS sequencing instruments.

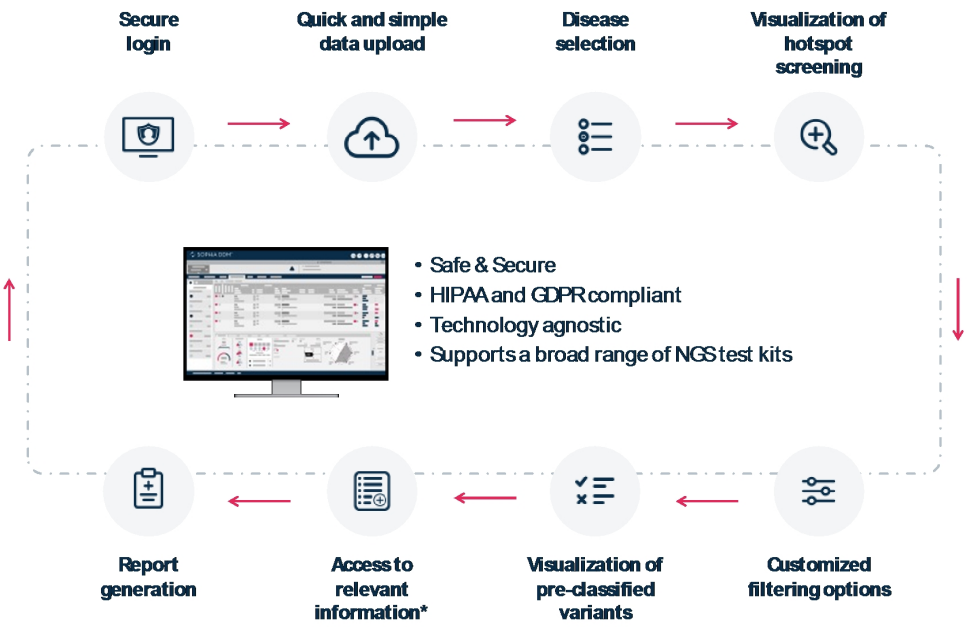
For somatic oncology applications, for example, the laboratory technician logs into our SOPHiA platform and loads the raw, pseudonymized, NGS data of multiple patients from the sequencing run, indicating the oncology indication to be investigated. The genomics data is securely transferred to our platform that operates globally in eight different regional data centers, keeping the data closest to the customer and complying with all local data handling requirements. The data is automatically recognized by our AI-based smart algorithms that check data quality. All types of genomic variants and

signatures are then detected and identified with high accuracy, including SNVs, indels, CNVs, fusions, MSI and TMB. This molecular information is then annotated and pre-classified using AI/ML techniques.

The principal investigator, usually a pathologist or geneticist (for germline applications), accesses the results and completes the interpretation. The principal investigator may flag or store the genomic variants that he or she has recognized as being associated with a certain disease on our platform. Because of the decentralized nature of our network, other users in different sites can see the aggregated flagging of a specific variant from the community to further assist their own interpretation. The more interpretations being conducted in our platform, the more novel knowledge is generated and made available to our community. Our platform is particularly easy to use as it does not require an additional technician and provides a user-friendly interface to upload data and navigate data analytics. We believe that this ease-of-use, coupled with the scale of our decentralized platform, will empower our users to continue to rapidly uncover new variants.

This workflow is technology-agnostic in terms of sequencer type and sample preparation technology and supported a broad range of different commercial NGS solutions as of December 31, 2021. The following figure shows our SOPHiA platform's genomics workflow.

Our SOPHiA Platform's End-to-End Genomics Workflow

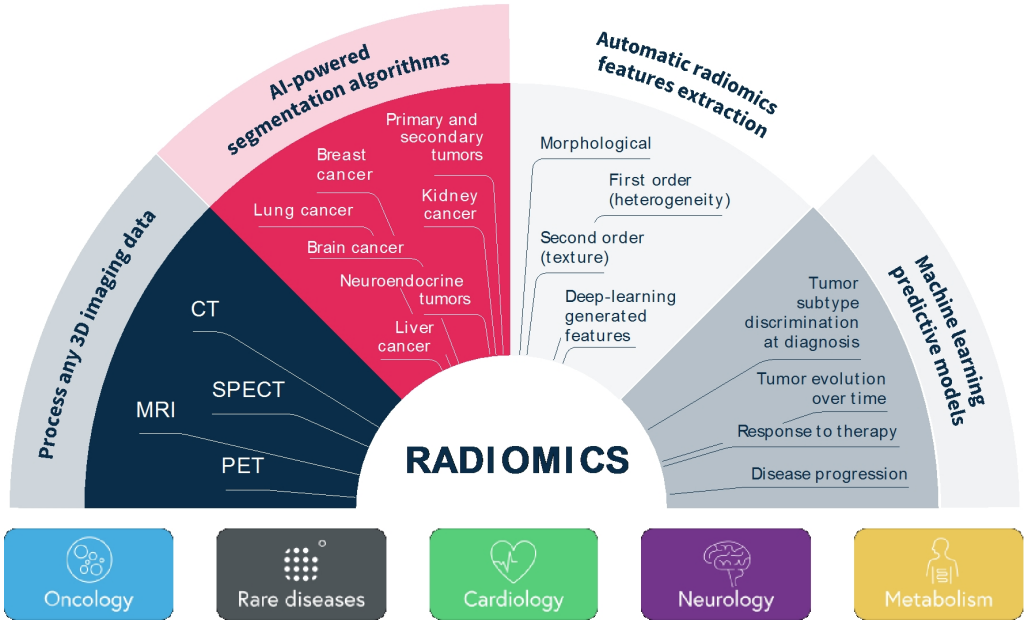


Our SOPHiA Platform in Radiomics

We believe that our technical capabilities are cutting-edge in the radiomics space. We can process and analyze data from any type of three-dimensional medical imaging technology, including CT, PET, MRI and SPECT scanners. We have developed AI/ML-powered segmentation algorithms that detect tumors in the scans and that segment and reconstruct tumors in three dimensions on our SOPHiA platform. Our current segmentation applications cover a wide range of major tumor types, including lung, breast, liver, kidney and brain cancer, supporting the analysis of primary and secondary (i.e., metastatic disease of another organ origin) tumors. In addition, we are developing new applications in areas such as colorectal, prostate, ovarian or neuroendocrine cancers. Radiomics features extraction is conducted on segmented tumors, generating hundreds of data points across volumetric, morphological, first order (i.e., heterogeneity), second order (i.e., texture), and deep-learning generated features. Our features extraction process is compliant with the Image Biomarker Standardization Initiative ("IBSI") recommendations, such that results from our radiomics analyses are standardized and can be readily compared with similar analyses globally. Through our segmentation and radiomics features extraction steps, we turn existing medical images into hundreds of novel data points. We offer radiomics applications ranging from disease detection, discrimination of disease histological subtypes, prediction of tumor evolution and prediction of disease progression. In the future, we intend to develop additional radiomics applications for existing and new tumor types, as well as for disease areas outside of oncology, such as cardiology, neurology and metabolism.

Additionally, we may expand applications to other imaging modalities such as two-dimensional modalities (e.g., ultrasound, traditional x-rays) as well as testing modalities that can be processed through imaging-based approaches (e.g., electrocardiograms). The following figure shows our SOPHiA platform's capabilities in radiomics.

Our SOPHiA Platform's Capabilities in Radiomics



While the data modality is different for radiomics compared to genomics, the same overall workflow and principles apply. The user, typically a radiologist, identifies the relevant medical images for a specific patient in the local picture archiving and communication system. The user then uploads the images into our SOPHiA platform. For a metastatic lung cancer case, for example, deep learning proprietary algorithms automatically detect the imaging modality, recognize the organ, segment the tumor and extract more than 200 radiomics features from the tumor image. These radiomics features can then be aggregated with genomics, clinical and biological data from the same patient. The following figure shows our SOPHiA platform workflow for radiomics.

Our SOPHiA Platform's End-to-End Radiomics Workflow

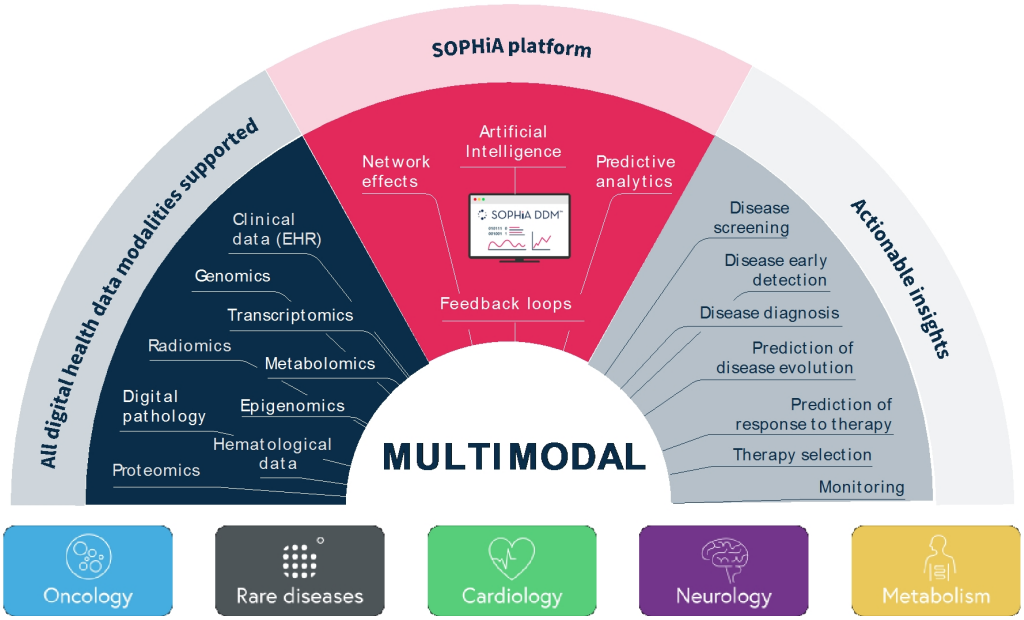
Our SOPHiA Platform in Multimodal Data Analytics

We can support the multimodal analysis of any source of digital health data, developing machine learning predictive models of aggregated multimodal data stacks for the same patient. We can support the analysis of clinical, biological, genomics, radiomics data today and intend to support additional data modalities such as digital pathology, proteomics, spatial genomics and metabolomics in the future.

We offer a range of predictive modelling applications ranging from disease screening, disease early detection, disease diagnosis and subtype discrimination, prediction of disease evolution, prediction of response to therapy, therapy selection and monitoring. We develop these multimodal predictive models in close collaboration with leading academic institutions together with cross-functional teams consisting of treating physicians (such as oncologists), radiologists and pathologists. Illustrative examples of advanced clinical research projects in which we have proof-of-concept data include prediction of response to anti-PD-1 immunotherapy for patients with metastatic non-small cell lung cancer, and prediction of pathological complete response after neoadjuvant therapy for patients with triple-negative breast cancer. For example, we sponsored a retrospective 57-patient analysis of the use of nivolumab for the treatment of relapsed or refractory non-small cell lung cancer to identify predictive markers of immune-oncology response based on multiple sources of data through machine learning analysis. We found that machine learning could help predict a patient's response using baseline data and can help identify markers that are predictive of the patient's response. We are sponsoring multimodal clinical studies to refine and assess the clinical significance of some of these multimodal signatures, which we believe will enable us to further improve our SOPHiA platform and develop new predictive algorithmic models that we can then deploy on our platform to serve a wide range of stakeholders, including oncologists and other treating physicians.

The following figure shows our SOPHiA platform's capabilities in multimodal data analytics.

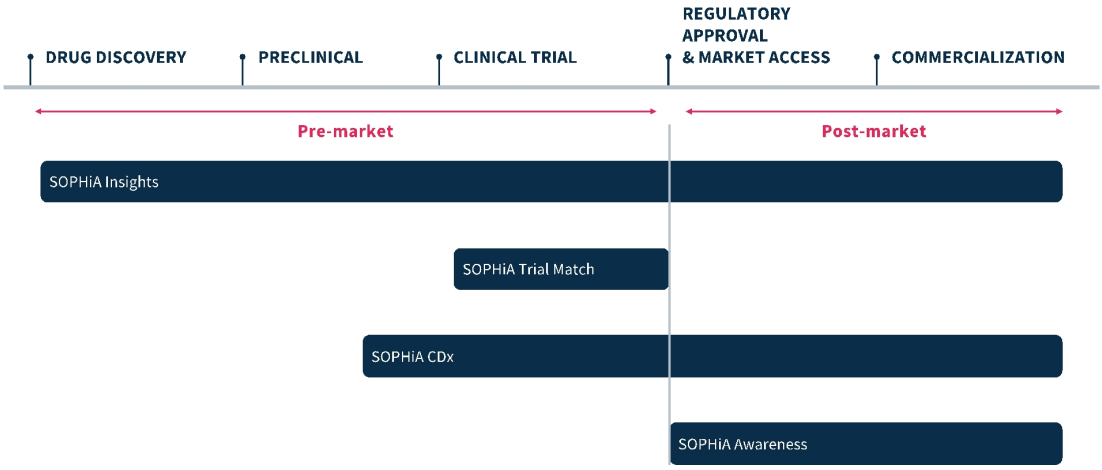
Our SOPHiA Platform's Capabilities in Multimodal Data Analytics



Biopharma Applications

In the biopharma market, we currently serve two main customers segments: pharmaceutical and biotechnology companies and CROs. Leveraging both our SOPHiA platform data and our customers' own proprietary data through our AI/ML-powered multimodal analytics capabilities, we help customers solve bottlenecks across the biopharma value chain, including through discovery, clinical development and commercialization stages. We currently serve our biopharma customers by offering four main applications: SOPHiA Insights, SOPHiA Trial Match, SOPHiA Awareness and SOPHiA CDx. The following figure shows our offerings across the biopharma value chain.

SOPHiA GENETICS' Offerings across Biopharma Value Chain



We began commercializing biopharma applications in 2019. Our biopharma applications are competitively positioned as insights programs, which utilize data already uploaded to the SOPHiA DDM platform or proprietary data provided directly by a biopharma customer. We believe that our customers value our biopharma applications for their ability to identify unique patient populations in clinical research and asset commercialization efforts. We signed our first biopharma customer in 2019. We had three biopharma customers in 2019, six biopharma customers in 2020 and five customers as of December 31, 2021.

SOPHiA Insights

Faced with a complex and fragmented precision medicine environment, we believe biopharmaceutical companies need access to high quality real-world data sets and advanced data analytics capabilities to generate insights from these data sets to inform their decision-making. However, currently, these data sets are often fragmented, siloed and of variable quality, while data analytics capabilities are typically more focused on single-modality applications.

We offer solutions to support biopharma customers by generating insights pre- and post-approval of a drug throughout the entire pharma value chain, including the research, development and commercialization stages. We can generate these insights both based on our SOPHiA platform real-world data sets and by leveraging our AI/ML-powered multimodal analytics capabilities on the biopharma customer's own data sets, including data from their clinical trials. For example, a biopharmaceutical company may ask us to generate insights from our platform regarding the real-life molecular epidemiology of rare genomic variants in a specific cancer type, including NGS sequencing install base and testing practices across geographies. A biopharmaceutical company may also ask us to support it in the AI/ML-powered multimodal analysis of its own data sets, which could include genomics, clinical, biological and medical imaging data from its clinical trials, for example to identify new biomarkers associated with patient subgroups that may have a higher likelihood of response to an investigational therapy. As we generate increasingly more multimodal patient-level data stacks in our SOPHiA platform, in the future, we may support biopharmaceutical companies on novel use cases, including real-world virtual control arms for clinical trials.

SOPHiA Trial Match

Challenges of clinical trial patient enrollment is a major bottleneck for clinical trial sponsors, which leads to delays, increased costs and clinical trial failures. This challenge is magnified in the case of biomarker-targeted investigational therapies associated with rare genomic variants due to the difficulty of finding and recruiting patients with the desired genomic traits.

With SOPHiA Trial Match, sponsors can place "molecular alerts" in our SOPHiA platform for specific genomic variants or signature that may indicate eligibility for a clinical trial. When a genomic patient profile matching the recruitment criteria is detected in our platform, the relevant local healthcare professionals who have signed up for this offering are notified in real-time and given the opportunity to connect with the clinical trial sponsor. We provide the real-time trial matching services for customers who have specifically signed up for this offering.

SOPHiA CDx

We are witnessing a steady growth in the number of regulatory approvals for therapies linked to companion diagnostic assays in oncology and other disease areas. Today, these CDx assays are typically used in a centralized model in which healthcare institutions lose access to their samples and data and which can suffer from poor turnaround times due to logistical issues. We believe that in the future CDx assays will become increasingly decentralized which will drive further testing uptake at scale and enable faster turnaround times.

We offer strategic and operational support for biopharma CDx programs. Biopharma customers can leverage our capabilities to develop genomic variant detection and identification solutions with high accuracy and precision, as well as our ability to decentralize such CDx solutions at scale through our global footprint. We believe that, in the future, CDx programs may become multimodal in nature, which we would be in a position to support through our multimodal analytics capabilities.

SOPHiA Awareness

As biopharmaceutical companies commercially launch new biomarker-targeted therapies (e.g., linked to a specific companion diagnostic assay), they face significant challenges in driving broad adoption and testing rates of specific biomarkers of interest. For example, the genomics testing landscape is currently fragmented with important regional and local variations. In that context, we believe it is imperative for biopharmaceutical companies to adequately manage parallel and interdependent adoption curves across the biomarker testing and therapy prescription dimensions. While biopharmaceutical companies tend to have insights into prescription patterns by health practitioners, they typically lack insights into real-life genomics testing practices across geographies.

We support biopharma customers with real-world insights on NGS testing trends to support their market-shaping and commercial strategies. For example, when novel therapies enter the market, a biopharmaceutical company may ask us to provide regular aggregated statistical reports on NGS testing results in specific geographies to optimize resource allocation for its go-to-market strategy. A biopharmaceutical company may also collaborate with us to increase the NGS testing rate of specific biomarkers in our network, thus supporting the identification of relevant genomic variants for targeted therapies, for example by sponsoring increased testing volumes and NGS panel upgrades. As more data modalities are computed in our SOPHiA platform, we envision additional market opportunities for SOPHiA Awareness.

Alamut Suite of Genomics Analysis Software

Our offering in the clinical genomics space also includes the Alamut suite of genomics mutations interpretation software. This add-on software is connected to our SOPHiA DDM platform through an API and provides our customers with advanced analytics capabilities for a deeper and more informed genomic data interpretation. It simplifies and accelerates variant interpretation workflows by providing an exploration and visualization application powered by an extensive collection of top-ranked external databases and proprietary prediction tools, which has the potential to be particularly impactful in deepening genomic investigations in rare diseases.

In the future, we plan to offer other add-on software solutions that are integrated with our SOPHiA platform, including software solutions from external collaborators, and that provide additional analytics capabilities. Such offerings have the potential to further increase the value of our SOPHiA platform through indirect network effects, attracting new types of customers and solutions to our network.

Clinical Publications

Our technology and its broad applications have been utilized in clinical trials and research projects discussed in more than 330 peer-reviewed publications as of December 31, 2021. These publications support scientists in new discoveries and applications across oncology, immunology, cardiology, neurology, rare diseases and other disease categories.

Access Models

We currently have three models through which customers access our SOPHiA platform. In the dry lab access model and the bundle access model, we empower customers to produce their own data. In the integrated access model, we help customers produce data through our existing network of institutions. In all cases, customers access their data through our SOPHiA platform.

The dry lab access model involves customers using the testing instruments and consumables of their choice and our SOPHiA platform and algorithms for variant detection and identification. In this model, we provide clinical genomics analytics capabilities without influencing the tools that customers use to generate the data. For example, in genomics, a laboratory might order an NGS kit directly from the manufacturer, conduct the sequencing using its installed sequencer and then use our smart algorithms in our SOPHiA platform for data analytics.

The bundle access model enables us to support our customers end-to-end across the data generation, analytics and reporting steps. In this model, we bundle third-party instruments and consumable products with our analytics solution to provide customers the ability to perform end-to-end workflows. By bundling our algorithmic capabilities with specific high-performance instruments and consumables from third parties, we can further increase the accuracy of our genomics solutions.

The integrated access model provides customers with the ability to access high-quality data on our platform even when they cannot generate data themselves. Customers that are not able or do not wish to locally conduct the sequencing steps, for example, due to a lack of appropriate resources, can have their samples processed and sequenced within our SOPHiA clinical network. We route their samples to selected SOPHiA platform collaborators who conduct the sequencing process for the customer and upload the resulting data into our SOPHiA platform. The customer is then able to access the data through our SOPHiA platform. Through this model, the selected SOPHiA platform collaborators can increase their sequencing volumes, while our SOPHiA platform is further enriched by the data produced.

The same conceptual access models apply to our radiomics solution. For radiomics, we are currently offering a dry lab access model, in which we provide the algorithmic analytics solutions while leaving the data generation at the discretion of our customers. We have developed, and intend to continue to develop, smart algorithms for specific radiomics applications, such as deep learning-enabled algorithms that can automatically recognize a lung CT scan image, detect an advanced lung cancer tumor, segment the tumor and extract radiomics features for further analysis. In the future, we may also offer a bundle access model, in which we offer solutions linked to specific imaging contrasting agents or imaging procedure modalities to optimize the performance of the final signal analysis.

We intend to apply the same conceptual access models to additional data modalities that we may support in our SOPHiA platform in the future, such as digital pathology, proteomics, spatial genomics and metabolomics.

Benefits to Customers

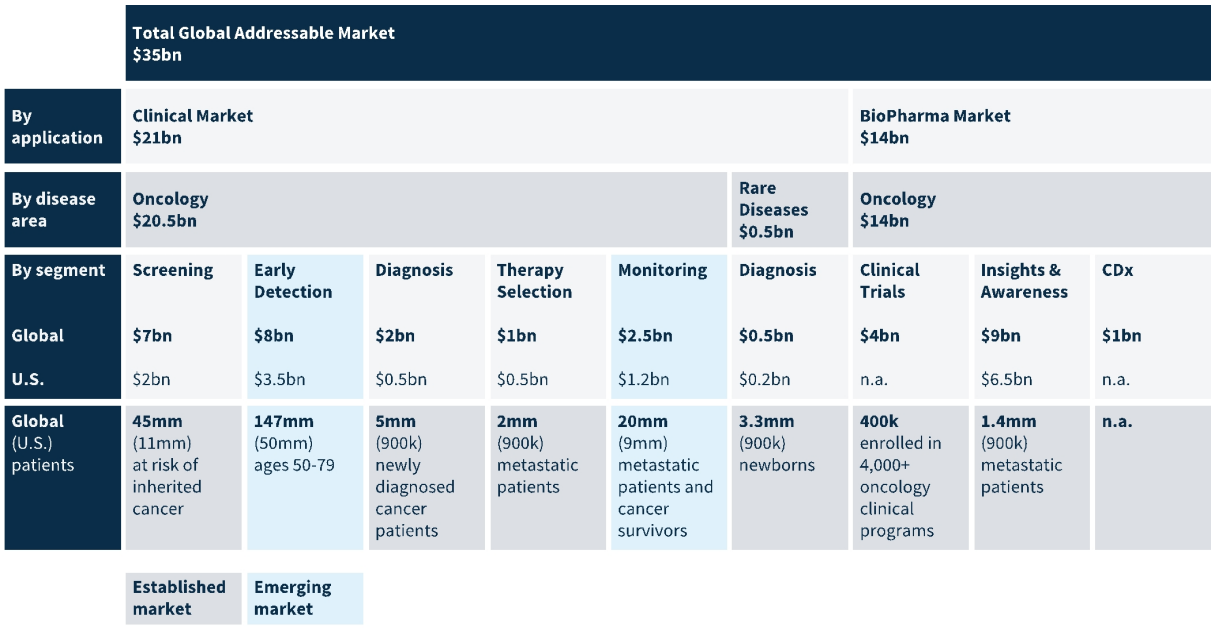
Our platform has the potential to offer the following benefits for customers, empowering them to adopt data-driven medicine to improve clinical and scientific outcomes:

- ***Accuracy.*** Our platform design and data analytics capabilities provide high accuracy analytics for our customers, who have access to high quality, standardized data through our SOPHiA platform.
- ***Turnaround time.*** We empower our customers to generate data themselves locally, which avoids delays associated with shipment, logistics and processing of samples through an external collaborator. We therefore significantly reduce the turnaround time, which is a critical factor in driving toward timely diagnosis and treatment of disease.
- ***Cost-control through increased efficiency.*** Customers can compute, detect and annotate any type of genomic alterations through our SOPHiA platform without the need for specific orthogonal assays, thus reducing additional testing costs.
- ***Maintenance and development of in-house expertise.*** By empowering our customers to retain ownership and access to their biological samples and data, we enable them to build in-house expertise while benefitting from world-class analytics accuracy through our SOPHiA platform's network effects.
- ***Accelerated launch of new precision medicine applications.*** The universal nature of our SOPHiA platform facilitates adding new applications to the same workflow once an institution adopts our platform. Our customers can avoid having to set up parallel and sometimes redundant workflows for different assays and technologies.

Markets

We estimate that our clinical and biopharma applications targeted a $35 billion global total addressable market opportunity in 2021, $14 billion of which was in the United States. These estimates are primarily based on epidemiological data, including incidence and prevalence estimates of addressable populations for each application, as well as a range of price assumptions for our products taking into account differences in panel sizes. Further, these estimates do not depend on obtaining regulatory clearances or approvals to market our products as IVD products for diagnostic use in the United States. Over time, we believe that our platform and insights enable market opportunity expansion through new applications and product development. The following figure shows our estimated total addressable market in 2021.

Our Total Addressable Market



Clinical Market Opportunity

We estimate our total addressable clinical market opportunity for our current offerings was $21 billion in 2021, with the largest market opportunity being in oncology.

Oncology. While the majority of commercial business today in the clinical market comprises diagnosis and advanced therapy selection, our capabilities enable us to serve the oncology testing market across the full patient journey. We can also support healthcare practitioners across tumor and sample types at any stage of the patient journey as long as genomic information or 3D medical imaging is applicable. Our clinical oncology market opportunity consists of five market segments: screening, early detection, diagnosis, therapy selection and monitoring.

Rare diseases. In rare diseases, we believe the adoption of data-driven medicine is just beginning and represents a significant opportunity for growth. In addition to our SOPHiA platform, our Alamut suite of genomics mutation interpretation software could be particularly impactful in deepening genomic investigations in rare diseases.

Other disease areas and conditions. We believe that the aggregate market opportunity linked to other disease areas beyond oncology and rare diseases could ultimately be larger than our current opportunity in oncology and rare diseases given their higher prevalence compared to cancer. Our SOPHiA platform has applications in areas such as cardiology, neurology and metabolism, through applications ranging from targeted gene panels to whole-exome solutions. While genomics applications are still emerging in these disease areas, we expect significant opportunity in the coming years as novel findings establish the genetic determinants of high-profile diseases such as inherited cardiovascular conditions, multiple sclerosis, Alzheimer's disease, autism and metabolic syndrome. We provide applications in each of these disease areas today, and plan to further penetrate the testing landscape in these disease areas through genomics and other data modalities in the future.

Other data modalities beyond genomics. We designed our platform architecture to be able to scale with new digital healthcare data modalities beyond genomics. We have already taken the next step in that direction by developing and deploying our proprietary radiomics analytics capabilities onto our SOPHiA platform. In radiomics, we offer analytics solutions for three-dimensional medical imaging technologies, including CT, MRI, SPECT and PET scanners, regardless of manufacturers. Additionally, we may expand applications to other imaging modalities such as two-dimensional modalities (e.g., ultrasound, traditional x-rays) as well as testing modalities that can be processed through imaging-based approaches (e.g., electrocardiograms). Beyond radiomics, we intend to support additional data modalities in the future, for example digital pathology, proteomics, spatial genomics and metabolomics. We believe that supporting additional data modalities in our SOPHiA platform, both as stand-alone modalities and in a multimodal approach, has the potential to open significant new market opportunities and increase our total addressable market in the future.

Biopharma Opportunity

We estimate our total addressable biopharma opportunity for our current offerings was $14 billion in 2021 based on three market segments: clinical trials, insights and awareness and CDx. We believe also that our strategic positioning as a healthcare data analytics platform will enable other business opportunities to become available in the future, in, for example, global public health solutions.

Other Market Opportunities Accessible with our Business Model

We believe that our strategic positioning as a healthcare data analytics platform has the potential to enable other business opportunities to become available in the future.

Universal analytics platform for digital health data. Leveraging our global network and customer base, we may enter into collaboration agreements with third-party providers of solutions and services that can be deployed through our SOPHiA platform and to our customer network, thereby generating new indirect network effects. We believe that we could provide a single, unified analytical workflow through our SOPHiA platform for instruments generating many kinds of digital health data, such as digital pathology, proteomics, single-cell sequencing and other similar applications. In the future, we could also offer third-party services through our SOPHiA platform, such as interpretation and telehealth services.

Global public health solutions. Our SOPHiA platform could provide a fast and reliable ecosystem to gather data on a global scale and inform public health agencies on significant health-related events, such as pandemics. The COVID-19 pandemic has demonstrated the need for solutions able to harmonize and analyze vast data sets on a global scale, for example, to track the evolution of new variants of the SARS-CoV-2 virus over time and across geographies. This may apply to other infectious diseases, and to human host factors such as detecting specific susceptibility characteristics through genomics and other phenotypic information across populations.

Value-based medicine. As data-driven medicine and multimodality diagnostic approaches are further adopted in the future, we may collaborate with healthcare stakeholders such as payors, providers and integrated healthcare systems to increase the overall affordability of healthcare. We may develop outcomes-based business models in which we enter into risk-sharing agreements with these stakeholders to support the optimal care management of specific patient populations with the goal of achieving better health and economic outcomes.

Drug discovery. The real-world data generated and collected from our applications may provide the basis for discovering new therapeutic agents. Based on the insights generated through our SOPHiA platform, we and our customers may be able to identify new therapeutic targets that can inform pharmaceutical research and development activities.

Animal and plant biology. We may leverage our genomics and multimodal analytics capabilities in other areas of biology, such as animal and plant biology. In this context, we may address opportunities in fields such as environmental biology and agricultural science and technology.

We believe also that our strategic positioning as a healthcare data analytics platform will enable other business opportunities to become available in the future, in, for example, global public health solutions.

Our Platform's Advantages

We believe our SOPHiA platform has several advantages over alternative genomics analytics platforms as well as other business models aimed at providing data-driven medicine.

Unique Value Proposition as a Genomics Analytics Platform

Our SOPHiA platform enables highly sensitive and specific testing and rapid turnaround time, enabling customers to compute, detect and annotate genomic alterations with high confidence. Our platform and its many applications also allow customers to rapidly build and scale precision medicine operations with different applications. We believe that a crucial characteristic for customers and a key differentiator of our platform is accuracy, leading to quality of insight. The accuracy of our pattern-recognition, AI/ML-based algorithms enable our platform to separate the signal from the noise and standardize data at high-quality levels. Our smart algorithms have high accuracy across applications, from oncology to rare diseases and cardiology, and reduce testing costs by obviating the need for orthogonal assays. The accuracy of our algorithms is a result of the scale and diversity of data within our database.

The following table shows how our SOPHiA platform performs on genomic variant detection from NGS data across a range of selected genomics applications versus the analytical performance of widely used orthogonal assays such as Sanger Sequencing, MLPA, array CGH and digital PCR.

Our SOPHiA Platform's Analytical Performance in Selected Current Genomics Applications

	Somatic Oncology[1]	Germline Oncology[2]	Rare Diseases[3]	Cardiology[4]
SENSITIVITY	98.77%	100.00%	98.93%	100.00%
SPECIFICITY	100.00%	99.99%	99.99%	99.99%
ACCURACY	99.97%	99.99%	99.99%	99.99%
PRECISION	100.00%	99.86%	99.41%	99.62%

1. Results of the CE-IVD study based on our Solid Tumor Solution (STS) that included data from 6 different sequencing centers and a total of 155 clinical and commercial FFPE samples in which 192 confirmed variants were used as the standard.
2. Results of the CE-IVD study based on our Hereditary Cancer Solution (HCS) that included data from 7 different sequencing centers and a total of 159 clinical and commercial samples in which 1252 confirmed variants were used as the standard.
3. Results based on the clinical exome analysis of the Ashkenazim trio (mother, father and son's DNA) from the Genome In a Bottle consortium that included data from 2 different sequencing centers and a total of 9 samples (including replicates) in which an average of 6241.2 confirmed variants per sample were used as the standard.
4. Results based on two similar studies that included data from 2 different sequencing centers and a total of 113 clinical and commercial samples in which 833 confirmed variants were used as the standard.

Sensitivity measures how often a test correctly generates a positive result for samples in which a certain genomic variant is present ("true positive" rate). Specificity measures how often a test correctly generates a negative result for samples in which a certain genomic variant is not present ("true negative" rate). Accuracy measures the proportion of tested samples that are correctly classified ("true positives" plus "true negatives"). Precision measures the ability for repeated analyses on the same samples to give similar results.

Broad and Growing Multimodal Application Offering

The breadth of our applications and multimodal capabilities enables our customers to deploy and scale their data-driven medicine operations rapidly and to incorporate additional clinically relevant data sets over time. We believe our platform is uniquely positioned to combine high-quality data at the patient level to generate multimodal insights, leveraging the power of advanced AI/ML models. We have developed proprietary capabilities in AI/ML-enabled exploration of multimodal signatures. Through these, we can unlock the synergistic power of next-generation healthcare data to advance predictive capabilities. We believe that over time, multimodal data will provide a superior means to diagnose and treat disease relative to the current approach focusing on just a single modality.

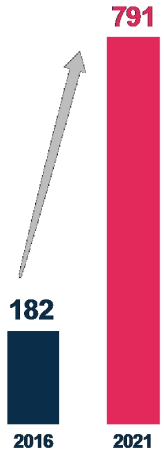
Software-based Platform Facilitates Rapid Global Scaling and Data Collection

We designed our cloud-based SaaS platform to be capable of scaling globally and to use AI to leverage the data that this scale provides. As of December 31, 2021, we served more than 790 hospital, laboratory and biopharma customers globally through our SOPHiA platform and related solutions, products and services. We believe that this global footprint is unique and enables us to capture a wide variety of real-world clinical data around the world. The following figure shows our customer base by region as of December 31, 2021.

Our SOPHiA Platform's Customer Base by Region

We have been rapidly expanding our customer base as well as the volume of data that we analyze. From December 31, 2016 to December 31, 2021, our number of active customers grew from 182 to 791. During the same period, the aggregate number of genomic profiles analyzed using our SOPHiA platform grew from approximately 80,000 profiles to approximately 910,000 profiles, recently growing by more than 20,000 new profiles on a monthly basis. The following figures show the growth in the total number of customers.

Growth in Total Number of our Customers



We regularly release platform updates, currently at a pace of once every two to three weeks. Through these updates, we offer our customers either new content, in the form of new applications or improvements to existing applications, such as new functionalities. We believe this update frequency is a competitive advantage in a rapidly evolving precision medicine ecosystem and allows our customers to benefit from new biological discoveries, such as genomic associations, that are reflected on the platform.

Ability to Work with All Stakeholders in the Healthcare Ecosystem

We are empowering our customers through a decentralized model and are able to support clinicians, laboratories and researchers across the healthcare ecosystem. This enables us to benefit from growth across the industry and provide the benefits of our network to different stakeholders. We are also able to collaborate with other product providers in the ecosystem to bundle our solutions to provide differentiated end-to-end solutions. For example, we collaborate with testing kit companies, testing hardware providers, software analytics companies, and diagnostic companies operating with a centralized model. We collaborate with companies including Twist, IDT and Agilent to create an integrated solution using our analytics platform and their library preparation products, including DNA enrichment kits, and with hardware providers such as Hamilton and PerkinElmer. We believe that we can support and collaborate with any industry player for their data analytics needs and are therefore not dependent on any specific business model or industry segment.

We believe that this unique ecosystem positioning strategy, coupled with our industry-leading analytics capabilities and our global footprint, position us as a global leading healthcare data analytics company. The following figure shows our unique position in the healthcare ecosystem.

SOPHiA GENETICS' Unique Position as an "Operating System"

Real-time Visibility into the Healthcare Ecosystem Provides Product and Application Expansion Opportunities

Our strategic positioning as a universal healthcare data analytics platform gives us real-time visibility into data and events in the healthcare ecosystem, including diagnosis, clinical data, customer behavior, performance of third-party technology solutions and other data important to stakeholders. We believe that we are well positioned to provide value to stakeholders across the healthcare ecosystem and to benefit from product and application expansion opportunities.

High Visibility and Predictability into Our Business

Once onboarded onto our SOPHiA platform, our customers tend to steadily increase their use of our SOPHiA platform, which offers a level of predictability that helps us project and manage our growth. In addition, customers rarely leave our SOPHiA platform given that we are generally integrated into their processes. These observed trends hold particularly well for our dry lab and bundle access model customers. We have a revenue churn rate, which we define as the annualized revenues we estimate to have lost from customers who access our platform through our dry lab access and bundle access models and have not generated revenue over the past 12 months in that period based on their average quarterly revenue contributions from point of onboarding as a percentage of total recurring platform revenue, of 3% across our customer base over the year ending December 31, 2021. Furthermore, our customers generally increase their use and adopt new applications of our SOPHiA platform as our relationship with them grows.

Our Growth Strategy

Our mission is to empower clinicians and researchers around the world to practice data-driven medicine and improve clinical and scientific outcomes. Our growth strategy is to:

- ***Drive innovation and advancement of our SOPHiA platform to increase its capabilities and broaden its applications*.** We plan to continue to invest in scientific innovation to bring new, high-impact content to our customers through regular updates to our platform. This may include new features, new applications, new data modalities and new services. Furthermore, we intend to augment our offering across a multimodality framework, generating novel insights enabled by our expanding data assets, including genomics data, radiomics analysis of medical imaging, clinical data and future additional data modalities such as digital pathology, proteomics, spatial genomics and metabolomics.

- ***Drive new customer adoption with clinical customers worldwide.*** We intend to continue to raise awareness of the benefits of data-driven medicine and drive adoption of our platform around the world through our direct sales force, our distributors and our collaborator network. We plan to further penetrate the U.S. market, which we see as our largest opportunity, by significantly investing in our direct sales force to further scale the size of our network, both in terms of the number and types of customers. In addition, we also plan to focus on commercializing our solutions by forming additional collaborations with reference and specialty laboratories. Outside the United States, we believe there is significant growth opportunity across EMEA and Latin America markets, as well as untapped potential in APAC, including in China, India, Korea and Japan. In selected geographies outside the United States, we intend to utilize a hybrid commercial model including direct sales force or direct collaborations and distributors.

- ***Increase utilization within our clinical customer base.*** We employ a “land and expand” commercial model that is focused on winning new customers and then driving utilization of our solution by those customers. Once we secure a customer, we use our direct sales force to build further engagement and help that customer profitably increase its testing operations. For example, we may initially support a customer in setting up its NGS testing operations for hereditary cancer screening, including operational support through our set-up programs. Once the customer is fully onboarded onto our SOPHiA platform, it is then comparatively easier to deploy additional germline testing solutions as well as somatic oncology testing solutions, creating synergies across the offerings and a unified workflow. We also target incremental users within each institution, for example, additional clinicians within a provider across expanded departments such as radiology or pathology.

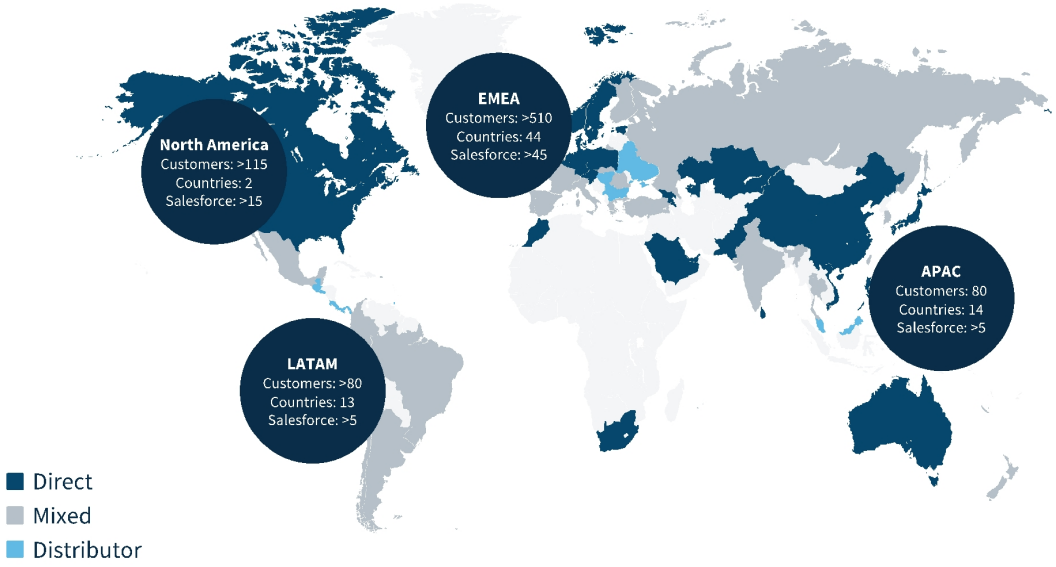
- ***Leverage our platform and database to drive adoption by biopharmaceutical companies.*** We have a distinct sales force focused on biopharma opportunities across the discovery, clinical development and commercialization value chain. We continue to promote our current products and services, which we believe will strengthen existing collaborations with biopharmaceutical companies as well as lead to new relationships. For example, we may collaborate with a biopharmaceutical company to generate insights on the real-world molecular epidemiology of specific genomic variants relevant for an investigational targeted therapy, including insights on testing trends across our network of customers. This may lead to additional collaborations on a multimodal program to investigate new biomarkers of response to the investigational therapy, a tailored companion diagnostic program, clinical trial recruitment efforts, and market-shaping activities on biomarker testing to support the asset go-to-market strategy. Additionally, we plan to develop new offerings for biopharma as we expand the number and type of new applications and data modalities on our platform. Our biopharma strategy is also highly synergistic to our virtuous cycle.

- ***Establish and grow industry collaborations across the healthcare ecosystem***. We intend to establish new industry collaborations with other companies providing products and services to our customers. We intend to collaborate with a diverse array of industry participants, including instruments, reagent and software companies in genomics and in other fields such as digital pathology and proteomics. We intend to collaborate with service providers such as centralized laboratory players and interpretation services providers to expand the breadth of our capabilities. We believe that each new collaboration we develop helps facilitate further adoption of our platform, the evolution of the solution we provide to customers and the growth of our network and product capabilities. A larger network enables us to continue to collaborate with customers to develop new solutions and to commercialize these solutions, benefiting all users across the healthcare ecosystem.

Commercial

We sell our SOPHiA platform and related solutions, products and services to healthcare providers, centralized laboratories and biopharmaceutical companies through our own sales force as well as through distributors and industry collaborators. As of December 31, 2021, our direct sales team consisted of more than 82 field-based commercial representatives, including sales and business development managers, key account managers and biopharma alliance managers who are engaged in sales efforts and promotional activities towards our customers. We also employ subject matter experts, clinical genomic experts and biopharma operations specialists who provide customer-facing technical and scientific support. As of December 31, 2021, we had a sales presence in 73 countries, including a direct sales presence in 61 countries and 12 countries in which we offer our SOPHiA platform and related solutions, products and services through distributors. The following figure shows our global commercial footprint as of December 31, 2021.

SOPHiA GENETICS' Global Footprint – Countries and Sales Force



Our initial focus has been on winning clinical customers in order to drive data capture and building our reputation for accuracy and quality in the clinical community. We estimate that there are more than 10,000 laboratories globally that are using NGS instrumentation. We believe that there is significant opportunity to expand our customer base as well as grow utilization of our SOPHiA platform by our existing customers. Our sales strategy is focused on both attracting new customers to our platform and driving their utilization and adoption of our applications. Once we win a new customer, our direct sales team provides set-up programs to accelerate the adoption of our SOPHiA platform and facilitates our customers to adopt our platform into their routines.

We started commercializing our biopharma services in 2019. Our initial focus was to establish pilot programs with large pharma and biotech companies to develop customer trust and raise awareness about our offerings. Our biopharma business development and operations team is now focused on developing and scaling joint collaborations and on continuing to refine our product offering across large pharma companies, biotech companies and CROs.

Suppliers and Manufacturers

Our platform is a cloud-based SaaS platform. To deploy our platform, we rely on cloud-based service providers. We also collaborate with consumables and hardware suppliers for the bundle access model and with platform customers for the integrated access model.

Platform Suppliers. Our platform production environment currently runs on Microsoft Azure. As our platform architecture is vendor-agnostic, we could readily deploy our solutions onto any cloud infrastructure, as well as on-premise if necessary. We have ongoing research and development projects on all major cloud solution providers, including Microsoft Azure, Amazon Web Services and Google Cloud Platform. This allows us a strong degree of flexibility and helps manage vendor risks.

Consumables and Hardware Suppliers. In the bundle access model, we work with IDT, Twist, Qiagen, Beckman Coulter Inc., Thermo Fisher Scientific Inc. ("Thermo Fisher") and others for consumables and with Hamilton, PerkinElmer and others for hardware equipment.

Platform Customers. In the integrated access model, we route a customer's samples to selected SOPHiA platform collaborators who conduct the sequencing process for the customer and upload the resulting data into our SOPHiA platform. As of December 31, 2021, we collaborated with eight laboratories across eight countries to provide this service.

We continually assess our dependence on our suppliers and manufacturers and evaluate alternative solutions. We have built our business such that we do not rely on any single supplier or manufacturer, such that we are able to switch suppliers and manufacturers as necessary. We believe that this mitigates risks to our business and provides us the opportunity to drive down costs.

Competition

We operate in a market characterized by rapidly advancing technologies and a strong emphasis on intellectual property. Our main competitors are institutions that collect multimodal data that have developed in-house analytics solutions, such as Tempus Labs, Inc. and F. Hoffmann-La Roche Ltd through its acquisition of Foundation Medicine, Inc. and Flatiron Health, Inc., but we believe these competitors also represent our potential customers. In addition, other companies such as Siemens AG, Koninklijke Philips N.V. and Konika Minolta, Inc. are also positioning themselves in the market with data analytics platform capabilities to build a multimodal world. We also face competition from companies that have developed software analytics platforms for genomics data, such as Agilent, Fabric Genomics, Inc., Illumina, Inc., PierianDx, Inc. and Thermo Fisher. We believe that our proprietary technology and the agility and the scalability of our platform distinguishes us from other players. We believe that our position as a "universal operating system" enables us to empower and sell to many different players in the ecosystem, including competitors. See "Item 3. Key Information—D. Risk Factors—Risks Related to Our Business and Industry—We face competition from many sources and we may be unable to compete successfully."

Intellectual Property

Intellectual property is of vital importance in the biotechnology field. Our success depends in part on our ability to obtain and maintain intellectual property and proprietary protection for our technology, defend and enforce our intellectual property rights, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating valid and enforceable intellectual property and proprietary rights of others.

We are actively involved in research and development and therefore seek to protect the investments made into the development of our technology by relying on a combination of patents, trademarks, copyrights, trade secrets, including know-how, and license agreements. We also seek to protect our proprietary technology, in part, by requiring our employees, consultants, contractors and other third parties to execute confidentiality agreements and invention assignment agreements and by implementing technological measures and other methods.

Our ability to stop third parties from making, using, selling, offering to sell or importing our platform, services and products depends on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property and proprietary rights that cover these activities. We pursue intellectual property protection to the extent we believe it would advance our business objectives. Notwithstanding these efforts, there can be no assurance that we will adequately protect our intellectual property or provide any competitive advantage. For more information regarding risks relating to intellectual property, see "Item 3. Key Information—D. Risk Factors—Risks Related to Intellectual Property."

Patents

Our intellectual property strategy is focused on protecting our ongoing research and development through patents and other intellectual property rights.

As of December 31, 2021, we solely owned two issued U.S. patents, 18 pending U.S. patent applications, 16 issued patents and approximately 26 pending patent applications in foreign jurisdictions, including Europe, Canada, Australia, Brazil, China, and India, wherein four are pending Patent Cooperation Treaty applications relating to laboratory methods and/or software to provide molecular diagnosis in germline diseases. These include filings for 17 families of utility patents and three families of design patents relating to graphical user interfaces. Such issued patents and any patents derived from such applications or applications that claim priority from such applications, if granted, would be expected to expire between 2028 and 2041, excluding any additional term for patent term adjustments.

As of December 31, 2021, our most material patents and patent applications consisted of (i) one issued patent in Israel, three pending U.S. patent applications and six pending foreign patent applications in Australia, Brazil, Canada, China, Europe, and India relating to our algorithm for next generation sequencing data which is used in our SOPHiA DDM platform, (ii) one pending U.S. patent application and one pending European patent application relating to a method for processing certain genomic data which is used in our SOPHiA DDM platform, (iii) one pending Patent Cooperation Treaty application for a method to improve accuracy of the estimate length of homopolymer and heteropolymer regions, which is used in our SOPHiA DDM platform, (iv) one pending Patent Cooperation Treaty application and one U.S. pending patent application relating to a unique molecular identifier and related analytics workflow which we plan to incorporate in our products and into our SOPHiA DDM platform, (v) one European pending patent application and one U.S. pending patent application for a method to detect microsatellite instability that will be used in our SOPHiA DDM platform, (vi) one pending European patent application and one U.S. pending patent application relating to a method to detect homologous recombination deficiency ("HRD"), which will be used in our HRD detection solution, and (vii) one pending European patent application relating to a variant calling method which is not currently used in our products. Any patents derived from such applications or applications that claim priority from such applications, if granted, would be expected to expire between 2035 and 2041, excluding any additional term for patent term adjustments.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file or intend to file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may 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 an earlier filed patent. We cannot be sure that patents will be granted with respect to any current pending patent application or with respect to any patent applications filed by us in the future, and we cannot be sure that any current or future patents will be commercially useful in protecting our platform, products, services, technologies and processes. In addition, any patents that we may hold, whether owned or licensed, may be challenged, circumvented or invalidated by third parties.

Trademarks

The success of our business strategy depends on our continued ability to use our existing intellectual property in order to increase brand awareness and develop our branded services.

As of December 31, 2021, we owned nine registered U.S. trademarks, approximately 125 registered foreign trademarks and two pending foreign trademark applications. Our trademark portfolio is designed to protect the brands of our current and future products and includes U.S. trademark registrations for our company name, "SOPHIA GENETICS", and product names, such as "SOPHIA DDM" and "ALAMUT". We have granted licenses to certain of our trademarks to our domestic and international collaborators.

We currently face oppositions before the USPTO against our U.S. trademark applications for "SOPHIA GENETICS" and "SOPHIA DDM". An adverse ruling in such proceedings could prevent us from using such names to distinguish our platform, solutions, products and services in the United States.

Trade Secrets

We also rely on trade secrets, including know-how, unpatented technology and other proprietary information, to strengthen our competitive position. We have determined that certain technologies that are not amenable to, or that we do not presently consider appropriate for, patent protection, such as our analysis techniques and analysis generated using our proprietary algorithms in the context of our SOPHiA DDM platform, are better kept as trade secrets in order to protect and maintain our competitive position and aspects of our business and prevent competitors from reverse-engineering or copying our technologies.

We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations or manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that the assignment agreements that have been entered into are self-executing. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, or claim ownership in intellectual property that we believe is owned by us. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Government Regulation

Laboratory Developed Tests

CLIA and State Laboratory Licensing

CLIA is a U.S. federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease, or impairment of, or the assessment of the health of, human beings. CLIA regulations require, among other things, clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, test management, and quality assurance. CLIA certification is also required for us to be eligible to bill state and federal healthcare programs, if such reimbursement is otherwise available, as well as many private third-party payors, for our products.

In addition to federal certification requirements of laboratories under CLIA, CLIA provides that states may adopt laboratory regulations and licensure requirements that are more stringent than those under federal law. A number of states have implemented their own more stringent laboratory regulatory requirements. Such laws, among other things, establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. For example, New York laws and regulations establish standards for day-to-day operation of a clinical laboratory, including training and skill levels.

We do not currently operate a CLIA-certified laboratory. Our customers are responsible for their own CLIA certification.

Federal Oversight of Laboratory Developed Tests

The laws and regulations governing the marketing of clinical laboratory testing and diagnostic products are evolving and extremely complex and, in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Clinical laboratory tests are regulated under CLIA, as administered by CMS, as well as by applicable state laws. In addition, the FDCA defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets.

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics that are designed, manufactured and used within a single laboratory for use only in that laboratory. These tests are referred to as LDTs.

Legislative and administrative proposals proposing to amend the FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements. For example, in recent years, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. The FDA could modify its current approach to LDTs in a way that would subject LDTs to additional regulatory requirements. Moreover, legislative measures could likewise result in a change to the approach to the FDA's regulation over LDTs, including a requirement for premarket review of LDTs, among other things.

AI/ML-Based Medical Software

The FDA recognizes that the traditional paradigm of medical device regulation was not designed for adaptive AI/ML technologies. The FDA has cleared or approved several AI/ML-based software as medical devices ("SaMD"). Typically, these have only included algorithms that are "locked" prior to marketing, where algorithm changes likely require FDA premarket review for changes beyond the original market authorization. However, not all AI/ML-based SaMD are locked; some algorithms can adapt over time. Following distribution, these types of continuously learning and adaptive AI/ML algorithms may provide a different output in comparison to the output initially cleared for a given set of inputs.

The FDA's Center for Devices and Radiological Health is currently considering a total product lifecycle-based regulatory framework for AI/ML technologies. On January 12, 2021, the FDA released its Artificial Intelligence/Machine Learning-Based Software as a Medical Device Action Plan, which outlines five actions that the FDA intends to take, including:

- further developing the proposed regulatory framework, including through issuance of draft guidance on a predetermined change control plan (for software's learning over time);
- supporting the development of good machine learning practices to evaluate and improve machine learning algorithms;
- fostering a patient-centered approach, including device transparency to users;
- developing methods to evaluate and improve machine learning algorithms; and
- advancing real-world performance monitoring pilots.

Medical Device Regulatory Framework

Pursuant to its authority under the FDCA, the FDA has jurisdiction over medical devices, which are defined to include, among other things, IVDs and SaMD. The FDA regulates the research, design, development, preclinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Specifically, if the FDA begins to actively regulate LDTs, then, unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States could require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA ("510(k) clearance") or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource-intensive, expensive, and lengthy, and require payment of significant user fees.

Device Classification

Under the FDCA, medical devices are classified into one of three classes (Class I, Class II or Class III) depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. While some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below, most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-supporting, life-sustaining devices or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, preclinical and clinical trial data, manufacturing information and labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The 510(k) Clearance Process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) premarket notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including data from samples collected in a clinical setting, to make a determination regarding substantial equivalence which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process or seek reclassification of the device through the De Novo classification process.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by an internal letter-to-file in which the manufacture documents its reasoning for why a change does not require premarket submission to the FDA. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters-to-file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

The De Novo Process

The De Novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. De Novo classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to the FDA.

The PMA Approval Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- The device may not be shown safe or effective to the FDA's satisfaction;
- The data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- The manufacturing process or facilities may not meet applicable requirements; and
- Changes in FDA clearance or approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not-approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy, and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer-term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

The Investigational Device Process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an investigational device exemption ("IDE") application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE–without affirmative submission of an IDE application to the FDA–once certain requirements are addressed and IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Such clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA for any clinical trials subject to FDA oversight. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a 510(k) premarket notification, for numerous reasons.

The Breakthrough Devices Program is a voluntary program intended to expedite the development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. All submissions for devices designated as Breakthrough Devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed. Although Breakthrough Device designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory clearance or approval for such product.

Research Use Only

In the United States, SOPHiA products labeled and sold for research use only, and not for the diagnosis or treatment of disease, are sold to a variety of parties, including biopharmaceutical companies, academic institutions and molecular laboratories. Because such products are not intended for use in clinical practice in diagnostics, and the products cannot include clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, while the FDA regulations require that RUO products be labeled "For Research Use Only. Not for use in diagnostic procedures," the regulations do not otherwise subject such products to the FDA's pre- and post-market controls for medical devices.

A significant change in the laws governing RUO products or how they are enforced may require a change to our business model in order to maintain compliance. For instance, in November 2013 the FDA issued the RUO Guidance, which highlights the FDA's interpretation that distribution of RUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as a laboratory, developed test is in conflict with RUO status. The RUO Guidance further articulates the FDA's position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories conflicts with RUO status. If we engage in any activities that the FDA deems to be in conflict with the RUO status held by the products that we sell, we may be subject to immediate, severe and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO products in a manner that is inconsistent with its regulations or guidance, we may be forced to stop distribution of our RUO tests until we are in compliance, which would reduce our revenues, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In addition, the FDA's proposed implementation for a new framework for the regulation of LDTs may negatively impact the LDT market and thereby reduce demand for RUO products.

If the FDA requires marketing authorization of our RUO products in the future, there can be no assurance that the FDA will ultimately grant any clearance or approval requested by us in a timely manner, or at all.

Post-Market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of investigational products or the promotion of “off-label” uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals or administrative detention, or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

Authorization to Market In Vitro Medical Devices in the European Economic Area

In the EEA, in vitro medical devices are currently required to conform with the essential requirements of the EU In Vitro Diagnostic Directive (IVDD Directive No 98/79/EC, as amended, the “IVDD”). The scope of 98/79/EC applies to IVD medical devices and accessories, which can include not just reagents and kits but also instruments and software. To demonstrate compliance, ISO 13485 is recognized as the harmonized standard for regulatory quality system compliance. Companies are required to meet the essential requirements of the IVDD.

EU IVD Regulatory Classification

The risk presented by a device determines the classification and therefore the level of control and regulatory review required. Annex II of the IVDD identifies specific device types that are categorized as either high risk (List A) or moderate risk (List B). General IVDs may self-certify without the intervention of a Notified Body in order to affix the CE Marking. Self-test IVDs, because of the greater risk associated with being used by untrained lay users, have special requirements, while all other devices not classified as either List A, List B or self-test are regarded as general IVDs. SOPHiA currently has self-certified products in the EU market through SwissMedic.

On April 5, 2017, the EU adopted the new In Vitro Device Regulation (EU) 2017/746 (the "IVDR"), which repeals and replaces Directive No 98/79/EC effective May 2022. Unlike directives, which must be implemented into the national laws of the EU member states, a regulation is directly applicable, i.e., without the need for adoption of EU member state laws implementing them, in all EEA member states. The IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for in vitro diagnostic medical devices and ensure a high level of safety and health while supporting innovation. The IVDR will not become fully applicable until five years following its entry into force. Once applicable, the IVDR will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number; and
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU.

On October 14, 2021, the EU announced a proposal for an updated phased transitional period for in vitro diagnostic medical devices with a certificate issued by a notified body in accordance with the Directive. The proposal was approved by the EU Parliament and Council on December 15, 2021. The new transitional periods are May 2025 for class D devices, May 2026 for class C devices and May 2027 for class B and A sterile devices. Moreover, the application of certain requirements for devices manufactured and used in the same health institution (so-called 'in-house devices') is delayed by two years until May 2024. If, however, the health institutions prove the unavailability of an equivalent device on the market, the transitional periods will end in May 2028. Any products currently on the market with a CE-IVD label before May 2022 may remain on the market until the new deadline or until the product undergoes a significant change, at which point, it must comply with all the requirements of the IVDR.

Brexit and the Regulatory Framework in the UK

On June 23, 2016, the electorate in the UK voted in favor of leaving the EU, commonly referred to as Brexit. On December 24, 2020, the UK and the EU entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for medical products in the UK covering quality, safety and efficacy of medical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical medical is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime which applies to medical products in the UK, as the UK legislation now has the potential to diverge from EU legislation. It remains to be seen how Brexit will impact regulatory requirements for medical products in the UK in the long-term. The Medicines and Healthcare products Regulatory Agency published detailed guidance for industry and organizations to follow from January 1, 2021, which will be updated as the UK's regulatory position on medicinal products evolves over time.

Following Brexit and the end of the transition period, there may be regulatory divergence between UK and EU regulations. Manufacturers located outside of the UK are required to appoint a UK Responsible Person in order to register and sell their products within the territory. A new UKCA mark will replace the CE mark in Great Britain (CE marks or CE UKNI marks will be required in Northern Ireland). CE marks will continue to be recognized in Great Britain for medical devices until June 30, 2023. However, all medical devices and IVDs must be registered with the Medicines and Healthcare products Regulatory Agency to be placed on the Great Britain market, subject to certain grace periods depending on the risk class of the medical device/IVD. From July 1, 2023, a UKCA mark will be required to place a device on the Great Britain market; however, manufacturers can use the UKCA mark on a voluntary basis prior to July 1, 2023. The nature of any new regulation in the UK is uncertain and as such we may experience delays in accessing the UK market.

EU-Swiss Institutional Framework Agreement

In May 2021, Switzerland decided to end seven years of negotiations with the EU and not sign the drafted EU-Swiss Institutional Framework Agreement (the “Framework Agreement”). The Framework Agreement was intended as the foundation to enhance and develop EU-Swiss bilateral relations for the future. At this stage, the impact on the termination of the EU-Swiss negotiations on medical product registration and market access is unknown and the nature of any new regulation in the EU or Switzerland is uncertain. As such, we may face additional requirements to market our products in the EU or Switzerland.

Other Jurisdictions

Outside the United States, the EU, the UK and Switzerland, regulatory pathways for the marketing of medical devices vary greatly from country to country. In many countries, local regulatory agencies conduct an independent review of medical devices prior to granting marketing approval and may require specific disclosure or localization to access the local market.

For instance, in Brazil all medical devices imported into or distributed within Brazil must first be registered with the Agência Nacional de Vigilância Sanitária (“ANVISA”) or the National Health Surveillance Agency. ANVISA is an autonomous regulatory agency responsible for the regulation and oversight of medical devices and other medical products in Brazil, including the registration of medical devices and the maintenance of a registered products database. The medical device company must be located in Brazil or arrange for a licensed third-party company to be the Brazilian registration certificate title holder. Resolution RDC 36/2015 of August 26, 2015 (“RDC 36/2015”) is the central regulation applicable to registration of in vitro diagnostic devices in Brazil, describing the protocol and documents required, including localization into Brazilian Portuguese. Chapter II set forth of RDC 36/2015 the classification scheme, assigning devices to one of four risk classes, based upon various rules enumerated therein. This classification structure is aligned with the EU’s one. If a device fits into more than one risk classification, its final risk class is the one associated with the highest risk level. Class I and Class II registrations do not expire. Class III and IV registrations are valid for ten years. Registration renewals must be initiated no earlier than one year and no later than six months prior to expiration. Manufacturers are also subject to audits to ensure compliance with the Brazilian Good Manufacturing Practices (“BGMP”) prior to receiving authorization to sell from ANVISA. BGMP audits may be fulfilled through other audits by recognized entities through the Medical Device Single Audit Program. RUO products are labeled accordingly and are not subject to these registration requirements. While we are currently able to market our SOPHiA platform and related solutions, products and services in Brazil, including through our Brazilian subsidiary, any changes to the regulatory framework for RUO products could result in additional costs to us, including expenses related to additional audits, translations and registration fees, or delays in accessing the Brazilian market, including due to the time required to obtain necessary ANVISA approvals.

In Turkey, medical devices are regulated by the Medicines and Medical Devices Agency within Ministry of Health and pursuant to the Medical Device Regulation, the Regulation on Active Implantable Medical Devices and the Regulation on In Vitro Diagnostic Medical Devices. These regulations generally resemble analogous EU directives and regulations. To be sold in Turkey, medical devices must bear a CE mark and must subsequently be registered in the Turkish Ministry’s online database (Turkish Drug and Medical Device National Databank, or TITUBB) in order to be marketed in Turkey. Manufacturers without local presence in Turkey must appoint a Local Authorized Representative. A product will generally be considered a medical device if it is marketed as a medical device in the EU. In recent years, software and mobile application medical devices have been increasing and the Medicines and Medical Devices Agency has considered certain software and mobile applications as medical devices, taking into consideration their intended use. In March 2021, the Product Safety and Technical Regulations Law No. 7223 (the “Product Safety Law”) became effective. The Product Safety Law reconciled some outstanding differences between Turkish and EU product safety standards, providing in part for manufacturer and importer liability in the event that a noncompliant or unsafe product causes harm or damage and mandating recall of such products. Because the current regulatory framework in Turkey closely parallels the EU’s framework, we do not currently experience material difficulties in marketing our SOPHiA platform and related solutions, products and services in Turkey that are unique to that jurisdiction.

Federal and State Health Care Laws

Federal Physician Self-Referral Prohibition

We are subject to the federal physician self-referral prohibition, commonly known as the Stark Law, and to comparable state laws. Together these restrictions generally prohibit us from billing a patient or governmental or private payor for certain designated health services, including clinical laboratory services, when the physician ordering the service, or a member of such physician's immediate family, has a financial relationship, such as an ownership or investment interest in or compensation arrangement, with us, unless the relationship meets an applicable exception to the prohibition. Several Stark Law exceptions are relevant to many common financial relationships involving clinical laboratories and referring physicians, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) space and equipment rental arrangements that satisfy certain requirements and (4) personal services arrangements that satisfy certain requirements. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law and Medicaid reimbursements may be at risk as well. These prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral. Penalties for violating the Stark Law include significant civil, criminal and administrative penalties, such as the return of funds received for all prohibited referrals, fines, civil monetary penalties, exclusion from the federal health care programs, integrity oversight and reporting obligations, and imprisonment. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the federal False Claims Act (the "FCA"), which can result in additional civil and criminal penalties.

Federal Anti-Kickback Law

The AKS makes it a felony for a person or entity, including a clinical laboratory, to knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in order to induce business that is reimbursable under any federal health care program. The government may also assert that a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the FCA, which is discussed in greater detail below. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Although the AKS applies only to items and services reimbursable under any federal health care program, a number of states have passed statutes substantially similar to the AKS that apply to all payors. Penalties for violations of such state laws include imprisonment and significant monetary fines. Federal and state law enforcement authorities scrutinize arrangements between health care providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. Generally, courts have taken a broad interpretation of the scope of the AKS, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases. In addition to statutory exceptions to the AKS, regulations provide for a number of safe harbors. If an arrangement meets the provisions of an applicable exception or safe harbor, it is deemed not to violate the AKS. An arrangement must fully comply with each element of an applicable exception or safe harbor in order to qualify for protection. Failure to meet the requirements of the safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances.

Other Health Care Laws

In addition to the requirements discussed above, several other health care fraud and abuse laws could have an effect on our business.

The FCA prohibits, among other things, a person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval and from making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim in order to secure payment or retain an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Several states have enacted comparable false claims laws which may be broader in scope and apply regardless of payor.

The Social Security Act includes civil monetary penalty provisions that impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. In addition, a person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable under the civil monetary penalties statute. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries, for example, in connection with patient assistance programs, can also be held liable under the AKS and FCA. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Office of Inspector General of the HHS emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient.

HIPAA created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and 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. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The EKRA prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal health care programs to include private insurance (i.e., it is an "all payor" statute). The full scope of EKRA is uncertain and is subject to a variety of interpretations.

The Physician Payments Sunshine Act, enacted as part of the ACA, also imposed annual reporting requirements on manufacturers of certain devices, drugs and biologics for payments and other transfers of value by them during the previous year to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

Also, many states have laws similar to those listed above that may be broader in scope and may apply regardless of payor.

Efforts to ensure that our internal operations and business arrangements with third parties comply with applicable laws and regulations involve substantial costs. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the fraud and abuse laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, integrity oversight and reporting obligations, limitations to the sale of certain products or services, diminished profits and future earnings, and the curtailment or restructuring of our operations.

Coverage and Reimbursement

Sales of our SOPHiA platform and related solutions, products and services, if approved for IVD use, may depend substantially on the extent to which they are covered by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors.

In the United States, many significant decisions about reimbursement for new diagnostics and medicines are made by CMS, which decides whether and to what extent a new diagnostic or medicine will be covered and reimbursed under Medicare, although it frequently delegates this authority to local MACs. Private payors tend to follow Medicare to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel platforms, products and services such as ours. Outside the United States, the reimbursement process and timelines vary significantly. Certain countries, including a number of member states of the EU, set prices and make reimbursement decisions for diagnostics and pharmaceutical products, or medicinal products, as they are commonly referred to in the EU, with limited participation from the marketing authorization or CE mark holders, or may take decisions that are unfavorable to the authorization or CE mark holder where they have participated in the process.

Health Reform

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system to contain costs, improve quality and expand access to care. For example, the ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will result in the development of new programs. There have been executive and judicial challenges to certain aspects of the ACA, as well as efforts to repeal, replace or alter the implementation of certain aspects of the ACA. Further, the Biden administration has taken executive action relating to the ACA and access to healthcare. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how any such challenges as well as the healthcare reform measures of the current U.S. presidential administration will affect our business, financial condition and results of operations. In addition, other legislative changes have been adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional congressional action is taken, with the exception of a temporary suspension of the 2% cut in Medicare payments from May 1, 2020 through December 31, 2021. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years. We expect that additional state, federal and foreign healthcare reform measures will be adopted in the future.

Data Privacy and Security

Health Insurance Portability And Accountability Act and Other U.S. Laws and Regulations

Under HIPAA, as amended by HITECH, HHS has issued security, privacy and breach notification regulations pertaining to PHI used or disclosed by certain entities, including certain health care providers such as us.

Three standards have been promulgated under HIPAA's and HITECH's regulations: the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures, and the Security Standards for the Protection of Electronic Protected Health Information, which require covered entities and business associates to implement and maintain certain security measures to safeguard certain electronic health information, including the adoption of administrative, physical and technical safeguards to protect such information.

The HIPAA privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain or transmit PHI on behalf of a covered entity or business associate, as well as their covered subcontractors. They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. The HIPAA security regulations establish requirements for safeguarding the confidentiality, integrity and availability of PHI that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose PHI is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal "floor" for PHI and do not preempt 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 PHI or insofar as such state laws apply to personal information that is broader in scope than PHI. In addition, individuals (or their personal representatives, as applicable) generally have the right to access test reports directly from laboratories and to direct that copies of those reports be transmitted to persons or entities designated by the individual.

HIPAA authorizes U.S. state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty-of-care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, violations of HIPAA could result in significant penalties imposed by the HHS's Office for Civil Rights. HIPAA also mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA-covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator. Our company may receive, as part of the normal course of its business, PHI that is covered by HIPAA. Considering this, we have certain obligations under HIPAA regarding the use and disclosure of any PHI that may be provided to us. Therefore, noncompliance with privacy and security requirements imposed by HIPAA and HITECH could subject us to significant administrative, civil and criminal penalties.

Further, various states, such as California, have implemented privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information, and such laws may differ from each other, all of which may complicate compliance efforts. For example, on June 28, 2018, California enacted the CCPA, which became effective on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers about their data collection, use and sharing practices and provide such consumers new data protection and privacy rights, including the ability to opt out of certain sales of personal information, as that phrase is broadly defined. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Additionally, on November 3, 2020, California voters approved a new privacy law, the CPRA, which significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. Many of the CPRA's provisions will become effective on January 1, 2023. State laws are changing rapidly and there is discussion in the United States of a new comprehensive federal data privacy law to which we would become subject if it is enacted.

Numerous other federal and state laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of patient health information. We intend to continue to comprehensively protect all personal information and to comply with all applicable laws regarding the protection of such information through our policies and procedures as well as through administrative, physical and technical safeguards.

General Data Protection Regulation and Other Foreign Laws and Regulations

As we are operating worldwide, including in the EU and the EEA member states, the UK, and Switzerland, we have to ensure the compliance of our processing activities with different data protection laws and regulations. Non-compliance with these data protection laws and regulations may not only result in high penalties, it can also cause a loss of reputation and trust.

In the EU and the EEA, processing operations of personal data, including health and genetic personal data, are governed by the GDPR. The GDPR strengthens the powers of the relevant authorities and adds a broad array of requirements for handling personal data, including, for example, requirements to establish a legal basis for processing, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, requirements to implement safeguards to protect the security and confidentiality of personal data that requires the adoption of administrative, physical and technical safeguards, shortened timelines for data breach notifications to appropriate data protection authorities or data subjects, limitations on retention and secondary use of information, increased requirements pertaining to health data and additional obligations when we contract third-party processors in connection with the processing of the personal data. EU and EEA member states are tasked under the GDPR to enact, and have enacted, certain implementing legislation that adds to and/or further interprets the GDPR requirements and potentially extends our obligations and potential liability for failing to meet such obligations. The GDPR, together with national legislation, regulations and guidelines of the EU and the EEA member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal data. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the EEA, security breach notifications and the security and confidentiality of personal data, including the following:

- Lawfulness, fairness and transparency: Personal data must be processed lawfully, fairly and in a transparent manner.
- Purpose limitation: Personal data must be obtained for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.
- Data minimization: Personal data processed must be adequate, relevant and limited to what is necessary.
- Accuracy: Personal data must be accurate and, where necessary, kept up to date.
- Storage limitation: Personal data must not be kept longer than is necessary.
- Integrity and confidentiality: Appropriate technical and organizational measures must be put in place to guard against unauthorized or unlawful processing, loss, damage or destruction.

The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater, and other administrative penalties. The UK has transposed the GDPR into domestic law, with its version of the GDPR that took effect on January 1, 2021, which could expose us to two parallel regimes, each of which potentially authorizes similar fines for certain violations.

In addition, processing of personal data may be governed by the FADP. The FADP provides for data protection principles that are substantially similar to those applied under the GDPR. The FADP is undergoing a revision that aims to ensure an adequate level of data protection and compatibility with the GDPR. The revised FADP is expected to enter into force in 2022. The purpose of the FADP is to protect the personality rights, including privacy rights, and the fundamental rights of data subjects. The FADP is broad in its material scope and applies to personal data processing activities carried out by federal authorities, private organizations and individual private persons (excluding processing activities for exclusively personal use). The territorial scope of the FADP goes beyond those processing operations carried out in Switzerland, also covering operations that have an effect in Switzerland, even if they originate in another country. Sensitive personal data, including health data, genetic data and biometric data, which unequivocally identify a natural person, are subject to stricter protective measures in various respects. For example, (i) if consent is required, it must be given expressly in the case of processing of sensitive personal data, (ii) controllers must declare their data files to the FDPIC if they regularly process sensitive personal data, (iii) sensitive data must not be disclosed to third parties without justification, (iv) the controller of a data file is obliged to inform the data subject of the collection of sensitive personal data and (v) disclosing sensitive personal data in breach of a professional confidentiality obligation may be criminally prosecuted. Processing activities by companies must not harm the privacy or personality of the data subject. If the FADP is violated, the FDPIC may request that the processing is fully or partially adjusted, suspended or terminated. Additionally, the FADP authorizes certain criminal fines of up to CHF 10,000. The revised FADP will authorize criminal fines for certain violations of up to CHF 250,000. Such fines are mainly imposed upon the individual responsible for the violation. However, the revised FADP also authorizes fines of up to CHF 50,000 on the responsible data controller or processor. Fines under the FADP may be imposed in addition to fines under other data protection regimes. As part of our processing activities, we implemented a global compliance plan with applicable laws and regulations, which includes in particular:

- the appointment of a Data Protection Officer;
- the creation of the Data Protection Committee and the Information Security Committee, of which the Data Protection Officer and the Information Security Director are the respective manager;
- the implementation of contractual documentation with our collaborators, aligned with the GDPR requirements;
- the preparation of procedures and guidelines, such as a global data protection policy, a data breach responses plan and standard operating procedures for data subject requests; and
- the realization of global data mapping by the Data Protection Officer, the Information Security Director and the Compliance Manager.

In particular, the purpose of the Data Protection Committee is to ensure the data and information we process are protected against data protection risks (in compliance with various data privacy regulations and principles of good governance) as well as to assess the effectiveness of our systems, controls and procedures.

The Data Protection Officer is in charge, in particular, of establishing and maintaining processes for receiving, documenting, tracking, investigating and taking actions on all complaints concerning data protection and considering the risks associated with processing operations, taking into account the nature, scope, context and purposes of processing.

For more information regarding risks relating to data privacy and security laws and regulations, see “Item 3. Key Information—D. Risk Factors—Risks Related to Governmental Regulation—We are subject to stringent privacy and, information security laws and regulations and changes in such laws and regulations could adversely affect our business.”

Information Security

We have implemented protections consistent with the ISO/IEC 27001:2013 standard with respect to technical and physical security in an effort to ensure a level of security appropriate to the risk of our processing activities, in particular with respect to protecting the personal data and customer data we process against damage, loss and unauthorized access, use, modification, disclosure, destruction or other misuse. For this purpose, we have what we believe are adequate data breach response plans, disaster recovery plans and security arrangements in place. However, there can be no assurance that our efforts will be successful in protecting against adverse events or successfully mitigating their effects. Updates to ISO/IEC 27001 are expected in 2022, and we plan to implement the appropriate changes to our security to remain consistent with the updated standard. These changes include: reorganization of controls into four categories / themes from 14 control domains, reduction of total control count by 21, merging of 24 controls from the previous 2013 standard, addition of 11 new controls and introduction of five types of "attributes of control" to improve categorization. For more information regarding risks relating to information security, see "Item 3. Key Information—D. Risk Factors—Risks Related to Our Business and Industry—Cyber security or data privacy breaches, other unauthorized or improper access, or (distributed) denial service lack of access (e.g., ransomware, persistent DoS/DDoS) could result in additional costs, loss of revenue, significant liabilities, harm to our brand and decreased use of our SOPHiA platform and related solutions, products or services."

Data Use Rights

As part of our activities, we process thousands of genetic profiles for all our customers around the world. As a result, and in accordance with applicable data protection laws and regulations, we may produce aggregate anonymized statistical data from the results of all analysis performed using our proprietary algorithms ("Insights"), which are our sole and exclusive property.

Hence, a distinction is made between customer data (i.e., the data uploaded by our customers on our SOPHiA platform) on the one hand and other data generated and developed by us (i.e., the results of the performance of our proprietary algorithms, such as Insights) on the other hand. In this respect, Insights are generated using our proprietary algorithms in the context of our SOPHiA platform and constitute our know-how and trade secrets.

As part of the performance of our services related to our commercial and research and development activities and in accordance with our contractual documentations accepted by our customers and collaborators, we may use our customers' and collaborators' data in particular: (i) for the performance of our contractual obligations; (ii) to anonymize data (and consequently reuse anonymized data); (iii) for scientific or research purposes; (iv) for inclusion in clinical trials; (v) in order to improve our products and/or services; and (vi) as permitted by applicable laws and regulations.

In addition, in accordance with the FADP and the GDPR, we can reuse customer data (including personal data) for further processing activities for statistical purposes. European data protection authorities have previously noted that processing for statistical purposes and for research purposes (including marketing research) are contexts where legitimate purpose can arise. In addition, the processing of personal data for purposes other than those for which the personal data was initially collected should be allowed where the processing is compatible with the purposes for which the personal data was initially collected.

Specific derogations apply for processing operations for statistical purposes, in accordance with the GDPR, as follows:

- personal data can be stored for longer periods insofar as the personal data will be processed solely for statistical purposes subject to implementation of the appropriate technical and organizational measures; information obligations in processing for statistical purposes do not apply if they would involve a disproportionate effort; consideration of this takes into account the number of data subjects and the age of the data, and appropriate safeguards must be adopted; and
- restrictions of the right of a data subject to exercise its "right to erasure" apply if it is likely to significantly impair processing for statistical purposes.

Meanwhile, processing for statistical purposes is subject to certain requirements to:

- set up appropriate safeguards to protect the rights and freedoms of the data subject; and
- implement adequate technical and security measures entrenching the principle of data minimization and using pseudonymized data as the default.

Insights consist of aggregated data providing general trends without identifying individual data subjects and do not contain personally identifiable information. The GDPR does not apply to data that does not relate to or identify an individual, such as aggregated data sets. Consequently, such data sets do not constitute personal data or identifiable information under the GDPR. We believe we have taken reasonable measures to ensure appropriate safeguards and adequate technical and security measures for the processing activities required to generate Insights.

Environmental, Health and Safety Regulations

We are subject to various federal, state, local and foreign environmental, health and safety laws and regulations and permitting and licensing requirements. Such laws include those governing laboratory practices, the generation, storage, use, manufacture, handling, transportation, treatment, remediation, release and disposal of, and exposure to, hazardous materials and wastes, and worker health and safety. Our operations involve the generation, use, storage and disposal of hazardous materials, and the risk of injury, contamination or non-compliance with environmental, health and safety laws and regulations or permitting or licensing requirements cannot be eliminated. Compliance with environmental laws and regulations has not had a material effect on our capital expenditures, earning, or competitive position.

International Regulations

Many countries in which we may offer any of our diagnostic tests in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national health care program. In situations involving physicians employed by state-funded institutions or national health care agencies, violation of the local anti-kickback law may also constitute a violation of the FCPA.

The FCPA prohibits U.S. and other individuals and companies, and their employees, agents, and intermediaries from offering, providing, giving or authorizing the provision of, directly or indirectly through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign government official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. We can also be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, the FCPA requires public companies to maintain accurate books or records and to maintain a system of internal accounting controls.

Violations of the FCPA's anti-bribery provisions for corporations and other business entities are subject to a fine of up to $2 million, and officers, directors, stockholders, employees, and agents are subject to a fine of up to $100,000 and imprisonment for up to five years. Other countries, including the UK and other member states of the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, have similar anti-corruption regulations, such as the United Kingdom Bribery Act 2010.

When marketing our diagnostic tests outside of the United States, we may be subject to foreign regulatory requirements governing human clinical testing, prohibitions on the import of tissue necessary for us to perform our diagnostic tests or restrictions on the export of tissue imposed by countries outside of the United States or the import of tissue into the United States, and marketing approval. These requirements vary by jurisdiction, differ from those in the United States and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

C. Organizational Structure

We have the following wholly owned subsidiaries:

Name of Subsidiary	Jurisdiction of incorporation
SOPHiA GENETICS S.A.S.	France
SOPHiA GENETICS LTD	UK
SOPHiA GENETICS, Inc.	Delaware (USA)
SOPHiA GENETICS Intermediação de Negócios EIRELI	Brazil
SOPHiA GENETICS PTY LTD	Australia
SOPHiA GENETICS S.R.L.	Italy

D. Property, Plants and Equipment

We do not own any real property. We believe that our facilities meet our present needs and we are continuously reviewing our space requirements. The table below sets forth the sizes and uses of our facilities as of December 31, 2021:

Location	Primary Function	Approximate Size
Rue du Centre 172, CH-1025 Saint-Sulpice Switzerland	Office	19,000 ft2
A-ONE Park Building B2 Z.A La Pièce 4, 1180 Rolle Switzerland(1)	Office & Laboratory	11,800 ft2
Technopole Izarbel 374 Allée Antoine d'Abbadie Créaticité bâtiment A 64210 Bidart France	Office	3,450 ft2
Bâtiment GIENAH 11 avenue de Canteranne 33600 Pessac France	Office	3,450 ft2
185 Dartmouth Street Boston, Massachusetts 02116 USA	Office	4,880 ft2

(1) Our lease at A-ONE Park includes additional 7,600 ft2 and 19,400 ft2 of office space leased as of January 1, 2022 and February 1, 2022, respectively.

We continuously review our anticipated requirements for facilities and, on the basis of that review, may from time to time acquire or lease additional facilities and/or dispose of existing facilities. We are not aware of any environmental issues or other constraints that would materially impact the intended use of our facilities.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

A. Operating Results

Overview

We are a healthcare technology company dedicated to establishing the practice of data-driven medicine as the standard of care and for life sciences research. We purposefully built a cloud-based SaaS platform capable of analyzing data and generating insights from complex multimodal data sets and different diagnostic modalities. Our platform standardizes, computes and analyzes digital health data and is used across decentralized locations to break down data silos. This enables healthcare institutions to share knowledge and experiences and to build a collective intelligence. We envision a future in which all clinical diagnostic test data is channeled through a decentralized analytics platform that will provide insights powered by large real-world data sets and AI. We believe that a decentralized platform is the most powerful and effective solution to create the largest network, leverage data and bring the benefits of data-driven medicine to customers and patients globally. In doing so, we can both support and benefit from growth across the healthcare ecosystem.

In 2014, we launched the first application of our platform to analyze NGS data for cancer diagnosis. We have a broad range of applications used by healthcare providers, clinical and life sciences research laboratories and biopharmaceutical companies for precision medicine across oncology, rare diseases, infectious diseases, cardiology, neurology, metabolism and other disease areas. In 2019, we launched our solution for radiomics data that enables longitudinal monitoring of cancer patients and tumor progression throughout their disease journey. Today, we believe that our SOPHiA platform, commercialized under the name "SOPHiA DDM," is one of the most widely used decentralized analytics platform globally for clinical genomics. As of December 31, 2021, we served more than 790 hospital, laboratory and biopharma customers globally through our SOPHiA platform and related solutions, products and services, and our SOPHiA platform has supported the analysis of more than 910,000 genomic profiles and has been utilized in clinical trials and research projects discussed in more than 330 peer-reviewed publications. As of December 31, 2021, we had 382 recurring SOPHiA platform customers (defined as the number of customers who generated revenue during the specified time period, which, in this case, is the twelve months ended December 31, 2021). We commercialize our SOPHiA platform and related solutions, products and services as RUO and CE-IVD products. In the United States, our products are labeled and sold for research use only. Because such products are not intended for use in clinical practice in diagnostics and the products cannot include clinical or diagnostic claims, the FDA regulations require that RUO products be labeled "For Research Use Only. Not for use in diagnostic procedures." In the EU, we have self-certified our products without the intervention of a notified body in order to affix the CE marking.

We began our operations in 2011 and launched our first application in 2014. Since then, our operations have focused on organizing and staffing our company, business planning, conducting research and development of our SOPHiA platform, selling and marketing our SOPHiA platform and raising capital.

Our clinical customers primarily include academic and non-academic hospitals and reference and specialty laboratories. Our biopharma customers primarily include pharmaceutical and biotechnology companies and CROs. Our customers are able to access our SOPHiA platforms through three primary access models: dry lab access, bundle access and integrated access. As of December 31, 2021, we operated a global direct sales team of more than 82 field-based commercial representatives across 61 countries in all four of our major regions of operations (North America, Latin America, EMEA and Asia-Pacific ("APAC")) and further supplemented our direct sales team with distributors in 12 additional countries. For the years ended December 31, 2021 and 2020, we generated $40.5 million and $28.4 million in revenue, respectively, representing 42% year-over-year growth.

We have funded our operations primarily through equity financings that have generated $498.3 million in gross proceeds as of December 31, 2021 and, to a lesser extent, through revenue generated from the sale of access to our SOPHiA platform and related licenses, solutions, products and services. As of December 31, 2021, we had cash and cash equivalents of $193.0 million and term deposits of $72.4 million. Since our inception, we have incurred net losses, which have been significant in recent periods. For the years ended December 31, 2021 and 2020, our net losses were $73.7 million and $39.3 million, respectively. As of December 31, 2021, we had an accumulated deficit of $211.4 million. We expect to continue to incur net losses for the foreseeable future as we continue to devote substantial resources to (i) research and development, in particular to further expand the features, applications and data modalities of our SOPHiA platform in order to accommodate multimodal data analytics capabilities across a wide range of disease areas, (ii) expanding our selling and marketing efforts for our SOPHiA platform and related solutions, products and services, in particular to drive new customer adoption with clinical customers and biopharmaceutical companies, (iii) establishing and maintaining relationships with our collaborators and customers across the healthcare system, and (iv) obtaining regulatory clearance or approval to offer our products as IVD products for diagnostic use. Our ability to achieve profitability depends on the successful commercialization and further development of our SOPHiA platform and related solutions, products and services.

Factors Affecting Our Performance

We believe that our financial performance has primarily been driven by, and in the foreseeable future will continue to be primarily driven by, the factors discussed below. While these factors present significant opportunities for our business, they also pose challenges that we must successfully address in order to sustain our growth and improve the results of our operations. Our ability to successfully address these challenges is subject to various risks and uncertainties described elsewhere in this prospectus, particularly in the section titled "Item 3. Key Information—D. Risk Factors."

Customer Acquisition and Analysis Volume

We principally derive revenue from the use of our SOPHiA platform by our customers as well as the sales of related licenses, solutions, products and services. Our analysis volume is dependent on both the acquisition of new customers as well as usage volume from our existing customers. We employ a "land and expand" commercial model focused on winning new customers and then driving subsequent recurring utilization of our solutions by those acquired customers. Once we secure a customer, we use our direct sales force to build further engagement and help that customer increase its testing operations. For example, we may initially support a customer in setting up its NGS testing operations for hereditary cancer screening, including operational support through our set-up programs. Once the customer is fully onboarded on our SOPHiA platform, it is then comparatively easier to deploy additional germline testing solutions as well as somatic oncology testing solutions, creating synergies across the offerings and a unified workflow. We also target incremental users within each customer, for example, additional clinicians within a provider across expanded departments such as radiology or pathology.

We expect our analysis volume to increase and new customer acquisitions to accelerate as we further expand the features, applications and data modalities of our SOPHiA platform, extend our presence into new geographies and further penetrate existing geographies, particularly geographies that represent largely underpenetrated opportunities such as North America. We intend to significantly invest in the development of our SOPHiA platform to accommodate multimodal data analytics capabilities across a wide range of disease areas, including underpenetrated disease areas such as cardiology and neurology, which we believe will allow us to attract new customers and increase usage of our SOPHiA platform within our existing customer base. To extend our presence into new geographies and further penetrate existing geographies, we intend to significantly invest in our direct sales force to further scale the size of our network in

underpenetrated geographies such as North America, form additional collaborations with reference and specialty laboratories and collaborate with collaborators and distributors in selected geographies outside of North America.

Revenue Mix

We derive revenue from the use of our SOPHiA platform by our customers as well as the sales of related licenses, solutions, products and services. Our clinical customers can access our platform using three different models: dry lab access, bundle access and integrated access. In the dry lab access model, our customers use the testing instruments and consumables of their choice and our SOPHiA platform and algorithms for variant detection and identification. In the bundle access model, we bundle DNA enrichment kits with our analytics solution to provide customers the ability to perform end-to-end workflows. In the integrated access model, our customers have their samples processed and sequenced through select SOPHiA platform collaborators within our clinical network and access their data through our SOPHiA platform.

We have experienced fluctuations in how our customers access our SOPHiA platform across the three access models. Specifically, certain customers may transition from one access model to another over time. For example, we have observed a trend with certain customers being onboarded onto our platform through the dry lab access model, but, over time, as our relationships with them grow, these customers transition to the bundle access model as customers trust us to curate a set of instruments and consumable products to help increase the accuracy of the analysis they generate. This trend is one illustration of our “land and expand” commercial model, as bundle access is typically a higher revenue-generating model compared to dry lab access based on the incremental value from the sale of consumables and instruments as well as higher platform usage on average for bundle access customers. Certain types of customers are also more likely to access our SOPHiA platform using one access model compared to other customers. For example, customers who are unable or do not wish to conduct sequencing locally are inclined to use the integrated access model. These customers have historically represented a small percentage of our customer base relative to the bundle access and dry lab access models. We expect that the revenue contribution from each of three access models will vary depending on our customer base and the rate of new customer acquisition.

We also derive revenue from the sale of licenses for our Alamut suite of genomics mutations interpretation software. While we view Alamut as a complementary add-on to our SOPHiA DDM platform, there are a number of Alamut users who currently are not customers of our SOPHiA DDM platform. We expect that revenue contribution from Alamut will continue to vary based on the number of stand-alone Alamut users as well as our ability to cross-sell our SOPHiA DDM platform to Alamut users and vice versa.

Seasonality

We typically experience lower usage of our SOPHiA platform in the third quarter compared to other quarters, which we believe is due to the seasonal slowdown at our customers’ European facilities attributable to summer vacations and European holiday schedules. As we expand in the North American market, we expect that we will be subject to lower seasonal variations in our usage per customer.

Biopharma Expansion

To date, the majority of our revenue is generated through our clinical customers, including academic and non-academic hospitals, and reference and specialty laboratories. However, we see potential for our biopharma business to comprise a more significant portion of our revenues. We began commercializing our biopharma product and service offerings in 2019. While we have the ability to offer a robust package of pre- and post-market solutions to our biopharma customers through SOPHiA Trial Match, SOPHiA Insights, SOPHiA CDx and SOPHiA Awareness, our biopharma business is still nascent with the initial focus on establishing pilot programs with large pharmaceutical and biotech companies to build customer trust and raise awareness about our offerings. We intend to leverage our platform and database to drive adoption by biopharmaceutical companies through our sales force focused on biopharma opportunities across the discovery, clinical development and commercialization value chain. In addition, we plan to develop new offerings for biopharma as we expand the number and type of new applications and data modalities on our platform.

Strategic Acquisitions and Collaborations

We vigilantly monitor the market for potential investments to expand or add key technologies to our offerings that we believe will improve our platform’s ability to address our customers’ needs and catalyze the commercialization of new products and services. Our investment strategy could take the form of a business acquisition, asset acquisition or strategic licensing of patented technology, all of which may affect our future financial results. For example, our acquisition of Interactive Biosoftware (“IBS”) in 2018 expanded the functionality of our SOPHiA platform. The Alamut suite of genomics mutation interpretation software is connected to our SOPHiA DDM platform and gives our customers advanced

analytics capabilities for a deeper and more informed genomic data interpretation. We view Alamut as a complement to our SOPHiA DDM platform and expect to be able to accelerate our growth by cross-selling our SOPHiA DDM platform to Alamut users and vice versa.

To complement our investment strategy, we have also collaborated, and intend to form additional collaborations, with other product providers in the ecosystem to bundle our solutions to provide differentiated end-to-end solutions. We currently collaborate with testing kit companies, testing hardware providers, software analytics companies and diagnostic companies operating with a centralized model. For example, we formed collaborations with companies including Twist, IDT and Agilent to create an integrated solution using our analytics platform and their library preparation products, including DNA enrichment kits. We continue to regularly evaluate our role in the genomics and radiomics value chain in order to provide both our existing and new customers with a comprehensive product offering, enhance our overall market and competitive position and expand into adjacent untapped markets and new geographies.

Research and Development

A significant aspect of our business is our continued investment in research and development, including new features, new applications, new data modalities and new services. We plan to continue investing in scientific innovation to bring innovative, high-impact content to our customers through regular updates of our platform.

Exchange Rates

We operate internationally and a majority of our revenue, expenses, assets, liabilities and cash flows are denominated in currencies other than our presentation currency, the U.S. dollar and the functional currency of SOPHiA GENETICS SA, the Swiss franc. Our revenues are generated primarily in the U.S. dollar, the euro and Swiss franc and, to a lesser extent, British pound, Australian dollar, Brazilian real, Turkish lira and Canadian dollar depending on our customers' geographic location. Our expenses are incurred primarily in the U.S. dollar, the euro and Swiss franc and, to a lesser extent, British pound, Australian dollar and Brazilian real. We expect that a part of our revenues and expenses will continue to be denominated in currencies other than the U.S. dollar. Therefore, part of the fluctuations in our operating results in any period may result from changes in exchange rates. We currently do not use any financial instruments to manage our exchange rate risks, which we have been partially mitigating by matching costs in the same foreign currency.

Impact of the COVID-19 Pandemic

The COVID-19 pandemic has negatively affected our overall and non-COVID-19 analysis-related revenue. Our hospital customers prioritized COVID-19-related services during the pandemic. In addition, as a result of pandemic containment measures, some of our customers experienced disruptions in their operations, refocused their research and development priorities and operated at reduced capacity. As a result, we observed a significant decrease in revenue and analysis volume in the second quarter of 2020. Although we have seen a sustained recovery for the rest of the year, we believe that we experienced lower growth in revenue and analysis volume in 2020 as a result of the COVID-19 pandemic than we otherwise would have achieved. With the loosening of COVID-19-related restrictions in 2021, we have seen a general recovery in our business, with the resumption of our customer acquisition initiatives and as customers returned to their labs and reallocated resources and focus to non-COVID-19-related operations. However, we are still subject to periodic disruptions resulting from the implementation and loosening of variant-related restrictions, such as what has been transpiring with the progression of the Omicron variant.

In addition, the COVID-19 pandemic resulted in restricted access to reference and specialty laboratories and prioritization of COVID-19-related testing at the expense of non-COVID-19 analysis. These restrictions hindered our ability to acquire new clinical customers. As a result, we believe that we experienced lower customer acquisition growth in 2020 as a result of the COVID-19 pandemic than we otherwise would have achieved.

COVID-19 has also created opportunities for us. For example, we collaborated with Paragon Genomics, Inc. to develop a NGS assay for COVID-19 that leverages our SOPHiA platform's analytical capabilities, allowing us to deliver the benefits of this solution to our customers worldwide. In early 2021, we introduced our own COVID-19 bundled access product and pipeline. We derived $2.6 million in revenue from our COVID-19 products and applications for the year ended December 31, 2021. While the NGS assay for COVID-19 did not constitute a significant part of our revenue, and we do not expect it do so in the future, we believe that this collaboration illustrates the flexibility and adaptability of our SOPHiA platform.

Key Operating Performance Indicators

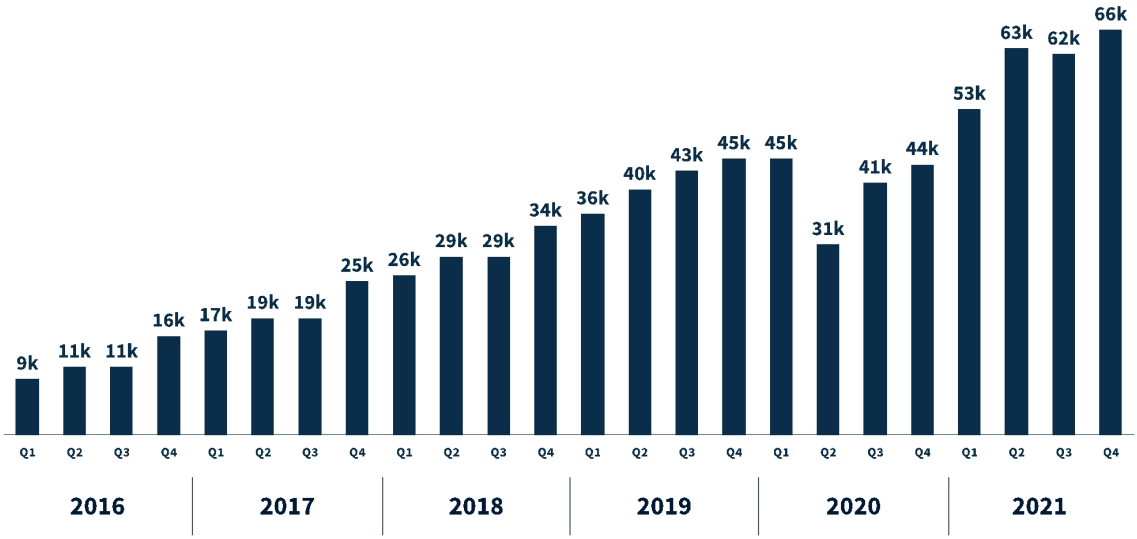
We regularly monitor a number of key operating performance indicators and metrics to evaluate our business, measure our performance, identify key operating trends and formulate financial projections and strategic plans. We believe that the

following metrics are representative of our current business, but the metrics we use to measure our performance could change as our business continues to evolve. Our key operating performance indicators primarily focus on metrics related to our SOPHiA platform metrics, as platform revenue comprises the majority of our revenues.

As used in this section, the term “customer” refers to any customer who accesses our SOPHiA platform through the dry lab and bundle access models. We exclude from this definition any customers accessing our SOPHiA platform using the integrated business model because they tend to use our platform in an ad hoc manner compared to our dry lab and bundle access customers who typically do so in a recurring fashion, generate an immaterial portion of our revenue and analysis volume and constitute a small part of our customer base. We also exclude from this definition customers who only use Alamut through our SOPHiA platform.

Platform Analysis Volume

Quarterly Platform Analysis Volume from Q1 2016 to Q2 2021



	Year ended December 31,	
	2021	2020
Platform analysis volume	243,394	161,049

Platform analysis volume represents a key business metric that reflects our overall business performance, as we generate revenue on a pay-per-analysis basis. Platform analysis volume measures the number of analyses that generated revenue to us and were conducted by our customers. Analysis volume is a direct function of the number of active customers and usage rates across our customer base during a specified time period. While our platform analysis volume is a major driver of our revenue growth, other factors, including product pricing, access model used and customer size mix, also affect our revenue. Because of that, our revenue may increase in periods in which our analysis volume decreases and vice versa.

Analysis volume increased to 243,394 in the year ended December 31, 2021 from 161,049 in the year ended December 31, 2020. We observed a significant increase in chargeable analysis volume of 51% for the year ended December 31, 2021, as compared to the year ended December 31, 2020. We believe this increase is primarily attributable to increased usage from our existing customers as well as new customers onboarded onto our platform, particularly as customers returned to their labs as COVID-19-related pandemic restrictions loosened, and customers reallocated resources and focus to non-COVID-19-related operations. While platform analysis volume is a primary driver of our overall revenue, there are other important factors that also contribute to our revenue performance, including access model mix, Alamut license sales, biopharma service revenue and workflow equipment and services revenue. These factors also contributed to year-over-year growth in our overall revenue in 2021.

Total Recurring Platform Customers

	Year ended December 31,	
	2021	2020
Existing recurring platform customers	292	265
New recurring platform customers	90	49
Total recurring platform customers	382	314

We track the number of our recurring platform customers, defined as the number of customers who generated revenue during the specified time period, as a key measure of our ability to generate recurring revenue from our install base. We further define our recurring platform customers as "existing" or "new" recurring platform customers based on the year in which they first accessed our SOPHiA platform and generated revenue for us. The analysis excludes customers without any usage of our SOPHiA platform over the past twelve months and customers who have executed agreements with us that have not generated any revenue to us, including customers that are in the process of being onboarded onto our SOPHiA platform. The analysis also excludes our customers who access our SOPHiA platform exclusively through the integrated access model.

Total recurring platform customers increased to 382 in the year ended December 31, 2021 from 314 in the year ended December 31, 2020. The increase is primarily attributable to our ability to renew our customer acquisition momentum that was impacted by COVID-19-related pandemic restrictions as restrictions were progressively loosened throughout the course of 2021. In particular, the return of the workforce to hospitals and laboratories and our customers' ability to reallocate resources to non-COVID-19-related operations allowed us to make significant progress in building out our customer base as restrictions began to loosen in 2021 with the availability of various vaccines.

Average Revenue per Platform Customer

	Year ended December 31,	
(in USD)	**2021**	**2020**
Average revenue per platform customer	92,028	70,004

Average revenue per platform customer is a key measure of our ability to create additional value from our existing customer relationships and the viability of our "land and expand" commercial strategy. We calculate average revenue per platform customer based on the total revenue generated by our customers divided by the total number of customers. Average revenue per platform customer is a function of analysis volume, product pricing, access model used and customer size mix.

Average revenue per platform customer increased to $92,028 in the year ended December 31, 2021 from $70,004 in the year ended December 31, 2020. The increase is primarily attributable to the "expand" aspect of our "land and expand" strategy through which we have been able to increase usage rates and adoption of our applications as our relationships with our customers deepened over time.

Lifetime Value (LTV) to Customer Acquisition Cost (CAC) Ratio

	Year ended December 31,	
(in USD thousands, except ratio)	**2021**	**2020**
LTV	2,089	882
CAC	272	275
LTV/CAC Ratio	7.7x	3.2x

We track the LTV to CAC ratio for our dry lab and bundle access customers as a measure of our ability to generate gross profit per customer relative to the cost to acquire a customer. We calculate LTV for the stated time period by dividing the average revenue per customer by the revenue churn rate, which we define as the annualized revenues we estimate to have lost from customers who have not generated revenue over the past 12 months in that period based on their average quarterly revenue contributions from point of onboarding as a percentage of total recurring platform revenue, and multiplying by average gross margin for dry lab and bundle access customers. We calculate CAC for the stated time period based on sales and marketing expenses divided by the number of new customers that we acquired who have generated revenue over the period. As our company continues to expand and scale, increasing and maintaining a high LTV to CAC ratio will be important to increasing profitability in parallel with increasing our market share.

Our LTV to CAC ratio over the last two years held steady at above the 3x threshold. Our LTV to CAC ratio increased to 7.7x in the year ended December 31, 2021 from 3.2x in the year ended December 31, 2020. The increase is attributable primarily to an increase in LTV. The higher LTV is a result of higher average revenue per platform user and lower percentage of revenue contributed by lost customers as a result of a low annualized revenue churn rate of 3%. We do not believe that this low revenue churn rate is sustainable in the long-term, and, as such, we expect a degree of normalization for our LTV to CAC ratio over time towards our historical above 3x threshold, as revenue churn normalizes.

Net Dollar Retention (NDR)

	Year ended December 31,	
	2021	**2020**
Net Dollar Retention	142%	110%

We track net dollar retention for our dry lab and bundle access customers as a measure of our ability to grow the revenue generated from our recurring platform customers through our “land and expand” strategy net of customer churn. To calculate net dollar retention, we first specify a measurement period consisting of the trailing two-year period from our fiscal year end. Next, we define a measurement cohort consisting of platform customers who use our dry lab access and bundle access models from whom we have generated revenues during the first month of the measurement period, which we believe is generally representative of our overall dry lab access and bundle access customer base. We then calculate our net dollar retention as the ratio between the revenue generated from this cohort in the second year of the measurement period and the revenue generated in the first year. Any customer in the cohort that did not use our platform in the second year are included in the calculation as having contributed zero revenue in the second year.

Net dollar retention increased to 142% as of December 31, 2021 from 110% as of December 31, 2020. The large year-over-year increase is attributable to our ability to grow average revenue per customer stemming from increased usage across our customer base as a part of the “expand” aspect of our strategy and as our customers resumed their non-COVID-19-related operations with the lifting of restrictions in 2021, while also maintaining a low annualized revenue churn rate of 3% for the year ended December 31, 2021. Given the outsized impact from COVID-19-related restrictions on our customers’ operations in 2020 and thereby our revenue and NDR, we expect smaller degrees of change in our NDR from period to period in the future.

Components of Results of Operations

Revenue

We generate revenue from goods and services rendered to our clinical customers and from our biopharma customers. Our clinical customers include academic and non-academic hospitals (including comprehensive cancer centers and children’s hospitals), and reference and specialty laboratories. Our biopharma customers include companies along the full biopharma value chain. We group our solutions that we offer our customers into two primary reporting segments: our SOPHiA platform and workflow equipment and services.

SOPHiA platform revenue comprises the bulk of our revenue and includes goods and services related to the use of our SOPHiA DDM platform, including our clinical genomics solutions, which span across a broad range of unique applications for analyzing genomic data; our Alamut suite of genomics mutation interpretation software, which gives our clinical customers advanced analytics capabilities for a deeper and more informed genomic data interpretation; and biopharma applications designed to help customers solve bottlenecks across the biopharma value chain, including discovery, clinical development and commercialization; and the sale of third-party instruments and consumables to our bundle access customers.

For clinical customers, our primary pricing strategy for our SOPHiA DDM platform is a pay-per-use model, in which customers access our platform free of charge but pay for each use of our platform. Pricing varies based on our customer mix, as customers require differing levels of customization. For Alamut, our primary pricing strategy is a licensing model, in which customers access our platform for a contracted price. For biopharma customers, we are continuing to refine our pricing strategy since we launched our initial applications for the biopharma market in 2019. We recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services. For revenue generated from our SOPHiA DDM platform customers, we recognize revenue from analyses as the analyses are conducted and revenue from bundled instruments and consumables at the point of delivery. For revenue generated from Alamut licenses, we recognize revenue over the course of the license period. Payments from our customers are typically due up to 180 days from the invoice date. We have a diverse range of customers and no single customer accounted for more than 3% of our revenue for the years ended December 31, 2021 or 2020.

Workflow equipment and services revenue includes all revenue from the sale of materials and services that do not form part of a contract for the provision of platform services rendered primarily to clinical customers. These include the provision of set-up programs and training and the sale of equipment that are not linked to the use of the platform, such as automation equipment. Set-up programs and training are typically combined with a customer's first order prior to the customer being onboarded onto our SOPHiA platform. Revenue from services is generally recognized when the services are performed. Revenue from materials are recognized when control of the goods is transferred to the customer, generally at the time of delivery.

We have demonstrated continued revenue growth during 2021 and 2020 as a result of the continued development of our platform and technology and further penetration of the market. Revenue performance is reflective of the strong foundation that has been built, focused around clinical and biopharma customers. This category of revenue also includes the revenue from the sale of DNA sequencing automation equipment accounted for under IFRS 16, *Leases* ("IFRS 16"), leasing and the fees charged for the maintenance of this equipment.

Cost of Revenue

Cost of revenue comprises costs directly incurred in earning revenue, including computational and storage-related costs and fees paid to hosting providers, manufacturing costs, materials and consumables, the cost of equipment leased out under finance leases, personnel-related expenses and amortization of capitalized development costs. Capitalized software development costs are amortized using the straight-line method over an estimated life of five years.

While we currently expect increased investments to accelerate growth, we also expect to realize increased efficiencies and economies of scale and undertake cost containment measures to reduce the cost of using cloud infrastructure. Over time, we expect our gross profit margin to increase as we broaden our customer base, increase customer engagement, expand our cloud infrastructure and negotiate additional arrangements with service providers, including with respect to computational and storage-related costs and fees paid to hosting providers. However, in the near term, we expect that our gross profit margin will be adversely impacted by increased computational and storage-related costs and fees as we have purchased, and may be required to continue to purchase, increased capacity at less favorable rates in order to address increased demand for our SOPHiA platform and related solutions, products and services. Our cost of revenue as a percentage of revenue may fluctuate from period to period depending on the interplay of the various components of cost of revenue.

Operating Expenses

Operating expenses consist of research and development, selling and marketing, general and administrative, and other operating income (expense), net.

Research and Development Costs

Research and development costs consist of personnel and related expenses for technology and product development, depreciation and amortization, laboratory supplies, consulting services, computational and storage-related costs and fees paid to hosting providers related to research and development and allocated overhead costs. These costs are stated net of government grants for research and development and innovation received as tax credits and net of capitalized costs.

In the short and long term, we expect our research and development costs to increase in absolute dollars, but not necessarily as a percentage of revenue, while we continue to develop, refine and optimize our platform, technology, products and services as we seek to expand the features, applications and data modalities of our SOPHiA platform, broaden our customer base and increase customer engagement to drive revenue growth. We expect research and development costs to continue to comprise the largest component of our overall operating expenses. Our research and development costs as a percentage of revenue may fluctuate from period to period due to the timing and extent of such expenses.

Selling and Marketing Costs

Selling and marketing costs consist of personnel and related expenses for the employees of our sales and marketing organization, costs of communications materials that are produced to generate greater awareness and utilization of our platform among our customers, costs of third-party market research, costs related to transportation and distribution of our products and allocated overhead costs, and commissions to sales employees. These costs are stated net of government grants under the U.S. Paycheck Protection Program for payroll and/or rental obligations received as a loan that is forgiven if utilized as intended.

In the short term, we expect our selling and marketing costs to increase in absolute dollars and as a percentage of revenue as we seek to broaden our customer base and increase customer engagement to drive revenue growth and as we hire additional sales personnel and related account management and sales support personnel to properly service our growing customer base. However, in the long term, we expect our selling and marketing costs to gradually and modestly decrease as a percentage of revenue. Our selling and marketing costs as a percentage of revenue may fluctuate from period to period due to the timing and extent of such expenses.

General and Administrative Costs

General and administrative costs consist of personnel and related expenses for our executive, accounting and finance, legal, quality, support and human resources functions, depreciation and amortization, professional services fees incurred by these functions, general corporate costs and allocated overhead costs, which include occupancy costs and information technology costs.

In the short term, we expect our general and administrative costs to increase in absolute dollars and as a percentage of revenue as we operate as a public company and as we continue to grow our business. As we transition to being a public company, we anticipate increased costs related to audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq and SEC requirements, director and officer insurance premiums, investor relations costs and the development and maintenance of effective internal controls over financial reporting. However, in the long term, we expect our general and administrative costs to gradually and modestly decrease as a percentage of revenue. Our general and administrative costs as a percentage of revenue may fluctuate from period to period due to the timing and extent of such expenses.

Other Operating Income (Expense), Net

Other operating income(expense), net consist of benefits from the COVID-19 loans and grants with a below-market interest rate (see “Liquidity and Capital Resources—Sources of Capital Resources”), gains and losses related to the disposal of tangible assets, write-offs of intangible assets and other operating income and expenses. We cannot predict the amount of other operating income (expense), net for future periods.

Finance Income (Expense), Net

Finance income (expense), net consists of interest income earned on cash and cash equivalents, term deposits and short-term investments and lease liabilities, interest expense on borrowings and COVID-19 loans and grants, interest expense on an earnout retention bonus resulting from the purchase of IBS, changes in the fair value of the derivative associated with the fee payable to TriplePoint Capital LLC (“TriplePoint”) upon the completion of our IPO and foreign exchange gains and losses arising principally from U.S. dollar cash balances and intercompany receivable balances in the parent company, whose functional currency is the Swiss franc.

We currently do not use any financial instruments to manage our interest risk exposure. We expect our interest expense to decrease in 2022 based on the repayment of loans and other debt instruments and the payment of a $2.5 million fee to TriplePoint in 2021. We also currently do not use any financial instruments to manage our exchange rate risks.

Taxation

We are subject to corporate taxation in Switzerland and other jurisdictions in which we operate, in particular, the United States, France, the UK, Brazil and Australia, where our wholly owned subsidiaries are incorporated.

Pursuant to a written agreement with the Swiss government, we are exempted from paying corporate taxes in Switzerland until December 31, 2022.

We are entitled under Swiss laws to carry forward any losses incurred for a period of seven years, which could be used to offset future taxable income. As of December 31, 2021, we had tax loss carryforwards totaling $193.6 million in Switzerland that can be carried forward through future periods that will expire at various dates between January 1, 2022 and December 31, 2028. In the United States, we had tax loss carryforwards of $8.9 million as of December 31, 2021, comprised of $5.0 million in federal tax loss carryforwards that have an unlimited carryforward period and $3.9 million in state and local tax loss carryforwards. Of the U.S. state and local tax loss carryforwards, $1.3 million are set to expire at various dates between January 1, 2034 and December 31, 2044, while the remaining balance has an unlimited carryforward period. In Brazil, we had tax loss carryforwards totaling $0.6 million as of December 31, 2021 that have an unlimited carryforward period. There is no certainty that we will make sufficient profits to be able to utilize these tax loss carryforwards in full during the allotted time periods.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Year ended December 31,		Change	
(in USD thousands, except %)	**2021**	**2020**	**$**	**%**
Revenue	$ 40,450	$ 28,400	$ 12,050	42%
Cost of revenue	(15,229)	(10,709)	(4,520)	42%
Gross profit	**25,221**	**17,691**	**7,530**	**43%**
Research and development costs	(26,578)	(18,588)	(7,990)	43%
Selling and marketing costs	(28,735)	(17,432)	(11,303)	65%
General and administrative costs	(41,505)	(18,965)	(22,540)	119%
Other operating income (expense), net	108	(93)	201	(216%)
Operating loss	**(71,489)**	**(37,387)**	**(34,102)**	**91%**
Finance expense, net	(2,018)	(3,838)	1,820	(47%)
Loss before income taxes	**(73,507)**	**(41,225)**	**(32,282)**	**78%**
Income tax (expense) benefit	(168)	1,886	(2,054)	(109%)
Loss for the year	**$ (73,675)**	**$ (39,339)**	**$ (34,336)**	**87%**

For a comparison of our results of operations for the years ended December 31, 2020 and 2019, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Comparison of the Years Ended December 31, 2020 and December 31, 2019” in our prospectus dated July 22, 2021, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Revenue

	Year ended December 31,		Change	
(in USD thousands, except %)	**2021**	**2020**	**$**	**%**
SOPHiA Platform	$ 39,465	$ 27,221	$ 12,244	45%
Workflow equipment and services	985	1,179	(194)	(16%)
Total revenue	**$ 40,450**	**$ 28,400**	**$ 12,050**	**42%**

Revenue was $40.5 million for the year ended December 31, 2021, compared to $28.4 million for the year ended December 31, 2020. This increase was primarily attributable to an increase in SOPHiA platform revenue, partially offset by a decrease in workflow equipment and services revenue. SOPHiA platform revenue was $39.5 million for the year ended December 31, 2021 compared to $27.2 million for the year ended December 31, 2020. This increase was primarily attributable to an increase in analysis volume, as total platform volume increased by 51% partially offset by a decline in our biopharma services revenue of $0.3 million. Workflow equipment and services revenue was $1.0 million for the year ended December 31, 2021, compared to $1.2 million for the year ended December 31, 2020. This decrease was primarily attributable to a re-classification of revenue derived from our COVID-19-related solution from workflow equipment and services to SOPHiA platform revenue, as we transitioned to offering our own bundled solution and completed the buildout of our COVID-19-related pipeline on our platform in early 2021. Revenue from our COVID-19-related solution was $2.6 million for the year-ended December 31, 2021.

Cost of Revenue

	Year ended December 31,		Change	
(in USD thousands, except %)	**2021**	**2020**	**$**	**%**
Cost of revenue	$ (15,229)	$ (10,709)	$ (4,520)	42%
Gross profit	$ 25,221	$ 17,691	7,530	43%
Gross margin	62%	62%		

Cost of revenue was $15.2 million for the year ended December 31, 2021, compared to $10.7 million for the year ended December 31, 2020. This increase was primarily attributable to our revenue growth. Our manufacturing and supply agreement with IDT and our OEM supply agreement with Qiagen contributed $2.5 million and $2.2 million to cost of revenue, respectively, for the year ended December 31, 2021, compared to $1.7 million and $1.5 million, respectively, for the year ended December 31, 2020.

Operating Expenses

(in USD thousands, except %)	Year ended December 31, 2021	2020	Change $	Change %
Research and development costs	$ (26,578)	$ (18,588)	$ (7,990)	43%
Selling and marketing costs	(28,735)	(17,432)	(11,303)	65%
General and administrative costs	(41,505)	(18,965)	(22,540)	119%
Other operating income (expense), net	108	(93)	201	(216%)
Total operating expenses	**$ (96,710)**	**$ (55,078)**	**$ (41,632)**	**76%**

Research and Development Costs

Research and development costs were $26.6 million for the year ended December 31, 2021, compared to $18.6 million for the year ended December 31, 2020. This increase was primarily attributable to an increase in employee-related expenses, including bonuses and share-based compensation, of $7.8 million for R&D initiatives related to the development of new products and applications as a result of increased hiring, partially offset by an increase in capitalization of development costs of $2.0 million.

Selling and Marketing Costs

Selling and marketing costs were $28.7 million for the year ended December 31, 2021, compared to $17.4 million for the year ended December 31, 2020. This increase was primarily attributable to a $9.6 million increase in employee-related expenses, including bonuses, share-based compensation and commissions, as compensation for existing employees increased with improved sales momentum.

General and Administrative Costs

General and administrative costs were $41.5 million for the year ended December 31, 2021, compared to $19.0 million for the year ended December 31, 2020. This increase was primarily attributable to the continued scale-up of our organization; the development of quality-related initiatives to support a potential expansion of our business into more regulated markets; an increase of $8.3 million in employee-related expenses, including bonuses and share-based compensation; and IPO and public company-related expenses.

Other *Operating Income (Expense), Net*

Other operating income was $0.1 million for the year ended December 31, 2021, compared to an expense of $0.1 million for the year ended December 31, 2020.

Finance (Expense), Net

(in USD thousands, except %)	Year ended December 31, 2021	2020	Change $	Change %
Finance expense, net	$ (2,018)	$ (3,838)	$ 1,820	(47%)

Finance expense was $2.0 million for the year ended December 31, 2021, compared to $3.8 million for the year ended December 31, 2020. This decrease was primarily attributable to a slight foreign exchange gain for the year ended December 31, 2021 as opposed to a loss for the year ended December 31, 2020, arising from intercompany transactions associated with the translation of foreign currency receivable balances and the U.S. dollar cash balances into SOPHiA GENETICS SA's functional currency of the Swiss franc and the U.S. dollar cash balances into SOPHiA GENETICS SA's functional currency of the Swiss. This was partially offset by an increase in finance expense associated with the payment of the $2.5 million success fee owed to TriplePoint upon the completion of our IPO.

Income Tax (Expense) Benefit

(in USD thousands, except %)	Year ended December 31, 2021	2020	Change $	Change %
Income tax (expense) benefit	$ (168)	$ 1,886	$ (2,054)	(109%)

Income tax expense was $0.2 million for the year ended December 31, 2021, compared to a $1.9 million tax benefit for the year ended December 31, 2020. This increase in tax expense is primarily attributed to a tax provision recorded on the operating results of our foreign subsidiaries during the year ended December 31, 2021 as opposed to the tax benefit recorded during the year ended December 31, 2020.

Off-Balance Sheet Arrangements
We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements or commitments that may have a material current or future effect on financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses.

B. Liquidity and Capital Resources

For a discussion of our liquidity and capital sources and cash flows for the year ended December 31, 2019, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources” in our prospectus dated July 22, 2021, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Sources of Capital Resources

Our principal sources of liquidity were cash and cash equivalents totaling $193.0 million as of December 31, which were held for a variety of growth initiatives and investments in our SOPHiA platform and related solutions, products and services as well as working capital purposes. Our cash and cash equivalents are comprised of bank and short-term deposits with maturities up to three months. Separately, we held term deposits with maturities between three and twelve months totaling $72.4 million as of December 31, 2021.

We have funded our operations primarily through equity financing and, to a lesser extent, through revenue generated from the sale of access to our SOPHiA platform and related licenses, solutions, products and services. For the year ended December 31, 2021, we received $243.4 million in total gross proceeds from the sale of 13,000,000 shares as part of our IPO in July 2021 and an additional 519,493 shares in August 2021 pursuant to the underwriters’ exercise of their option to purchase additional shares. We also received an additional $20.0 million in gross proceeds from the sale of 1,111,111 shares to Instrumentarium Holdings, Inc., an affiliate of GE Healthcare, in July 2021 concurrent with the completion of the IPO. For the year ended December 31, 2020, we received $108.7 million in gross proceeds from our sale of an aggregate of 9,316,940 Series F preferred shares in June and September 2020. For the year ended December 31, 2021 and 2020, our revenue was $40.5 million and $28.4 million, respectively. Invoices for our products and services are a substantial source of revenue for our business, which are included on our consolidated balance sheet as trade receivables prior to collection. Accordingly, collections from our customers have a material impact on our cash flows from operating activities. As we expect our revenue to grow, we also expect our accounts receivable and inventory balances to increase, which could result in greater working capital requirements.

During 2020, we received several COVID-19 loans and grants. On March 26, 2020, SOPHiA GENETICS SA received a $0.5 million (CHF 0.5 million) loan from Credit Suisse (Switzerland) Ltd. under the government program in Switzerland, which bore interest at 0% per annum and was repaid in full on March 26, 2021. On May 29, 2020, SOPHiA GENETICS S.A.S. received a $1.6 million (€1.4 million) loan from Credit Agricole Pyrénées Gascogne under the government program in France, which bore interest at 0% per annum and matured on May 25, 2021 and was prepaid in full upon maturity. On May 29, 2020, SOPHiA GENETICS SA received a $1.0 million (CHF 1.0 million) loan from Credit Suisse (Switzerland) Ltd. under the government program in Switzerland, which bore interest at 1.175% per annum and matured on January 31, 2021 and was repaid in full upon maturity. On June 3, 2020, SOPHiA GENETICS, Inc. received a $0.8 million loan from Citizens Bank under the U.S. Paycheck Protection Program, which bore interest at 1.0% per annum and was forgiven along with the accrued interest pursuant to the U.S. Paycheck Protection Program on February 24, 2021. This loan was treated as a government grant for accounting purposes. We do not have any outstanding COVID-19-related loan obligations.

On April 1, 2021, we entered into a credit agreement with Credit Suisse (Suisse) SA that provides for maximum borrowings of $3.3 million (€2.7 million) (the “Credit Facility”). Borrowings under the Credit Facility accrue interest at 3.95% per annum. The term of each loan under the Credit Facility is fixed and agreed separately for each loan. The Credit Facility expires on March 31, 2022. We intend to renew this facility prior to its expiration. Borrowings under the Credit Facility can only be used to finance laboratory automation equipment for NGS purposes. As of December 31, 2021, we had no borrowings outstanding under the Credit Facility.

Uses of Capital Resources

Since our inception, we have incurred net losses, which have been significant in recent periods. For the years ended December 31, 2021 and 2020, our net losses were $73.7 million and $39.4 million, respectively. As of December 31, 2021, we had an accumulated deficit of $211.4 million. Our primary use of capital sources has been to fund our operations and grow our business.

Operating Capital Requirements

We expect to continue to incur net losses for the foreseeable future as we continue to devote substantial resources to research and development, in particular, to further expand the applications and modalities of our SOPHiA platform in order to accommodate multimodal data analytics capabilities across a wide range of disease areas; selling and marketing efforts for our SOPHiA platform to establish and maintain relationships with our collaborators and customers; and obtaining regulatory clearances or approvals for our SOPHiA platform and our products and services. We believe that our existing cash and cash equivalents will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months. Our future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our ability to secure any required regulatory clearance or approval for additional features, applications and data modalities of our SOPHiA platform and related solutions, products and services;
- the ability of our customers and collaborators to secure any required regulatory clearance or approval for their product candidates, other products and services the development of which they rely on our SOPHiA platform and related solutions, products and services;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our SOPHiA platform and related solutions, products and services;
- the rate of progress in establishing payor coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors by us with respect to our products, if approved for IVD use, and by our customers and collaborators, with respect to their product candidates, other products and services;
- the cost of expanding our research and development, manufacturing and laboratory operations and products and services offerings;
- the cost of building out our facilities, including our corporate headquarters in Switzerland and our locations around the world;
- our ability to maintain and expand our collaborations with biopharmaceutical companies, both advanced and early stage, and reference and specialist laboratories;
- our rate of progress in, and cost of research and development activities associated with, early research and development efforts;
- the effect of competing technological and market developments;
- market acceptance of our platform, solutions, products and services;
- costs related to international expansion; and
- the potential cost of, and delays in, product development as a result of regulatory oversight.

Unless and until we can generate sufficient revenue to finance our cash requirements, which may never happen, we may seek additional capital through a variety of means, including through public and private equity offerings and debt financings, credit and loan facilities and collaborations. Additional funds may not be available when we need them or on terms that are acceptable to us. See “Item 3. Key Information —D. Risk Factors—Risks Related to Our Financial Position and Capital Requirements.”

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2021 and 2020:

	Year ended December 31,	
(in USD thousands)	**2021**	**2020**
Net cash from (used in):		
Operating activities	$ (57,939)	$ (31,730)
Investing activities	(56,934)	(24,323)
Financing activities	237,773	107,045
Net increase (decrease) in cash and cash equivalents	**$ 122,900**	**$ 50,992**
Effect of exchange rate differences on cash and cash equivalents	$ (4,563)	$ 5,564

Operating Activities

For the year ended December 31, 2021, net cash used in operating activities was $57.9 million, primarily attributable to our net loss of $73.7 million, which was reflective of our continued research and development of and commercialization activities for our SOPHiA platform and an increase in general and administrative expenses as we transitioned to a public company, partially offset by a decrease in net working capital and an increase in share-based compensation.

For the year ended December 31, 2020, net cash used in operating activities was $31.7 million, primarily attributable to our net loss of $39.3 million, which was reflective of our continued research and development of and commercialization activities for our SOPHiA platform.

Investing Activities

For the year ended December 31, 2021, net cash used in investing activities was $56.9 million, primarily attributable to our capital expenditures to support research and development and revenue-generation activities and an investment in a term deposit.

For the year ended December 31, 2020, net cash used in investing activities was $24.3 million, primarily attributable to our capital expenditures to support research and development and revenue-generation activities and an investment in a term deposit.

Financing Activities

For the year ended December 31, 2021, net cash provided by financing activities was $237.8 million, primarily attributable to the $243.4 million in aggregate gross proceeds from our sale of an aggregate of 13,519,493 ordinary shares in our IPO and $20.0 million in aggregate gross proceeds from our sale of 1,111,111 ordinary shares to Instrumentarium Holdings, Inc., an affiliate of GE Healthcare, concurrent with the IPO. This was partially offset by the repayment of our COVID-19-related borrowings and the payment of a success fee to TriplePoint upon the completion of our IPO.

For the year ended December 31, 2020, net cash provided by financing activities was $107.0 million, primarily attributable to the $108.7 million in aggregate gross proceeds from our sale of an aggregate of 9,316,940 Series F preferred shares in June and September 2020, partially offset by the use of proceeds to repay existing loan obligations.

C. Research and Development, Patents and Licenses

See “Item 4. Information on the Company—B. Business Overview” and “Item 5. Operating and Financial Review and Prospects—A. Operating Results—Results of Operations.”

D. Trend Information

See “Item 5. Operating and Financial Review and Prospects—A. Operating Results.”

E. Critical Accounting Estimates

The preparation of financial statements in conformity with IFRS requires the use of accounting estimates. It also requires management to exercise judgement in applying our accounting policies. Disclosed below are the areas which require a high degree of judgment, significant assumptions and/or estimates.

Revenue

We recognize revenue when control of promised goods or services is transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Significant judgment is required to determine the stand-alone selling price ("SSP") for each performance obligation in our SOPHiA platform, the amount allocated to each performance obligation and whether it depicts the amount that we expect to receive in exchange for the related product and/or service. As the selling prices of our analyses are highly variable, we estimate SSP of our analyses using the residual approach when the analyses are sold with other products and services and observable SSPs exist for the other products and services. While the majority of sales agreements contain standard terms and conditions, we do enter into biopharma contracts that contain multiple products or services or non-standard terms and conditions.

We enter into arrangements with multiple performance obligations where it could be difficult to determine whether there is more than one performance obligation under a sales agreement; in such cases, how and when revenue should be recognized is subject to certain estimates or assumptions. Should these judgments and estimates not be correct, revenue recognized for any reporting period could be adversely affected.

SOPHiA Platform

The majority of SOPHiA platform revenue is derived from each use of our SOPHiA platform by customers to generate analysis on their patient data. Analysis revenue is recognized as analysis results are made available to the customer on our SOPHiA platform. Contract assets are recognized on the balance sheet as accrued contract revenue for any analyses performed by customers that have not been invoiced at the reporting period date. Any payments received in advance of customers generating analyses are recorded as deferred contract revenue until the analyses are performed.

Customers use our SOPHiA platform to perform analyses under three different models: dry lab access; bundle access; and integrated access.

For dry lab arrangements, customers use the testing instruments and consumables of their choice and our SOPHiA platform and algorithms for variant detection and identification. In these arrangements, we have identified one performance obligation, which is the delivery of the analysis result to the customer.

For bundle arrangements, customers purchase a DNA enrichment kit along with each analysis. Customers use the DNA enrichment kit in the process of performing their own sequencing of each sample. Customers then upload their patient data to our SOPHiA platform for analysis. In these arrangements, we have identified two performance obligations: the delivery of the DNA enrichment kits and the performance of the analyses. Revenue is recognized for the DNA enrichment kits when control of products has transferred to the customer, which is generally at the time of delivery, as this is when title and risk of loss have been transferred. Revenue for the performance of the analyses is recognized on delivery of the analysis results to the customer. Refer to "—*Arrangements with multiple performance obligations"* below for how revenue is allocated between the performance obligations.

Deferred contract revenue balances relating to analyses not performed within 12 months from the date of the delivery date are recognized as revenue. This policy is not based on contractual conditions but on the Company's experience of customer behavior and expiration of the kits associated with the analyses.

For integrated arrangements, customers have their samples processed and sequenced through selected SOPHiA platform partners within the clinical network and access their data through our SOPHiA platform. We have identified one performance obligation, which is delivery of the analysis results to the customer.

Through our SOPHiA platform, we also sell access to our Alamut software products. Some arrangements with customers allow customers to use Alamut as a hosted software service over the contract period without the customer taking possession of the software. Other customers take possession of the software, but the utility of that software is limited by access to our proprietary SOPHiA database, which is provided to the customer on a fixed term basis. Under both models, revenue is recognized on a straight-line basis over the duration of the agreement.

We also derive revenue from our SOPHiA platform by providing services to biopharma customers who engage us to (i) develop and perform customized genomic analyses and/or (ii) access the database for use in clinical trials and other research projects.

The biopharma contracts are generally unique, so the following steps are performed to determine the amount of revenue to be recognized and when it should be recognized: (1) identify the contract or contracts; (2) determine whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (3) measure the transaction price, including the constraint on variable consideration; (4) allocate the transaction price to the performance obligations based on estimated selling prices; and (5) recognize revenue when (or as) each performance obligation is satisfied.

Generally, the primary performance obligation in these arrangements is the delivery of analysis results in the form of a final report, resulting in revenue being recognized, in most cases, upon the issuance of the final report or successful recruitment of clinical trial participants.

Workflow Materials and Services

Revenue from workflow materials and services includes all revenue from the sale of materials and services that do not form part of a contract for the provision of platform services. These include the provision of set-up programs and training and the sale of kits and tests that are not linked to use of the platform. Set-up programs and training are typically combined with a customer's first order prior to the customer beginning to use our SOPHiA platform.

Revenue from services is generally recognized when the services are performed. Revenue from materials is recognized when control of the goods is transferred to the customer, generally at the time of delivery. This category of revenue also includes the revenue from the sale of DNA sequencing automation equipment accounted for under IFRS 16, Leasing and the fees charged for the maintenance of this equipment.

Arrangements with Multiple Performance Obligations

For multi-element arrangements the following steps are performed to determine the amount of revenue to be recognized and when it should be recognized: (1) identify the contract or contracts; (2) determine whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (3) measure the transaction price, including the constraint on variable consideration; (4) allocate the transaction price to the performance obligations based on estimated selling prices; and (5) recognize revenue when (or as) each performance obligation is satisfied.

We have determined that the stand-alone selling prices for services and DNA enrichment kits are directly observable. For set-up programs and training services sold along with dry lab arrangements or bundle arrangements, the stand-alone selling price of these services is determined on a time and materials basis. For DNA enrichment kits sold as part of a bundle, the stand-alone selling price is based on an expected cost-plus-margin approach.

We have determined that the stand-alone selling price for the analyses, in both a dry lab arrangement and bundle arrangement, is highly variable and therefore a representative stand-alone selling price is not discernible from past transactions. As a result, the residual approach is used to determine the stand-alone selling price of the analyses in dry lab arrangements that include services and in bundle arrangements that include DNA enrichment kits and, in some cases, services.

We also have a small number of bundle contracts with a fixed term, generally four years, that also include providing the customer with DNA sequencing automation equipment, which we have determined is an IFRS 16 leasing component. In these arrangements, we provide DNA sequencing automation equipment to the customer over the fixed term and at completion of the contract term the customer takes possession of the equipment. We have determined that we are a dealer lessor and provision of this equipment to the customer is classified as a finance lease. As a result, upon delivery of leased equipment at the inception of the agreement, a selling profit is recognized based on the fair value of the underlying equipment less the cost of the equipment. Over the term of the agreement, the minimum lease payment is deducted from the proceeds of the bundle sales in order to reduce the net investment in the corresponding lease receivable over the contract term and interest income is recognized as the discount on the lease receivable unwinds. The remaining proceeds from the contract are accounted for under IFRS 15, *Revenue from Contracts with Customers* ("IFRS 15"), using the policies described above.

Capitalized Internal Software Development Costs

All work performed by our research and development personnel is tracked and allocated to codes based on the nature of the work done. The hours spent are costed on the basis of the related salaries, benefits and share-based compensation. The cost of work attributable to the development of new data analytics solutions and services or to the improvement or enhancement of existing solutions and services is capitalized, once it is evident that the project is technically and financially feasible and that it will bring economic benefits to us. Capitalized software development costs are amortized using the straight-line method over an estimated life of five years.

Costs incurred for research, for development projects that do not meet the capitalization criteria, for maintenance and for minor modifications are expensed when incurred and presented as research and development costs. Other, administrative costs are expensed and presented as general and administrative costs.

Share-Based Compensation

For the years ended December 31, 2020 and 2021, we granted share options under two plans: the SOPHiA GENETICS 2019 Incentive Stock Option Plan (as amended from time to time, the "2019 ISOP") and the SOPHiA GENETICS 2021 Equity Incentive Plan (the "2021 Equity Incentive Plan" or the "2021 EIP"). Under these plans, directors may offer options to directors, employees and advisors. The exercise price of the share options is set at the time they are granted. Options, once vested, can be exchanged for an equal number of ordinary shares.

Measuring the Cost of Share Options

The fair value of the options outstanding under both plans is measured at each reporting date using an adjusted form of the Black-Scholes option pricing model, taking into account the terms and conditions upon which the options were granted.

For options up to September 2020, the fair value at grant date is independently determined using an adjusted form of the Black-Scholes option pricing model that takes into account the strike price, the fair value of the share at grant date, the expected life of the award, the expected price volatility of the underlying share, the risk-free interest rate for the term of the award and the expected dividend yield. For options granted from September 2020 to the IPO in July 2021, the fair value at grant date is based on a probability-weighted expected returns method that takes account of both the value derived by using an adjusted form of the Black-Scholes option pricing model, as described above, and a discounted estimate of the price that might be achieved in a future transaction. For options granted after the IPO in July 2021, the fair value at grant date is determined using a Black-Scholes option pricing model.

The key inputs used in the valuation model for the stock options are outlined below.

	ISOP 2019		EIP 2021
	Year ended December 31,		Year ended December 31,
	2021	2020	2021
Weighted average strike price (in USD)	$4.22	$4.02	$17.90
Share price at grant date (in USD)	$5.59	$4.36 - $4.87	$16.81 - $18.00
Expected life of share options (years)	6.05 - 6.19	5.67 - 6.43	5.50 - 7.00
Expected volatility (%)	41.26% - 41.45%	39.84% - 43.56%	41.60% - 59.77%
Risk free interest rate (%)	(0.63)% - (0.48)%	(0.80)% - (0.53)%	0.87% - 1.36%
Dividend yield (%)	—%	—%	—%

Prior to our Initial Public Offering ("IPO"), the price of the ordinary shares at grant date under the 2019 ISOP, which represents a critical input into this model, has been determined on one of the following two bases:

- by reference to a contemporaneous transaction involving another class of share, using an adjusted form of the Black-Scholes option pricing model as described above, and considering the timing, amount, liquidation preferences and dividend rights of issues of other classes of shares; or
- on the basis of discounted cash flow forecasts, where there was no contemporaneous or closely contemporaneous transaction in another class of share and the time interval was too large to permit an assumption that there had been no significant change in our equity value.

We used an independent valuation firm to assist in calculating the fair value of the award grants per participant.

Subsequent to the IPO, we used the most recent public market close price of our stock on the date of grant as the strike price.

Recognizing the Cost of Share Options

At each reporting date, we take a charge for the vested options granted and for partially earned but non-vested portions of options granted. This results in a front-loaded charge to the statement of income/loss. In addition, at each reporting date we reappraise our estimate of the likelihood and date of a future transaction that would cause all outstanding options to vest and, if necessary, accelerates the recognition of the unrecognized cost in the statement of income/loss. We account for these plans as equity-settled. The charge to the statement of income/loss therefore results in a corresponding credit being booked to “Other reserves” within equity.

Goodwill Impairment Testing

Goodwill arises from our acquisition of IBS in June 2018. Through this acquisition, we were able to add Alamut to our existing SOPHiA platform.

Goodwill is tested for impairment annually and also when there is an indication of impairment. No impairment charge has been recorded in relation to goodwill. As we operate as one segment, goodwill is tested by considering its recoverability in terms of the entire business. Management assesses the recoverable value of goodwill by comparing the value of our equity value, either inferred from the prices of share issues or based on discounted cash flow forecasts, with the net assets as reported in our financial statements. The values as of December 31, 2020 was based on discounted cash flow projections, which in turn were based on historical results and ratios updated to reflect management’s expectations of future growth and profitability and discounted using a weighted average cost of capital derived from an analysis of comparable selected public companies. Critically, the values based on a discounted cash flow approach were found to be consistent with a value based on the share transaction in September 2020. The value as of December 31, 2021 was based on our market capitalization which is a factor of the Company’s outstanding shares multiplied by the price of the Company’s stock on the last day of trading in 2021.

Defined Benefit Pension Liabilities

The liability or asset recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the end of the reporting period less the fair value of plan assets. The defined benefit obligation is calculated annually by independent actuaries using the projected unit credit method.

The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms approximating to the terms of the related obligation. In countries where there is no deep market in such bonds, the market rates on government bonds are used.

The net interest cost is calculated by applying the discount rate to the net balance of the defined benefit obligation and the fair value of plan assets. This cost is included in employee benefit expense in the statement of income/loss.

Remeasurement gains and losses arising from experience adjustments and changes in actuarial assumptions are recognized in the period in which they occur, directly in other comprehensive income. They are included in retained earnings in the statement of changes in equity and in the balance sheet.

Changes in the present value of the defined benefit obligation resulting from plan amendments or curtailments are recognized immediately in income as past service costs.

For defined contribution plans, we pay contributions to publicly or privately administered pension insurance plans. Employee contributions to these plans is voluntary and these contributions are matched by the employer. We have no further payment obligations once the contributions have been paid. The contributions are recognized as employee benefit expense when they are due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in the future payments is available. Contributions are charged to the statement of income/loss as incurred.

Expected Credit Losses

Accounts receivable-trade balances are non-interest bearing and payment terms are generally under agreements with payment terms of up to 180 days. Our customers are mainly government-owned or government-funded hospitals and laboratories with a low credit risk. We have had minimal instances of actual credit losses and consider that this will continue to be the case.

We have adopted the simplified method indicated in IFRS 9 to build our allowance for expected credit losses. No provision matrix is used, as we have not identified any patterns or correlations that would form the basis for such a matrix. Allowance is made for lifetime expected credit losses as invoices are issued. The amount of allowance initially recognized is based on historical experience, tempered by expected changes in future cash collections, due, for example, to expected improved customer liquidity or more active credit management.

Income Taxes

Unrecognized Deferred Tax Liability on Retained Earnings of Subsidiaries

We do not provide for foreign income and withholding taxes, Swiss income taxes or tax benefits on the excess of the financial reporting basis over the tax basis of our investments in foreign subsidiaries to the extent that such amounts are indefinitely reinvested to support operations and continued growth plans outside of Switzerland. We review our plan to indefinitely reinvest on a periodic basis. In making our decision to indefinitely reinvest, we evaluate our plans of reinvestment, our ability to control repatriation and to mobilize funds without triggering basis differences, and the profitability of our Swiss operations and their cash requirements and the need, if any, to repatriate funds. If the assessment of our company with respect to any earnings of our foreign subsidiaries' changes, deferred Swiss income taxes, foreign income taxes, and foreign withholding taxes may have to be accrued. Based on our assessment, we plan to indefinitely reinvest any undistributed foreign earnings as of December 31, 2021. In addition, the determination of any unrecognized deferred tax liabilities for temporary differences related to our investment in foreign subsidiaries is not practicable.

Uncertain Tax Positions

We file tax returns as prescribed by the tax laws of the jurisdictions in which we operate and are, therefore, subject to tax examinations by various taxing authorities. In the normal course of business, we are subject to examinations by local tax authorities in Switzerland, France, Italy, Brazil, Australia, the UK, and the United States. We are currently under examination in France for our 2018 and 2019 tax returns and are not aware of any additional issues under review that could result in significant payments, accruals or material deviation from our tax positions. There are no other tax examinations in progress.

We record tax liabilities or benefits for all years, subject to examination based upon management's evaluation of the facts, circumstances and information available at the reporting date. There is inherent uncertainty in quantifying income tax positions, especially considering the complex tax laws and regulations in each of the jurisdictions in which we operate and their interpretations that may vary.

Derivatives

We had an obligation to pay a success fee to TriplePoint, the providers of a loan repaid in 2020 upon an initial public offering or a sale. On September 27, 2021, we paid TriplePoint a fee in the amount of $2.5 million for the fee obligation payable upon the completion of our IPO, thereby extinguishing all remaining obligations associated with the loan.

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

The following table presents information about our executive officers and directors. Ages are as of February 1, 2022.

Name	Position(s)	Age
Executive Officers and Directors		
Jurgi Camblong	Chief Executive Officer and Director	43
Ross Muken	Chief Financial Officer	42
Daan van Well	Chief Legal Officer	47
Manuela da Silva Valente	Chief People Officer	52
Zhenyu Xu	Chief Scientific Officer	39
Philippe Menu	Chief Medical Officer	40
Non-Executive Directors		
Troy Cox	Chairman of the Board of Directors	57
Tomer Berkovitz	Director	42
Kathy Hibbs	Director	58
Didier Hirsch	Director	70
Vincent Ossipow	Director	53
Milton Silva-Craig	Director	54

Executive Officers

Jurgi Camblong, Ph.D., M.B.A., has served as our Chief Executive Officer and a member of our board of directors since March 2011 when he co-founded our company with Dr. Pierre Hutter and Professor Lars Steinmetz. From 2010 to 2011, Dr. Camblong served as the Chief Executive Officer of Gene Predictis SA. Prior to that, Dr. Camblong was a post-doctoral associate researcher at Oxford University and at the University of Geneva. Dr. Camblong was a member of the Advisory Council on Digital Transformation to the Swiss Government and is a Board member of the Swiss Biotech Association. In addition to our board of directors, Dr. Camblong serves as Chair of the Board of AgoraCare SA. Dr. Camblong holds a Ph.D. in life sciences from the University of Geneva and an Executive M.B.A. in management of technology from EPFL/HEC Lausanne.

Ross Muken, B.Sc., has served as our Chief Financial Officer since February 2021. From 2019 to 2020, Mr. Muken served as the Chief Financial Officer of Click Therapeutics, Inc. From 2012 to 2019, Mr. Muken served as the Senior Managing Director and Partner of Equity Research at Evercore/ISI Group. Prior to that, Mr. Muken served in various roles at Deutsche Bank, including as Managing Director of Equity Research, and at Thomas Weisel Partners. Mr. Muken holds a B.Sc. in business administration from Boston University.

Daan van Well, LL.M., M.B.A., has served as our Chief Legal Officer since June 2019. Mr. Van Well has more than 20 years of legal, governance and compliance experience. From 2018 to 2019, Mr. Van Well served as the founder and managing partner of consulting firm SpringWorks Sàrl. From 2010 to 2017, Mr. Van Well served in various legal positions with PwC Switzerland, including as the Head of Legal from 2011 to 2017. Prior to that, Mr. Van Well served as corporate secretary and senior legal counsel of Royal Ahold N.V. (currently Koninklijke Ahold Delhaize N.V.) and practiced law at Loyens & Loeff N.V. in Rotterdam, The Netherlands. Mr. Van Well holds a LL.M. in Dutch civil law from Utrecht University and an Executive M.B.A. in management and corporate finance from HEC Lausanne.

Manuela da Silva Valente, B.A., has served as our Chief People Officer since January 2019. Ms. Da Silva Valente has more than 20 years of human resources experience. From 2011 to 2018, Ms. Da Silva Valente served in various human resources leadership roles at IQVIA (formerly Quintiles and IMS Health Inc.), including as Global Senior Director of Human Resources from 2016 to 2018. Prior to that, Ms. Da Silva Valente held various human resources roles at Outcome Sciences, Inc. prior to its acquisition by IQVIA. Ms. Da Silva Valente holds a B.A. in business administration from the Business Management School of Zurich and a Management & Human Resources Diploma from CEFCO Lausanne.

Zhenyu Xu, Ph.D., has served as our Chief Scientific Officer since January 2021 and was previously our Chief Technology Officer since May 2014. Dr. Xu was the leader of the technology team that developed our SOPHiA platform. Prior to that, Dr. Xu was a post-doctoral fellow at the European Molecular Biology Laboratory. Dr. Xu holds a Ph.D. in molecular and computational biology from the European Molecular Biology Laboratory.

Philippe Menu, M.D., Ph.D., M.B.A., has served as our Chief Medical Officer since February 2020. From 2011 to 2020, Dr. Menu was a management consultant with McKinsey & Company, focusing on the biopharmaceutical sector and in particular innovative therapies and diagnostics in oncology and rare diseases. Prior to that, Dr. Menu was a post-doctoral fellow at the University of Lausanne. Dr. Menu holds an M.D./Ph.D. in life sciences from the University of Lausanne and an M.B.A. from the Open University Business School.

Non-Executive Directors

Troy Cox, M.B.A., has served as the Chairman of our board of directors since June 2019. From 2017 to 2019, Mr. Cox served as the chief executive officer of Foundation Medicine Inc. From 2010 to 2017, Mr. Cox served as the senior vice president of U.S. commercial of Genentech, Inc. Prior to that, Mr. Cox held various executive and senior positions at UCB S.A., Sanofi-Aventis U.S. LLC and Schering-Plough Corporation. In addition to our board of directors, Mr. Cox serves on the board of directors of Massachusetts Biotechnology Council, Zymeworks Inc., LetsGetChecked, Somalogic Inc., BioSplice Therapeutics, Inc. and previously served on the board of directors of Foundation Medicine Inc. Mr. Cox holds an M.B.A. from the University of Missouri.

Tomer Berkovitz, Ph.D., has served as a member of our board of directors since March 2021. Since 2018, Dr. Berkovitz has served as General Partner of aMoon Fund, where he co-leads its Growth fund. From 2014 to 2018, Dr. Berkovitz served as the Chief Operating Officer and Chief Financial Officer of Alcobra Ltd. Prior to that, Mr. Berkovitz served as an Executive Director in J.P. Morgan's investment banking division in New York. In addition to our board of directors, Dr. Berkovitz serves on the board of directors of several other healthcare companies in the aMoon portfolio. Dr. Berkovitz holds a Ph.D. in finance from Columbia Business School.

Kathy Hibbs, J.D., has served as a member of our board of directors since March 2021. Since 2022, Ms. Hibbs has served as the Chief Administrative Officer of 23andMe, Inc. and prior to that role as the Chief Legal and Regulatory Officer from 2014 to 2022. Before joining 23andMe, Inc., Ms. Hibbs held various leadership roles in legal, business development and compliance functions at Genomic Health, Inc., Monogram Biosciences Inc. and Varian Medical Systems, Inc. Ms. Hibbs previously served on the board of directors of Decipher Biosciences, Inc. Ms. Hibbs holds a J.D. from the University of California, Hastings College of Law.

Didier Hirsch, M.Sc., M.S., has served as a member of our board of directors since June 2020. From 2010 to 2018, Mr. Hirsch served as the senior vice president and chief financial officer of Agilent Technologies, Inc. Prior to that, Mr. Hirsch held various leadership roles in finance at Agilent Technologies, Inc. and Hewlett-Packard Company. In addition to our board of directors, Mr. Hirsch serves on the board of directors of Knowles Corporation and previously served on the board of directors of Logitech International S.A. and International Rectifier Corporation. Mr. Hirsch holds an M.Sc. in computer science from Toulouse University and an M.S. in industrial administration from Purdue University.

Vincent Ossipow, Ph.D., has served as a member of our board of directors since June 2014. Dr. Ossipow has been a partner at Omega Funds. Dr. Ossipow has also served as the Chief Scientific Officer of Omega Alpha SPAC. Prior to that, Dr. Ossipow held various investment management positions at Sectoral Asset Management and Pictet Bank. In addition to our board of directors, Dr. Ossipow serves on the board of directors of Immunic, Inc., BioInvent International AB, FoRx SA, SwissThera SA, and eTheRNA immunotherapies NV, and previously served on the board of directors of Andrew Alliance S.A., Lifespan, Inc., Raindance Technologies, CNx SA and Kuros Biosciences AG. Dr. Ossipow holds a Ph.D. in molecular biology from the University of Geneva.

Milton Silva-Craig, J.D., M.B.A., has served as a member of our board of directors since November 2019. Since 2014, Mr. Silva-Craig has served as the Chief Executive Officer of Q-Centrix, LLC. Prior to that, Mr. Silva-Craig held executive positions at TransUnion LLC, Technology Solutions Company, Emageon Inc and General Electric Healthcare. In addition to our board of directors, Mr. Silva-Craig serves on the board of directors for Q-Centrix, LLC and previously served on the board of directors of HealthMyne, Inc. Mr. Silva-Craig holds a J.D. and M.B.A. from the University of Wisconsin – Madison.

Relationships

All of our directors were appointed pursuant to our shareholders' agreement that was terminated upon the completion of our initial public offering. There are no family relationships among any of our directors or executive officers.

B. Compensation

Compensation of Directors and Executive Officers

For the year ended December 31, 2021, the aggregate compensation paid or accrued to the members of our board of directors and our executive officers for services in all capacities, including retirement and similar benefits, was $3.5 million, the total fair value of stock options and non-vested share awards granted to the members of our board of directors and our executive officers was $18.4 million, and the amount set aside or accrued by us to provide pension, retirement or similar benefits to the members of our board of directors and our executive officers was $0.2 million. We incorporate by reference into this Annual Report the information in "Item 2. Compensation of the Board of Directors" and "Item 3. Compensation of the Members of the Executive Committee" of Exhibit 99.4 to our report on Form 6-K filed with the SEC on March 15, 2022.

Equity Incentive Plans

On June 29, 2021, our shareholders approved the 2021 Equity Incentive Plan that our board of directors had previously adopted. The purpose of the 2021 Equity Incentive Plan is to motivate and reward performance of our employees, directors, consultants and advisors and further the best interests of the Company and our shareholders.

Plan Administration. The 2021 Equity Incentive Plan is administered by the compensation committee of our board of directors, subject to the board of directors' discretion to administer or appoint another committee to administer it.

Awards. Equity incentive awards under the 2021 Equity Incentive Plan may be granted in the form of options (including incentive stock options and non-qualified stock options), share appreciation rights, restricted shares, restricted share units, performance awards or other share-based awards. Options and share appreciation rights will have an exercise price determined by the compensation committee and, in the case of options granted to a participant subject to U.S. taxation, will not be less than fair market value of the underlying ordinary shares on the date of grant (or, if such options consist of incentive stock options and the participant owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock (a "ten percent shareholder"), an exercise price not be less than 110% of the fair market value of the underlying ordinary shares on the date of grant). In addition, under the 2021 Equity Incentive Plan, options and share appreciation rights may not have a term that exceeds ten years (or, in the case of an incentive stock option granted to a ten percent shareholder, a term that exceeds five years).

Eligible Participants. The compensation committee is able to offer equity awards at its discretion under the 2021 Equity Incentive Plan to (1) any employees of us or any of our subsidiaries, (2) any non-employee directors serving on our board of directors and (3) any consultants or other advisors to us or any of our subsidiaries; *provided* that only employees of our company or certain of our subsidiaries may be granted incentive stock options. To the extent required by applicable law and our articles of association in effect from time to time, all awards and rights, payments and benefits granted or made under the 2021 Equity Incentive Plan to our directors and executive officers are subject to the approval of the relevant total amount of compensation by our shareholders.

Share Reserve. The maximum number of ordinary shares initially reserved for issuance pursuant to awards under the 2021 Equity Incentive Plan is 7,800,740 ordinary shares, which will be increased on the first day of each fiscal year of the Company, beginning with the 2022 fiscal year, in an amount equal to the least of (i) a number of ordinary shares equal to five percent (5%) of the total number of shares of all classes of shares of the Company outstanding on the last day of the immediately preceding fiscal year, (ii) such number of shares determined by our board of directors, and (iii) the aggregate number of shares available to our board of directors under our articles of association or otherwise that may be granted as, or be subject to, equity incentive awards on such date. To ensure that our board of directors can reserve a sufficient number of ordinary shares for purposes of the 2021 Equity Incentive Plan, we plan to request its shareholders approve annual increases to the Company's conditional share capital for employee participation. Notwithstanding the foregoing, no more than 7,800,740 ordinary shares may be issued in respect of incentive stock options. In addition, ordinary shares reserved for issuance under the 2021 Equity Incentive Plan are subject to adjustment in the event of certain corporate transactions or events if necessary to prevent dilution or enlargement of the benefits made available under the 2021 Equity Incentive Plan.

Vesting. The vesting conditions for grants under the equity incentive awards under the 2021 Equity Incentive Plan are set forth in the applicable award documentation.

Termination of Service and Change in Control. In the event of a participant's termination of employment or service, the compensation committee may determine in the applicable award agreement the extent to which an equity incentive award may be exercised, settled, vested, paid or forfeited. Unless otherwise provided in the applicable award agreement, in the event of a change in control by way of a merger, a sale of the Company's securities, a sale of all or substantially all of the Company's assets or similar transaction, each award that is outstanding as of immediately prior to such change in control will, (i) to the extent not then vested, accelerate and become fully vested (with any performance award assumed to have achieved the applicable performance criteria at the greater of target and maximum level of performance), and (ii) be cancelled and converted into the right to receive a payment in cash with a value equal to the value of such award based on the per share value of consideration received or to be received by other shareholders of the Company in such change in control, with the value of the any such award that is an option or a share appreciation right reduced by the applicable exercise price. In the event of a change in control, the compensation committee may also, in lieu of the acceleration and cash out of outstanding awards described above, take any one or more of the following actions with respect to outstanding awards that the compensation committee determines to be appropriate: (i) cancel any such award in exchange for a payment in securities or other property other than cash or any combination thereof with a value equal to the value of such award based on the per share value of consideration received or to be received by other shareholders in the event (or without payment of consideration if the compensation committee determines that no amount would have been realized upon the exercise of the award or other realization of the participant's rights); (ii) require the exercise of any outstanding option; (iii) provide for the assumption, substitution, replacement or continuation of any award by the successor or surviving corporation, along with appropriate adjustments with respect to the number and type of securities (or other consideration) of the successor or surviving corporation, subject to any replacement awards, the terms and conditions of the replacement awards (including performance targets) and the grant, exercise or purchase price per share for the replacement awards; (iv) make any other adjustments in the number and type of securities (or other consideration) subject to awards that may be granted in the future; (v) provide that any such award shall be accelerated and become exercisable, payable and/or fully vested with respect to all ordinary shares covered thereby or (vi) provide that any award shall not vest, be exercised or become payable as a result of such event.

Termination and Amendment. Unless terminated earlier, the 2021 Equity Incentive Plan will continue for a term of ten years. Our board of directors has the authority to amend or terminate the 2021 Equity Incentive Plan subject to shareholder approval with respect to certain amendments. However, no such action may materially adversely affect the rights of any participant under any outstanding award without the consent of the affected participant.

During the year ended December 31, 2021, we have granted to the members of our board of directors and to our executive officers, in the aggregate, the right to acquire 981,133 ordinary shares at a weighted-average price of $18.00 per ordinary share under the 2021 Equity Incentive Plan and 1,024,000 ordinary shares at a weighted-average price of $6.22 per ordinary share under the 2019 ISOP. The expiration dates for these awards are on July 22, 2032 for rights to acquire shares granted under the 2021 Equity Incentive Plan and range from January 28, 2031 to March 26, 2031 for rights to acquire shares under the 2019 ISOP. In July 2021, we granted to certain of our executive officers, in the aggregate, 144,443 RSUs under the 2021 Equity Incentive Plan. The restricted share units vest ratably over a four-year period, subject to the executive officer's continued employment with us, and any unvested RSUs will be forfeited should the executive officer terminate his or her employment with us.

Employment Agreements

We have entered into employment agreements with certain of our executive officers. Each of these agreements provides for an initial salary and annual bonus opportunity, as well as participation in certain pension and welfare benefit plans. These agreements may require advance notice of termination and in some cases provide for paid garden leave. Some of our executive officers have agreed to covenants not to compete against us or solicit our employees or customers during employment and for a period of up to one year following termination. We may be required to pay some of our executive officers compensation for their covenant not to compete with us following termination. If we experience a “change in control”, then our executive officers’ then-unvested awards will become fully vested at such time.

C. Board Practices

Board Composition and Election of Directors

Our board of directors is composed of seven members. Each director is elected for a one-year term. The current members of our board of directors will serve until our annual general meeting of shareholders in 2022.

Board Practices

We are a foreign private issuer under the rules of the SEC. As a result, in accordance with Nasdaq listing standards, we rely on home country governance requirements and certain exemptions thereunder rather than on Nasdaq corporate governance requirements. For an overview of our corporate governance principles, see “Item 10. Additional Information—B. Memorandum and Articles of Association” and “Item 16G—Corporate Governance.”

Director Independence

Our board of directors has affirmatively determined that each of Troy Cox, Tomer Berkovitz, Kathy Hibbs, Didier Hirsch, Vincent Ossipow, and Milton Silva-Craig is an independent director within the meaning of applicable Nasdaq standards.

Diversity

Our board of directors values diversity among its members. Our nomination and corporate governance committee, within the purview of its mandate, has the responsibility to take diversity into consideration as part of the overall director selection and nomination processes and to make the identification of diverse candidates a search criterion. The matrix below sets forth a summary of the diversity of our board of directors as of February 1, 2022:

Country of Principal Executive Offices: Switzerland

Foreign Private Issuer: Yes

Disclosure Prohibited under Home Country Law: No

Total Number of Directors: 7

	Female	Male	Non-Binary	Did Not Disclose
Part I: Gender Identity	1	6	0	0
Part II: Demographic Background				
Underrepresented individual in home country jurisdiction	2			
LGBTQ+	1			
Did not disclose	0			

Board Meetings

In 2021, our board of directors held 11 meetings.

Committees of the Board of Directors

Our board of directors has three committees: an audit committee, a compensation committee and a nomination and corporate governance committee.

Audit Committee

The audit committee, which consists of Didier Hirsch (chair), Kathy Hibbs, and Milton Silva-Craig, assists our board of directors in overseeing our accounting and financial reporting processes and the audits of our consolidated financial statements. In addition, the audit committee is directly responsible for the compensation, retention and oversight of the work of our independent registered public accounting firm that our shareholders elect as our external auditors. The audit committee consists exclusively of members of our board of directors who are financially literate, and each of Didier Hirsch and Milton Silva-Craig is considered an "audit committee financial expert" as defined by the SEC. Our audit committee complies with Rule 10A-3(b)(1) of the Exchange Act. Our board of directors has determined that each of Didier Hirsch, Kathy Hibbs and Milton Silva-Craig satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act.

The audit committee is governed by a charter that complies with the Nasdaq listing standards that apply to us. The audit committee has the responsibility to, among other things:

- select, appoint, compensate, retain, terminate and oversee the work of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services;
- pre-approve the audit services and non-audit services (including the fees and terms thereof) to be provided by the independent auditor pursuant to pre-approval policies and procedures;
- review and approve the planned scope and timing of our independent registered public accounting firm's annual audit plan(s);
- discuss significant findings from the audit and any problems or difficulties encountered, including any restrictions on the scope of our independent registered public accounting firm's activities or on access to requested information, and any significant disagreements with management;
- evaluate the independent auditor's qualifications, performance and independence, and present its conclusions with respect to the independent auditor to the board of directors on at least an annual basis;
- supervise the ethics committee as provided in the Code of Ethics, consider related party transactions and supervise compliance with any other policies over which the audit committee has oversight authority;
- review and discuss with management and the independent auditor the annual audited consolidated and stand-alone financial statements and unaudited quarterly financial statements and make its recommendation to the board of directors for their presentation to the general meeting of shareholders for approval;
- review with management and the independent auditor (i) any analyses or other written communications prepared by management and/or the independent auditor setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, (ii) our critical accounting policies and practices, (iii) the effect of regulatory and accounting initiatives, as well as off-balance-sheet transactions and structures, on our financial statements and (iv) any major issues regarding accounting principles and financial statement presentations;
- in conjunction with the chief executive officer and chief financial officer, review disclosure controls and procedures and internal control over financial reporting;
- review and discuss with the independent auditor any audit problems or difficulties and management's response thereto;

- discuss with the chief financial officer and the chief executive officer the results of its review of the management or internal control letter issued by the independent auditor;
- resolve disagreements between management and the auditor regarding our financial reporting;
- review our risk assessment and risk management policies and practices;
- establish procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters, as well as the receipt of summary whistleblower reports and the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters;
- review our compliance with laws and regulations; and
- review any major litigation or investigations against us that may have a material impact on our financial statements.

The audit committee meets as often as it determines is appropriate to carry out its responsibilities, but in any event meets at least quarterly.

Compensation Committee

The compensation committee, which consists of Milton Silva-Craig (chair), Tomer Berkovitz, and Vincent Ossipow, supports our board of directors in establishing and reviewing the compensation and benefits strategy and guidelines as well as in preparing the proposals to the annual general meeting of shareholders regarding the compensation of the members of the board of directors and the executive officers. The compensation committee may submit proposals to the board of directors on other compensation-related matters. Swiss law requires that we have a compensation committee, so in accordance with Nasdaq listing standards, we follow home country requirements with respect to the compensation committee. As a result, our practice vary from Nasdaq listing standards, which set forth certain requirements as to the responsibilities, composition and independence of compensation committees for domestic issuers. Swiss law requires that our board of directors submit the aggregate amount of compensation of all members of our board of directors and of all executive officers to a binding shareholder vote every year. Commencing with our annual general meeting of shareholders in 2022, the members of the compensation committee will be elected by our annual general meeting of shareholders. The board of directors appoints the chair of the compensation committee and fills any vacancies until the following annual general meeting of shareholders.

The compensation committee has the responsibility to, among other things:

- regularly review and make recommendations to the board of directors regarding our compensation and benefits strategy and guidelines;
- review and make recommendations to the board of directors regarding the compensation of the members of the board of directors, of the executive committee and of our extended management team;
- prepare the proposals to the shareholders' meeting regarding the compensation of the members of the board of directors and of the executive committee;
- review and approve the recommendation of our chief executive officer regarding the fixed and variable compensation, including incentive plan participation and benefits, of the members of the management team other than members of the executive committee;
- review and make recommendations to the board of directors regarding our compensation and benefits plans (cash and/or equity-based plans) and, where appropriate or required, make recommendations to adopt, amend and terminate such plans;
- to the extent not delegated by the compensation committee to a different body or a third party, administer our compensation and benefits plans; and
- review and assess risks arising from our employee compensation policies and practices and whether any such risks are reasonably likely to have a material adverse effect on us.

Nomination and Corporate Governance Committee

The nomination and corporate governance committee, which consists of Kathy Hibbs (chair), Troy Cox and Didier Hirsch, is responsible for director and board committee nominations, succession planning, performance evaluation and reviewing and amending, if required, our corporate governance framework and guidelines. The members of the nomination and corporate governance committee and its chair are appointed by our board of directors.

The nomination and corporate governance committee has the responsibility to, among other things:

- determine selection criteria for the succession of the members of the board of directors and board committees, our chief executive officer and our chief financial officer, and establish such succession planning
- (including for the event of the incapacitation, retirement or removal of such individuals) by making recommendations to the board of directors;
- oversee searches, identify qualified individuals and recommend individuals for membership on the board of directors and for the position of chief executive officer;
- recommend individuals for appointment to the audit committee annually and as vacancies or newly created positions occur;
- at least annually, prepare the board of directors' assessment of the performance of the board of directors and board committees and of our chief executive officer;
- review the recommendations of the other board committees based on their self-evaluations and discuss its own evaluation with the board of directors;
- monitor and assess developments and trends in corporate governance to the extent that these do not have an impact on the activities and tasks of the audit committee or the compensation committee;
- review proposals to be made to the board of directors for the amendment of our articles of association, our organizational regulations, and any other charter, rules or regulations;
- approve in advance any acceptance by a member of our management of a position as member of the board of directors in companies not belonging to our group;
- periodically review and assess the adequacy of the charter of the nomination and corporate governance committee and recommend any proposed changes to the board of directors for approval;
- if it deems necessary, develop and recommend to the board of directors corporate governance guidelines for us;
- periodically review and reassess the adequacy of the Code of Ethics and recommend any proposed changes to the board of directors;
- oversee compliance with the Code of Ethics and report on such compliance to the board of directors;
- supervise the ethics committee as provided in the Code of Ethics; and
- review and consider any requests for waivers of the Code of Ethics for members of our board of the directors, our management and other senior financial officers, and make a recommendation to our board of directors with respect to such request for a waiver.

D. Employees

We employ great minds in biotechnology and machine learning who continuously advance our algorithms, products and services to benefit clinical researchers around the world. Approximately 30% of our employees hold doctoral degrees in diverse fields that range from cell biology to computer science. Our employees bring widely varied expertise and competencies to our company. Our multidisciplinary team includes bioinformaticians, medical and genetic experts, scientists, software engineers, web developers, graphic designers, commercial experts and lab specialists, as well as staff in our administrative and corporate teams.

We pride ourselves on the excellence and integrity of our employees. We work towards the best quality and target the highest performance. Our corporate DNA, rooted in quality, precision and robustness, is the key to our success. We strive to foster an entrepreneurial, innovative and unique culture that ignites employees' passion and inspires them to challenge the status quo. We create work environments that preserve and value individuality and diversity of viewpoints and approaches such that our employees trust each other and collaborate to achieve our collective goals.

The following strategies help ensure that we attract and retain high quality employees:

- *Attracting Talent*. Our dedicated and experienced global talent acquisition team identifies and attracts the most qualified candidates. Our locations were strategically selected to attract highly educated talent from renowned universities and engineering schools, and we regularly attend events and use social media to increase awareness of our brand to prospective candidates. As part of our hiring process, we conduct scientific and technical assessment to ensure that candidates have the appropriate skills and expertise.

- *Retaining and Developing Talent*. As part of our effort to continuously motivate and engage our employees and provide professional development for our employees, we provide corporate talent reviews and follow-up individual development plans for our employees and have created career ladders with grading systems for all departments with detailed job descriptions on what is required at each level. We also perform employee engagement surveys that inform our dedicated taskforces as they continuously strive to increase employee satisfaction and morale.

- *Training*. To help our employees integrate into our company, advance their knowledge and skills and remain at the forefront of innovation, we created Learning@SOPHiA, which consists of (i) an onboarding program with a new hire learning path, a manager's guide to onboarding and a buddy system for new hires, (ii) ongoing learning paths with department specific training modules, technical and non-technical training, cross-functional information sessions, mentoring and soft skill training, and (iii) leadership and development programs for managers. In addition, for our salespersons, our sales success department provides commercial training, including consultative sales, negotiations skills and cold call training.

As of December 31, 2021, we had 518 employees across 29 countries, of whom 401 were located in EMEA, 99 were located in North America, 10 were located in Latin America and 8 were located in Asia Pacific. In addition, we had 11 temporary employees located in EMEA. Over the course of the year ended December 31, 2021, we employed, on average, 459 employees. Approximately 44% of our employees are engaged in research and development.

In certain countries in which we operate, we are subject to, and comply with, local labor law requirements, which may automatically make our employees subject to industry-wide collective bargaining agreements. For instance, our employees in France are covered by the Syntec Collective Bargaining Agreement. In addition, pursuant to French regulations, we have established at our French subsidiary a Comité Social et Économique or Social and Economic Committee. We are not subject to any other collective bargaining agreements. We believe that our relationship with our employees is good.

E. Share Ownership

See "Item 7. Major Shareholders and Related Party Transactions—A. Major shareholders."

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table presents information relating to the beneficial ownership of our ordinary shares as of February 15, 2022 by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each of our executive officers and directors and persons nominated to serve in such positions; and
- all executive officers and directors and persons nominated to serve in such positions as a group.

The number of ordinary shares beneficially owned by each entity, person, executive officer or director is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days from February 15, 2022 through the exercise of any option or other right. Except as otherwise indicated, and subject to applicable community property laws, we believe that the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person based on information provided to us by such person.

The percentage of outstanding ordinary shares beneficially owned is computed on the basis of 63,898,164 ordinary shares outstanding as of February 15, 2022. Ordinary shares that a person has the right to acquire within 60 days are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all executive officers and directors as a group. Unless otherwise indicated below, the business address for each beneficial owner is SOPHiA GENETICS SA, Rue du Centre 172, CH-1025 Saint-Sulpice, Switzerland.

Principal Shareholders	Number of Ordinary Shares Beneficially Owned	Percentage of Ordinary Shares Beneficially Owned
5% or Greater Shareholders		
Alychlo NV(1)	6.993,800	10.95%
Generation IM Sustainable Solutions Fund III, L.P.(2)	6,789,560	10.63%
Balderton Capital VI, S.L.P.(3)	3,361,880	5.26%
Executive Officers and Directors		
Tomer Berkovitz	-	*
Jurgi Camblong	2,211,240	3.46%
Troy Cox	111,420	*
Kathy Hibbs	-	*
Didier Hirsch	-	*
Philippe Menu	10,000	*
Ross Muken	-	*
Vincent Ossipow	275,980	*
Milton Silva-Craig	78,760	*
Manuela da Silva Valente	20,000	*
Daan van Well	30,000	*
Zhenyu Xu	382,500	*
All executive officers and directors as a group (12 persons)	3,119,900	4.88%

* Less than 1% of our total outstanding ordinary shares.

(1) This information is based solely on a Schedule 13G filed by Alychlo NV and Marc Coucke with the SEC on February 14, 2022. Marc Coucke is the principal shareholder, chairman and managing director of Alychlo NV. The principal business address of each of the foregoing persons or entities is Lembergsesteenweg 19, 9820 Merelbeke, Belgium.

(2) This information is based solely on a Schedule 13G filed by Generation Investment Management LLP, Generation IM Sustainable Solutions III, GP Ltd and Generation IM Sustainable Solutions Fund III, L.P. with the SEC on February 15, 2022. The principal business address of each of the foregoing entities is 20 Air Street, 7th floor, London, United Kingdom W1B 5AN.

(3) This information is based solely on a Schedule 13G filed by Balderton Capital VI, S.L.P. with the SEC on February 10, 2022. Balderton Capital General Partner VI, S.a.r.l. is the managing general partner of Balderton Capital VI, S.L.P. and may be deemed to have voting, investment and dispositive power with respect to these securities. Adrian Rainey, Donatien-Xavier Martin and Marie Calinet are the managers of Balderton Capital General Partner VI, S.a.r.l. and may each be deemed to share voting, investment, and dispositive power with respect to these securities.

As of February 15, 2022, we had approximately 235 shareholders of record of our ordinary shares. We estimate that as of February 15, 2022, approximately 50.50% of our outstanding ordinary shares are held by 24 U.S. record holders. The actual number of shareholders is greater than this number of record holders and includes shareholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust or by other entities.

We have experienced significant changes in the percentage ownership held by major shareholders as a result of our initial public offering. Prior to our initial public offering, our principal shareholders were Alychlo NV, Generation Investment Management LLP and Balderton Capital VI, S.L.P., which held ordinary shares representing 14.2%, 13.8% and 6.8% of our outstanding ordinary shares prior to our initial public offering.

B. Related Party Transactions

The following is a description of certain related party transactions we have entered into since January 1, 2021 with any of our executive officers and directors or their affiliates and holders of more than 10% of any class of our voting securities in the aggregate, which we refer to as related parties, other than compensation arrangements, which are described under “Item 6. Directors, Senior Management and Employees—B. Compensation.”

Indemnification Agreements

We have entered into indemnification agreements with our executive officers and directors. The indemnification agreements and our articles of association require us to indemnify our executive officers and directors to the fullest extent permitted by law.

Related Person Transaction Policy

We have adopted a related person transaction policy. Our related person transaction policy states that any related person transaction must be approved or ratified by our audit committee or board of directors. In determining whether to approve or ratify a transaction with a related person, our audit committee or board of directors will consider all relevant facts and circumstances, including, without limitation, the commercial reasonableness of the terms of the transaction, the benefit and perceived benefit, or lack thereof, to us, the opportunity costs of an alternative transaction, the materiality and character of the related person’s direct or indirect interest and the actual or apparent conflict of interest of the related person. Our audit committee or board of directors will not approve or ratify a related person transaction unless it has determined that, upon consideration of all relevant information, such transaction is in, or not inconsistent with, our best interests and the best interests of our shareholders.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

Financial Statements

See “Item 18. Financial Statements,” which contains our financial statements prepared in accordance with IFRS.

Legal Proceedings

From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. The results of litigation and claims cannot be predicted with certainty. As of the date of this Annual Report, we do not believe that we are party to any claim or litigation the outcome of which would, individually or in the aggregate, be reasonably expected to have a material adverse effect on our business.

Dividends and Dividend Policy

We have never declared or paid cash dividends on our share capital. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions and business prospects and other factors our board of directors may deem relevant.

Under Swiss law, any dividend must be approved by our shareholders. In addition, our auditors must confirm that the dividend proposal of our board of directors to the shareholders conforms to Swiss statutory law and our articles of association. A Swiss corporation may pay dividends only if it has sufficient distributable profits from the previous business year (*bénéfice de l’exercice*) or brought forward from previous business years (*report des bénéfices*) or if it has distributable reserves (*réserves à libre disposition*), each as evidenced by its audited stand-alone statutory balance sheet prepared pursuant to Swiss law and after allocations to reserves required by Swiss law and its articles of association have been deducted. Distributable reserves are generally booked either as free reserves (*réserves libres*) or as reserves from capital contributions (apports de capital). Distributions out of share capital, which is the aggregate par value of a corporation’s issued shares, may be made only by way of a share capital reduction. See “Item 10. Additional Information—B. Memorandum and Articles of Association.”

B. Significant Changes

There have been no significant changes in our business since the date of the annual financial statements, other than those described under “Item 4. Information on the Company—B. Business Overview.”

Item 9. The Offer and Listing.

A. Offer and Listing Details

Our ordinary shares are listed on Nasdaq under the symbol “SOPH.” For a description of our ordinary shares, see “Item 10. Additional Information—B. Memorandum and Articles of Association.”

C. Markets

See “—A. Offer and Listing Details.”

Item 10. Additional Information

B. Memorandum and Articles of Association

See Exhibit 2.1 to this Annual Report for a description of our ordinary shares and articles of association.

C. Material Contracts

The following descriptions of our material agreements are not complete and are qualified in their entirety by reference to the full text of such agreements, which are filed as exhibits to this Annual Report and incorporated herein by reference.

License Agreements

Normandie Valorisation—Exclusive License Agreements

In March of 2018, we entered into an exclusive license of patents and results (the “2018 Normandie Agreement”) with the University of Rouen Normandy, the Henri Becquerel Centre, INSERM Transfert SA (collectively, the “Co-Owners”) and Normandy University, acting through Normandie Valorisation, pursuant to which we obtained an exclusive, royalty-bearing, non-sublicenseable license under certain patents related to methods for diagnosing hematological malignancies and an associated diagnostic kit to develop, manufacture and sell products for the diagnosis of acute myeloblastic leukemia, acute lymphoblastic leukemia and chronic myeloid leukemia in the countries covered by the licensed patents.

In May 2019, we entered into an additional Exclusive License of Patents and Results (the “2019 Normandie Agreement”) with the same parties, pursuant to which we obtained an identical license under the same patents for products for the diagnosis of carcinomas other than acute myeloblastic leukemia, acute lymphoblastic leukemia and chronic myeloid leukemia.

Under each agreement, we are obligated to act with a standard of care to develop, manufacture and sell the licensed products. Our failure to meet the standard of care requirement could subject us to a reduction of applicable territory or respective field of use by way of an amendment to the applicable agreement if (i) we have not marketed nor implemented necessary steps for the marketing of the applicable licensed products within a reasonable time following the end of the agreed-upon development plan for the commercialization of such products or (ii) our delay in executing the development plan exceeds a certain specified time. Pursuant to both agreements, Normandie Valorisation is responsible for the prosecution, maintenance and defense of the licensed patents.

Pursuant to the 2018 Normandie Agreement, we paid Normandie Valorisation a low five-digit Euro upfront fee and are obligated to pay to Normandie Valorisation a low-tens Euro fee per each analysis utilizing Myeloid Plus Solution (MYS+). Pursuant to the 2019 Normandie Agreement, we paid Normandie Valorisation a low five-digit Euro upfront fee and are obligated to pay Normandie Valorisation a mid-single-digit Euro fee per each analysis utilizing Solid Tumor Plus Solution (STS+).

The term of each agreement continues until the expiration of the last-to-expire licensed patent in September 2033, unless automatically terminated upon our cessation of business, bankruptcy or insolvency or upon the invalidation of the applicable licensed patents in France. In addition, Normandie Valorisation may terminate either agreement if we challenge the validity or enforceability of the licensed patents. Either party may terminate either agreement in the event of non-performance by the other party of one or more of its obligations under such agreement which is not cured within three months of receipt of written notice of such non-performance. Either party may also terminate the 2019 Normandie Agreement at any time, with one year’s prior written notice.

SATT Aquitaine—Software Sublicense Agreement

In November 2017, we entered into a software sublicense agreement with Aquitaine Science Transfert ("SATT Aquitaine"), pursuant to which SATT Aquitaine granted us a non-exclusive, worldwide sublicense under certain intellectual property rights exclusively licensed to SATT Aquitaine to reproduce, adapt, use and distribute, and create derivative works based on, certain modeling software applications in the field of oncology. The right to use such software applications granted to us includes the right to provide software-related services to our customers.

In exchange for the rights granted to us, we paid SATT Aquitaine a low six-digit Euro upfront payment. Intellectual property rights in any derivative software applications developed by us shall be owned by us in accordance with French intellectual property law.

The agreement is effective for 15 years unless automatically terminated upon our cessation of business, dissolution, bankruptcy or liquidation. In addition, either party may terminate the agreement in the event of non-performance by the other party of one or more of its obligations under the agreement which are not cured within three months of receipt of written notice of such non-performance.

Collaboration Agreements

We have built an agnostic platform that enables others to get the most out of their data. As such, our model is valuable to all types of players within the health care ecosystem. For hardware and consumable players our platform and smart algorithms bring large benefits to their customer base as it allows for a more rapid set-up of their technology, better results in terms of clinical outcomes on the same hardware, bringing value to a larger number of samples and as such higher volumes.

We collaborate not only to provide valuable technologies to hospitals and laboratories around the world directly or through collaborators, but also to increase our channels and to offer a variety of product choices to our large customer base.

GE Healthcare—Master Alliance Agreement

In November 2021, we entered into a Master Alliance Agreement with GE Healthcare. Under this agreement, we will be working together with GE Healthcare on a variety of opportunities in the healthcare market and will collaborate on different initiatives and projects in the fields of digital oncology and radiogenomic analysis. The first projects we and GE Healthcare are working on together relate to the creation of infrastructure to integrate data between GE Healthcare's Edison platform and our SOPHiA platform, as well as a commercial collaboration focused on co-marketing and pilot site recruitment in the digital oncology and radiogenomic analysis space. We also intend to work together to combine our and GE's existing capabilities to jointly develop and provide multimodal analytics.

Each party agreed that, for six months after the execution of the Master Alliance Agreement, it will not negotiate, execute or otherwise enter into any material collaboration with certain specified third parties.

The term of the Master Alliance Agreement is five years, with automatic one-year renewals thereafter, unless earlier terminated for cause or, after three years after the execution of the Agreement, if no statements of work are in effect.

Agilent—Co-Marketing Agreement

In December 2020, we entered into an agreement for the co-marketing of products and services (the "Co-Marketing Agreement"), with Agilent, pursuant to which we agreed to collaborate with Agilent for the development and commercialization of sequencing diagnostic products.

Pursuant to the Co-Marketing Agreement, we agreed to collaborate with Agilent to develop a diagnostic product for worldwide commercialization that will be specifically compatible with Agilent's Magnis SureSelect assays. The collaboration under the Co-Marketing Agreement is non-exclusive, and neither party is restricted from entering into similar collaborations with other third parties so long as it does not breach its obligations to perform under the Co-Marketing Agreement.

Each party retains all rights to its background intellectual property provided in connection with the development or commercialization of any diagnostic product developed under the Co-Marketing Agreement, including the commercialization rights thereto, subject to certain non-exclusive licenses granted by each party to the other under its trademarks and confidential information. Any intellectual property arising from the performance of the Co-Marketing Agreement that is substantially developed solely by a party will be owned by such party. Any intellectual property that is substantially developed jointly under the Co-Marketing Agreement shall be jointly owned by the parties, and both parties are prohibited from using such jointly-owned intellectual property for any purposes other than certain specified activities relating to gene panels. The parties may enter into additional agreements regarding the use and rights relating to such jointly-developed intellectual property.

The Co-Marketing Agreement is effective for two years, with potential successive one-year renewal options exercisable by the parties, and may be terminated by either party upon (i) a material breach by the other party (subject to a certain specified cure period) or (ii) 180 days' prior written notice, provided that the parties must follow an express wind-down procedure upon any expiration or termination.

IDT—Manufacturing and Supply Agreement

In December 2015, we entered into a manufacturing and supply agreement with IDT for the manufacture and supply of various commercial and research products, in particular DNA enrichment kits. The agreement was amended and restated in October 2018 and amended in March 2019.

Under the agreement, IDT committed to manufacture and supply to us or directly to our customers, as applicable, various products, in particular DNA enrichment kits. IDT shall manufacture the products covered by this agreement in accordance with product specifications provided by us, (such products, "commercial products"). IDT is required to certify that the delivered products were manufactured in accordance with said specifications. In addition, we can purchase products already manufactured by IDT pursuant to its own specifications, (such products, "research products") and resell such products to our customers and collaborators.

Purchase prices for both commercial and research products are set upon completion of the corresponding master specification document. We are obligated to provide IDT on a quarterly basis with written good faith non-binding purchasing forecasts of the aggregate quantities of commercial products to be purchased by us in the following twelve months and IDT is obligated to ensure sufficient inventory and manufacturing capacity to deliver the forecasted quantities. We are not required to purchase the commercial products from IDT in the previously forecasted quantities. However, if we fail to purchase a specified percentage of the forecasted quantities of commercial products, IDT will have the right to increase the prices of such products by amounts in excess of the additional manufacturing costs associated with our reduced purchase. At the same time, we have the right to place purchase orders for products beyond the previously forecasted quantities and IDT is obligated to use its commercially reasonable efforts to fill such orders at regular prices. We are not required to provide IDT with forecasts for research products that we intend to purchase in any given period. The purchase prices for such products are not adjustable based on the quantities actually ordered by us.

All inventions made directly as a result of the manufacture of commercial and research products that are improvements to such products will be owned by us. IDT will obtain a fully-paid up, royalty-free, worldwide license under such improvements to make, have made, use and sell the commercial and research products exclusively for and to us.

The agreement has an initial term of five years. It will automatically renew for additional one-year periods unless a party notifies the other of its decision not to renew the agreement. We also have the right to terminate the agreement if we do not agree with changes made by IDT in accordance with the provisions of the agreement, including in connection with changes to master specification documents for any research or commercial product. In addition, each party has the right to terminate the agreement effective immediately if the other party fails to meet essential terms of the agreement and such failure is not cured.

Qiagen—OEM Supply Agreement

In January 2018, we entered into an OEM supply agreement with Qiagen for the supply of certain amplification technologies required to complement our NGS technologies. The agreement was amended in June 2019.

Under the agreement, we receive the exclusive right to offer and resell the products manufactured by Qiagen as part of "bundle" solutions. We cannot offer such products as stand-alone or single items, unless it is required for product replacement or quality control reasons or in other special circumstances discussed by the parties in good faith. Qiagen is obligated to use its commercially reasonable efforts to manufacture and deliver products in quantities ordered by us. We are required to provide Qiagen in writing with a monthly rolling forecast covering the next six months. In addition, both parties shall meet at least once every quarter to discuss any adjustments to the forecast. Furthermore, we are obligated to purchase minimum quantities of products every year. If we fail to do so in any given calendar year, we will be obligated to make a one-time payment at the end of the year in an amount equal to the difference between the value of the products forecasted to be purchased in that year and the products actually purchased.

The agreement had an initial term of three years. It automatically extended for one 2-year period which will be followed by 1-year periods unless a party notifies the other of its decision not to renew the agreement. The parties may terminate the agreement effective immediately for cause or upon notice in certain situations.

NEB – Supply Agreement

In January 2019, we entered into a supply agreement with NEB for the supply of various reagents. These products may only be used in the research field and in compliance with applicable intended use statements, limited use statements or limited label licenses.

We are required to provide NEB with twelve-months' rolling written forecasts of our estimated product supply requirements. The forecasts for the certain months of each twelve-month rolling period are binding, and the forecasts for the remaining months are non-binding and serve only as a good faith estimate to facilitate NEB's production scheduling.

New England Biolabs shall not unreasonably reject any purchase order and shall use commercially reasonable efforts to fill purchase orders for any quantity of product that, alone or cumulatively with other purchase orders submitted to it for product delivery during the relevant calendar quarter, exceeds the amount specified in the binding portion of the then-current rolling forecast.

Prior to each shipment of products, NEB shall perform quality control procedures reasonably necessary to ensure that the products to be shipped conform fully to the specifications as agreed upon by us with NEB from time to time.

The agreement had an initial term of three years. It has been automatically extended for a two-year period and thereafter it will automatically extend for successive two-year periods, unless either party notifies the other party in writing at least six months prior to the expiration of the then-current term that such party does not wish to continue the agreement.

Twist—Supply Agreement

In November 2019, we entered into a supply agreement with Twist for the manufacture and supply of various RUO products, in particular target enrichment and library construction reagent sets.

Under the agreement, we may offer and resell products manufactured by Twist as part of "bundle" solutions. We may not offer such product as stand-alone products, unless we obtain Twist's written consent. Twist is obligated to use its commercially best efforts to manufacture and deliver products in quantities ordered by us. We are required to provide Twist with a non-binding good faith six-months' rolling written forecast, setting out forecasted quantities of the products to be purchased by us in monthly increments.

We can provide Twist with specifications of the products to be supplied by Twist or order ready-to-use products already manufactured by Twist. Once Twist accepts a purchase order from us, we are not allowed to cancel such an order, but Twist may cancel the purchase order if it cannot fulfill such order despite using commercially best efforts.

The agreement has an initial term of three years. It will automatically extend for one-year periods unless a party notifies the other of its decision not to renew the agreement. In addition, either party may terminate it without cause.

D. Exchange Controls

There are no Swiss governmental laws, decrees or regulations that restrict, in a manner material to us, the export or import of capital, including any foreign exchange controls, or that generally affect the remittance of dividends or other payments to non-residents or non-citizens of Switzerland who hold our ordinary shares.

E. Taxation

The following discussion is based on the tax laws, regulations and regulatory practices of Switzerland and the United States as in effect on the date hereof, which are subject to change (or subject to changes in interpretation), possibly with retroactive effect.

Current and prospective shareholders are advised to consult their own tax advisers in light of their particular circumstances as to the Swiss or U.S. tax laws, regulations and regulatory practices that could be relevant for them, the acquiring, owning and selling or otherwise disposing of our ordinary shares and receiving dividends and similar cash or in-kind distributions on our ordinary shares (including dividends on liquidation proceeds and share dividends) or distributions on our ordinary shares based upon a capital reduction or reserves paid out of capital contributions and the consequences thereof under the tax laws, regulations and regulatory practices of Switzerland or the United States.

Swiss Tax Considerations

Swiss Federal Withholding Tax

Dividends and other cash or in-kind distributions (including scrip or stock dividends), if any, on ordinary shares made or paid by us out of reserves from capital contributions (*réserves d'apports de capital*) and distributions, if any, on ordinary shares made or paid by us based upon a reduction of nominal value of ordinary shares (*réduction de la valeur nominale*) and the purchase price for ordinary shares bought back, if any, by us for a capital reduction booked against reserves from capital contributions and nominal value of ordinary shares, are exempt from Swiss federal withholding tax. The proceeds from the offering of the ordinary shares (net of certain deductions) will qualify as reserves from capital contributions and as nominal value of the ordinary shares.

Dividends and other cash or in-kind distributions (including scrip or stock dividends), if any, on ordinary shares made or paid by us out of profit or reserves other than reserves from capital contributions and the purchase price for ordinary shares bought back, if any, by us for a capital reduction booked against reserves other than reserves from capital contributions, are subject to Swiss federal withholding tax at a rate of 35%. Any Swiss federal withholding tax must be withheld by us on the gross amount of the dividend or distribution or purchase price, as applicable, and be remitted to the Swiss Federal Tax Administration.

Capital gains realized on the sale of ordinary shares in the secondary market are not subject to Swiss federal withholding tax.

Refund of Withholding Tax on Taxable Distributions

The Swiss Federal Tax Administration or the relevant cantonal tax authority, as applicable, will refund or credit Swiss federal withholding tax on dividends or other cash or in-kind distributions (including scrip or stock dividends), if any, on ordinary shares made or paid by us, or the purchase price paid by us for ordinary shares bought back, if any, for a capital reduction, out of or against profit or reserves other than tax-exempt reserves from capital contributions in full to holders who are individuals resident in Switzerland and to holders, who hold the ordinary shares on which the dividends or other distributions have been paid, as part of a trade or business in Switzerland, and, who, in each case, *inter alia*, are the beneficial owners of the ordinary shares and duly report the dividend or distributions or the purchase price paid by us for ordinary shares bought back for a capital reduction in the income tax return or the financial statements, respectively, for the relevant tax period.

A holder who is a resident of the United States for purposes of the double taxation agreement between the United States and Switzerland (the "Treaty") without taxable presence in Switzerland to which the ordinary shares are attributable or who is a qualified U.S. pension fund and who, in each case, is the beneficial owner of the ordinary shares and the dividend or distribution and who meets the conditions of the Treaty may apply for a full refund of the Swiss federal withholding tax in the case of qualified U.S. pension funds or in excess of the amount of the 15% treaty rate in all other cases. The claim for refund must be filed on Swiss Tax Form 82 (82C for corporations, 82I for individuals, 82E for other entities and 82R for regulated investment companies), which forms together with an instruction form may be obtained from any Swiss consulate general in the United States, the Swiss Federal Tax Administration at the address below or be downloaded from the Swiss Federal Tax Administration's website. Four copies of the form must be duly completed and signed before a notary public of the United States, and three of them must be sent to the Swiss Federal Tax Administration (currently at Eigerstrasse 65, CH-3003, Bern, Switzerland). The form must be accompanied by suitable evidence of deduction of the Swiss federal withholding tax, such as certificates of deduction, bank vouchers or credit slips. The form must be filed no later than December 31 of the third year following the calendar year in which the dividend subject to the tax became payable.

Any other holder who is not resident in Switzerland and who does not hold the ordinary shares as part of a trade or business in Switzerland, may be entitled to a full or partial refund of the Swiss federal withholding tax deducted if the country in which the recipient resides for tax purposes has entered into a bilateral treaty for the avoidance of double taxation with Switzerland, the recipient is the beneficial owner of the ordinary shares and the dividend or distribution or the purchase price and the other conditions of the treaty are met. Refund forms are available on the Swiss Federal Tax Administration's website.

Swiss Federal Issue Stamp Tax

We will be liable to Swiss federal issue stamp tax on the issuance (*droit d'émission sur capital propre)* of the ordinary shares of 1% of the proceeds from the offering, net of certain deductions.

Swiss Federal Securities Turnover Tax

The delivery of ordinary shares to the initial purchasers of the ordinary shares against payment of the offer price will not be subject to Swiss securities turnover tax (*droit de négociation*).

Any subsequent transactions in ordinary shares in the secondary markets are subject to Swiss federal securities turnover tax at a rate of 0.15% of the purchase price of the ordinary shares if a Swiss or Liechtenstein domestic bank or securities dealer (as defined in the Swiss Federal Stamp Tax Act) is a party or an intermediary to the transaction, and none of the exemptions provided for in the Swiss Federal Stamp Tax Act applies. Generally, half of the tax is charged to the one party to the transaction and the other half to the other party, subject to applicable statutory exemptions in respect of the one or the other party to the transaction and their respective halves of the tax. Secondary market dealings in ordinary shares where no domestic bank or securities dealer is a party or an intermediary to the transaction are not subject to Swiss federal securities turnover tax.

Swiss Federal, Cantonal and Communal Income Taxes

Ordinary Shares Held By Holders Resident Outside Of Switzerland and With No Trade or Business in Switzerland

Holders of ordinary shares who are not residents of Switzerland for tax purposes, and who during the taxable year have not held ordinary shares through a permanent establishment within Switzerland for tax purposes, are not subject to any Swiss federal, cantonal or communal income tax in respect of the receipt of dividends, or other distributions, if any, on ordinary shares, or gain realized on the sale or other disposition of ordinary shares.

For a discussion of the Swiss federal withholding tax treatment of dividends and distributions or capital gains on ordinary shares, see above "—Swiss Federal Withholding Tax." For a discussion of the automatic exchange of information in tax matters, see below "—International Automatic Exchange of Information in Tax Matters" and for a discussion of the Swiss facilitation of the implementation of the FATCA, see below "—Swiss Facilitation of the Implementation of FATCA."

Ordinary Shares Held By Swiss Resident Individuals as Private Investments

Dividends and other cash or in-kind distributions (including scrip or stock dividends), if any, on ordinary shares, to the extent made or paid by us out of reserves from capital contributions and distributions, if any, to the extent made or paid by us on ordinary shares based upon a capital reduction, and the purchase price of ordinary shares bought back for a capital reduction charged to reserves from capital contributions are exempt from Swiss federal, cantonal and communal income tax for holders of ordinary shares who are individuals resident in Switzerland for tax purposes and who hold the ordinary shares as private investments.

Conversely, any dividends and other cash or in-kind distributions (including scrip or stock dividends), if any, on ordinary shares to the extent made or paid by us out of profit and reserves other than reserves from capital contributions, and the purchase price for ordinary shares bought back, if any, by us for a capital reduction to the extent booked against reserves other than reserves from capital contributions, will be subject to Swiss federal, cantonal and communal taxable income for such holders.

A capital gain realized by a holder on the sale of ordinary shares (other than a sale to us in a share buy-back for capital reduction) held as private investments classifies as tax-exempt private capital gain and, vice versa, a capital loss as non-tax deductible private capital loss for purposes of Swiss federal, cantonal and communal income tax.

See below "—Ordinary shares held as assets of a Swiss business" for a summary of the taxation treatment of Swiss resident individuals who, for income tax purposes, are classified as "professional securities dealers."

Ordinary Shares Held As Assets of a Swiss Business

For a corporate or an individual who holds the ordinary shares as part of a trade or business carried on in Switzerland, any dividends and any other distributions, if any, made or paid by us on ordinary shares, and any capital gain or loss realized on the sale of ordinary shares, are includible in, or deductible from, respectively, the taxable income in the relevant taxation period for purposes of Swiss federal, cantonal and communal individual or corporate income tax. This taxation treatment also applies to Swiss resident private individuals who, for income tax purposes, are classified as "professional securities dealers."

Corporate taxpayers will be eligible for dividend relief (*réduction pour participations*) in respect of dividends and distributions, if any, on ordinary shares if either the market value of the ordinary shares held by them equals or exceeds CHF 1.0 million or the ordinary shares represent 10% or more of our share capital.

International Automatic Exchange of Information in Tax Matters

Switzerland has concluded a multilateral agreement with the EU on the international automatic exchange of information ("AEOI") in tax matters, which applies to all EU member states. In addition, Switzerland signed the multilateral competent authority agreement on the automatic exchange of financial account information (the "MCAA") and a number of bilateral AEOI agreements with other countries, most of them on the basis of the MCAA. Based on these agreements and the implementing laws of Switzerland, Switzerland collects and exchanges data in respect of financial assets held in, and income derived thereon and credited to, accounts or deposits (including ordinary shares held in such accounts or deposits) with a paying agent in Switzerland for the benefit of individuals resident in an EU member state or in another treaty state. An up-to-date list of the AEOI agreements to which Switzerland is a party that are in effect, or signed but not yet in effect, can be found on the website of the State Secretariat for International Financial Matters SIF.

Swiss Facilitation of the Implementation of FATCA

The United States and Switzerland entered into an intergovernmental agreement (the "U.S.-Switzerland IGA") to facilitate the implementation of FATCA. Under the U.S.-Switzerland IGA, financial institutions acting out of Switzerland generally are directed to become participating foreign financial institutions. The U.S.-Switzerland IGA ensures that accounts held by U.S. persons with Swiss financial institutions (including accounts in which ordinary shares are held) are disclosed to the U.S. tax authorities either with the consent of the account holder or by means of group requests within the scope of administrative assistance, on the basis of the Treaty. The Treaty, as amended in 2019, includes a mechanism for the exchange of information in tax matters upon request between Switzerland and the United States, which is in line with international standards, and allows the United States to make group requests under FATCA concerning non-consenting U.S. accounts and non-consenting U.S. accounts and non-consenting non-participating foreign financial institutions for periods from June 30, 2014. Furthermore, the Swiss Federal Council approved a mandate for negotiations with the United States on October 8, 2014, with regard to a change from the current direct-notification-based regime to a regime where the relevant information is sent to the Swiss Federal Tax Administration, which in turn provides the information to the U.S. tax authorities. It is not yet known when negotiations will continue and if and when any new regime would come into force.

Material U.S. Federal Income Tax Consequences for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders, as defined below, of owning and disposing our ordinary shares. It does not describe all tax consequences that may be relevant to a particular person's decision to acquire ordinary shares.

This discussion applies only to a U.S. Holder that holds ordinary shares as capital assets for U.S. federal income tax purposes within the meaning of Section 1221 of the Code (generally, property held for investment). In addition, it does not describe any tax consequences other than U.S. federal income tax consequences, including state and local tax consequences and estate or gift tax consequences, and does not describe 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 special tax accounting rules under Section 451(b) of the Code, the potential application of the

Medicare contribution tax on net investment income, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares as part of a straddle, wash sale, conversion transaction or other integrated transaction or persons entering into a constructive sale with respect to the ordinary shares;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities or arrangements classified as partnerships or S corporations for U.S. federal income tax purposes and investors in such entities;
- tax-exempt entities, including an “individual retirement account” or “Roth IRA” or governmental entities;
- real estate investment trusts or regulated investment companies;
- former U.S. citizens or long-term residents of the United States;
- persons that own or are deemed to own 10% or more of the voting power or value of our shares; or
- persons holding ordinary shares in connection with a trade or business conducted outside of the United States or in connection with a permanent establishment or other fixed place of business outside of the United States.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary 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 ordinary shares in their circumstances.

This discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and 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 ordinary shares, who is eligible for the benefits of the Treaty and who is:

- an individual who is a citizen or 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 ordinary shares in their particular circumstances.

Except where otherwise indicated, this discussion assumes that we are not, and will not become, PFIC, as described below.

Taxation of Distributions

As discussed above under “Dividend Policy,” we do not currently expect to make distributions on our ordinary shares. In the event that we do make distributions of cash or other property, distributions paid on ordinary shares, other than certain pro rata distributions of ordinary shares, will generally 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). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to the discussion under “—Passive Foreign Investment Company” below, for so long as our ordinary shares are listed on the NYSE or we are eligible for benefits under the Treaty, dividends paid to certain non-corporate U.S. Holders will be eligible for taxation as “qualified dividend income” and therefore, subject to applicable holding period requirements, will be taxable at rates not in excess of the long-term capital gain rate applicable to such U.S. Holder.

The amount of a dividend will include any amounts withheld by us in respect of Swiss 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 generally 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 Swiss francs 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. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. 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.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder’s particular circumstances, Swiss income taxes withheld from dividends on ordinary shares (at a rate not exceeding the rate provided by the Treaty) may be creditable against the U.S. Holder’s U.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, at their election, deduct foreign taxes, including any Swiss income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or Other Disposition of Ordinary Shares

Subject to the discussion below under “—Passive Foreign Investment Company,” gain or loss realized by a U.S. Holder on the sale or other disposition of ordinary shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder’s holding period for such ordinary shares was more than one year as of the date of the sale or other disposition. The amount of the gain or loss will equal the difference between the U.S. Holder’s tax basis in the ordinary shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. Long-term capital gain recognized by a non-corporate U.S. Holder is subject to U.S. federal income tax at rates lower than the rates applicable to ordinary income and short-term capital gains, while short-term capital gains are subject to U.S. federal income tax at the rates applicable to ordinary income. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to various limitations.

Passive Foreign Investment Company

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 consists 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 generally includes dividends, interest, 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, including goodwill, which is based on the market price of our ordinary shares in 2021, we believe that we were not a PFIC for our 2021 taxable year. However, there can be no assurance that the IRS will agree with our conclusion. In addition, whether we were a PFIC in 2021 or will be a PFIC any future year is uncertain because, among other things, (i) we hold a substantial amount of cash, which is generally categorized as a passive asset and (ii) our PFIC status for any taxable year will depend on the composition of our income and assets and the value of our assets from time to time (which may be determined, in part, by reference to the market price of our ordinary shares, which could be volatile). 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 ordinary shares, we would generally continue to be treated as a PFIC with respect to such holder for all succeeding years during which such holder holds ordinary shares, even if we ceased to meet the threshold requirements for PFIC status. If we were a PFIC for any taxable year and any of our subsidiaries or other companies in which we owned or were treated as owning equity interests were also a PFIC (any such entity, a "Lower-tier PFIC"), a U.S. Holder would be deemed to own a proportionate amount (by value) of the shares of each Lower-tier PFIC and would be subject to U.S. federal income tax according to the rules described in the subsequent paragraph on (i) certain distributions by a Lower-tier PFIC and (ii) dispositions of shares of Lower-tier PFICs, in each case as if such holder held such shares directly, even though such holder will not have received the proceeds of those distributions or dispositions.

If we were a PFIC for any taxable year during which a U.S. Holder held any of our ordinary shares, such holder would generally be subject to adverse tax consequences. Generally, gain recognized upon a disposition (including, under certain circumstances, a pledge) of ordinary shares would be allocated ratably over a U.S. Holder's holding period for the ordinary shares. The amounts allocated to the taxable year of disposition and to years 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 that taxable year for individuals or corporations, as appropriate, and an interest charge would be imposed on the tax on such amount. Further, to the extent that any distributions received on a U.S. Holder's ordinary shares during a taxable year exceeded 125% of the average of the annual distributions on those shares during the preceding three years or such holder's holding period, whichever was shorter, those distributions would be subject to taxation in the same manner as gain, described immediately above.

Alternatively, if we were a PFIC and if the ordinary shares were "regularly traded" on a "qualified exchange," a U.S. Holder would be eligible to make a mark-to-market election that would result in tax treatment different from the general tax treatment for PFICs described above. The ordinary shares would be treated as "regularly traded" for the year of this offering if more than a de minimis quantity of the ordinary shares were traded on a qualified exchange on at least 1/6 of the days remaining in the quarter in which this offering occurs, and on at least 15 days during each remaining calendar quarter (the "15-Day Test"), and for years other than this year based on the 15-Day Test. The Nasdaq, on which the ordinary shares are expected to be listed, is a qualified exchange for this purpose. Once made, the election cannot be revoked without the consent of the IRS unless the shares cease to be marketable.

If a U.S. Holder makes the mark-to-market election, such holder will generally recognize as ordinary income any excess of the fair market value of such holder's ordinary 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 ordinary 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, such holder's tax basis in their ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary 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). This election will not apply to any of our non-U.S. subsidiaries. Accordingly, a U.S. Holder may continue to be subject to tax under the PFIC excess distribution regime with respect to any Lower-tier PFICs notwithstanding a mark-to-market election for the ordinary shares.

In addition, if we were a PFIC for any taxable year in which we paid a dividend or for the prior taxable year, the preferential dividend rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If a company that is a PFIC provides certain information to U.S. Holders, a U.S. Holder can then avoid certain adverse tax consequences described above by making a "qualified electing fund" election to be taxed currently on its proportionate share of the PFIC's ordinary income and net capital gains. However, because we do not intend to prepare or provide the information necessary for a U.S. Holder to make a qualified electing fund election, such election will not be available to U.S. Holders.

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC, such holder must generally 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, generally with such holder's federal income tax return for that year.

U.S. Holders should consult their tax advisers regarding whether we are a PFIC and the potential application of the PFIC rules.

Information Returns

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC or in which we hold a direct or indirect equity interest in a Lower-tier PFIC, the U.S. Holder generally must file an annual report on IRS Form 8621 with respect to each such PFIC containing such information as the U.S. Treasury may require, generally with the U.S. Holder's U.S. federal income tax return for the relevant year. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with respect to the items required to be included in such report until three years after the U.S. Holder files the annual report and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period.

PROSPECTIVE U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE CONSEQUENCES OF OUR POTENTIAL PFIC STATUS ON AN INVESTMENT IN ORDINARY SHARES.

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 generally 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 U.S. 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.

Information with Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain U.S. financial institutions). Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S. Holder to which the information relates may not close until three years after such information is filed. U.S. Holders should consult their tax advisers regarding the effect, if any, of this legislation on their ownership and disposition of the ordinary shares.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act. Accordingly, we 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 site at *www.sec.gov* that contains reports, proxy and information statements and other information we have filed electronically with the SEC. 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 are not 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.

Additionally, pursuant to Swiss law, any shareholder of record has the right to receive a free copy of this Annual Report and to inspect this Annual Report at any time at our registered office in Saint-Sulpice, Canton of Vaud, Switzerland.

We also make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is *www.sophiagenetics.com*. The reference to our website is an inactive textual reference only, and information contained therein or connected thereto is not incorporated into this Annual Report.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We had cash and cash equivalents totaling $193.0 million and $74.6 million as of December 31, 2021 and 2020, respectively, which are comprised of bank and short-term deposits with maturities up to three months. We also had term deposits totaling $72.4 million and $22.7 million as of December 31, 2021 and 2020, respectively. Our cash and cash equivalents are subject to market risk due to changes in interest rates. Fixed rate securities may have their market value adversely affected due to a rise in interest rates. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates.

As we currently do not have any outstanding debt, we are not subject to interest rate risk related to debt obligations.

We do not believe that a hypothetical 100 basis points change in interest rates would have a material effect on our business, financial condition or results of operations. We do not enter into investments for trading or speculative purposes. We do not use any financial instruments to manage our interest rate risk exposure.

Foreign Exchange Risk

We operate internationally and a portion of our revenue, expenses, assets, liabilities and cash flows are denominated in currencies other than our presentation currency. As a result, we are exposed to fluctuations in foreign exchange rates.

The sensitivity of our income to possible changes in foreign exchange rates is measured at the local entity level as it depends on the functional currency of each entity. For the years ended December 31, 2021 and 2020, we were exposed principally to movements in four cross-currency pairs. The sensitivity of our loss before tax to such changes was as follows:

	December 31,	
	2021	2020
(in USD thousands)	**Decrease (Increase) in loss before tax**	
Increase / (decrease) in USD/CHF exchange rate by 10%	$19,499 / ($19,499)	$1,453 / ($1,453)
Increase / (decrease) in EUR/CHF exchange rate by 10%	648 / (648)	836 / (836)
Increase / (decrease) in GBP/CHF exchange rate by 10%	(18) / 18	351 / (351)
Increase / (decrease) in USD/EUR exchange rate by 10%	$726 / ($726)	$155 / ($155)

We do not believe that foreign exchange risk associated with other cross-currency pairs is material to our business, financial condition or results of operations.

Credit Risk

We are exposed to credit risk from our operating activities, primarily trade receivables. Credit risk is the risk that a counterparty will be unable to meet its obligations under a financial instrument or customer contract. Allowance is made for lifetime expected credit losses as invoices are issued. The amount of allowance initially recognized is based on historical experience, tempered by expected changes in future cash collections, due to, for example, expected improved customer liquidity or more active credit management.

We do not believe that credit risk had a material effect on our business, financial condition or results of operations. The largest outstanding balance represented 18% of trade and other receivables in 2021, which is attributable to our largest distributor. This is due to a large distributor having long payment terms and a multitude of end customers to which the distributor sells our products and services. The distributor has a strong payment history and is in good standing with us. Our cash and cash equivalents are deposited with reputable financial institutions. If customers representing a significant percentage of our trade receivables are unable to meet their payment obligations to us, we may suffer harm to our business, financial condition or results of operations.

Inflation Risk

We do not believe that inflation had a material effect on our business, financial condition or results of operations. Our general terms and conditions allow us to adjust prices based on market conditions, including but not limited to inflation, which in general enables us to partially pass through increases in our costs onto our customers. However, if our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition or results of operations.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

On July 22, 2021, the SEC declared effective our Registration Statement on Form F-1 (No. 333-257646) filed in connection with our initial public offering. J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Cowen and Company, LLC and Credit Suisse Securities (USA) LLC acted as underwriters in the initial public offering. In the initial public offering, we issued and sold a total of 13,519,493 ordinary shares, including 519,493 ordinary shares pursuant to the underwriters' exercise of their option to purchase additional shares. The public offering price was $18.00 per share. Our net proceeds from the initial public offering was $220.2 million, after deducting underwriting discounts and commissions of $17.0 million and offering expenses of $6.2 million. There has been no material changes in the planned use of proceeds as described in the our prospectus dated July 22, 2021, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

On July 27, 2021, in a private placement exempt from registration under Section 4(a)(2) of the Securities Act and the rules and regulations promulgated thereunder, we issued and sold ordinary shares to GE Healthcare. No underwriter or placement agent acted on our behalf in the private placement. In the private placement, we issued and sold 1,111,111 ordinary shares. The offering price was $18.00 per share. Our net proceeds from the private placement was $19.6 million, after deducting offering expenses of $0.4 million. We intend to use the net proceeds from the private placement for working capital and general corporate purposes.

Item 15. Controls and Procedures

A. Disclosure Controls and Procedures

Disclosure Controls

As required by Rule 13a-15 under the Exchange Act, management, including our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosures.

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on such evaluations, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, our disclosure controls and procedures were not effective due to the material weaknesses in our internal controls over financial reporting, as described below.

Material Weaknesses in Internal Controls Over Financial Reporting

A company's internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by a company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with IFRS. 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 the annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the preparation of our consolidated financial statements and audit process for the years ended December 31, 2020 and December 31, 2019, we and our independent registered public accounting firm have identified material weaknesses in our internal controls related to financial reporting. For each of the fiscal years ended December 31, 2020 and 2019, we have determined that we did not:

- design or maintain an effective control environment commensurate with our financial reporting requirements due to lack of sufficient accounting professionals with the appropriate level of skill, experience and training. Specifically, we lack sufficient financial reporting and accounting personnel with appropriate knowledge of IFRS to address complex technical accounting issues and to prepare consolidated financial statements and related disclosures;

- design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, year-end reporting and disclosures, including controls over the preparation and review of account reconciliations, journal entries and period end financial reporting; and

- design and maintain effective controls over certain information technology general controls for IT systems that are relevant to the preparation of our consolidated financial statements. Specifically, we did not design and maintain: (a) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate personnel, (b) program change management controls to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, and (c) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These material weaknesses resulted in adjustments to our consolidated financial statements during the audit process.

Since our IPO, we have taken and continue to take steps to remediate the aforementioned material weaknesses and to enhance our overall control environment. Regarding the material weakness related to the lack of sufficient accounting professionals with the appropriate level of skill, experience and training, we have hired a number of key employees in our accounting department, including a new Controller and Assistant Controller, to support our Chief Financial Officer and retained accounting consultants to provide additional support to our technical accounting and financial reporting capabilities and support our finance department in the design and implementation of an improved internal controls system. We have also begun the process of reviewing and documenting our accounting and financial processes and internal controls, improving and formalizing accounting and reporting policies, and building out the appropriate technical, financial management and reporting systems infrastructure to automate and standardize such policies.

We believe that the professionals that we have hired to date have the appropriate level of skills, experience, and training to put us in the position to remediate the first aforementioned material weakness once they have been fully integrated into our control environment and operated those controls across a sufficient number of reporting periods. To address the other two aforementioned material weaknesses, we also are continuing to improve our process of reviewing and documenting our accounting and financial processes and internal controls, to improve and formalize accounting and reporting policies, and to build out the appropriate technical, financial management and reporting systems infrastructure to automate and standardize such policies.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses.

B. Management’s Annual Report on Internal Control Over Financial Reporting

This Annual Report does not include a report of management’s assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of the company’s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies and because we are an emerging growth company under the JOBS Act.

D. Changes in Internal Control Over Financial Reporting

Other than the remediation activities described above, there were no changes to internal control over financial reporting during the year ended December 31, 2021 that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our board of directors has determined that each of Didier Hirsch and Milton Silva-Craig is considered an “audit committee financial expert” as defined by the SEC. Our board of directors has determined that each of Didier Hirsch, Kathy Hibbs and Milton Silva-Craig satisfy the “independence” requirements set forth in Rule 10A-3 under the Exchange Act.

Item 16B. Code of Ethics

We have adopted the Code of Ethics, which is applicable to all of our employees, executive officers and directors. The Code of Ethics will be available on our website *www.sophiagenetics.com*. Our board of directors is responsible for overseeing the Code of Ethics and will be required to approve any waivers of the Code of Ethics for our executive officers and directors. We expect that any amendments to the Code of Ethics, or any waivers of its requirements, will be disclosed in our annual report on Form 20-F. For the year ended December 31, 2021, we did not grant any waivers of the Code of Ethics.

Item 16C. Principal Accountant Fees and Services

Fees

	For the year ended December 31,	
	2021	**2020**
Audit fees	$ 1,856,044	$ 1,500,873
Audit-related fees	9,834	-
Tax services	34,273	-
All other fees	409,389	88,167
Total fees	**$ 2,309,540**	**$ 1,589,040**

For the year ended December 31, 2021 and 2020, PricewaterhouseCoopers SA was the Company’s auditor for the IFRS and statutory accounts.

Audit fees include the standard audit work performed each fiscal year necessary to allow the auditor to issue an opinion on our financial statements and to issue an opinion on the local statutory financial statements. Audit fees also include services that can be provided only by the external auditor such as reviews of quarterly financial results and review of our securities offering documents as well as fees accrued in association with services performed in connection with our IPO.

Audit-related fees consist of fees billed for assurance and related services reasonably related to the performance of the audit or review of our financial statements or for services traditionally performed by an external auditor.

Tax services represent tax compliance, assistance with historical tax matters, and other tax-related services.

Other services include advisory services relating to the adoption of IFRS and other reporting guidance databases.

Pre-Approval Policies and Procedures

In accordance with the requirements of the Sarbanes-Oxley Act and rules issued by the SEC, we review and pre-approve of any services performed by PricewaterhouseCoopers SA. The procedures require that all proposed future engagements of PricewaterhouseCoopers SA for audit and permitted non-audit work are submitted to the audit committee of our board of directors for approval prior to the beginning of any such service. In accordance with this policy, all services performed by and fees paid to PricewaterhouseCoopers SA in this Item 16C. were approved by the audit committee.

Item 16D. Exemptions from the Listing Standards for Audit Committees

None.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 16F. Change in Registrant's Certifying Accountant

The information required by Item 16F. was previously reported on our Registration Statement on Form F-1 (No. 333-257646) and our prospectus dated July 22, 2021, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act.

Item 16G. Corporate Governance

As a "foreign private issuer," as defined by the SEC, we are permitted to follow home country corporate governance practices instead of certain corporate governance standards required by Nasdaq for U.S. companies. Accordingly, we follow Swiss corporate governance rules in lieu of certain of Nasdaq's corporate governance requirements. The significant differences between our Swiss corporate governance rules and Nasdaq's corporate governance requirements are set forth below:

- Exemption from the requirement that a majority of the board of directors be comprised of independent directors and that there be regularly scheduled meetings with only the independent directors present. Swiss law does not have such a requirement.
- Exemption from the requirements that the compensation committee and the nomination and corporate governance committee be comprised of independent directors. Swiss law does not have such requirements.
- Exemption from quorum requirements applicable to meetings of shareholders. Swiss law does not have such quorum requirements.
- Exemption from the requirement that independent directors meet at regularly scheduled executive sessions. Swiss law does not have such a requirement.
- Exemption from the requirement to disclose within four business days of any determination to grant a waiver of the Code of Ethics to directors and executive officers. Although we will require approval by our board of directors for any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq listing standards.
- Exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans. Our articles of association provide that our board of directors is authorized, in certain instances, to issue a certain number of ordinary shares without re-approval by our shareholders.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that it nevertheless complies with Nasdaq's Notification of Noncompliance requirement (Rule 5625) and the Voting Rights requirement (Rule 5640) and that it has an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). We intend to use these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 17. Financial Statements

See “Item 18—Financial Statements.”

Item 18. Financial Statements

The financial statements are filed as part of this Annual Report, beginning on page F-1.

Item 19. Exhibits

The following documents are filed as part of Annual Report on Form 20-F:

		Incorporation by Reference			
Exhibit No.	Description	Form	File No.	Exhibit No.	Filing Date
1.1	Articles of Association of SOPHiA GENETICS SA	6-K	001-40627	99.1	August 25, 2021
2.1	Description of Securities				
4.1#	Exclusive License Agreement of Patents and Results between SOPHiA GENETICS SA and ComUE Normandy University, INSERM Transfert SA, The Henri Becquerel Centre and The University of Rouen Normandy, dated March 19, 2018	F-1	333-257646	10.1	July 2, 2021
4.2#	Exclusive License Agreement of Patents and Results between SOPHiA GENETICS SA and ComUE Normandy University, INSERM Transfert SA, The Henri Becquerel Centre and The University of Rouen Normandy, dated May 29, 2019	F-1	333-257646	10.2	July 2, 2021
4.3#	Software Sublicense Agreement between SOPHiA GENETICS SA and SATT Aquitaine, Aquitaine Science Transfert, SAS, dated November 30, 2017	F-1	333-257646	10.3	July 2, 2021
4.4#	Agreement for the Co-Marketing of Products and Services between SOPHiA GENETICS SA and Agilent Technologies, Inc., dated December 18, 2020	F-1	333-257646	10.4	July 2, 2021
4.5#	Amended and Restated Manufacturing and Supply Agreement between SOPHiA GENETICS SA and Integrated DNA Technologies, Inc., dated October 9, 2018	F-1	333-257646	10.5	July 2, 2021
4.6#	Amendment No. 1 to Manufacturing and Supply Agreement between SOPHiA GENETICS SA and Integrated DNA Technologies, Inc., dated May 4, 2019	F-1	333-257646	10.6	July 2, 2021
4.7#	OEM Supply Agreement between SOPHiA GENETICS SA and QIAGEN GmbH, dated as of January 19, 2018	F-1	333-257646	10.7	July 2, 2021
4.8#	Amendment No. 1 to the SOPHiA GENETICS SA Agreement between SOPHiA GENETICS SA and QIAGEN GmbH, dated June 7, 2019	F-1	333-257646	10.8	July 2, 2021
4.9#	Supply Agreement between SOPHiA GENETICS SA and Twist Biosciences Corporation, dated November 12, 2019	F-1	333-257646	10.9	July 2, 2021
4.10#†	Master Alliance Agreement between SOPHiA GENETICS SA and GE Precision Healthcare LLC, dated September 11, 2021				
4.11#†	Supply Agreement between SOPHiA GENETICS SA and New England Biolabs, Inc., dated January 4, 2019				
4.12§	Form of Indemnity Agreement with directors and officers	F-1	333-257646	10.10	July 2, 2021

4.13§	SOPHiA GENETICS SA 2021 Equity Incentive Plan	F-1	333-257646	10.13	July 2, 2021

8.1	List of subsidiaries
12.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1	Consent of PricewaterhouseCoopers SA
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Portions of this exhibit have been omitted because they are both (i) not material and (ii) customarily and actually treated by the registrant as private or confidential.

† Certain schedules to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule will be furnished supplementally to the SEC upon request; provided, however, that the parties may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any document so furnished.

§ Indicates a management contract or compensatory plan.

Signatures

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

SOPHiA GENETICS SA
By: /s/ Jurgi Camblong
Name: Jurgi Camblong
Title: Chief Executive Officer
Date: March 15, 2022

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of SOPHiA GENETICS SA

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of SOPHiA GENETICS SA and its subsidiaries (the “Company”) as of December 31, 2021 and 2020 and the related consolidated statements of loss, comprehensive loss, changes in equity, and cash flow for each of the three years in the period ended December 31, 2021, including 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 as of December 31, 2021 and 2020 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated 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 of these consolidated financial statements 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 consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers SA

Lausanne, Switzerland
March 15, 2022

We have served as the Company’s auditor since 2020.

SOPHiA GENETICS SA, Saint-Sulpice
Consolidated Statements of Loss
(Amounts in USD thousands, except per share data)

	Notes	Year ended December 31, 2021	2020	2019
Revenue	**4**	$ 40,450	$ 28,400	$ 25,362
Cost of revenue	**5**	(15,229)	(10,709)	(7,532)
Gross profit		**25,221**	**17,691**	**17,830**
Research and development costs	**6**	(26,578)	(18,588)	(15,018)
Selling and marketing costs	**6**	(28,735)	(17,432)	(19,414)
General and administrative costs	**6**	(41,505)	(18,965)	(15,669)
Other operating income (expense), net	**7**	108	(93)	(16)
Operating loss		**(71,489)**	**(37,387)**	**(32,287)**
Finance expense, net	**8**	(2,018)	(3,838)	(1,342)
Loss before income taxes		**(73,507)**	**(41,225)**	**(33,629)**
Income tax (expense) benefit	**9**	(168)	1,886	(162)
Loss for the year		**(73,675)**	**(39,339)**	**(33,791)**
Attributable to the owners of the parent		**$ (73,675)**	**$ (39,339)**	**$ (33,791)**
Loss per share				
Basic and diluted loss per share	**10**	**$ (1.33)**	**$ (0.93)**	**$ (0.90)**

The Notes form an integral part of these consolidated financial statements

SOPHiA GENETICS SA, Saint-Sulpice
Consolidated Statements of Comprehensive Loss
(Amounts in USD thousands)

	Notes	Year ended December 31, 2021	2020	2019
Loss for the year		**$ (73,675)**	**$ (39,339)**	**$ (33,791)**
Other comprehensive (loss) income:				
Items that may be reclassified to statement of loss (net of tax)				
Currency translation differences		(4,736)	7,338	272
Total items that may be reclassified to statement of loss		**$ (4,736)**	**$ 7,338**	**$ 272**
Items that will not be reclassified to statement of loss (net of tax)				
Remeasurement of defined benefit plans	**22**	461	184	(1,523)
Total items that will not be reclassified to statement of loss		**$ 461**	**$ 184**	**$ (1,523)**
Other comprehensive (loss) income for the year		**$ (4,275)**	**$ 7,522**	**$ (1,251)**
Total comprehensive loss for the year		**$ (77,950)**	**$ (31,817)**	**$ (35,042)**
Attributable to owners of the parent		**$ (77,950)**	**$ (31,817)**	**$ (35,042)**

The Notes form an integral part of these consolidated financial statements

SOPHiA GENETICS SA, Saint-Sulpice
Consolidated Balance Sheets
(Amounts in USD thousands)

	Notes	December 31, 2021	December 31, 2020
Assets			
Current assets			
Cash and cash equivalents	**11**	$ 192,962	$ 74,625
Term deposits	**12**	72,357	22,720
Accounts receivable	**13**	6,278	6,363
Inventory	**14**	5,729	3,384
Prepaids and other current assets	**15**	5,529	2,602
Total current assets		**282,855**	**109,694**
Non-current assets			
Property and equipment	**16**	4,663	1,772
Intangible assets	**17**	15,673	13,282
Right-of-use assets	**18**	11,292	3,767
Deferred tax assets	**9**	1,990	2,114
Other non-current assets		3,700	1,486
Total non-current assets		**37,318**	**22,421**
Total assets		**$ 320,173**	**$ 132,115**
Liabilities and equity			
Current liabilities			
Accounts payable	**19**	$ 6,737	$ 5,907
Accrued expenses	**20**	15,972	9,081
Deferred contract revenue	**4**	4,069	2,642
Current portion of borrowings	**24**	—	2,873
Current portion of lease liabilities	**18**	1,813	1,036
Other current liabilities		12	48
Total current liabilities		**28,603**	**21,587**
Non-current liabilities			
Deferred contract revenue, net of current portion	**4**	—	142
Borrowings, net of current portion	**24**	—	457
Lease liabilities, net of current portion	**18**	11,246	2,883
Defined benefit pension liabilities	**22**	4,453	5,158
Other non-current liabilities	**21**	471	1,378
Total non-current liabilities		**16,170**	**10,018**
Total liabilities		**44,773**	**31,605**
Equity			
Share capital		3,328	2,460
Share premium		470,887	227,429
Other reserves		12,539	8,300
Accumulated deficit		(211,354)	(137,679)
Total equity		**275,400**	**100,510**
Total liabilities and equity		**$ 320,173**	**$ 132,115**

The Notes form an integral part of these consolidated financial statements

SOPHiA GENETICS SA, Saint-Sulpice
Consolidated Statement of Changes in Equity
(Amounts in USD thousands, except share data)

	Notes	Shares	Share capital	Share premium	Other reserves	Accumulated deficit	Total
January 1, 2019		**37,625,260**	**$ 1,912**	**$ 117,502**	**$ (47)**	**$ (64,549)**	**$ 54,818**
Loss for the period			—	—	—	(33,791)	(33,791)
Other comprehensive loss			—	—	(1,251)	—	(1,251)
Total comprehensive loss			—	—	(1,251)	(33,791)	(35,042)
Share-based compensation	**23**		—	—	717	—	717
Transactions with owners							
Share options exercised		694,500	35	1,725	—	—	1,760
December 31, 2019		**38,319,760**	**1,947**	**119,227**	**(581)**	**(98,340)**	**22,253**
Loss for the period			—	—	—	(39,339)	(39,339)
Other comprehensive loss			—	—	7,522	—	7,522
Total comprehensive loss			—	—	7,522	(39,339)	(31,817)
Share-based compensation	**23**		—	—	1,359	—	1,359
Transactions with owners							
Share options exercised		319,000	17	1,055	—	—	1,072
Issue of share capital, net of transaction costs	**27**	9,316,940	496	107,147	—	—	107,643
December 31, 2020		**47,955,700**	**2,460**	**227,429**	**8,300**	**(137,679)**	**100,510**
Loss for the period			—	—	—	(73,675)	(73,675)
Other comprehensive loss			—	—	(4,275)	—	(4,275)
Total comprehensive loss			—	—	(4,275)	(73,675)	(77,950)
Share-based compensation	**23**		—	—	8,514	—	8,514
Transactions with owners							
Share options exercised		1,271,300	69	4,458	—	—	4,527
Sale of ordinary shares in initial public offering, net of transaction costs	**26**	13,000,000	710	210,953	—	—	211,663
Sale of ordinary shares in private placement, net of transaction costs	**26**	1,111,111	61	19,587	—	—	19,648
Sale of ordinary shares in greenshoe offering, net of transaction costs	**26**	519,493	28	8,460	—	—	8,488
December 31, 2021		**63,857,604**	**$ 3,328**	**$ 470,887**	**$ 12,539**	**$ (211,354)**	**$ 275,400**

The Notes form an integral part of these consolidated financial statements

SOPHiA GENETICS SA, Saint-Sulpice
Consolidated Statement of Cash Flows
(Amounts in USD thousands)

	Notes	Year ended December 31, 2021	2020	2019
Operating activities				
Loss before tax		$ (73,507)	$ (41,225)	$ (33,629)
Adjustments for non-monetary items				
Depreciation	**16,18**	2,517	1,758	1,546
Amortization	**17**	1,092	632	367
Interest expense	**8**	658	1,224	1,073
Interest income	**8**	(20)	(96)	(86)
Gain on TriplePoint success fee	**25**	(430)	—	—
Expected credit loss allowance	**13**	(988)	763	872
Share-based compensation	**23**	8,514	1,359	717
Intangible assets write-off	**17**	30	226	—
Movements in provisions, pensions, and government grants		(23)	1,203	580
Research tax credit		(1,597)	(763)	(447)
Loss on disposal of property and equipment	**16**	22	—	—
Working capital changes				
(Increase) decrease in accounts receivable		1,806	1,118	(4,352)
(Increase) decrease in prepaids and other assets		(2,330)	2,347	(2,009)
(Increase) decrease in inventory		(2,336)	536	(862)
Increase (decrease) in accounts payables, accrued expenses, deferred contract revenue, and other liabilities		8,980	(185)	5,603
Cash used in operating activities				
Income tax received (paid)		(55)	153	(252)
Interest paid		(286)	(855)	(837)
Interest received		14	75	36
Net cash flows used in operating activities		**(57,939)**	**(31,730)**	**(31,680)**
Investing activities				
Purchase of property and equipment	**16**	(2,683)	(450)	(1,355)
Acquisition of intangible assets	**17**	(130)	(318)	(1,678)
Capitalized development costs	**17**	(3,858)	(2,436)	—
Proceeds upon maturity of term deposits and short-term investments	**12**	21,878	—	—
Purchase of term deposits and short-term investments	**12**	(72,141)	(21,119)	—
Net cash flow used in investing activities		**(56,934)**	**(24,323)**	**(3,033)**
Financing activities				
Proceeds from exercise of share options	**23**	4,527	1,072	1,760
Proceeds from issuance of share capital, net of transaction costs	**27**	—	107,643	—
Proceeds from initial public offering, net of transaction costs	**26**	211,663	—	—
Proceeds from greenshoe, net of transaction costs	**26**	8,488	—	—
Proceeds from private placement, net of transaction costs	**26**	19,648	—	—
Payment of TriplePoint success fee	**25**	(2,468)	—	—
Proceeds from borrowings	**24**	—	15,839	—
Repayments of borrowings	**24**	(3,167)	(16,529)	(1,967)
Payments of principal portion of lease liabilities	**18**	(918)	(980)	(816)
Net cash flow provided from (used in) financing activities		**237,773**	**107,045**	**(1,023)**
Increase (decrease) in cash and cash equivalents		**122,900**	**50,992**	**(35,736)**
Effect of exchange differences on cash balances		(4,563)	5,564	(102)
Cash and cash equivalents at beginning of the year		74,625	18,069	53,907
Cash and cash equivalents at end of the year		**$ 192,962**	**$ 74,625**	**$ 18,069**

The Notes form an integral part of these consolidated financial statements

1. Company information and operations

General information

SOPHiA GENETICS SA and its consolidated subsidiaries (NASDAQ: SOPH) ("the Company") is a limited liability healthcare technology company, incorporated on March 18, 2011, and headquartered in Saint-Sulpice, Switzerland. The Company is dedicated to establishing the practice of data-driven medicine as the standard of care in health care and for life sciences research. The Company has built a cloud-based software-as-a-service ("SaaS") platform capable of analyzing data and generating insights from complex multimodal datasets and different diagnostic modalities. This platform, commercialized as "SOPHiA DDM," standardizes, computes and analyzes digital health data and is used in decentralized locations to break down data silos.

As of December 31, 2021, the Company had the following wholly-owned subsidiaries:

Name	Country of domicile
SOPHiA GENETICS S.A.S.	France
SOPHiA GENETICS LTD	UK
SOPHiA GENETICS, Inc.	USA
SOPHiA GENETICS Intermediação de Negócios EIRELI	Brazil
SOPHiA GENETICS PTY LTD	Australia
SOPHiA GENETICS S.R.L.	Italy

Interactive Biosoftware S.A.S., a wholly owned subsidiary located in France and acquired in 2018, was merged into SOPHiA GENETICS S.A.S. in 2020.

On April 9, 2021, SOPHiA GENETICS PTY LTD, a wholly owned subsidiary located in Australia, was incorporated.

On May 27, 2021, SOPHiA GENETICS S.R.L., a wholly owned subsidiary located in Italy, was incorporated.

The Company's Board of Directors approved the issue of the consolidated financial statements on March 15, 2022.

Share split

On June 30, 2021, the Company effected a one-to-twenty share split of its outstanding shares. Accordingly, all share and per share amounts for all periods presented in these consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this share split.

Initial public offering

In July 2021, the Company completed its initial public offering ("IPO") in the United States on the Nasdaq Global Market ("Nasdaq") under the trading ticker symbol "SOPH". Trading on the Nasdaq commenced at market open on July 23, 2021. The Company completed the IPO of 13,000,000 ordinary shares, at an IPO price of $18.00 per share, par value $0.05 (CHF 0.05). The aggregate net proceeds received from the IPO, net of underwriting discounts and commissions and offering expenses, was $211.7 million. Immediately prior to the completion of the IPO, all then outstanding shares of preferred shares were converted into 24,561,200 shares of ordinary shares on a one-to-one basis.

Concurrent with the IPO, the Company closed a private placement, in which it sold 1,111,111 ordinary shares to an affiliate of GE Healthcare at a price of $18.00 per share, par value $0.05 (CHF 0.05). The aggregate net proceeds received from the private placement, net of offering expenses, was $19.6 million.

On August 25, 2021, the underwriters of the IPO elected to exercise in part their option to purchase an additional 519,493 ordinary shares ("greenshoe") at the IPO price of $18.00 per share, par value $0.05 (CHF 0.05). The aggregate net proceeds received from the greenshoe, net of underwriting discounts and commissions and offering expenses, was $8.5 million.

2. Significant accounting policies

Basis of preparation

Compliance with International Financial Reporting Standards

The consolidated financial statements of the Company have been prepared in accordance with International Financial Reporting Standards ("IFRS") and interpretations issued by the IFRS Interpretations Committee ("IFRS IC") applicable to companies reporting under IFRS. The consolidated financial statements comply with IFRS as issued by the International Accounting Standards Board ("IASB").

Basis of consolidation

A subsidiary is an entity over which the Company has control. The Company controls an entity when it has the power to direct its activities and has rights to its variable returns. Subsidiaries are fully consolidated from the date on which control is transferred to the Company and deconsolidated from the date that control ceases.

During the consolidation process intercompany transactions, balances, and unrealized gains on transactions between companies are eliminated. Unrealized losses are also eliminated unless there is evidence of an impairment of the transferred asset. In order to ensure consistency with the accounting policies of the Company, the accounting policies of subsidiaries have been changed where necessary.

Foreign currency translation

Items included in the consolidated financial statements of each of the Company's entities are measured using the currency of the primary economic environment in which the entity operates ("functional currency"). In individual entities, transactions in foreign currencies are translated as of transaction date. Monetary assets and liabilities in foreign currencies are translated at month end rates. The Company's reporting currency of the Company's consolidated financial statements is the U.S. dollar ("USD"). Assets and liabilities denominated in foreign currencies are translated at the month-end spot exchange rates, income statement accounts are translated at average rates of exchange for the period presented, and equity is translated at historical exchange rates.

On consolidation, assets and liabilities of foreign operations reported in their local functional currencies are translated into USD. Differences arising from the retranslation of opening net assets of foreign operations, together with differences arising from the translation of the net results for the year of foreign operations, are recognized in other comprehensive income under currency retranslations. Gains or losses resulting from foreign currency transactions are included in net income.

The Company selected the U.S. dollar as its presentation currency for purposes of its consolidated financial statements instead of the Company's functional currency, the Swiss franc, because of the global nature of its business, its expectation that an increasing portion of revenues and expenses will be denominated in USD, and its plans to access U.S. capital markets.

Use of estimates

The preparation of consolidated financial statements in conformity with IFRS requires the use of accounting estimates. It also requires management to exercise judgement in applying the Company's accounting policies. The Company's significant estimates and judgements included in the preparation of the consolidated financial statements are related to revenue recognition, capitalized internal software development costs, share-based compensation, expected credit loss, goodwill, defined benefit pension liabilities, uncertain tax positions, and derivatives.

Disclosed in the corresponding sections within the footnotes are the areas which require a high degree of judgment, significant assumptions, and/or estimates.

Going concern basis

The consolidated financial statements have been prepared on a going concern basis (See Note 31 – "Capital management").

Historical cost convention

The consolidated financial statements have been prepared on a historical cost basis except for certain assets and liabilities, which are carried at fair value.

Accounting policies

The significant accounting policies adopted in the preparation of the consolidated financial statements have been consistently applied, unless otherwise stated.

Provisions and contingencies

Provisions comprise liabilities of uncertain timing or amount. The provisions and liabilities are recognized when the Company has a present legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation, and the amount can be reliably estimated. Provisions are not recognized for future operating losses. Provisions are measured at the present value of management's best estimate of the expenditure required to settle the present obligation at the end of the reporting period, unless the impact of discounting is immaterial. The discount rate used to determine the present value is a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The increase in the provision due to the passage of time is recognized as interest expense.

Contingent liabilities are possible obligations that arise from past events and whose existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not fully within the control of the Company.

The likelihood of occurrence of provisions and contingent liabilities requires use of judgement. Judgement is also required to determine if an outflow of economic resources is probable, or possible but not probable. Where it is probable, a liability is recognized, and further judgement is used to determine the level of the provision. Where it is possible but not probable, further judgement is used to determine if the likelihood is remote, in which case no disclosures are provided; if the likelihood is not remote then judgement is used to determine the contingent liability disclosed.

Financial assets classification

Upon recognition, financial assets are classified on the basis of how the financial assets are measured: at amortized cost or fair value through income.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Company's business model for managing them. Except for accounts receivable that do not contain a significant financing component, the Company initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through income, transaction costs. Accounts receivable that do not contain a significant financing component are measured at the transaction price.

The Company's business model for managing financial assets is defined by whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets held in order to collect contractual cash flows are measured at amortized cost. Financial assets held both to collect contractual cash flows and for sale are measured at fair value through other comprehensive income/loss.

Purchases or sales of financial assets that require delivery of assets within a time frame established by regulation or convention in the marketplace (regular way trades) are recognized on the trade date, i.e., the date that the Company commits to purchase or sell the asset.

Financial assets measured at amortized cost

Financial assets initially measured at amortized cost are subsequently measured using the effective interest rate ("EIR") method and are subject to impairment. Gains and losses are recognized in income when the asset is derecognized, modified, or impaired. The Company's financial assets at amortized cost include cash, term deposits and accounts receivable.

Financial assets—derecognition

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (i.e., removed from the Company's consolidated balance sheet) when:

- The rights to receive cash flows from the asset have expired or;

- The Company has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either;
- the Company has transferred substantially all the risks and rewards of the asset, or;
- the Company has neither transferred nor retained substantially all the risks and rewards of the asset but has transferred control of the asset.

When the Company has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risks and rewards of ownership.

When the Company has neither transferred nor retained substantially all of the risks and rewards of the asset, nor transferred control of the asset, the Company continues to recognize the transferred asset to the extent of its continuing involvement. In that case, the Company also recognizes an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Company has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Company could be required to repay.

Financial assets—impairment

For cash, cash equivalents, and term deposits, the Company invests in assets where it has never incurred and does not expect to incur credit losses.

For accounts receivable the Company recognizes a loss allowance based on lifetime estimated credit losses ("ECL") at each reporting date. When estimating the ECL the Company takes into consideration: readily available relevant and supportable information (this includes quantitative and qualitative data), the Company's historical experience and forward-looking information specific to the receivables and the economic environment.

See Note 13 – "Accounts receivable" for further information about the Company's accounting for trade receivables.

Financial liabilities classification

Financial liabilities are classified upon initial recognition as financial liabilities measured at fair value through income or at amortized cost. The Company's financial liabilities include accounts payable and debt (including borrowings and lease liabilities), which are measured at amortized cost, and derivatives, which are measured at fair value through income.
Interest-bearing borrowings are initially recognized at fair value less directly attributable costs and subsequently measured at amortized cost using the EIR method. Gains and losses are recognized in income when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of income/loss.

Financial liabilities—derecognition

A financial liability is derecognized when the obligation under the liability is discharged or 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 in the statements of loss.

New standards, amendments to standards and interpretations not yet adopted

New standards, amendments to standards, and interpretations issued not yet effective

In January 2020, IASB issued amendments to paragraphs 69 to 76 of IAS 1, *Presentation of Financial Statements* ("IAS 1"), to specify the requirements for classifying liabilities as current or non-current, effective for annual reporting periods beginning on or after January 1, 2023. The Company is still evaluating the potential impact of the amendment.

There are no other IFRS or IFRS IC interpretations that are not yet effective and that could have a material impact to the consolidated financial statements.

3. Segment reporting

The Company operates in a single operating segment. The Company's financial information is reviewed, and its performance assessed as a single segment by the senior management team led by the Chief Executive Officer ("CEO"), the Company's Chief Operating Decision Maker ("CODM").

An analysis of revenue by customer location is presented below (in USD thousands):

	Year ended December 31,		
	2021	2020	2019
France	$ 7,405	$ 6,060	$ 5,874
Italy	6,124	2,994	3,150
United States	3,944	2,636	1,989
Spain	3,765	2,356	2,105
Turkey	2,682	1,222	1,714
Austria	1,835	1,310	927
Brazil	1,621	1,535	1,186
United Kingdom	1,500	1,147	1,213
Switzerland	1,394	1,708	722
Germany	1,280	1,146	1,140
Other	8,900	6,286	5,342
Total revenue	**$ 40,450**	**$ 28,400**	**$ 25,362**

For the years ended December 31, 2021 and 2020, respectively, the Company had a physical presence in four countries outside of its headquarters in Switzerland: France, the United States, the UK, and Brazil. An analysis of the location of non-current non-financial assets by country is as follows (in USD thousands):

	Year ended December 31,	
	2021	2020
Switzerland	$ 28,974	$ 17,362
France	3,480	2,656
United States	2,924	996
United Kingdom	527	416
Brazil	8	7
Total non-current non-financial assets	**$ 35,913**	**$ 21,437**

4. Revenue

Critical accounting estimates and judgements

The Company recognizes revenue when control of promised goods or services is transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. Significant judgment is required to determine the stand-alone selling price ("SSP") for each performance obligation in the SOPHiA platform, the amount allocated to each performance obligation and whether it depicts the amount that the Company expects to receive in exchange for the related product and/or service.

The Company enters into arrangements with multiple performance obligations where it could be difficult to determine the performance obligations under a sales agreement; in such cases, how and when revenue should be recognized is subject to certain estimates or assumptions. Should these judgments and estimates not be correct, revenue recognized for any reporting period could be adversely affected.

Accounting policies

Revenue represents amounts received and receivable from third parties for goods supplied and services rendered to customers. Revenues are reported net of rebates and discounts and net of sales and value added taxes in an amount that

reflects the consideration that is expected to be received for goods or services. The majority of the sales revenue is recognized: (i) when customers generate analyses on their patient data through the SOPHiA platform, (ii) when consumables, namely DNA enrichment kits, are delivered to customers at which point control transfers, (iii) when services, namely set-up programs, are performed and (iv) over the duration of the software licensing arrangements for the Alamut software offerings.

Products and services are sold both directly to customers and through distributors, generally under agreements with payment terms of up to 180 days. Therefore, contracts do not contain a significant financing component.

For all contracts with customers the following steps are performed to determine the amount of revenue to be recognized and when it should be recognized: (1) identify the contract or contracts; (2) determine whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (3) measure the transaction price, including the constraint on variable consideration; (4) allocate the transaction price to the performance obligations based on estimated selling prices; and (5) recognize revenue when (or as) each performance obligation is satisfied.

SOPHiA Platform

The majority of the SOPHiA platform revenue is derived from each use of the SOPHiA platform by customers to generate analysis on their patient data. Analysis revenue is recognized as analysis results are made available to the customer on the SOPHiA platform. Contract assets are recognized on the balance sheet as accrued contract revenue for any analyses performed by customers that have not been invoiced at the reporting period date. Any payments received in advance of customers generating analyses are recorded as deferred contract revenue until the analyses are performed.
Customers use the SOPHiA platform to perform analyses under three different models: dry lab access; bundle access; and integrated solutions.

For dry lab contracts, customers use the testing instruments and consumables of their choice and the SOPHiA platform and algorithms for variant detection and identification. In these arrangements, the Company has identified one performance obligation, which is the delivery of the analysis result to the customer.

For bundle arrangements, customers purchase a DNA enrichment kit along with each analysis. Customers use the DNA enrichment kit in the process of performing their own sequencing of each sample. Customers then upload their patient data to the SOPHiA platform for analysis. In these arrangements, the Company has identified two performance obligations: the delivery of the DNA enrichment kits and the performance of the analyses. Revenue is recognized for the DNA enrichment kits when control of products has transferred to the customer, which is generally at the time of delivery, as this is when title and risk of loss have been transferred. Revenue for the performance of the analyses is recognized on delivery of the analysis results to the customer. Refer to *Arrangements with multiple performance obligations* below for how revenue is allocated between the performance obligations.

Deferred contract revenue balances relating to analyses not performed within 12 months from the date of the delivery date are recognized as revenue. This policy is not based on contractual conditions but on the Company’s experience of customer behavior and expiration of the kits associated with the analyses.

For integrated arrangements, customers have their samples processed and sequenced through selected SOPHiA platform partners within the clinical network and access their data through the SOPHiA platform. The Company has identified one performance obligation, which is delivery of the analysis results to the customer through the SOPHiA platform.

The Company also sells access to Alamut software products (“Alamut”) through the SOPHiA platform. Some arrangements with customers allow customers to use Alamut as a hosted software service over the contract period without the customer taking possession of the software. Other customers take possession of the software, but the utility of that software is limited by access to the Company’s proprietary SOPHiA database, which is provided to the customer on a fixed term basis. Under both models, revenue is recognized on a straight-line basis over the duration of the agreement.

The Company also derives revenue from the SOPHiA platform by providing services to biopharma customers who engage the Company to (i) develop and perform customized genomic analyses and/or (ii) access the database for use in clinical trials and other research projects.

The Company does enter into biopharma contracts that contain multiple products or services or non-standard terms and conditions. The biopharma contracts are generally unique in nature and each contract is assessed upon execution.

Generally, the primary performance obligation in these arrangements is the delivery of analysis results in the form of a final report, resulting in revenue being recognized, in most cases, upon the issuance of the final report or successful recruitment of clinical trial participants.

Workflow materials and services

Revenue from workflow materials and services includes all revenue from the sale of materials and services that do not form part of a contract for the provision of platform services. These include the provision of set-up programs and training and the sale of kits and tests that are not linked to use of the platform. Set-up programs and training are typically combined with a customer's first order prior to the customer beginning to use the SOPHiA platform.

Revenue from services is generally recognized when the services are performed. Revenue from materials is recognized when control of the goods is transferred to the customer, generally at the time of delivery. This category of revenue also includes the revenue from the sale of DNA sequencing automation equipment accounted for under IFRS 16, *Leases* ("IFRS 16"), leasing and the fees charged for the maintenance of this equipment.

Arrangements with multiple performance obligations

The Company sells different combinations of analyses, consumables, and services to its customers under its various SOPHiA platform models.

The Company has determined that the stand-alone selling prices for services and DNA enrichment kits are directly observable. For set-up programs and training sold along with dry lab arrangements or bundle arrangements, the stand-alone selling price of these services is determined on a time and materials basis. For DNA enrichment kits sold as part of a bundle, the SSP is based on an expected cost-plus-margin approach of the kit portion of the bundle.

The Company has determined that the SSP for the analyses, in both a dry lab arrangement and bundle arrangement, is highly variable and therefore a representative SSP is not discernible from past transactions. As a result, the residual approach is used to determine the stand-alone selling price of the analyses in dry lab arrangements that include services and in bundle arrangements that include DNA enrichment kits and, in some cases, services.

The Company also has a small number of bundle contracts with a fixed term that also include providing the customer with DNA sequencing automation equipment, which the Company has determined is an IFRS 16 leasing component. In these arrangements the Company provides DNA sequencing automation equipment to the customer over the fixed term and at completion of the contract term the customer takes possession of the equipment. The Company has determined that it is a dealer lessor and provision of this equipment to the customer is classified as a finance lease. As a result, upon delivery of the leased equipment at the inception of the arrangement, a selling profit is recognized based on the fair value of the underlying equipment less the cost of the equipment. Over the term of the agreement, the minimum lease payment is deducted from the proceeds of the bundle sales in order to reduce the net investment in the corresponding lease receivable over the contract term and interest income is recognized as the discount on the lease receivable unwinds. The remaining proceeds from the contract are accounted for under IFRS 15, *Revenue from Contracts with Customers* ("IFRS 15"), using the policies described above.

Contract assets and liabilities

Accrued contract revenue

Accrued contract revenue is related to unbilled SOPHiA platform analyses and are recorded in accounts receivable. As of December 31, 2021 and December 31, 2020, accrued contract revenue was $0.7 million and $0.3 million, respectively. The Company recorded no loss allowance related to the accrued contract revenue as of December 31, 2021 and December 31, 2020, respectively

Deferred contract costs

Deferred contract costs comprise deferred fulfillment costs related to biopharma, prepayments on contracts, and prepaid maintenance costs relating to DNA sequencing automation equipment.

Costs are incurred to fulfill obligations under certain contracts once obtained, but before transferring goods or services to the customer. Fulfillment costs are recognized as an asset, provided these costs are not addressed by other accounting standards, if the following criteria are met: (i) the costs relate directly to a contract or an anticipated contract that the Company can specifically identify, (ii) the costs generate or enhance resources of the Company that will be used in satisfying (or continuing to satisfy) performance obligations in the future and (iii) the costs are expected to be recovered.
The asset recognized from deferring the costs to fulfill a contract is recorded in the consolidated balance sheet as deferred contract costs within other current assets and amortized on a systematic basis consistent with the pattern of the transfer of the goods or services to which the asset relates, which depends on the nature of the performance obligation(s) in the contract. The amortization of these assets is recorded in cost of revenue.

The timing of revenue recognition and billings can result in accrued contract revenue and deferred contract costs, which are presented within other current assets in the consolidated balance sheet and deferred contract revenue which is presented on the face of the consolidated balance sheet.

Deferred contract revenue

Deferred contract revenue relates to prepayments received from customers before revenue is recognized and is primarily related to SOPHiA platform analyses invoiced in advance of the customers performing the analyses, deferred Alamut software revenue and progress payments received as part of biopharma contracts. For reporting purposes, deferred revenue billed, but not collected at period end, is deducted from deferred revenue and accounts receivable, so that both balances are reported net of unpaid deferred revenue.

Deferred contract revenue brought forward as of January 1, 2021 and January 1, 2020 amounts to $2.9 million and $2.2 million, respectively. During the twelve months ended December 31, 2021 and 2020, the Company satisfied the performance obligations associated with that deferred contract revenue to the extent that revenue was recognized of $3.0 million and $2.0 million, respectively.

The majority of the platform revenue is derived from contracts with an original expected length of one year or less. However, there are certain biopharma and Alamut contracts in which performance obligations extend over multiple years. The Company has elected to apply the practical expedient not to disclose the value of remaining performance obligations associated with these types of contracts.

Revenue streams

The Company's revenue from contracts with customers has been allocated to the revenue streams indicated in the table below (in USD thousands):

	Year ended December 31,		
	2021	**2020**	**2019**
SOPHiA platform	$ 39,465	$ 27,221	$ 23,710
Workflow equipment and services	985	1,179	1,652
Total revenue	**$ 40,450**	**$ 28,400**	**$ 25,362**

Workflow equipment and services includes revenues from payments from leased equipment recognized under IFRS 16, Leases, of $0.2 million, $0.1 million, and $0.2 million for the years ended December 31, 2021, December 31, 2020, and December 31, 2019, respectively.

5. Cost of revenue

Accounting policies

Cost of revenue comprises costs directly incurred in earning revenue, including computer costs and data storage fees paid to hosting providers, manufacturing costs, materials and consumables, the cost of equipment leased out under finance leases, personnel-related expenses and amortization of capitalized development costs.

6. Operating expense

Accounting policies

Research and development

Research and development costs consist of personnel and related expenses for technology and product development, depreciation and amortization, laboratory supplies, consulting services, computer costs and data storage fees paid to hosting providers related to research and development and allocated overhead costs. These costs are stated net of government grants for research and development and innovation received as tax credits and net of capitalized costs.

Government grants for research and development and innovation received as tax credits

The Company receives government grants in France for research and development and innovation by way of tax credits. Total government grants for research and development and innovation recognized in the statement of loss amounts to $0.4 million, $0.8 million, $0.4 million for the years ended December 31, 2021, December 31, 2020, and December 31, 2019, respectively. There are no unfulfilled conditions or other contingencies attached to these grants. Refer to the Note 24 – “Borrowings” for additional discussion on COVID loans.

Selling and marketing costs

Selling and marketing costs consist of personnel and related expenses for the employees of the sales and marketing organization, costs of communications materials that are produced to generate greater awareness and utilization of the platform among customers, costs of third-party market research, costs related to transportation and distribution of our products, and allocated overhead costs. These costs are stated net of government grants under the US Paycheck Protection Program (“PPP”) for payroll and/or rental obligations received as a loan that is forgiven if utilized as intended.

The Company pays sales commission to its employees for obtaining contracts. These costs are expensed as part of employee compensation in selling and marketing costs. They are not capitalized as contract costs as the commissions either represent bonuses payable for revenue earned in the period or have a service condition attached.

General and administrative costs

General and administrative costs consist of personnel and related expenses for our executive, accounting and finance, legal, quality, support and human resources functions, depreciation and amortization, professional services fees incurred by these functions, general corporate costs and allocated overhead costs, which include occupancy costs and information technology costs.

Operating expense by nature

The table presents operating expenses by nature (in USD thousands):

	For the year ended December 31,		
	2021	**2020**	**2019**
Changes in inventories of finished goods and work in progress	$ 568	$ (259)	$ 729
Raw materials and consumables used	(9,650)	(3,843)	(3,180)
Employee benefit expenses	(53,802)	(36,732)	(27,237)
Social charges	(8,373)	(6,983)	(4,218)
COVID—salaries reimbursement	—	1,129	—
Research tax credit	1,597	763	447
Share-based compensation	(8,514)	(1,359)	(717)
Depreciation	(2,517)	(1,758)	(1,546)
Amortization	(1,092)	(632)	(367)
Professional fees	(11,318)	(5,371)	(5,357)
Office expenses	(5,333)	(2,006)	(2,774)
Travel	(1,576)	(1,361)	(4,416)
Marketing	—	(972)	(1,761)
Licenses	(2,021)	(1,647)	(996)
Less: capitalized software development costs ("Note 17 - Intangible assets")	3,858	2,436	—
Other expense	(13,874)	(7,099)	(6,240)
Total	**$ (112,047)**	**$ (65,694)**	**$ (57,633)**

Depreciation and amortization have been charged in the following expense categories (in USD thousands):

	For the year ended December 31,					
	2021		**2020**		**2019**	
	Depreciation	**Amortization**	**Depreciation**	**Amortization**	**Depreciation**	**Amortization**
Cost of revenue	$ —	$ (483)	$ —	$ (111)	$ —	$ —
Research and development costs	(1,028)	—	(727)	—	(624)	—
Selling and marketing costs	(744)	—	(543)	—	(550)	—
General and administrative costs	(745)	(609)	(488)	(521)	(372)	(367)
Total	**$ (2,517)**	**$ (1,092)**	**$ (1,758)**	**$ (632)**	**$ (1,546)**	**$ (367)**

The table presents employee costs by function, which consists of “Employee benefit expenses”, “Social charges” and “Share-based compensation” from the operating expense table (in USD thousands):

	For the year ended December 31,		
	2021	**2020**	**2019**
Research and development costs	$ 23,899	$ 16,109	$ 10,622
Selling and marketing costs	21,659	12,085	10,579
General and administrative costs	25,131	16,880	10,244
Total	**$ 70,689**	**$ 45,074**	**$ 31,445**

7. Other operating income (expense), net

Accounting policies

The Company records income and expenses that are not regularly occurring or normal business income and expense to other operating income (expense). Other operating income (expense) consists of government grants, gains on disposal of tangible assets, intangible write-offs, and other operating income (expense).

COVID-19 loans are granted at below-market rates of interest and represent a form of government grant. The COVID-19 loans are initially measured at fair value, calculated on the basis of the contractual future cashflows discounted at the market interest rate. The surplus of the loan proceeds over the fair value of the loan is recognized initially on the balance sheet in deferred government grant income within other liabilities and released to income within other operating income over the life of the loan. The loan is subsequently accounted for at amortized cost using the effective interest rate method.

Certain government grants for payroll and/or rental obligations are received as loans that are forgiven if the proceeds are utilized as intended within the specified timeframe. As soon as it is clear that the conditions for forgiveness will be fulfilled, these loans are recognized in the statement of income/loss as a reduction in the operating expense costs that they are intended to fund. Refer to Note 24 – “Borrowings” for discussion on the conditions for loan forgiveness.

8. Finance expense, net

	December 31,		
	2021	**2020**	**2019**
Interest income	$ 20	$ 96	$ 86
Total interest income	**$ 20**	**$ 96**	**$ 86**
Interest on loans	(120)	(513)	(715)
Interest on lease liabilities	(225)	(121)	(129)
Other interest	(313)	(206)	(132)
Total interest expense	**$ (658)**	**$ (840)**	**$ (976)**
Derivative fair value (losses)	(1,444)	(384)	(98)
Foreign exchange gains (losses), net	64	(2,710)	(354)
Total finance income (expense), net	**$ (2,018)**	**$ (3,838)**	**$ (1,342)**

Accounting policies

Interest income consists of interest income earned on cash and cash equivalents, short-term investments, and lease receivables.

Interest expense on lease liabilities and loans, which includes, interest on commercial borrowings, and also interest on COVID-19 loans using the effective interest rate method. The relevant accounting policy is disclosed in Note 7 - “Other operating income (expense).”

The foreign exchange gains and losses arise principally on USD cash balances and intercompany receivable balances in the parent company, whose functional currency is the Swiss Franc.

The derivative fair value losses arise on the revaluation of a success fee associated with a loan and explained in Note 21 – “Non-current liabilities.”

The Company had an obligation to pay a success fee linked to a loan that is now repaid. The obligation had many features of a cash-settled share option. It was revalued at fair value at each reporting date using an option pricing model based on a Monte Carlo simulation. This model demands inputs that require the exercise of considerable judgement. Refer to Note 25 - “TriplePoint success fee” for additional discussion on the derivative accounting.

9. Income tax

Critical accounting estimates and judgements

Uncertain tax positions

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates and therefore subject to tax examination by various taxing authorities. In the normal course of business, the Company is subject to examination by local tax authorities in Switzerland, France, Brazil, the UK and the US. The Company is currently under examination in France for its 2018 and 2019 tax returns and is not aware of any additional issues under review that could result in significant payments, accruals or material deviation from its tax positions. There are no other tax examinations in progress.

The Company records tax liabilities or benefits for all years subject to examination based upon management's evaluation of the facts, circumstances and information available at the reporting date. There is inherent uncertainty in quantifying income tax positions, especially considering the complex tax laws and regulations in each of the jurisdictions in which the Company operates.

Accounting policies

The Company is subject to taxes in different countries. Taxes and related fiscal assets and liabilities recognized in the Company's consolidated financial statements reflect management's best estimate of the outcome based on the facts known at the balance sheet date in each individual country. These facts may include but are not limited to change in tax laws and interpretation thereof in the various jurisdictions where the Company operates. They may have an impact on the income tax as well as the resulting income tax assets and liabilities. Any differences between tax estimates and final tax assessments are charged to the statement of income/loss in the period in which they are incurred. Taxes include current and deferred taxes on income as well as actual or potential withholding taxes on current and expected transfers of income from subsidiaries and tax adjustments relating to prior years. Income tax is recognized in the statement of income/loss, except to the extent that it relates to an item directly taken to other comprehensive income/loss or equity, in which case it is recognized against other comprehensive income/loss or equity, respectively.

Current income tax liabilities refer to the portion of the tax on the current year taxable profit (as determined according to the rules of the taxation authorities) and includes uncertain tax liabilities. The Company determines the taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates consistently with the tax treatment used or planned to be used in its income tax filings if the Company concludes it is probable that the taxation authority will accept an uncertain tax treatment.

Otherwise, the Company reflects the effect of uncertainty using either the most likely outcome or the expected value outcome, depending on which method the entity expects to better predict the resolution of the uncertainty.

Deferred taxes are based on the temporary differences that arise when taxation authorities recognize and measure assets and liabilities with rules that differ from the accounting policies of the Company's consolidated financial statements. They also arise on temporary differences stemming from tax losses carried forward. Deferred taxes are measured at the rates of tax expected to prevail when the temporary differences reverse, subject to such rates being substantively enacted at the balance sheet date. Any changes of the tax rates are recognized in the statement of income/loss unless related to items directly recognized against other comprehensive income. Deferred tax liabilities are recognized on all taxable temporary differences excluding non-deductible goodwill. Deferred tax assets are recognized for unused tax losses, unused tax credits and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which they can be used. Future taxable profits are determined based on the reversal of relevant taxable temporary differences. If the amount of taxable temporary differences is insufficient to recognize a deferred tax asset in full, then future taxable profits, adjusted for reversals of existing temporary differences, are considered, on the basis of the business plans for individual subsidiaries in the Company. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized; such reductions are reversed when the probability of future taxable profits improves.

The tax impact of a transaction or item can be uncertain until a conclusion is reached with the relevant tax authority or through a legal process. The Company uses in-house tax experts when assessing uncertain tax positions and seeks the advice of external professional advisors where appropriate.

As of December 31, 2021, and 2020, the Company recorded a provision of $0.1 million and $0.2 million for unrecognized tax liabilities including interest and penalties. The Company records interest and penalties related to income tax amounts as a component of income tax expense.

Presentation of tax (expense) benefits

The following table presents the current and deferred tax (expense) benefits (in USD thousands):

	For the year ended December 31,		
	2021	2020	2019
Current income tax expense			
Current year	$ —	$ —	$ (86)
Uncertain tax positions	(110)	(74)	(76)
Total current income tax expense	**$ (110)**	**$ (74)**	**$ (162)**
Deferred income tax (expense) benefit			
Origination and reversal of temporary differences	$ (58)	$ 1,960	$ —
Total deferred income tax (expense) benefit	**$ (58)**	**$ 1,960**	**$ —**
Total income tax (expense) benefit	**$ (168)**	**$ 1,886**	**$ (162)**

The following table presents the reconciliation of the expected tax expense to the tax expense report in the statement of loss (in USD thousands):

	For the year ended December 31,		
	2021	2020	2019
Loss before tax	**$ (73,507)**	**$ (41,225)**	**$ (33,629)**
Tax at Swiss statutory rate	9,907	5,541	4,519
Effect of tax rates in foreign jurisdictions	(218)	(177)	568
Tax effect of:			
Unrecognized deferred tax assets	*(9,077)*	*(3,276)*	*(5,110)*
Income not subject to tax (expense not deductible for tax purposes)	*(805)*	*41*	*(1)*
Uncertain tax positions	*(110)*	*(74)*	*(76)*
Other	*135*	*(169)*	*(62)*
Income tax (expense)/benefit	**$ (168)**	**$ 1,886**	**$ (162)**

Movement in the deferred tax balances

During the year ended December 31, 2020, the Company recognized deferred tax assets for its foreign subsidiaries due to the implementation of intercompany transfer pricing arrangements that will assure realization of their respective deferred tax assets in each country. The following table presents the changes in the Company's deferred tax assets and deferred tax liabilities (in USD thousands):

	Depreciation & amortization	Bad debt reserves	Accrued pension	ROU asset	Lease liability	Other	Net operating loss carryforward	Total
January 1, 2021	**$ 288**	**$ 433**	**$ 35**	**$ (311)**	**$ 301**	**$ (10)**	**$ 1,378**	**$ 2,114**
Recognized in profit or loss	(309)	(65)	12	(34)	331	38	(31)	(58)
Currency translation differences	(8)	(27)	(3)	(7)	(2)	68	(87)	(66)
December 31, 2021	**$ (29)**	**$ 341**	**$ 44**	**$ (352)**	**$ 630**	**$ 96**	**$ 1,260**	**$ 1,990**
Deferred tax assets	*—*	*341*	*44*	*—*	*630*	*361*	1,260	*2,636*
Deferred tax liabilities	*(29)*	*—*	*—*	*(352)*	*—*	*(265)*	*—*	*(646)*

	Depreciation & amortization	Bad debt reserves	Accrued pension	ROU asset	Lease liability	Other	Net operating loss carryforward	Total
January 1, 2020	**$ —**	**$ —**	**$ —**	**$ —**	**$ —**	**$ —**	**$ —**	**$ —**
Recognized in profit or loss	268	403	33	(289)	280	(17)	1,282	1,960
Recognized in OCI	—	—	7	—	—	—	—	7
Currency translation differences	20	30	(5)	(22)	21	7	96	147
December 31, 2020	**$ 288**	**$ 433**	**$ 35**	**$ (311)**	**$ 301**	**$ (10)**	**$ 1,378**	**$ 2,114**
Deferred tax assets	*288*	*433*	*35*	*—*	*301*	*—*	*1,378*	*2,435*
Deferred tax liabilities	*—*	*—*	*—*	*(311)*	*—*	*(10)*	*—*	*(321)*

Unrecognized deferred tax assets

As of December 31, 2021 and December 31, 2020, the Company recognized deferred tax assets to the extent that it was probable that they would be realized. The following table consists of the deferred tax assets that have not been recognized because it is not probable that there will be future taxable profits to use these benefits (in USD thousands):

	December 31,			
	2021		2020	
	Gross amount	Tax effect	Gross amount	Tax effect
Deductible temporary differences	$ 5,101	$ 729	$ 5,371	$ 722
Net operating loss carryforwards	202,394	28,597	141,896	20,616
Total	**$ 207,495**	**$ 29,326**	**$ 147,267**	**$ 21,338**

Net operating loss carryforwards

As of December 31, 2021 and December 31, 2020, the Company had various net operating loss (“NOL”) carryforwards in Switzerland, France, the UK, the US, and Brazil that are available to reduce future taxable income and income taxes, the majority of which will expire at various dates through 2027. As of December 31, 2021 and December 31, 2020, the Company had the following expiring amounts of unrecognized NOL carryforwards (in USD thousands):

	December 31,	
	2021	2020
One year	$ 7,625	$ 3,262
Two years	12,170	7,265
Three years	16,482	12,170
Four years	15,772	16,482
Thereafter and unlimited	150,345	102,717
Net operating loss carryforwards	**$ 202,394**	**$ 141,896**

Future realization of the tax benefits of existing temporary differences and NOL carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2021, the Company performed an evaluation to determine the likelihood of realization of these tax benefits. In assessing the realization of the deferred tax assets, the Company considered whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is not probable that all of the deferred tax assets will be realized in Switzerland but has recognized deferred tax assets in France, the UK, the US and Brazil.

Unrecognized deferred tax liability on retained earnings of subsidiaries

The Company does not provide for foreign income and withholding taxes, Swiss income taxes or tax benefits on the excess of the financial reporting basis over the tax basis of its investments in foreign subsidiaries to the extent that such amounts are indefinitely reinvested to support operations and continued growth plans outside of Switzerland. The Company reviews its plan to indefinitely reinvest on a periodic basis. In making its decision to indefinitely reinvest, the Company evaluates its plans of reinvestment, its ability to control repatriation and to mobilize funds without triggering basis differences, and the profitability of its Swiss operations and their cash requirements and the need, if any, to repatriate funds. If the assessment of the Company with respect to any earnings of its foreign subsidiaries' changes, deferred Swiss income taxes, foreign income taxes, and foreign withholding taxes may have to be accrued. Based on its assessment, the Company plans to indefinitely reinvest any undistributed foreign earnings as at December 31, 2021. In addition, the determination of any unrecognized deferred tax liabilities for temporary differences related to the Company's investment in foreign subsidiaries is not practicable.

During the years ended December 31, 2021 and 2020, only the Company's French subsidiary had positive retained earnings, amounting to $6.1 million and $1.1 million, respectively.

10. Loss per share

Share data have been revised retrospectively to give effect to the share split explained in Note 1 - "Company information and operations - Share split" and Note 1 - "Company information and operations – Initial Public Offering".

The Company's shares comprised of ordinary shares. Each share has a nominal value of $0.05 (CHF 0.05). The basic loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares in issue during the period. The table presents the loss for the year ended December 31, 2021, 2020, and 2019, respectively (in USD thousands, except shares and loss per share):

	Year ended December 31,		
	2021	**2020**	**2019**
Net loss attributed to shareholders	$ (73,675)	$ (39,339)	$ (33,791)
Weighted average number of shares in issue	55,299,863	42,350,757	37,775,948
Basic and diluted loss per share	**$ (1.33)**	**$ (0.93)**	**$ (0.90)**

11. Cash and cash equivalents

Accounting policies

Cash and cash equivalents include cash on hand, deposits held at call with external financial institutions and other short- term highly liquid investments with original maturities of three months or less. They are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates.

The following table presents the allocation between the Company's cash and cash equivalents (in USD thousands):

	December 31,	
	2021	**2020**
Cash	$ 39,578	$ 42,880
Cash equivalents	$ 153,384	$ 31,745
Cash and cash equivalents	**$ 192,962**	**$ 74,625**

Designated cash

In July 2021, the Company designated $30.0 million to a separate bank account to be used exclusively to settle potential liabilities arising from claims against Directors and Officers covered under the Company's Directors and Officers Insurances Policy ("D&O Policy"). Setting up the designated account has significantly reduced the premiums associated with the D&O Policy. The Company expects to continue to designate this cash balance for this sole use under the current D&O Policy.

12. Term deposits

The following table presents the allocation between the Company's term deposits (in USD thousands):

	December 31,	
	2021	2020
Term deposits, over 3 months, up to 12 months	$ 72,357	$ 22,720
Total term deposits	**$ 72,357**	**$ 22,720**

13. Accounts receivable

Significant accounting estimates and judgements

The Company has adopted the simplified method indicated in IFRS 9, *Financial Instruments* ("IFRS 9"), to build its allowance for expected credit losses ("ECL"). No provision matrix is used, as the Company has not identified any patterns or correlations that would form the basis for such a matrix. Allowance is made for lifetime expected credit losses as invoices are issued. The amount of allowance initially recognized is based on historical experience, tempered by expected changes in future cash collections, due to, for example, expected improved customer liquidity or more active credit management.

Accounting policies

Accounts receivable balances are non-interest bearing and payment terms are generally under agreements with payment terms of up to 180 days. The Company's customers are mainly government-owned or government-funded hospitals and laboratories with a low credit risk. The Company has had minimal instances of actual credit losses and considers that this will continue to be the case.

The following table presents the accounts receivable and lease receivable less the expected credit loss (in USD thousands):

	December 31, 2021	December 31, 2020
Accounts receivable	$ 7,060	$ 8,877
Accrued contract revenue	657	—
Lease receivable	237	150
Allowance for expected credit losses	(1,676)	(2,664)
Net accounts receivable	**$ 6,278**	**$ 6,363**

The movement in the allowance for expected credit losses in accounts receivable is presented below (in USD thousands):

	2021	2020
As of January 1	**$ 2,664**	**$ 1,831**
Increase	1,273	1,069
Reversals	(1,612)	(379)
Write-off	(572)	(16)
Currency translation differences	(77)	159
As of December 31	**$ 1,676**	**$ 2,664**

As of December 31, 2021, and 2020, the Company's largest customer balance represented 18% and 5% of accounts receivable. All customer balances that individually exceeded 1% of accounts receivable in aggregate amounted to $4.6 million and $4.5 million as of December 31, 2021 and 2020, respectively.

Accounts receivable includes amounts receivable that relate to leases. The Company is the lessor under finance leases related to the leasing out of DNA sequencing automation equipment. The Company recorded long-term lease receivables in other non-current assets in the amount of $0.0 million and $0.2 million as of December 31, 2021, and 2020, respectively. As of December 31, 2021, and 2020, the Company had recorded net lease receivables in the amount of $0.2 million and $0.4 million.

14. Inventory

Accounting policies

Raw materials and finished goods are stated at the lower of cost calculated using the first-in, first-out (“FIFO”) method and net realizable value. Work in progress is stated at the lower of its weighted average cost and net realizable value. Cost comprises direct materials, direct labor and an appropriate proportion of variable and fixed overhead expenditure, the latter being allocated on the basis of normal operating capacity.

Inventory consists of the following (in USD thousands):

	December 31,	
	2021	**2020**
Raw materials	$ 5,105	$ 3,248
Work in progress	1,330	722
Finished goods	87	127
Provision	(793)	(713)
Total	**$ 5,729**	**$ 3,384**

Inventory provision movement for the years ended December 31, 2021 and 2020, respectively are as follows (in USD thousands):

	2021	**2020**
As of January 1,	**$ (713)**	**$ (182)**
Increase in provision	(105)	(512)
Currency Translation Adjustment	25	(19)
As of December 31,	**$ (793)**	**$ (713)**

15. Prepaids and other current assets

The following table presents the other current assets (in USD thousands):

	December 31, 2021	**December 31, 2020**
Accrued contract revenue	$ —	$ 262
Deferred contract costs	150	18
Research tax credit receivable	—	863
Prepayments	3,943	1,084
VAT receivable	811	300
Government grants receivable	—	66
Other	625	9
Total	**$ 5,529**	**$ 2,602**

16. Property and equipment

Accounting policies

Property and equipment include leasehold improvements, computer hardware, machinery and furniture and fixtures.

Property and equipment are shown on the balance sheet at their historical cost. The cost of an asset, less any residual value, is depreciated using the straight-line method over the useful life of the asset. For this purpose, assets with similar useful lives have been grouped as follows:

- Leasehold improvements—Shorter of the useful life of the asset or the remaining term of the lease
- Computer hardware—Three to five years
- Machinery and equipment—Five years
- Furniture and fixtures—Five years

Useful lives, components, and residual amounts are reviewed annually. Such a review takes into consideration the nature of the assets, their intended use, including but not limited to the closure of facilities, and the evolution of the technology and competitive pressures that may lead to technical obsolescence. Depreciation of property and equipment is allocated to the appropriate headings of expenses by function in the statement of loss.

Reviews of the carrying amount of the Company's property and equipment are performed when there is an indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated. The recoverable amount of an asset is the greater of its value in use and its fair value less costs of disposal. In assessing the value in use, the estimated future cash flows are discounted to their present value, based on the time value of money and the risks specific to the country where the assets are located.

For the year ended December 31, 2021 and 2020, the Company recorded $0.5 million and less than $0.1 million in accrued expense related to amounts to be paid within the next 12 months, respectively.

Property and equipment, net movement for the years ended December 31, 2021 and 2020, respectively are as follows (in USD thousands):

	Leasehold improvements	Machinery and equipment	Computer hardware	Furniture and fixtures	Total
January 1, 2021	**$ 890**	**$ 615**	**$ 1,799**	**$ 623**	**$ 3,927**
Additions	2,447	608	421	420	3,896
Disposals	(49)	(85)	(294)	(31)	(459)
Currency Translation Adjustment	(28)	(22)	(71)	(5)	(126)
December 31, 2021	**$ 3,260**	**$ 1,116**	**$ 1,855**	**$ 1,007**	**$ 7,238**
Accumulated depreciation					
January 1, 2021	**$ (258)**	**$ (398)**	**$ (1,230)**	**$ (269)**	**$ (2,155)**
Additions	(352)	(119)	(341)	(130)	(942)
Disposals	29	85	292	31	437
Currency Translation Adjustment	11	14	51	9	85
December 31, 2021	**$ (570)**	**$ (418)**	**$ (1,228)**	**$ (359)**	**$ (2,575)**
Net book value at December 31, 2021	**$ 2,690**	**$ 698**	**$ 627**	**$ 648**	**$ 4,663**

	Leasehold improvements	Machinery and equipment	Computer hardware	Furniture and fixtures	Total
January 1, 2020	**$ 664**	**$ 541**	**$ 1,817**	**$ 496**	**$ 3,518**
Additions	201	19	101	130	451
Disposals	(50)	—	(266)	(54)	(370)
Currency Translation Adjustment	75	55	147	51	328
December 31, 2020	**$ 890**	**$ 615**	**$ 1,799**	**$ 623**	**$ 3,927**
Accumulated depreciation					
January 1, 2020	**$ (130)**	**$ (253)**	**$ (1,030)**	**$ (192)**	**$ (1,605)**
Additions	(157)	(112)	(347)	(109)	(725)
Disposals	50	—	263	54	367
Currency Translation Adjustment	(21)	(33)	(116)	(22)	(192)
December 31, 2020	**$ (258)**	**$ (398)**	**$ (1,230)**	**$ (269)**	**$ (2,155)**
Net book value at December 31, 2020	**$ 632**	**$ 217**	**$ 569**	**$ 354**	**$ 1,772**

17. Intangible Assets

Critical accounting estimate and judgements

Goodwill

The Company operates as one segment or cash-generating unit ("CGU"), goodwill is tested by considering its recoverability in terms of the entire business. Management assesses the recoverable value of goodwill by comparing the Company's equity value, either from observable market prices or based on discounted cash flow forecasts, to the net assets as reported in the Company's consolidated financial statements. The values as of December 31, 2020 were based on discounted cash flow projections, which in turn were based on historical results and ratios updated to reflect management's expectations of future growth and profitability and discounted using a weighted average cost of capital derived from an analysis of comparable selected public companies. Critically, the values based on a discounted cash flow approach were found to be consistent with a value based on the share transaction in September 2020. The value as of December 31, 2021 was based on the Company's market capitalization which is a factor of the Company's outstanding shares multiplied by the price of the Company's stock on the last day of trading in 2021.

Capitalized internally developed software costs

Capitalized costs are based on the employment costs of individuals working on software development and based on timesheets. Special attention is paid to distinguishing between costs incurred on developing new software or software upgrades, which may be eligible for capitalization, and costs incurred in maintenance and in the correction of problems, which is not eligible.

Judgement is required in identifying whether individual projects meet all of the criteria required to permit capitalization, in particular, whether the software will generate probable future economic benefits.

Accounting policies

Goodwill

Goodwill is initially measured as the difference between the aggregate of the value of the consideration transferred and the fair value of net assets acquired. Goodwill is not amortized but it is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it might be impaired and is carried at cost less accumulated impairment losses. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

Impairment testing

Intangible assets are allocated to CGUs for the purpose of impairment testing. The allocation is made to those CGUs or groups of CGUs that are expected to benefit from the business combination in which the goodwill arose. The CGUs or groups of CGUs are identified at the lowest level at which goodwill is monitored for internal management purposes, being the operating segments. As the Company operates as a single operating segment or CGU, the Company has only a single cash generating unit for impairment testing.

Management assesses the recoverable value of goodwill by comparing the value of the Company equity value, either inferred from the public prices of share issues or based on discounted cash flow forecasts, with the net assets as reported in its consolidated financial statements. The discounted cash flow approach involves key assumptions that leave considerable scope for judgement. The Company only used the discounted cash flow method for the fiscal year ended as of December 31, 2020.

Purchased software

The costs of accessing software services are not capitalized if the Company does not have any contractual right to take possession of the software at any time during the term of the agreement and it is not feasible for the Company either to run the software on its own hardware or to contract with a third party unrelated to the vendor. Such costs represent SaaS costs and are expensed as incurred.

The Company does capitalize software implementation costs, such as fees paid to outside consultants to set up a software arrangement.

For cloud computing costs, the Company capitalized costs for certain configuration and customization costs paid by a customer in a cloud computing or hosting arrangement. The guidance aligns the accounting treatment of these costs incurred in a hosting arrangement treated as a service contract with the requirements for capitalization and amortization costs to develop or obtain an intangible asset.

Purchased software and associated capitalized costs are amortized using the straight-line method over an estimated life of five years.

Capitalized internally developed software costs

Costs incurred in the internal development of software are capitalized as intangible assets when the criteria required by IAS 38 as set out below.

Software development costs consist entirely of capitalized internally generated costs that are directly attributable to the design, testing and enhancement of identifiable and unique software products controlled by the Company and incorporated principally within the Company's SOPHiA platform. They are recognized as intangible assets where the following criteria are met:

- it is technically feasible to complete software so that it will be available for use;
- management intends to complete the software and use or sell it;
- there is an ability to use or sell the software;
- it can be demonstrated how the software will generate probable future economic benefits;
- adequate technical, financial and other resources to complete the development and to use or sell the software are available, and;
- the expenditure attributable to the software during its development can be reliably measured.

Directly attributable costs that are capitalized as part of the software comprise principally employee costs. Capitalized development costs are recorded as intangible assets and amortized from the point at which the asset is ready for use on a straight-line basis over its expected useful life. Capitalized software development costs are amortized using the straight-line method over an estimated life of five years.

The Company considers that it is only since the beginning of 2020 that development costs have fulfilled the criteria for recognition as intangible assets set out in IAS 38.

Intangible assets, net movement for the years ended December 31, 2021 and 2020, respectively are as follows (in USD thousands):

	Goodwill	Purchased software	Capitalized internally developed software costs	Total intangible assets
January 1, 2021	**$ 8,598**	**$ 3,071**	**$ 2,621**	**$ 14,290**
Additions	—	130	3,858	3,988
Disposals	—	—	(30)	(30)
Currency Translation Adjustment	(300)	(111)	(90)	(501)
December 31, 2021	**$ 8,298**	**$ 3,090**	**$ 6,359**	**$ 17,747**
Accumulated depreciation				
January 1, 2021	**$ —**	**$ (889)**	**$ (119)**	**$ (1,008)**
Additions	—	(565)	(527)	(1,092)
Disposals	—	—	—	—
Currency Translation Adjustment	—	22	4	26
December 31, 2021	**$ —**	**$ (1,432)**	**$ (642)**	**$ (2,074)**
Net book value at December 31, 2021	**$ 8,298**	**$ 1,658**	**$ 5,717**	**$ 15,673**

	Goodwill	Purchased software	Capitalized internally developed software costs	Total intangible assets
January 1, 2020	**$ 7,834**	**$ 2,761**	**$ —**	**$ 10,595**
Additions	—	324	2,436	2,760
Disposals	—	(286)	—	(286)
Currency Translation Adjustment	764	272	185	1,221
December 31, 2020	**$ 8,598**	**$ 3,071**	**$ 2,621**	**$ 14,290**
Accumulated depreciation				
January 1, 2020	**$ —**	**$ (359)**	**$ —**	**$ (359)**
Additions	—	(521)	(111)	(632)
Disposals	—	60	—	60
Currency Translation Adjustment	—	(69)	(8)	(77)
December 31, 2020	**$ —**	**$ (889)**	**$ (119)**	**$ (1,008)**
Net book value at December 31, 2020	**$ 8,598**	**$ 2,182**	**$ 2,502**	**$ 13,282**

Goodwill arises from the Company's acquisition of Interactive Biosoftware ("IBS") in June 2018. Through this acquisition the Company added Alamut (a health technology diagnostic) to its existing SOPHiA platform.

Goodwill is tested for impairment on an annual basis and at the occurrence of a potential indication of impairment. As of December 31, 2021 and 2020, respectively, no impairment charged was recorded related to the Company's goodwill.

As of December 31, 2020, the estimated equity value of the Company was $465.3 million, which exceeds the reported net assets of the Company of $100.5 million at that date by $364.8 million.

As of December 31, 2021, the estimated equity value of the Company was $900.4 million, which exceeds the reported net assets of the Company of $275.4 million at that date by $626.5 million.

On the basis of the analyses performed, the Company concludes that the recoverable amount exceeds the carrying amount of the goodwill and no impairment is needed as of December 31, 2021 and December 31, 2020.

18. Leases

Accounting policies

Lessee

The Company assesses at inception of the contract whether a contract is or contains a lease. This assessment involves determining whether the Company obtains substantially all the economic benefits from the use of that asset, and whether the Company has the right to direct the use of the asset. When these conditions are met, the Company recognizes a right-of-use (“ROU”) asset and a lease liability at the lease commencement date, except for short-term leases of 12 months or less, which are expensed in the statement of income/loss on a straight-line basis over the lease term.

At inception, the ROU asset comprises the initial lease liability, initial direct costs, and any obligations to refurbish the asset, less any incentives granted by the lessors.

The ROU asset is depreciated over the shorter of the duration of the lease contract (including contractually agreed optional extension periods whose exercise is deemed to be reasonably certain) and the useful life of the underlying asset.

The ROU asset is subject to testing for impairment if there is an indicator for impairment, as for owned assets.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that is not readily determinable, the incremental borrowing rate (“IBR”) at the lease commencement date. The IBR is the rate of interest that the Company would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the ROU asset in a similar economic environment. Lease payments can include fixed payments; variable payments that depend on an index or rate known at the commencement date; and extension option payments or purchase options that the Company is reasonably certain to exercise.

The lease liability is subsequently measured at amortized cost using the effective interest rate method and remeasured (with a corresponding adjustment to the related ROU asset) when there is a change in future lease payments due to renegotiation, changes in an index or rate or a reassessment of options.

Some of the Company’s leases include options to extend the lease, and these options are included in the lease term to the extent they are reasonably certain to be exercised.

Lessor

The Company leases out laboratory equipment to certain customers. These leases are classified as finance leases as the Company transfers substantially all the risks and rewards incidental to ownership of the asset to the customer.

At the commencement of the lease term, the Company records revenue and the associated costs of sales, being the sale proceeds at fair value of the asset (computed at cost plus a margin) and the cost of the asset, derecognizes the leased asset from inventory, and recognizes a finance lease receivable in the balance sheet equal to the net investment in the lease.

Company leases

During the year ended December 31, 2021, the Company entered into two significant leases as described below.

Rolle office

On March 3, 2021, the Company entered into a 120-month lease for office space in Rolle, Switzerland primarily to support the expansion of the research and development department. The lease in total is for approximately 38,750 square feet

with the Company gaining access to areas on prescribed dates. The Company gained access to 11,840 square feet on July 1, 2021. The Company will gain access to 7,535 square feet on January 1, 2022 and the remaining 19,375 square feet on February 1, 2023. The expected lease commitments resulting from this contract are less than $0.1 million in 2021, $0.5 million in 2022, $1.0 million in 2023 onwards, and $1.14 million from 2024 onward. The expected lease commitments are linked to changes in the Swiss Consumer Price Index as published by Swiss Federal Statistical Office.

The Company makes fixed payments and additional variable payments depending on the usage of the asset during the contract period. Upon commencement of the lease, the Company recorded a ROU asset of $7.7 million and a lease liability of $8.5 million. The difference between the ROU and lease liability of $0.8 million is driven by lease incentives and expected restoration costs.

Boston office

On August 9, 2021, the Company entered into a 40-month new lease for office space in Boston, Massachusetts to support the expansion of the Company's growth in the United States. The lease in total is for approximately 9,192 square feet. The expected lease commitments resulting from this contract are $0.5 million a year starting in 2022 through the end of the lease in 2024. The Company makes fixed payments and additional variable payments depending on the usage of the asset during the contract period. Upon commencement of the lease, the Company recorded a right-of-use asset of $1.2 million and a lease liability of $1.4 million. The difference between the ROU and lease liability of $0.2 million is driven by lease incentives.

Generally, lease terms for office buildings are between one and ten years. Any leases with terms less than 12 months and/or with low value are expensed in accordance with the IFRS 16 practical expedients for short-term leases and low-value leases. These expenses amounted to $0.3 million and $0.5 million for the years ended December 31, 2021 and 2020, respectively. The Company had cash outflows related to leases less than 12 months and/or with low value of $0.3 million and $0.5 million for the years ended December 31, 2021 and 2020, respectively.

The Company has lease liabilities amounting to $10.8 million and $3.9 million for the years ended December 31, 2021 and 2020, respectively, that are linked to consumer price indices in Switzerland and France.

The future cash flow in relation to short-term leases and leases of low value assets is disclosed in Note 29 – "Commitments and contingencies."

The Company has several leases with extension and termination options. Management determines, on the basis of the business needs, whether they expect to exercise these options.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that is not readily determinable, the IBR at the lease commencement date. The IBR is the rate of interest that the Company would have had to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the ROU asset in a similar economic environment. On the basis of this policy, the IBRs used by the Company to discount lease payments outstanding at December 31, 2021 and 2020, respectively, in the countries in which it has recognized right-of-use assets and lease liabilities have been in the range of 2.61% to 3.47% and 2.61% to 3.47%, respectively.

The following table presents the movements in the ROUs (in USD thousands):

	2021	2020
As of January 1	**$ 3,767**	**$ 4,535**
Additions	9,205	—
Depreciation charge	(1,575)	(1,033)
Currency translation effects	(105)	265
As Of December 31	**$ 11,292**	**$ 3,767**

The following table presents the movements in the lease liabilities (in USD thousands):

	2021	2020
As of January 1	**$ 3,919**	**$ 4,626**
Additions	10,165	—
Cash outflows (principle and interest)	(1,143)	(1,101)
Non-cash interest	225	121
Currency translation effects	(107)	273
As Of December 31	**$ 13,059**	**$ 3,919**

19. Accounts payable

Accounts consist of the following (in USD thousands):

	December 31, 2021	December 31, 2020
Trade payables	2,337	1,281
Employee related payables	3,509	3,232
VAT and sales taxes	891	1,394
Total	**$ 6,737**	**$ 5,907**

20. Accrued expenses

Accrued expenses consist of the following (in USD thousands):

	December 31, 2021	December 31, 2020
Accrued Compensation	$ 9,148	$ 5,198
Accrued Professional fees	2,743	2,380
Accrued inventory purchases	2,472	—
Accrued IT support	25	753
Accrued Legal fees	125	462
Accrued Other	1,459	288
Total	**$ 15,972**	**$ 9,081**

21. Other non-current liabilities

Other non-current liabilities consist of the following (in USD thousands):

	December 31, 2021	December 31, 2020
Derivative	—	$ 1,024
Lease restoration costs	$ 160	—
Provisions	311	304
Deferred government grant income	—	50
Total	**$ 471**	**$ 1,378**

22. Post-employment benefits

Significant accounting estimates and judgements

The liability or asset recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the end of the reporting period less the fair value of plan assets. The defined benefit obligation is calculated annually by independent actuaries using the projected unit credit method.

The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and

that have terms approximating to the terms of the related obligation. In countries where there is no deep market in such bonds, the market rates on government bonds are used.

The net interest cost is calculated by applying the discount rate to the net balance of the defined benefit obligation and the fair value of plan assets. This cost is included in employee benefit expense in the statement of income/loss.
Remeasurement gains and losses arising from experience adjustments and changes in actuarial assumptions are recognized in the period in which they occur, directly in other comprehensive income. The remeasurement gains and losses are included in retained earnings in the statement of changes in equity and in the balance sheet.

Changes in the present value of the defined benefit obligation resulting from plan amendments or curtailments are recognized immediately in income as past service costs.

For defined contribution plans, the Company pays contributions to publicly or privately administered pension insurance plans. Employee contributions to these plans is voluntary and these contributions are matched by the employer. The Company has no further payment obligations once the contributions have been paid. The contributions are recognized as employee benefit expense when they are due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in the future payments is available. Contributions are charged to the statement of income/loss as incurred.

Accounting policies

The Company operates defined benefit and defined contribution pension plans. Funded schemes are generally funded through payments to insurance companies or trustee-administered funds, determined by periodic actuarial calculations. A defined contribution plan is a pension plan under which the Company pays fixed contributions into a separate entity (a fund) and has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods. A defined benefit plan is a pension plan that is not a defined contribution plan. Typically, defined benefit plans define an amount of pension benefit that an employee will receive on retirement, usually dependent on one or more factors such as age, years of service and compensation.

The actual return on plan assets, excluding interest income measured at the discount rate, is recognized in other comprehensive income/loss within defined benefit plan remeasurements.

The Company has a funded defined benefit plan in Switzerland, an unfunded defined benefit plan in France and a defined contribution plans in the US. The Company has no occupational pension plans in the UK and Brazil.

Swiss pension plan

The Company contracted with the Swiss Life Collective BVG Foundation based in Zurich for the provision of occupational benefits. All benefits in accordance with the regulations are reinsured in their entirety with Swiss Life SA within the framework of the corresponding contract. This pension solution fully reinsures the risks of disability, death and longevity with Swiss Life. Swiss Life invests the vested pension capital and provides a 100% capital and interest guarantee. The pension plan is entitled to an annual bonus from Swiss Life comprising the effective savings, risk and cost results.
Although the amount of ultimate pension benefit is not defined, certain legal obligations of the plan create constructive obligations on the employer to pay further contributions to fund an eventual deficit; this results in the plan nevertheless being accounted for as a defined benefit plan.

French pension plan

In France, the bulk of pensions are paid by national pension schemes, which are unfunded. In addition, French employers are obliged by law to pay a retirement indemnity. Its amount depends on the last salary of the employee and on the period of activity with its employer. Rights to this benefit are acquired during the service life with the same employer on the condition that the employee will be with its employer at retirement date; it means that the rights are only vested on retirement date. This indemnity is in substance a defined benefit plan.

The following table provides additional details on the defined pension plans' funded status (in USD thousands):

	December 31,	
	2021	2020
Present value of defined benefit obligation	$ (17,889)	$ (15,938)
Fair value of plan assets	13,436	10,780
Net pension liability	**$ (4,453)**	**$ (5,158)**

The following table presents the movement in the defined benefit obligation (in USD thousands):

	2021			2020		
	Funded	Unfunded	Total	Funded	Unfunded	Total
January 1	**$ (15,773)**	**$ (165)**	**$ (15,938)**	**$ (10,703)**	**$ (75)**	**$ (10,778)**
Service Cost	(1,054)	(80)	(1,134)	(1,547)	(49)	(1,596)
of which current service cost	*(1,382)*	*(80)*	*(1,462)*	*(1,435)*	*(49)*	*(1,484)*
of which past service cost	*328*	*—*	*328*	*(112)*	*—*	*(112)*
Interest expense	(49)	(1)	(50)	(6)	(1)	(7)
Actuarial gains (losses)	471	26	497	244	(30)	214
Actual plan participants' contributions	(1,171)	—	(1,171)	(771)	—	(771)
Transfers (in) out due to (joiners) leavers	(651)	—	(651)	(1,663)	—	(1,663)
Currency translation differences	541	17	558	(1,327)	(10)	(1,337)
December 31	**$ (17,686)**	**$ (203)**	**$ (17,889)**	**$ (15,773)**	**$ (165)**	**$ (15,938)**

The service cost and interest expense are charged to the statement of income/loss as pension cost. Actuarial gains (losses) are credited or charged to other comprehensive income (loss) as defined benefit plan remeasurements.
As of December 31, 2021, the Swiss and French plans had 252 and 105 active members, respectively. As of December 31, 2020, the Swiss and French plans had 173 and 86 active members, respectively.

As a result of the reduction in conversion factors, the Company incurred a past service cost gain of $0.3 million for the year ended December 31, 2021.

The following table presents the movement in the defined benefit plans' assets (in USD thousands):

	2021	2020
As of January 1	**$ 10,780**	**$ 6,715**
Interest income	39	4
Return on plan assets, excl. interest income	(32)	(45)
Administrative expenses	(62)	(42)
Employer contributions	1,257	819
Employee contributions	1,171	771
Transfers in (out) due to joiners (leavers)	651	1,663
Currency translation differences	(368)	895
As of December 31	**$ 13,436**	**$ 10,780**

The following table presents the defined benefit plan assets, which include the following (in USD thousands):

	December 31,	
	2021	2020
Cash	$ 528	$ 319
Insurance policies	12,908	10,461
Total	**$ 13,436**	**$ 10,780**

The Swiss Life Collective BVG Foundation, to which the Swiss pension plan is affiliated, manages its funds in the interests of all members, with due attention to the priorities of liquidity, security, and return. The Company's pension plan benefits from the economies of scale and diversification of risk available through this affiliation. The Company has no influence over the investment policy.

The follow table presents the pension costs recognized in statement of loss (in USD thousands):

	December 31,								
	2021			2020			2019		
	Funded	Unfunded	Total	Funded	Unfunded	Total	Funded	Unfunded	Total
Service cost	$ (1,054)	$ (80)	$ (1,134)	$ (1,547)	$ (49)	$ (1,596)	$ (843)	$ (26)	$ (869)
Interest cost	(49)	(1)	(50)	(6)	(1)	(7)	(68)	(1)	(69)
Total recognized	**$ (1,103)**	**$ (81)**	**$ (1,184)**	**$ (1,553)**	**$ (50)**	**$ (1,603)**	**$ (911)**	**$ (27)**	**$ (938)**

The follow table presents the pension remeasurement recognized in statement other comprehensive loss (in USD thousands):

	December 31,								
	2021			2020			2019		
	Funded	Unfunded	Total	Funded	Unfunded	Total	Funded	Unfunded	Total
Changes in demographic assumptions	$ 1,278	$ —	$ 1,278	$ 1,039	$ —	$ 1,039	$ —	$ —	$ —
Changes in financial assumptions	37	13	50	157	(16)	141	(949)	(15)	(964)
Experience adjustments	(844)	13	(831)	(952)	(14)	(966)	(431)	10	(421)
Total actuarial gains (losses)	**471**	**26**	**497**	**244**	**(30)**	**214**	**(1,380)**	**(5)**	**(1,385)**
Return on plan assets	(32)	—	(32)	(45)	—	(45)	(93)	—	(93)
Currency translation differences	(4)	—	(4)	13	2	15	(45)	—	(45)
Total recognized	**$ 435**	**$ 26**	**$ 461**	**$ 212**	**$ (28)**	**$ 184**	**$ (1,518)**	**$ (5)**	**$ (1,523)**

The positive impact of changes in demographic assumptions in 2021 was due principally to an increase in the expected employee salaries increased from 100% to 125%. This implies that more members are expected to have a higher pensionable amount before pensionable age.

The positive impact of changes in demographic assumptions in 2020 was due principally to an increase in the expected employee turnover rate from 11% to 15%. This implies that more members are expected to leave the plan before pensionable age.

The negative experience adjustments in 2021 and 2020 were due largely to the shortfall between the additional defined benefit obligation attributable to new joiners and the assets that they transferred into the plan.

Key actuarial assumptions by plan

Discount rate

In estimating the defined benefit obligation, the discount rates used were, for the Swiss plan, 0.30% and 0.20% and, for the French plan, 0.35% and 0.70% for the years ended December 31, 2021 and 2020, respectively.

Expected rate of salary increase

The expected rate of annual salary increase was assumed to be, for the Swiss plan 1.25% and 1.00% and for the French plan 1.50% and 2.30% for the years ended December 31, 2021 and 2020, respectively.

Pension plan modified duration

The weighted average modified duration of the Swiss plan is 15.9 years and 18.8 years and of the French plan 25.9 years 26.8 years for the years ended December 31, 2021 and 2020, respectively.

Interest rates

For the Swiss plan, the interest on old age accounts is based, for the LPP account, on the LPP interest rate, which was 1.00% and 1.00% and, for the extra mandatory part, is equivalent to the discount rate, which was 0.30% and 0.35% for the years ended December 31, 2021 and 2020, respectively.

Inflation

For the Swiss plan, the expected annual rate of inflation is based on the inflation forecast of the Swiss National Bank and was assumed to be 0.75% and 0.50% for the years ended December 31, 2021 and 2020, respectively.

Mortality tables

Assumptions regarding future mortality experience are set based on actuarial advice provided in accordance with published statistics and experience and are based on the mortality generational tables BGV 2020 (Swiss) and TH/TF 00-02 (French). For the Swiss plan, the average life expectancy in years after retirement of a pensioner retiring at age 65 (male) and 64 (female) on the balance sheet date is, respectively, 22.57 and 22.72 and 24.37 and 24.76, for the years ended December 31, 2021 and 2020, respectively.

Sensitivity analysis

The following tables demonstrate the sensitivity of the defined benefit obligations to changes in the discount rate, expected rates of salary increase, interest credited on savings accounts, inflation and life expectancy at retirement age.
The table below presents the sensitivity analysis for the funded plans (in USD thousands):

	2021	2020
Discount rates		
Increase of 25 basis points	(576)	(637)
Decrease of 25 basis points	635	697
Expected rates of salary increases		
Increase of 25 basis points	122	137
Decrease of 25 basis points	(120)	(134)
Interest rate		
Increase of 25 basis points	189	206
Decrease of 25 basis points	(185)	(199)
Inflation		
Increase of 25 basis points	121	134
Decrease of 25 basis points	(118)	(130)
Life expectancy		
Increase of 1 year	145	177
Decrease of 1 year	(145)	(176)

The table below presents the sensitivity analysis for the unfunded plans (in USD thousands):

	2021	2020
Discount rates		
Increase of 50 basis points	(26)	(18)
Decrease of 50 basis points	30	20
Expected rates of salary increases		
Increase of 50 basis points	30	20
Decrease of 50 basis points	(26)	(18)

The above sensitivity analyses are based on a change in an assumption while holding all other assumptions constant. In practice, this is unlikely to occur, and changes in some of the assumptions may be correlated. When calculating the sensitivity of the defined benefit obligation to significant actuarial assumptions the same method (present value of the

defined benefit obligation calculated with the projected unit credit method at the end of the reporting period) has been applied as when calculating the pension liability recognized within the balance sheet.

The methods and types of assumptions used in preparing the sensitivity analysis did not change compared to the prior period.

Future employer contributions

Expected employer contributions to the Swiss defined benefit pension plan for the year ending December 31, 2022 amount to $1.6 million.

Defined contribution plans

US pension plan

The Company has a multiple employer 401(k) defined contribution plan in the USA. The expense recognized in respect of the defined contribution plan in the USA was $0.2 million and less than $0.1 million for the years ended December 31, 2021 and 2020, respectively. The Company incurred no expense in the year ended December 31, 2019.

23. Share-based compensation

Significant accounting estimates and judgements

Measuring the cost of share options

The fair value of the options under all plans are measured at each grant date using an adjusted form of the Black-Scholes option pricing model, taking into account the terms and conditions upon which the options were granted.

For options up to September 2020, the fair value at grant date is independently determined using an adjusted form of the Black-Scholes option pricing model that takes into account the strike price, the fair value of the share at grant date, the expected life of the award, the expected price volatility of the underlying share, the risk-free interest rate for the term of the award and the expected dividend yield. For options granted on and subsequent to September 2020 until July 22, 2021, the fair value at grant date is based on a probability-weighted expected returns method that takes account of both the value derived by using an adjusted form of the Black-Scholes option pricing model, as described above, and a discounted estimate of the price that might be achieved in a future transaction. For options granted on and subsequent to July 22, 2021, the fair value at grant date is determined by using the Black-Scholes option pricing model.

The Company has used an independent valuation firm to assist in calculating the fair value of the award grants per participant.

The key inputs used in the valuation model, for the stock options granted in the years ended December 31, 2021 and 2020, respectively, are outlined below. Stock options were only granted under the 2019 Incentive Share Option Plan (“2019 ISOP”), and the 2021 Employee Incentive Plan (“2021 EIP”). No grants have been made under the SOPHiA GENETICS Incentive Share Option Plan (“2013 ISOP”) since 2019.

Prior to the Company’s IPO, the price of the ordinary shares at grant date, which represents a critical input into this model, has been determined on one of the following two bases:

- By reference to a contemporaneous transaction involving another class of share, using an adjusted form of the Black-Scholes option pricing model as described above, and considering the timing, amount, liquidation preferences and dividend rights of issues of other classes of shares.

- On the basis of discounted cash flow forecasts, where there was no contemporaneous or closely contemporaneous transaction in another class of share and the time interval was too large to permit an assumption that there had been no significant change in the Company’s equity value.

Subsequent to the IPO, the price of the ordinary shares at grant date, which represents a critical input into this model, has been determined on the most recent close price of the Company’s stock price on the date of grant.

Accounting policies

The Company has three share option plans for directors, employees, and advisors which are accounted for as equity-settled share- based compensation plans.

The fair value of options granted under these plans is recognized as an employee benefits expense, with a corresponding increase in equity. The total amount to be expensed is determined by reference to the fair value of the options granted:

- including any market performance conditions (e.g., the entity's share price);
- excluding the impact of any service and non-market performance vesting conditions (e.g., profitability, sales growth; targets and remaining an employee of the entity over a specified time period), and;
- including the impact of any non-vesting conditions (e.g., the requirement for employees to save or hold shares for a specific period of time).

The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied. At the end of each period, the entity revises its estimates of the number of options that are expected to vest based on the non-market vesting and service conditions. It recognizes the impact of the revision to original estimates, if any, in income, with a corresponding adjustment to equity.

Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires determination of the most appropriate inputs to the valuation model including the share price, or the fair value of a share, the expected life of the share option, the volatility of the share price, the risk-free interest rate, the dividend yield, and making certain assumptions about the inputs. The assumptions used for estimating fair value for share-based payment transactions are disclosed below.

If the shares are not listed, estimating their fair value also requires determination of the most appropriate valuation model, such as:

- By reference to a contemporaneous transaction involving another class of share, using an adjusted form of an option pricing model above, and considering the timing, amount, liquidation preferences and dividend rights of issues of other classes of shares;
- On the basis of discounted cash flow forecasts, where there was no contemporaneous or closely contemporaneous transaction in another class of share and the time interval was too large to permit an assumption that there had been no significant change in the Company's equity value;
- Share based compensation expense is measured at the fair value of the options at the grant date and recognized over the vesting period. Share based compensation expense is presented in the statement of income/loss and allocated to the various expense categories based on the functions of the employees to whom the options are granted (e.g., research and development, selling and marketing, general & administrative).

The calculation of the cost of the Company's share option grants and of the fair value of the ordinary shares at the grant date requires the selection of an appropriate valuation model and is based on key assumptions that leave considerable scope for judgement.

Recognizing the cost of share options

At each reporting date, the Company takes a charge for the vested options granted and for partially earned but non-vested portions of options granted. This results in a front-loaded charge to the statement of loss. Prior to the IPO, at each reporting date, the Company reappraised its estimate of the likelihood and date of a future transaction that would cause all options which would vest six months from the transaction date to vest and, if necessary, accelerated the recognition of the unrecognized cost in the statements of loss. The Company accounts for these plans as equity-settled transactions. The charge to the statements of loss therefore results in a corresponding credit being booked to "Other reserves" within equity.

Share data have been revised to give effect to the share split explained in Note 1 - "Company information and operations - Share split".

The plans

The Company has three share option plans: the 2013 ISOP (launched in September 2013), the 2019 ISOP (launched March 2019), and the 2021 EIP (launched June 2021). Under these plans, directors may offer options to directors, employees and advisors. The exercise price of the share options is set at the time they are granted. Options, once vested, can be exchanged for an equal number of ordinary shares. Under the 2021 EIP, the Company can grant restricted stock units ("RSUs") which represent the right to receive ordinary shares upon meeting specific vesting requirements. RSUs are able to be granted to directors, executives, and employees.

The options have a life of ten years. Options under the 2013 ISOP vest 50% on the second anniversary of the grant date and a further 50% on the third anniversary of the grant date. Options under the 2019 ISOP vest 25% on each anniversary of the grant date over four years. The options under the 2021 EIP vest 25% on the first anniversary of the grant date and the remaining 75% vesting ratably on a monthly basis over the remaining three years. Refer to *Restricted Stock Units* below for the vesting schedules of the RSUs under the 2021 EIP.

On April 22, 2021, the Board amended the 2019 ISOP to the effect that, in the event of a successful IPO or public listing of the Company's shares, only those unvested options that otherwise would vest within six months following the effective date of the IPO or such public listing should become fully vested immediately as of such date (accelerated vesting). The remaining unvested options (i.e., unvested options that would only vest after the six-month period following the effective date of the IPO or public listing) would not be subject to accelerated vesting and, subject to certain conditions, would vest on the basis of the original vesting schedule. Additionally, the Board instituted a black-out period, irrespective of a successful IPO or public listing of the Company, in which no options could be exercised from May 1, 2021 to January 19, 2022, and to accelerate the vesting of options that would otherwise vest during that period.

The Company assessed the amendment to the 2019 ISOP and concluded it resulted in a modification. As such, the Company assessed the valuation of the options immediately prior to and subsequently after the modification. As a result of the modification, the Company incurred an additional expense of $0.2 million year ended December 31, 2021.

2013 ISOP

Activity for the year ended December 31, 2021, under the 2013 ISOP was as follows:

	Number of options	Weighted average exercise price	Weighted average remaining life in years
Outstanding as of January 1, 2021	**1,751,560**	**$ 3.10**	**6.39**
Exercised	(892,020)	3.00	—
Outstanding as of December 31, 2021	**859,540**	**$ 2.75**	**5.08**
Exercisable as of December 31, 2021	**849,540**	**$ 2.75**	**5.06**

Activity for the year ended December 31, 2020, under the 2013 ISOP was as follows:

	Number of options	Weighted average exercise price	Weighted average remaining life in years
Outstanding as of January 1, 2020	**2,026,560**	**$ 2.95**	**7.36**
Exercised	(275,000)	3.10	**—**
Outstanding as of December 31, 2020	**1,751,560**	**$ 3.10**	**6.39**
Exercisable as of December 31, 2020	**1,385,060**	**$ 3.01**	**6.39**

Options outstanding as of December 31, 2021, under the 2013 ISOP expire between 2022 and 2029.

2019 ISOP

Activity for the year ended December 31, 2021, under the 2019 ISOP was as follows:

	Number of options	Weighted average exercise price	Weighted average remaining life in years
Outstanding as of January 1, 2021	**1,972,500**	**$ 4.22**	**9.11**
Granted	1,369,000	8.75	9.12
Forfeited	(149,750)	5.54	—
Exercised	(379,250)	4.00	—
Outstanding as of December 31, 2021	**2,812,500**	**$ 5.83**	**8.61**
Exercisable as of December 31, 2021	**455,500**	**$ 1.37**	**7.85**

The valuation inputs for the 2019 ISOP grants were as follows:

	Twelve months ended December 31,		
	2021	2020	2019
Share price at grant date (in USD)	$5.59	$4.36 - $4.87	$3.32 - $4.16
Expected life of share options (years)	6.05 - 6.19	5.67 - 6.43	6.43 - 6.91
Expected volatility	41.26% - 41.45%	39.84% - 43.56%	39.70% - 40.70%
Risk free interest rate	(0.63)% - (0.48)%	(0.80)% - (0.53)%	(0.85)% - (0.47)%
Dividend yield (%)	—%	—%	—%

Activity for the year ended December 31, 2020, under the 2019 ISOP was as follows:

	Number of options	Weighted average exercise price	Weighted average remaining life in years
Outstanding as of January 1, 2020	**679,000**	**$ 4.02**	**9.63**
Granted	1,393,000	4.22	9.30
Forfeited	(55,500)	4.22	—
Exercised	(44,000)	4.22	—
Outstanding as of December 31, 2020	**1,972,500**	**$ 4.22**	**9.11**
Exercisable as of December 31, 2020	**115,760**	**$ 4.22**	**8.63**

Options outstanding as of December 31, 2021, under the 2019 ISOP expire between 2029 and 2031.

2021 EIP

Activity for the year ended December 31, 2021, under the 2021 EIP was as follows:

	Number of options	Weighted average exercise price	Weighted average remaining life in years
Outstanding as of January 1, 2021	**—**	**$ —**	**—**
Granted	1,595,314	17.96	9.57
Forfeited	(19,245)	18.00	—
Outstanding as of December 31, 2021	**1,576,069**	**$ 17.96**	**9.57**
Exercisable as of December 31, 2021	**—**	**$ —**	**—**

Options outstanding as of December 31, 2021, under the 2021 EIP expire in 2031.

The valuation inputs for the 2021 EIP grants were as follows::

	Twelve months ended December 31, 2021
Share price at grant date (in USD)	$16.81 - $18.00
Expected life of share options (years)	5.50 - 7.00
Expected volatility	41.60% - 59.77%
Risk free interest rate	0.87% - 1.36%
Dividend yield (%)	—%

Share options outstanding at the year ended December 31, 2021

The weighted average fair value of options granted during the years ended December 31, 2021 and 2020, respectively (in USD):

	2021	2020
2019 ISOP	$ 2.12	$ 1.75
2021 EIP	$ 9.87	$ —

Movements in the share-based compensation reserve were as follows (in USD thousands):

	Total
January 1, 2020	**$ 1,589**
Movement in the period	1,359
December 31, 2020	2,948
Movement in the period	8,514
December 31, 2021	**$ 11,462**

Commitment to grant options to CEO on IPO

In addition to the options granted, as set out above, the Board committed on November 29, 2018 to award to the CEO 300,000 share options, if the Company completed an IPO that valued the Company at a minimum of $1.0 billion. No other terms and conditions were specified, although it was assumed that the strike price would be equal to the IPO share price and that there could be further vesting conditions in terms of service beyond the IPO date.

On March 25, 2021, the Board formally clarified the conditions of this commitment to grant options to the CEO upon an IPO. Specifically, the Board set the grant date as November 29, 2018, set the strike price at $3.33 (CHF 3.15), confirmed the condition of an IPO that valued the Company at a minimum of $1 billion and set the life of the option at five years. On the basis of these terms, the award was valued as of that date at $0.3 million. This value will not be updated at a later date as all terms and conditions of the award were approved. The expense of $0.3 million will be recognized when it becomes probable that an IPO that values the Company at a minimum of $1.0 billion will occur before November 29, 2023. The Company recognized $0.3 million for the year ended December 31, 2021, related to the Company's IPO in July 2021.

Restricted Stock Units

As part of the 2021 EIP, the Company initiated granting of RSUs, which represent the right to receive shares of ordinary shares upon meeting specified vesting requirements. In the year ended December 31, 2021, the Company issued 290,407 RSU under the 2021 plan. Under the terms of the 2021 plan, 234,852 of the RSUs issued are subject to a four-year vesting schedule with 25% vesting on the first anniversary of the grant date and the remaining 75% ratably on a monthly basis over the remaining three years, and the remaining 55,555 of the RSUs issued are subject to vesting upon the Company's Annual General Meeting. The activity for the year ended December 31, 2021 was as follows:

	Shares	Weighted-average grant date fair value per share
Unvested as of January 1, 2021	—	$ —
Granted	290,407	$ 17.97
Forfeited	(2,832)	$ 18.00
Unvested as of December 31, 2021	**287,575**	**$ 17.97**

24. Borrowings

The following is the activity of the Company's borrowings for the years ended December 31, 2021 and 2020, respectively (in USD thousands):

	Borrowings
January 1, 2021	**$ 3,330**
Principal repayments	(3,167)
Transfer to deferred government grant income	39
Interest accrued	50
Interest paid	(170)
Currency translation differences	(82)
December 31, 2021	**$ —**
January 1, 2020	**$ 3,838**
New borrowing proceeds	15,839
Principal repayments	(16,529)
Transfer to deferred government grant income	(163)
Interest accrued	513
Interest paid	(435)
Currency translation differences	267
Total	**$ 3,330**

$6.0 million (EUR 5.2 million) 9.75% loan

On June 18, 2018, the Company signed the Plain English Growth Capital Loan Agreement with TriplePoint. The Company issued a Plain English Growth Capital Promissory Note and received a loan of $6.0 million (EUR 5.2 million). The purpose of the loan was to finance the acquisition of IBS, a company based in France. The loan bore an annual interest of 9.75% (Prime Rate plus 4.75%), and the Company agreed to pay a terminal amount of $0.4 million (EUR 0.3 million) equal to 6.25% of this Promissory Note, on June 1, 2021 (end of term payment). This 3-year borrowing was payable in monthly installments with principal repayments starting as of January 1, 2019. The loan was subject to a number of general covenants. The interest expense was calculated by applying the effective interest rate method to the initial fair value of the loan and to the actual cash outflows resulting from the payment of interest and repayment of the principal. The loan was subsequently carried at amortized cost.

The loan was repaid early, on November 16, 2020, at an amount equivalent to the principal, plus both the interest accrued at the nominal amount up to the date of repayment and the terminal payment.

In addition, the Company agreed to pay to TriplePoint a success fee upon an initial public offering of the Company or a sale of the Company. The obligation to make this success fee payment has been accounted for as an embedded derivative. In September 2021, the Company paid the TriplePoint success fee.

COVID loans

During 2020, the Company took advantage of financing opportunities put in place by governments in jurisdictions where it has its affiliates in order to support businesses during the spread of the COVID-19 pandemic.

The following loans were granted:

- On March 26, 2020, SOPHiA GENETICS SA was granted a $0.5 million (CHF 0.5 million) loan from Credit Suisse maturing on March 26, 2025. This loan carried an interest of 0% and was scheduled to be repaid in eight equal semi-annual installments starting on September 26, 2021. The Company repaid this loan early on March 26, 2021, using cash on hand.
- On May 29, 2020, SOPHiA GENETICS SAS was granted a $1.6 million (EUR 1.4 million) loan from Credit Agricole Pyrénées Gascogne maturing on May 31, 2021. This loan carried an interest rate of 0% and was subject to a 0.25% state guarantee fee. It was repaid on maturity.
- On May 29, 2020, SOPHiA GENETICS SA was granted a $1.0 million (CHF 1.0 million) loan from Credit Suisse maturing on January 31, 2021. This loan carried an interest rate of 1.175% and was repaid on maturity.

- On June 3, 2020, SOPHiA GENETICS Inc. was granted a $0.8 million loan from Citizens Bank under the PPP maturing on June 3, 2022. This loan carried an interest of 1% and was scheduled to be repaid in twelve monthly installments starting from July 3, 2021. The loan agreement allowed for the Company to apply for loan forgiveness if the Company used the proceeds for payroll and/or rental obligations within the 8-week period after the disbursement of the loan.

For the PPP loan, the Company was confident from inception of the loan that it would meet the conditions for non-repayment of the loan and accounted for it as a government grant. The loan proceeds were recognized as a reduction in employee benefit expenses within selling and marketing costs in the 8-week period after disbursement of the loan.

The Company submitted an application for loan forgiveness in January 2021 and the loan including interest due was confirmed to be forgiven on February 24, 2021.

Credit Suisse loan

On April 1, 2021, the Company entered into a credit agreement (the “Credit Facility”) with Credit Suisse that provides for maximum borrowings of up to $3.3. million (EUR 2.7 million). Borrowings under the Credit Facility accrue interest at 3.95% per annum and are repayable in installations over 36 months. Borrowings under the Credit Facility can only be used to finance laboratory automation equipment for next generation sequencing (“NGS”) purposes. As of the date of these consolidated financial statements, the Company had no borrowings outstanding under the Credit Facility.

During the period since January 1, 2020, the Company has not been subject to any externally imposed capital requirements.

25. TriplePoint success fee

Significant accounting estimates and judgements

The derivative included in the table below presents the change in fair value of a success fee payable to TriplePoint Capital LLC (“TriplePoint”), the providers of a loan repaid in 2020 (see Note 24 - “Borrowings”) upon an initial public offering of the Company or a sale of the Company. The amount of the success fee will be computed as the excess of the value per share realized in such a transaction over a strike price of $3.65 (CHF 3.65) multiplied by 6.5% of the committed loan facility of EUR 10 million translated to CHF at a rate of 1.16 and divided by the strike price of $3.65 (CHF 3.65).

Accounting Policies

In the third quarter of 2021, the Company paid the success fee payable to TriplePoint, which became due upon an IPO of the Company or a sale of the Company. The Company’s IPO in July 2021 triggered the success fee to become due. The approach used to determine the fair value of the derivative was based on a Monte Carlo simulation and accounted for as embedded derivative.

The following table presents the loss recognized by the Company on the derivative associated with the TriplePoint loan (in USD thousands):

	2021	2020	2019
As of January 1	**$ 1,024**	**$ 557**	**$ 447**
Loss on derivative	1,444	467	110
As of December 31	**$ 2,468**	**$ 1,024**	**$ 557**

Key assumptions in the valuation of the derivative in 2021 and 2020 included (in USD thousands when noted in USD):

	December 31,	
	2021	2020
Equity value of the Company	N/A	$465,307
Expected time of the sale or IPO	N/A	75% - 3 years 25% - 0.75 years
Volatility	N/A	50%

If the key assumptions were varied as indicated below, the derivative would have the values set out in the table below (in USD thousands):

	December 31,	
	2021	2020
Equity value of the Company +10%	N/A	1,179
Equity value of the Company -10%	N/A	864
Expected time of the IPO or sale 3 months earlier	N/A	1,039
Expected time of the IPO or sale 3 months later	N/A	1,016
Volatility +10%	N/A	1,055
Volatility -10%	N/A	993

As the derivative became payable in September 2021, the Company did not have any assumptions as of December 31, 2021 as the actual value was determined.

The Company recognized a loss of $1.4 million and a loss of $0.5 million to finance income (expense) on the Consolidated Statement of Loss for the year ended December 31, 2021 and 2020, respectively. In September 2021, the Company successfully negotiated a $0.4 million reduction of the success fee to $2.5 million from $2.9 million. The reduction resulted in a $0.4 million gain in Finance expense, net. The Company paid the $2.5 million success fee in September 2021.

26. Initial Public Offerings

On July 27, 2021, the Company completed its IPO in the United States on the Nasdaq Global Market (“Nasdaq”) under the trading ticker symbol “SOPH”. Trading on the Nasdaq commenced at market open on July 23, 2021. The Company completed the IPO of 13,000,000 common shares, at the IPO price of $18.00 per share, par value $0.05 (CHF 0.05). The IPO resulted in gross proceeds of $234.0 million. The Company incurred an estimated $22.3 million in issuance costs associated with the IPO, resulting in net proceeds of $211.7 million.

Concurrent with the IPO, the Company closed a private placement, in which it sold 1,111,111 ordinary shares to an affiliate of GE Healthcare. Gross proceeds from the private placement, before deducting estimated expenses payable, were $20 million. The Company incurred $0.4 million of issuance costs, resulting in net proceeds of $19.6 million.

On August 25, 2021, the underwriters of the IPO elected to exercise in part their option to purchase an additional 519,493 ordinary shares (“greenshoe”) at the IPO price of $18.00 per share. The greenshoe resulted in additional gross proceeds of $9.4 million. The Company incurred an additional $0.9 million of additional issuance costs, resulting in net proceeds of $8.5 million. With the addition of the underwriters’ option to purchase additional shares, the total number of shares sold in the Company’s IPO increased to 13,519,493 shares for aggregate gross proceeds, before deducting underwriting discounts and commissions and estimated fees and offering expenses, of $243.4 million.

As a result of the IPO, the Company paid a success fee related to the TriplePoint loan (Note 25 – TriplePoint success fee).

Immediately prior to the completion of the Company’s IPO and current with the private placement, the Company’s outstanding preferred shares converted on a one-to-one basis into ordinary shares.

27. Share capital issuance

On June 25, 2020, the Company issued 5,664,480 preferred F shares at a price per share of $11.53 per share, which resulted in gross proceeds of $65.3 million and, after deduction of transaction costs of $0.7 million, in net proceeds of $64.6 million.

On September 23, 2020, the Company issued 3,652,460 preferred F shares at a price per share of $11.89 per share, which resulted in gross proceeds of $ 43.4 and, after deduction of transaction costs of $0.4 million, in net proceeds of $43.0 million.

Pursuant to the Articles of Association, in the event of certain defined liquidation events, holders of the preferred F shares are entitled to receive the higher of (i) a pro rata share of the liquidation proceeds and (ii) one time the subscription price paid for the preferred F shares.

Pursuant to the Articles of Association, in the event of certain defined liquidation events, and subject to the liquidation preference of the preferred F shares, holders of the preferred E shares are entitled to receive the higher of (i) a pro rata share of the liquidation proceeds and (ii) one time the subscription price paid for the preferred E shares.

Pursuant to the Articles of Association, in the event of certain defined liquidation events, and subject to the liquidation preferences of the preferred F shares and of the preferred E shares, holders of the preferred D shares are entitled to receive the higher of (i) a pro rata share of the liquidation proceeds and (ii) one time the subscription price paid for the preferred D shares.

On June 30, 2021, the Company performed a one-to-twenty share split and converted all preferred shares to ordinary shares. Refer to Note 1 – “Share split - Company information and operations.”

On July 22, as part of the Company IPO, the Company converted all preferred shares to ordinary shares. Refer to Note 1- “Initial public offering – Company information and operations.”

At the next ordinary Annual General Meeting, the Board of Directors will not propose any dividend in respect of the year ended December 31, 2021.

28. Related parties

Related parties comprise the Company’s executive officers and directors, including their affiliates, and any person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control, with the Company.

Key management personnel comprised of six Executive Officers and Directors and six Non-Executive Directors for the year ended December 31, 2021. Key management personnel comprised of four Executive Officers and Directors and four Non-Executive Directors for the year ended December 31, 2020. Key management personnel comprised of three Executive Officers and Directors and three Non-Executive Directors for the year ended December 31, 2019.

Compensation for key management and non-executive directors recognized during the year comprised (in USD thousands):

	December 31,		
	2021	**2020**	**2019**
Salaries and other short-term employee benefits	$ 2,761	$ 1,155	$ 756
Pension costs	117	70	32
Share-based compensation expense	6,906	1,065	441
Other compensation	44	146	24
Total	**$ 9,828**	**$ 2,436**	**$ 1,253**

On March 25, 2021, the Board changed the strike price on 127,000 options granted to the CEO in September 2018 from $4.22 (CHF 4.00) to $3.33 (CHF 3.15). The Company calculated the fair value of these options using the same approach as that used to value share options granted since September 2020, which resulted in an increase of $0.1 million. This incremental cost is now being recognized as an expense over the period from March 25, 2021, until the end of the vesting period of the original grant.

On March 25, 2021, the Board also clarified the terms of an award made to the CEO on November 29, 2018. This award is conditional on the achievement by November 29, 2023, of a successful IPO that values the Company at a minimum of $1.0 billion. Further details of the award and its accounting treatment are set out in Note 23 - “Share-based compensation”.

Related parties participated in the sale of Series F preferred shares during the year to the following extent:

Name of shareholder	Number of preferred shares purchased
Alychlo NV	233,580
Generation IM Sustainable Fund III, L.P	389,300
Total	**622,880**

Three members of key management participated in share issuances in 2020 acquiring a total of 65,920 shares.

Share data have been revised to give effect to the share split explained in Note 1 - “Significant accounting policies— Share split.”

29. Commitments and contingencies

Commitments

The Company has commitments for future lease payments under short-term leases not recognized in the balance sheet amounting as of December 31, 2021 and 2020 of $0.3 million, and $0.4 million, respectively.

Contingencies

As of December 31, 2021, and 2020 the Company had no contingent assets or liabilities.

30. Financial instruments and risks

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

The Company hold the following financial instruments (in USD thousands):

	December 31,	
	2021	2020
Financial assets at amortized cost		
Cash and cash equivalents	$ 192,962	$ 74,625
Term deposits	72,357	22,720
Accounts receivable	5,621	6,363
Other financial non-current assets	1,405	984
Total financial assets at amortized cost	**$ 272,345**	**$ 104,692**
Financial assets at fair value through statement of loss		
Total financial assets	**$ 272,345**	**$ 104,692**
Financial liabilities at amortized cost		
Accounts payable	6,737	1,281
Accrued expenses	15,972	9,081
Borrowings	—	3,330
Lease liabilities	13,059	3,919
Total financial liabilities at amortized cost	**35,768**	**17,611**
Financial liabilities at fair value through statement of loss		
Derivative	—	1,024
Total financial liabilities	**$ 35,768**	**$ 18,635**

The Company’s exposure to various risks associated with the financial instruments is discussed in below in “Financial risk management.” The maximum exposure to credit risk at the end of the reporting period is the carrying amount of each class of financial assets mentioned above. See Note 13 - “Accounts receivable” for expected credit loss provisions on accounts receivable.

Fair value measurement

As of December 31, 2021 and 2020, the carrying amount was a reasonable approximation of fair value for the following financial assets and liabilities:

Financial assets

- Cash and cash equivalents
- Term deposits
- Accounts receivable
- Other non-current assets—lease deposits and lease receivable

Financial liabilities

- Accounts payable
- Accrued liabilities
- Lease liabilities
- Derivatives
- Borrowings

Fair value measurement methodology

The Company measures financial instruments at fair value at each balance sheet date. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability or, in the absence of a principal market, in the most advantageous market for the asset or liability.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the or by selling it to another market participant.

The Company uses valuation techniques to measure fair value maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the consolidated financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1—Quoted (unadjusted) market prices in active markets for identical assets or liabilities.

Level 2—Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable.

Level 3—Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

For assets and liabilities that are recognized in the consolidated financial statements at fair value on a recurring basis, the Company determines whether transfers have occurred between levels in the hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

Management determines the policies and procedures for both recurring fair value measurement and for non-recurring measurement with the involvement of experts and external consultants when needed.

Borrowings, current and non-current, are carried at amortized cost at a total carrying value of $0.0 million and $2.9 million and $0.0 million and $0.5 million as of December 31, 2021, and 2020, respectively. The fair value of these borrowings at

December 31, 2021, and 2020, $0.0 million $3.3, respectively. The fair value of borrowings is based on discounted cash flows using current borrowing rates. The basis of measurement is considered to be level 3 owing to the use of unobservable inputs, including own credit risk.

Derivatives, which were extinguished in July 2021, included within other current liabilities (see Note 21 - “Other non-current liabilities”), comprised of a success fee payable upon an initial public offering or a sale of the Company. This option was carried at fair value. The fair value of the option had been estimated using a Monte Carlo simulation. The basis of measurement is considered to be level 3 owing to the use of unobservable inputs, including the fair value of the Company’s own shares.

In 2021 and 2020 there were no significant changes in the business or economic circumstances that affect the fair value of the Company’s financial assets and financial liabilities. There were also no transfers between categories.

Financial risk management

Financial risks

Senior management regularly review the Company’s cash forecast and related risks. They also perform the risk assessment, define any necessary measures and ensure the monitoring of the internal control system.
The Company’s principal financial liabilities include accounts payable, lease liabilities and borrowings. The Company’s principal financial assets include cash and cash equivalents, term deposits and short-term investments and accounts receivable.

In the course of its business, the Company is exposed to a number of financial risks including credit and counterparty risk, funding and liquidity risk and market risk (i.e. foreign currency risk and interest rate risk). This note presents the Company’s objectives, policies, and processes for managing these risks.

Credit and counterparty risk management

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. The Company is exposed to credit risk from its operating activities, primarily accounts receivable.

Concentration risk arises when a number of counterparties are engaged in similar business activities, or activities in the same geographical region, or have economic features that would cause their ability to meet contractual obligations to be similarly affected by changes in economic, political or other conditions.

The Company’s policy with regard to assessing and providing for expected credit losses on accounts receivable is set out in Note 13 - “Accounts receivable.”

Credit risk from balances with banks and financial institutions is managed by the Company’s treasury department in accordance with the Company’s policy.

Financial transactions are predominantly entered into with investment grade financial institutions and in principle the
Company requires a minimum long-term rating of A3/A- for its cash investments. The Company may deviate from this requirement from time to time for operational reasons. The highest exposure to a single financial counterparty within cash and cash equivalents and term deposits and short-term investments amounted to $115.0 million and $45.7 million as of December 31, 2021 and 2020, respectively.

Other non-current financial assets include cash deposits for leases.

Funding and liquidity risk management

Funding and liquidity risk is the risk that a company may encounter difficulties in meeting its obligations associated with financial liabilities that are settled by delivering cash or other financial assets. Such risk may result from inadequate market depth or disruption or refinancing problems.

The Company views equity funding as its primary source of liquidity only partly complemented with revenue generated from the sale of the platform, products and services and some borrowings. The Company has no outstanding borrowing

facilities. Short term liquidity is managed based on projected cash flows. As of December 31, 2021 and 2020, the Company's liquidity consisted of $193.0 million and $74.6 million in cash and cash equivalents, respectively. On the basis of the current operating performance and liquidity position, management believes that the available cash balances will be sufficient for operating activities, working capital, interest, capital expenditures and scheduled debt repayments for the next 12 months.

The COVID-19 pandemic has negatively affected the Company's overall and non-COVID-19 analysis-related revenue. The Company's hospital customers prioritized COVID-19-related services during the pandemic. In addition, as a result of pandemic containment measures, some customers experienced disruptions in their operations, refocused their research and development priorities and operated at reduced capacity. As a result, there was a significant decrease in revenue and analysis volume in the second quarter of 2020. Although there has been a sustained recovery for the rest of the year, management believes that the Company experienced lower growth in revenue and analysis volume in 2020 as a result of the COVID-19 pandemic than it otherwise would have achieved. Given the sustained recovery in 2020 and 2021, management does not believe the COVID-19 pandemic will have a significant impact on the Company's ability to continue as a going concern.

The table below summarizes the maturity profile of the Company's financial liabilities based on contractual undiscounted cashflows (in USD thousands):

	Net carrying amount	Within 1 year	Between 1 and 5 years	After 5 years	Total
December 31, 2021					
Lease liabilities	$ 13,059	$ 2,018	$ 8,467	$ 4,075	$ 14,560
Accounts payable	6,737	6,737	—	—	6,737
Accrued expenses	15,972	15,972	—	—	15,972
Total contractual liabilities	**$ 35,768**	**$ 24,727**	**$ 8,467**	**$ 4,075**	**$ 37,269**
December 31, 2020					
COVID CHF 1M	1,132	1,137	—	—	1,137
COVID CHF 500K	507	71	497	—	568
COVID EUR 1.4M	1,691	1,718	—	—	1,718
Total loans	**$ 3,330**	**$ 2,926**	**$ 497**	**$ —**	**$ 3,423**
Lease liabilities	3,919	1,134	3,005	14	4,153
Accounts payable	1,281	1,281	—	—	1,281
Accrued expenses	9,081	1,281	—	—	1,281
Other financial non-current liabilities	1,024	—	1,024	—	1,024
Total contractual liabilities	**$ 18,635**	**$ 6,622**	**$ 4,526**	**$ 14**	**$ 11,162**

Market risk

Market risk includes currency risk and interest rate risk.

Currency risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates.

The significant exchange rates that have been applied to these consolidated financial statements are listed below:

	December 31,		For the twelve months ended December 31,		
	2021	2020	2021	2020	2019
Currency	Spot rate	Spot rate	Average rate	Average rate	Average rate
USD/CHF	0.91210	0.88030	0.91437	0.94703	0.99467
USD/EUR	0.88290	0.81490	0.84579	0.88423	0.89154
USD/GBP	0.74190	0.73260	0.72707	0.78132	0.78588
USD/BRL	5.57130	5.19400	5.39288	5.06281	3.92513

The sensitivity of the Company's income to possible changes in foreign exchange rates is measured at the local entity level as it depends on the functional currency of each entity. As of December 31, 2021 and 2020, the Company was exposed principally to movements in four cross currency pairs. The sensitivity of the Company's loss before tax to such changes was as follows (in USD thousands):

	December 31,		
	2021	2020	2019
Increase / (decrease) in USD/CHF exchange rate by 10%	19,499 / (19,499)	1,453 / (1,453)	741 / (741)
Increase / (decrease) in EUR/CHF exchange rate by 10%	648 / (648)	836 / (836)	410 / (410)
Increase / (decrease) in GBP/CHF exchange rate by 10%	(18) / 18	351 / (351)	328 / (328)
Increase / (decrease) in USD/EUR exchange rate by 10%	726 / (726)	155 / (155)	322 / (322)

The Company's exposure to foreign currency changes for all other currencies is not material. The significant increase/decrease between USD/CHF resulted from the Company's IPO, which occurred in USD. The Company does not use derivative financial instruments to hedge exposures and under no circumstances may enter into derivative instruments for speculative purposes.

The sensitivity of the Company's reported equity or net assets to possible changes in foreign exchange rates is measured at the consolidated level as it depends on the presentation currency selected for the consolidated financial statements. Such effects are reported not in income but in the currency translation account within other reserves. As of December 31, 2021 and 2020 the sensitivity of the Company's equity to such changes, measured against the USD, was as follows (in USD thousands):

	December 31,	
	2021	2020
Increase / (decrease) in USD/CHF exchange rate by 10%	54 / (54)	11,279 / (11,279)
Increase / (decrease) in USD/EUR exchange rate by 10%	(89) / 89	467 / (467)
Increase / (decrease) in USD/GBP exchange rate by 10%	(27) / 27	211 / (211)
Increase / (decrease) in USD/BRL exchange rate by 10%	77 / (77)	64 / (64)

Interest rate risk

The Company's cash and cash equivalents and term deposits are subject to market risk associated with interest rate fluctuations. Fixed rate securities may have their market value adversely affected due to a rise in interest rates. The Company conclude fluctuations in the interest rate did not have a material impact on our cash equivalents and term deposit balances.

The Company's principal interest-bearing liabilities comprise three COVID-related government loans, which haves fixed interest rates between 0% and 1.175%. As a result, the Company has no cash flow risk and only a minimal fair value risk associated with its interest-bearing debt.

31. Capital management

The Company considers equity as equivalent to the IFRS equity on the balance sheet (including share capital, share premium and all other equity reserves attributable to the owners of the Company).

The primary objective of the Company's capital management is to maximize shareholder value. The Board regularly reviews its shareholders' return strategy. For the foreseeable future, the Board will maintain a capital structure that supports the Company's strategic objectives through managing funding and liquidity risks and optimizing shareholder return.

As of December 31, 2021 and 2020, the Company's cash and cash equivalents amounted to $193.0 million and $74.6 million, respectively. In addition, its outstanding debt amounted to only $0.0 million and $3.3. million as of December 31, 2021 and 2020, respectively. The Company's government-issued COVID loans have below-market interest rates, of which all have since been repaid as of December 31, 2021.

The Board of Directors believes that the Company has sufficient financial resources to meet all of its obligations for at least the next twelve months. Moreover, the Company is not exposed to liquidity risk through requests for early repayment of loans.

32. Events after the reporting date

The Company has evaluated, for potential recognition and disclosure, events that occurred prior to the date at which the consolidated financial statements were available to be issued. There were no material subsequent events.

Exhibit 2.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Changes in Our Share Capital During the Last Three Fiscal Years

As of December 31, 2021, our share capital as registered with the commercial register of the Canton of Vaud, Switzerland (the "Commercial Register") amounted to 63,857,604 ordinary shares, all of which were outstanding, each with a par value of CHF 0.05 per share.

In this section, share amounts are presented as of the date of the relevant transaction. Since January 1, 2018, our share capital has changed as follows:

- On May 29, 2020, our share capital as registered with the Commercial Register was updated to reflect the issuance of 39,975 ordinary shares out of conditional share capital;
- On June 25, 2020, our share capital as registered with the Commercial Register on June 25, 2020, was increased by issuing 283,224 Series F preferred shares;
- On September 23, 2020, our share capital as registered with the Commercial Register on September 29, 2020 was increased by issuing 182,623 Series F preferred shares;
- On June 25, 2021, our share capital as registered with the Commercial Register was updated to reflect the issuance 74,265 ordinary shares out of conditional share capital;
- In the one-to-twenty share split of all issued shares effected on June 30, 2021, each of our issued shares was split into 20 shares of the same class with a par value of CHF 0.05 per share;
- On July 26, 2021, our entire share capital as registered with the Commercial Register on July 27, 2021 was converted into ordinary shares;
- On July 26, 2021, our share capital as registered with the Commercial Register on July 27, 2021 was increased by issuing 14,111,111 ordinary shares; and
- On August 24, 2021, our share capital as registered with the Commercial Register on August 25, 2021 was increased by issuing 519,493 ordinary shares.

Articles of Association

Ordinary Capital Increase, Authorized and Conditional Share Capital

Under Swiss law, we may increase our share capital (*capital-actions*) with a resolution of the general meeting of shareholders (ordinary capital increase) that must be carried out by the board of directors within three months of the respective general meeting in order to become effective. Under our articles of association and Swiss law, in the case of subscription and increase against payment of contributions in cash, a resolution passed by an absolute majority of the shares represented at the general meeting of shareholders is required. In the case of subscription and increase against contributions in kind or to fund acquisitions in kind, when shareholders' statutory pre-emptive subscription rights or advance subscription rights are limited or withdrawn or where transformation of freely disposable equity into share capital is involved, a resolution passed by two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the par value of the shares represented is required.

Furthermore, under the Swiss Code of Obligations (*Code des obligations*) (the "Code of Obligations"), our shareholders, by a resolution passed by two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the par value of the shares represented, may empower our board of directors to issue shares of a specific aggregate par value up to a maximum of 50% of the share capital in the form of:

- conditional share capital (*capital-actions conditionnel*) for the purpose of issuing shares in connection with, among other things, (i) option and conversion rights granted in connection with warrants and convertible bonds of the Company or one of our subsidiaries or (ii) grants of rights to employees, members of our board of directors or consultants or to our subsidiaries or other persons providing services to the Company or a subsidiary to subscribe for new shares (conversion or option rights); or

- authorized share capital (*capital-actions autorisé*) to be utilized by the board of directors within a period determined by the shareholders but not exceeding two years from the date of the shareholder approval.

Pre-emptive and Advance Subscription Rights

Pursuant to the Code of Obligations, shareholders have pre-emptive subscription rights (*droits de souscription préférentiels*) to subscribe for new issuances of shares. With respect to conditional capital in connection with the issuance of conversion rights, convertible bonds or similar debt instruments, shareholders have advance subscription rights (*droit de souscrire préalablement*) for the subscription of such conversion rights, convertible bonds or similar debt instruments.

A resolution passed at a general meeting of shareholders by two-thirds of the shares represented and the absolute majority of the par value of the shares represented may authorize our board of directors to withdraw or limit pre-emptive subscription rights or advance subscription rights in certain circumstances.

If pre-emptive subscription rights are granted, but not exercised, the board of directors may allocate the unexercised pre-emptive subscription rights at its discretion.

Our Authorized Share Capital

Under our articles of association, our board of directors is authorized at any time, including to prevent takeovers and changes in control, until June 27, 2023 at the latest to increase our nominal share capital by a maximum aggregate amount of CHF 1,450,000 through the issuance of not more than 29,000,000 shares, which would have to be fully paid-in, each with a par value of CHF 0.05 per share.

Increases in partial amounts are permitted. The board of directors has the power to determine the date of issue, the conditions for the exercise of pre-emptive subscription rights, the type of contributions, the issue price and the date on which the dividend entitlement starts.

With respect to our authorized share capital, the board of directors is authorized by our articles of association to withdraw or to limit the pre-emptive subscription rights of shareholders, and to allocate them to third parties or to us, in the event that the newly issued shares are issued under the following circumstances:

- if the issue price of the new registered shares is determined by reference to the market price;

- for raising of capital (including private placements) in a fast and flexible manner, which would not be possible, or might only be possible with great difficulty or delays or at significantly less favorable conditions, without the exclusion of the statutory pre-emptive subscription rights of the existing shareholders;

- for the acquisition of an enterprise, parts of an enterprise or participations, for the acquisition of products, intellectual property or licenses by or for investment projects of the Company or any of its group companies, or for the financing or refinancing of any of such transactions through a placement of shares;

- for purposes of broadening the shareholder constituency of the Company in certain geographic, financial or investor markets, for purposes of the participation of strategic partners, or in connection with the listing of new shares on domestic or foreign stock exchanges;
- for purposes of granting an over-allotment option or an option to purchase additional shares in a placement or sale of shares to the respective initial purchaser(s) or underwriter(s);
- for the participation of members of the board of directors or equivalent corporate body, members of the executive committee, employees, contractors, consultants or other persons performing services for the benefit of the Company or any of its group companies;
- following a shareholder or a group of shareholders acting in concert having accumulated shareholdings in excess of 15% of our share capital registered in the Commercial Register without having submitted to all other shareholders a takeover offer recommended by the board of directors;
- for the defense of an actual, threatened or potential takeover bid, that the board of directors, upon consultation with an independent financial adviser retained by it, has not recommended or will not recommend to the shareholders for acceptance on the basis that the board of directors has not found the takeover bid to be financially fair to the shareholders or not to be in the Company's interest; or
- for other valid grounds in the sense of Article 652b para. 2 of the Code of Obligations.

This authorization is exclusively linked to the particular available authorized share capital set out in the respective article. If the period to increase our share capital out of authorized share capital lapses without having been used by the board of directors, the authorization to withdraw or to limit the pre-emptive subscription rights lapses simultaneously with such capital.

Our Conditional Share Capital

Conditional Share Capital for Financing, Acquisitions and Other Purposes

Our nominal share capital may be increased, including to prevent takeovers and changes in control, by a maximum aggregate amount of CHF 870,000 through the issuance of not more than 17,400,000 ordinary shares, which would have to be fully paid-in, each with a par value of CHF 0.05 per share, by the exercise of option and conversion rights granted in connection with warrants, convertible bonds or similar instruments of the Company or one of our subsidiaries. Shareholders will not have pre-emptive subscription rights in such circumstances, but will have advance subscription rights to subscribe for such warrants, convertible bonds or similar instruments. The holders of warrants, convertible bonds or similar instruments are entitled to the new shares upon the occurrence of the applicable conversion feature.

When issuing convertible bonds, warrants or similar instruments, the board of directors is authorized to withdraw or to limit the advance subscription right of shareholders:

- for the purpose of financing or refinancing, or the payment for, the acquisition of enterprises, parts of enterprises, participations, intellectual property rights, licenses or investments;
- if the issuance occurs in domestic or international capital markets, including private placements;
- following a shareholder or a group of shareholders acting in concert having accumulated shareholdings in excess of 15% of the share capital registered in the Commercial Register without having submitted to all other shareholders a takeover offer recommended by the board of directors; or
- for the defense of an actual, threatened or potential takeover bid that the board of directors, upon consultation with an independent financial adviser retained by it, has not recommended or will not recommend to the shareholders to accept on the basis that the board of directors has not found the takeover bid to be financially fair to the shareholders or not to be in the Company's interest.

To the extent that the advance subscription rights are withdrawn or limited, (i) the convertible bonds, warrants or similar instruments are to be issued at market conditions; (ii) the term to exercise the convertible bonds, warrants or similar instruments may not exceed ten years from the date of issue of the respective instrument and (iii) the conversion, exchange or exercise price of the convertible bonds, warrants or similar instruments has to be set with reference to or be subject to change based upon the valuation of the Company's equity or market conditions.

Conditional Share Capital for Employee Participation

Our nominal share capital may, to the exclusion of the pre-emptive subscription rights and advance subscription rights of shareholders, be increased by a maximum aggregate amount of CHF 580,000 through the (direct or indirect) issuance of not more than 11,600,000 ordinary shares, which would have to be fully paid-in, each with a par value of CHF 0.05 per share, by the exercise of options, other rights to receive shares or conversion rights that have been granted to employees, members of the board of directors or equivalent corporate body, contractors or consultants of the Company or of one of our subsidiaries or other persons providing services to the Company or to a subsidiary.

Uncertificated Securities

Our shares are in the form of uncertificated securities (*droits-valeurs*, within the meaning of Article 973c of the Code of Obligations). In accordance with Article 973c of the Code of Obligations, we will maintain a non-public register of uncertificated securities (*registre des droits-valeurs*). We may at any time convert our shares from one form into another form (including uncertificated securities into registered uncertificated securities (*droits-valeurs inscrits*, within the meaning of Article 973d of the Code of Obligations), share certificates (or global certificates), one kind of certificate into another, or share certificates, global certificates or registered uncertificated securities into uncertificated securities. Following entry in the share register, a shareholder may at any time request from us a written confirmation in respect of his or her shares. Shareholders are not entitled, however, to request the conversion and/or printing and delivery of share certificates. We may print and deliver certificates for shares at any time.

General Meeting of Shareholders

Ordinary/Extraordinary Meetings, Powers

The general meeting of shareholders is our supreme corporate body. Under Swiss law, an annual general meeting of shareholders must be held annually within six months after the end of a corporation's financial year. In our case, this generally means on or before June 30. In addition, extraordinary general meetings of shareholders may be held.

The following powers are vested exclusively in the general meeting of shareholders:

- adopting and amending the articles of association, including the change of a company's purpose or domicile;
- electing the members of the board of directors, the chairman of the board of directors, the members of the compensation committee, the auditors and the independent proxy;
- approving the management report, the annual statutory and consolidated financial statements and deciding on the allocation of profits as shown on the balance sheet, in particular with regard to dividends;
- approving the aggregate amount of compensation of members of the board of directors and the executive committee;
- discharging the members of the board of directors and the executive committee from liability with respect to their conduct of business;

- dissolving a company with or without liquidation; and
- deciding matters reserved to the general meeting of shareholders by law or the articles of association or submitted to it by the board of directors.

An extraordinary general meeting of shareholders may be called by a resolution of the board of directors or the general meeting of shareholders or, under certain circumstances, by a company's auditor, liquidator or the representatives of bondholders, if any. In addition, the board of directors is required to convene an extraordinary general meeting of shareholders if shareholders representing at least 10% of our share capital request such general meeting of shareholders in writing. Such request must set forth the items to be discussed and the proposals to be acted upon. The board of directors must convene an extraordinary general meeting of shareholders and propose financial restructuring measures if, based on our stand-alone annual statutory balance sheet, half of our share capital and statutory reserves are not covered by our assets.

Voting and Quorum Requirements

Shareholder resolutions and elections (including elections of members of the board of directors) require the affirmative vote of the absolute majority of shares represented at the general meeting of shareholders, unless otherwise stipulated by law or our articles of association.

Under Swiss law and our articles of association, a resolution of the general meeting of the shareholders passed by two-thirds of the shares represented at the meeting and the absolute majority of the par value of the shares represented is required for:

- amending the Company's corporate purpose;
- creating shares with privileged voting rights;
- cancelling or amending the transfer restrictions of shares;
- creating authorized or conditional share capital;
- increasing share capital out of equity, against contributions in-kind or for the purpose of acquiring specific assets and granting specific benefits;

  limiting or withdrawing shareholders' pre-emptive subscription rights;
- changing a company's domicile;
- amending or repealing certain of the authorizations of the board of directors to place shares with affiliates or third parties without existing shareholders having statutory pre-emptive rights, or amending or repealing the voting and recording restrictions, the provision setting a maximum board size or the indemnification provision for the board of directors and the executive committee set forth in our articles of association;
- converting registered shares into bearer shares;
- removing the chairman or any member of the board of directors before the end of his or her term of office; and
- dissolving or liquidating the Company.

The same voting requirements apply to resolutions regarding transactions among corporations based on Switzerland's Federal Act on Mergers, Demergers, Transformations and the Transfer of Assets of 2003, as amended (the "Swiss Merger Act"). See "—Articles of Association—Compulsory Acquisitions; Appraisal Rights."

In accordance with Swiss 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 Nasdaq listing standards, which require 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.

Notice

General meetings of shareholders must be convened by the board of directors at least 20 days before the date of the meeting. The general meeting of shareholders is convened by way of a notice appearing in our official publication medium, currently the Swiss Official Gazette of Commerce. Registered shareholders may also be informed by ordinary mail or e-mail. The notice of a general meeting of shareholders must state the items on the agenda, the motions to the shareholders and, in case of elections, the names of the nominated candidates. A resolution on a matter which is not on the agenda may not be passed at a general meeting of shareholders, except for motions to convene an extraordinary general meeting of shareholders or to initiate a special investigation, on which the general meeting of shareholders may vote at any time. No previous notification is required for motions concerning items included in the agenda or for debates that do not result in a vote.

All of the owners or representatives of our shares may, if no objection is raised, hold a general meeting of shareholders without complying with the formal requirements for convening general meetings of shareholders (a universal meeting). This universal meeting of shareholders may discuss and pass binding resolutions on all matters within the purview of the general meeting of shareholders, provided that the owners or representatives of all the shares are present at the meeting.

Agenda Requests

Pursuant to Swiss law and our articles of association, one or more shareholders whose combined shareholdings represent the lesser of (i) one tenth of our share capital and (ii) an aggregate par value of at least CHF 1,000,000 may request that an item be included in the agenda for a general meeting of shareholders. To be timely, the shareholder's request must be received by us generally at least 45 calendar days in advance of the meeting. The request must be made in writing and contain, for each of the agenda items, the following information:

- a brief description of the business desired to be brought before the general meeting of shareholders and the reasons for conducting such business at the general meeting of shareholders;
- the motions regarding the agenda item;
- the name and address, as they appear in the share register, of the shareholder proposing such business;
- the number of shares which are beneficially owned by such shareholder (including documentary support of such beneficial ownership);
- the dates upon which the shareholder acquired such shares;
- any material interest of the proposing shareholder in the proposed business;
- a statement in support of the matter; and
- all other information required under the applicable laws and stock exchange rules.

In addition, if the shareholder intends to solicit proxies from the shareholders of a company, such shareholder shall notify the company of this intent in accordance with SEC Rule 14a-4 and/or Rule 14a-8.

Our business report, the compensation report and the auditor's report must be made available for inspection by the shareholders at our registered office no later than 20 days prior to the general meeting of shareholders. Shareholders of record may be notified of this in writing.

Voting Rights

Each of our ordinary shares entitles a holder to one vote. The ordinary shares are not divisible. The right to vote and the other rights of share ownership may only be exercised by shareholders (including any nominees) or usufructuaries who are entered in the share register at a cut-off date determined by the board of directors. Those entitled to vote in the general meeting of shareholders may be represented by the independent proxy holder (annually elected by the general meeting of shareholders), by its legal representative or by another registered shareholder with written authorization to act as proxy. The chairman has the power to decide whether to recognize a power of attorney.

Our articles of association contain provisions that prevent investors from acquiring and exercising voting rights exceeding 15% of our issued share capital. Specifically, if an individual or legal entity acquires ordinary shares and, as a result, directly or indirectly, has voting rights with respect to more than 15% of the registered share capital recorded in the Commercial Register, the registered shares exceeding the limit of 15% shall be entered in the share register as shares without voting rights (*limitation à l'inscription*). This restriction applies equally to parties acting in concert and to shares held or acquired via a nominee, including via Cede & Co., New York (or any successor), as the nominee of The Depository Trust Company ("DTC"), New York, acting in its capacity as clearing nominee. Specifically, if shares are being held by a nominee for third-party beneficiaries, which control (alone or together with third parties) voting rights with respect to more than 15% of the share capital recorded in the Commercial Register, our articles of association provide that the board of directors may cancel the registration of the shares with voting rights held by such nominee in excess of the limit of 15%. Our articles of association also contain provisions that allow the board of directors to make the registration with voting rights of shares held by a nominee subject to conditions, limitations and reporting requirements or to impose or adjust such conditions, limitations and requirements once registered.

Furthermore, our articles of association contain provisions that prevent shareholders and proxies from exercising voting rights attached to their own or represented ordinary shares that would collectively exceed 15% the share capital recorded in the commercial register. This restriction applies equally to parties acting in concert and to shares held or acquired via a nominee, as described above, but not to the independent proxy acting as proxy on behalf of shareholders.

Notwithstanding the above, any shareholders holding more than 15% prior to the filing and effectiveness of our amended and restated articles of association will remain registered with voting rights for such shares and will be able to exercise their voting rights in full. Furthermore, the board of directors may in special cases approve exceptions to these restrictions.

Dividends and Other Distributions

Our board of directors may propose to shareholders that a dividend or other distribution be paid but cannot itself authorize the distribution. Dividend payments require a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders. In addition, our auditors must confirm that the dividend proposal of our board of directors conforms to Swiss statutory law and our articles of association.

Under Swiss law, we may pay dividends only if we have sufficient distributable profits from the previous business year (*bénéfice de l'exercice*), or brought forward from the previous business years (*report des bénéfices*) or if we have distributable reserves (*réserves à libre disposition*), each as evidenced by the Company's audited stand-alone statutory balance sheet prepared pursuant to Swiss law and after allocations to reserves required by Swiss law and by the articles of association have been deducted. We are not permitted to pay interim dividends out of profit of the current business year.

Distributable reserves are generally booked either as “free reserves” (*réserves libres*) or as “reserve from capital contributions” (*apports de capital*). Under the Code of Obligations, if our general reserves (*réserve générale*) amount to less than 20% of our share capital recorded in the Commercial Register (i.e., 20% of the aggregate par value of our issued capital), then at least 5% of our annual profit must be retained as general reserves. In addition, if our general reserves amount to less than 50% of our share capital recorded in the Commercial Register, 10% of the amounts distributed beyond payment of a dividend of 5% must be retained as general reserves. The Code of Obligations permits us to accrue additional general reserves. Further, a purchase of our own shares (whether by us or a subsidiary) reduces the distributable reserves in an amount corresponding to the purchase price of such own shares. Finally, the Code of Obligations under certain circumstances requires the creation of revaluation reserves, which are not distributable.

Distributions out of issued share capital (i.e., the aggregate par value of our issued shares) are not allowed and may be made only by way of a share capital reduction. Such a capital reduction requires a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders. The resolution of the shareholders must be recorded in a public deed and a special audit report must confirm that claims of our creditors remain fully covered despite the reduction in our share capital recorded in the Commercial Register. Our share capital may be reduced below CHF 100,000 only if and to the extent that at the same time the statutory minimum share capital of CHF 100,000 is reestablished by sufficient new, fully paid-up capital. Upon approval by the general meeting of shareholders of the capital reduction, the board of directors must give public notice of the capital reduction resolution in the Swiss Official Gazette of Commerce three times and notify creditors that they may request, within two months of the third publication, satisfaction of or security for their claims. The reduction of our share capital may be implemented only after expiration of this time limit.

Our board of directors determines the date on which the dividend entitlement starts. Dividends are usually due and payable shortly after the shareholders have passed the resolution approving the payment, but shareholders may also resolve at the annual general meeting of shareholders to pay dividends in quarterly or other installments.

Transfer of Shares

Shares in uncertificated form (*droits-valeurs*) may only be transferred by way of assignment. Shares or the beneficial interest in shares, as applicable, credited in a securities account may only be transferred when a credit of the relevant intermediated securities to the acquirer’s securities account is made in accordance with applicable rules. Our articles of association provide that in the case of securities held with an intermediary such as a registrar, transfer agent, trust corporation, bank or similar entity, any transfer, grant of a security interest or usufructuary right in such intermediated securities and the appurtenant rights associated therewith requires the cooperation of the intermediary in order for such transfer, grant of a security interest or usufructuary right to be valid against us.

Voting rights may be exercised only after a shareholder has been entered in the share register (*registre des actions*) with his or her name and address (in the case of legal entities, the registered office) as a shareholder with voting rights. For a discussion of the restrictions applicable to the control and exercise of voting rights, see “—Articles of Association—Voting Rights.”

Inspection of Books and Records

Under the Code of Obligations, a shareholder has a right to inspect the share register with respect to his or her own shares and otherwise to the extent necessary to exercise his or her shareholder rights. No other person has a right to inspect the share register. Our books and correspondence may be inspected with the express authorization of the general meeting of shareholders or by resolution of the board of directors and subject to the safeguarding of our business secrets and other legitimate interests. See “—Comparison of Swiss Law and Delaware Law—Inspection of books and records.”

Special Investigation

If the shareholders' inspection rights as outlined above prove to be insufficient in the judgment of the shareholder, any shareholder may propose to the general meeting of shareholders that specific facts be examined by a special examiner in a special investigation. If the general meeting of shareholders approves the proposal, we or any shareholder may, within 30 calendar days after the general meeting of shareholders, request a court at our registered office (currently Saint-Sulpice, Canton of Vaud, Switzerland) to appoint a special examiner. If the general meeting of shareholders rejects the request, one or more shareholders representing at least 10% of our share capital or holders of shares in an aggregate par value of at least CHF 2,000,000 may request that the court appoint a special examiner. The court will issue such an order if the petitioners can demonstrate that the board of directors, any member of the board of directors or our executive committee infringed the law or our articles of association and thereby caused damages to the Company or the shareholders. The costs of the investigation would generally be allocated to us and only in exceptional cases to the petitioners.

Compulsory Acquisitions; Appraisal Rights

Business combinations and other transactions that are governed by the Swiss Merger Act (i.e., mergers, demergers, transformations and certain asset transfers) are binding on all shareholders. A statutory merger or demerger requires approval of two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the par value of the shares represented.

If a transaction under the Swiss Merger Act receives all of the necessary consents, all shareholders are compelled to participate in such transaction.

Swiss corporations may be acquired by an acquirer through the direct acquisition of the shares of the Swiss corporation. The Swiss Merger Act provides for the possibility of a so-called "cash-out" or "squeeze-out" merger with the approval of holders of 90% of the issued shares. In these limited circumstances, minority shareholders of the corporation being acquired may be compensated in a form other than through shares of the acquiring corporation (for instance, through cash or securities of a parent corporation of the acquiring corporation or of another corporation). For business combinations effected in the form of a statutory merger or demerger and subject to Swiss law, the Swiss Merger Act provides that if equity rights have not been adequately preserved or compensation payments in the transaction are unreasonable, a shareholder may request the competent court to determine a reasonable amount of compensation.

In addition, under Swiss law, the sale of "all or substantially all of our assets" by us may require the approval of two-thirds of the number of shares represented at a general meeting of shareholders and the absolute majority of the par value of the shares represented. Whether a shareholder resolution is required depends on the particular transaction, including whether the following test is satisfied:

- a core part of our business is sold, without which it is economically impracticable or unreasonable to continue to operate the remaining business;
- our assets, after the divestment, are not invested in accordance with our corporate purpose as set forth in the articles of association; and
- the proceeds of the divestment are not earmarked for reinvestment in accordance with our corporate purpose but, instead, are intended for distribution to our shareholders or for financial investments unrelated to our corporate purpose.

A shareholder of a Swiss corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights. As a result, such shareholder may, in addition to the consideration (be it in shares or in cash) receive an additional amount to ensure that the shareholder receives the fair value of the shares held by the shareholder. Following a statutory merger or demerger, pursuant to the Swiss Merger Act, shareholders can file an appraisal action against the surviving company. If the consideration is deemed inadequate, the court will determine an adequate compensation payment.

Board of Directors

Our articles of association provide that the board of directors shall consist of at least three and not more than seven members.

The members of the board of directors and the chairman are elected annually by the general meeting of shareholders for a period until the completion of the subsequent annual general meeting of shareholders and are eligible for re-election. Each member of the board of directors must be elected individually.

Powers

The board of directors has the following non-delegable and inalienable powers and duties:

- the ultimate direction of the business of the Company and issuing of the relevant directives;
- laying down the organization of the Company;
- formulating accounting procedures, financial controls and financial planning;
- nominating and removing persons entrusted with the management and representation of the Company and regulating the power to sign for the Company;
- the ultimate supervision of those persons entrusted with management of the Company, with particular regard to adherence to law, our articles of association and regulations and directives of the Company;
- issuing the business report and the compensation report, and preparing for the general meeting of shareholders and carrying out its resolutions; and
- informing the court in case of over-indebtedness.

The board of directors may, while retaining such non-delegable and inalienable powers and duties, delegate some of its powers, in particular direct management, to a single or to several of its members, committees or to third parties (such as executive officers) who need be neither members of the board of directors nor shareholders. Pursuant to Swiss law and our articles of association, details of the delegation and other procedural rules such as quorum requirements have been set in the organizational rules established by the board of directors.

Indemnification of Executive Officers and Directors

Subject to Swiss law, our articles of association provide for indemnification of the existing and former members of the board of directors and the executive committee and their heirs, executors and administrators against liabilities arising in connection with the performance of their duties in such capacity, and permit us to advance the expenses of defending any act, suit or proceeding to our directors and executive officers to the extent not included in insurance coverage or advanced by third parties.

In addition, under general principles of Swiss employment law, an employer may be required to indemnify an employee against losses and expenses incurred by such employee in the proper execution of his or her duties under the employment agreement with the employer. See “—Comparison of Swiss Law and Delaware Law—Indemnification of directors and executive officers and limitation of liability.”

Conflict of Interest, Management Transactions

Swiss law does not have a general provision regarding conflicts of interest. However, the Code of Obligations contains a provision that requires our directors and executive officers to safeguard the Company’s interests and imposes a duty of loyalty and duty of care on our directors and executive officers. This rule is generally understood to disqualify directors and executive officers from participation in decisions that directly affect them. Our directors and executive officers are personally liable to us for

breaches of these obligations. In addition, Swiss law contains provisions under which directors and all persons engaged in the Company's management are liable to the Company, each shareholder and the Company's creditors for damages caused by an intentional or negligent violation of their duties. Furthermore, Swiss law contains a provision under which payments made to any of the Company's shareholders or directors or any person related to any such shareholder or director, other than payments made at arm's length, must be repaid to the Company if such shareholder or director acted in bad faith.

Our board of directors has adopted a Code of Ethics and other policies that cover a broad range of matters, including the handling of conflicts of interest.

Principles of the Compensation of the Board of Directors and the Executive Committee

Pursuant to Swiss law, beginning at our first annual general meeting as a public company in 2022, our shareholders must annually approve the aggregate amount of compensation of the board of directors and the persons whom the board of directors has, fully or partially, entrusted with the management (which we refer to as our "executive committee") of the Company. All of our executive officers named in "Management" are deemed to be members of our executive committee.

The board of directors must issue, on an annual basis, a written compensation report that must be reviewed by our auditors. The compensation report must disclose all compensation granted by the Company, directly or indirectly, to current members of the board of directors and the executive committee and, to the extent related to their former role within the Company or not on customary market terms, to former members of the board of directors and former executive officers.

The disclosure concerning compensation, loans and other forms of indebtedness must include the aggregate amount for the board of directors and the executive committee, respectively, as well as the particular amount for each member of the board of directors and for the highest-paid executive officer, specifying the name and function of each of these persons.

We are prohibited from granting certain forms of compensation to members of our board of directors and executive committee, such as:

- severance payments (compensation due until the termination of a contractual relationship does not qualify as severance payment);
- advance compensation;

  incentive fees for the acquisition or transfer of companies, or parts thereof, by the Company or by companies being directly or indirectly controlled by us;
- loans, other forms of indebtedness, pension benefits not based on occupational pension schemes and performance-based compensation not provided for in the articles of association; and
- equity-based compensation not provided for in the articles of association.

Compensation to members of the board of directors and the executive committee for activities in entities that are directly or indirectly controlled by the Company is prohibited if (i) the compensation would be prohibited if it were paid directly by the Company, (ii) the articles of association do not provide for it, or (iii) the compensation has not been approved by the general meeting of shareholders.

Beginning in 2022, the general meeting of shareholders will annually vote on the proposals of the board of directors with respect to:

- the maximum aggregate amount of compensation of the board of directors for the term of office until the next annual general meeting of shareholders;

- the maximum aggregate amount of fixed compensation of the executive committee for the following financial year; and
- the maximum aggregate amount of variable compensation of the executive committee for the current financial year.

The board of directors may submit for approval at the general meeting of shareholders deviating or additional proposals relating to the same or different periods.

If, at the general meeting of shareholders, the shareholders do not approve a compensation proposal of the board of directors, the board of directors must prepare a new proposal, taking into account all relevant factors, and submit the new proposal for approval by the same general meeting of shareholders at a subsequent extraordinary general meeting of shareholders or the next annual general meeting of shareholders.

In addition to fixed compensation, members of the board of directors and the executive committee may be paid variable compensation depending on the achievement of certain performance criteria. The performance criteria may include individual targets, targets of the Company or parts thereof and targets in relation to the market, other companies or comparable benchmarks, taking into account the position and level of responsibility of the recipient of the variable compensation. The board of directors or, where delegated to it, the compensation committee shall determine the relative weight of the performance criteria and the respective target values.

Compensation may be paid or granted in the form of cash, shares, financial instruments, in kind, or in the form of other types of benefits. The board of directors or, where delegated to it, the compensation committee shall determine grant, vesting, exercise, restriction and forfeiture conditions.

Borrowing Powers

Neither Swiss law nor our articles of association restrict our power to borrow and raise funds. The decision to borrow funds is made by or under the direction of our board of directors and no approval by the shareholders is required in relation to any such borrowing.

Repurchases of Shares and Purchases of Own Shares

The Code of Obligations limits our ability to repurchase and hold our own shares. We and our subsidiaries may repurchase shares only to the extent that (i) we have freely distributable reserves in the amount of the purchase price and (ii) the aggregate par value of all shares held by us does not exceed 10% of our share capital. Pursuant to Swiss law, where shares are acquired in connection with a transfer restriction set out in the articles of association, the foregoing upper limit is 20%. If we own shares that exceed the threshold of 10% of our share capital, the excess must be sold or cancelled by means of a capital reduction within two years.

Shares held by us or our subsidiaries are not entitled to vote at the general meeting of shareholders but are entitled to the economic benefits applicable to the shares generally, including dividends and pre-emptive subscription rights in the case of share capital increases.

In addition, selective share repurchases are only permitted under certain circumstances. Within these limitations, as is customary for Swiss corporations, we may, subject to applicable law, purchase and sell our own shares from time to time in order to meet imbalances of supply and demand, to provide liquidity and to even-out variances in the market price of shares.

Notification and Disclosure of Substantial Share Interests

The disclosure obligations generally applicable to shareholders of Swiss corporations under the Federal Act on Financial Market Infrastructures and Market Conduct in Securities and Derivatives Trading, or the Financial Market Infrastructure Act (the "FMIA"), do not apply to us since our shares are not listed on a Swiss exchange.

Pursuant to Article 663c of the Code of Obligations, Swiss corporations whose shares are listed on a stock exchange must disclose their significant shareholders and their shareholdings in the notes to their statutory annual financial statements, to the extent that this information is known or ought to be known. Significant shareholders are defined as shareholders and groups of shareholders linked through voting rights who hold more than 5% of all voting rights.

Mandatory Bid Rules

The obligation of any person or group of persons that acquires more than one third of a company's voting rights to submit a cash offer for all the outstanding listed equity securities of the relevant company at a minimum price pursuant to the FMIA does not apply to us since our shares are not listed on a Swiss exchange.

Transfer Agent and Registrar of Shares

Our share register is kept by Computershare Trust Company, N.A., which acts as transfer agent and registrar. The share register reflects only record owners of our shares. Swiss law does not recognize fractional share interests.

Comparison of Swiss law and Delaware law

The Swiss laws applicable to Swiss corporations and their shareholders differ from laws applicable to U.S. corporations and their shareholders. The following table summarizes significant differences in shareholder rights between the provisions of the Code of Obligations and the Swiss Ordinance against excessive compensation in listed stock corporations (*Ordonnance contre les rémunérations abusives dans les sociétés anonymes cotées en bourse*) (the "OAEC") applicable to our Company and the Delaware General Corporation Law applicable to companies incorporated in Delaware and their shareholders. Please note that this is only a general summary of certain provisions applicable to companies in Delaware. Certain Delaware companies may be permitted to exclude certain of the provisions summarized below in their charter documents.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Mergers and similar arrangements	
Under the Delaware General Corporation Law, with certain exceptions, a merger, consolidation, sale, lease or transfer of all or substantially all of the assets of a corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon. A shareholder of a Delaware corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights pursuant to which such shareholder may receive cash in the amount of the fair value of the shares held by such shareholder (as determined by a court) in lieu of the consideration such shareholder would otherwise receive in the transaction. The Delaware General Corporation Law also provides that a parent corporation, by resolution of its board of directors, may merge with any subsidiary, of which it owns at least 90.0% of each class of capital stock without a vote by the shareholders of such subsidiary. Upon any such merger, dissenting shareholders of the subsidiary would have appraisal rights.	Under Swiss law, with certain exceptions, a merger or a demerger of the corporation or a sale of all or substantially all of the assets of a corporation must be approved by two-thirds of the voting rights represented at the respective general meeting of shareholders as well as the absolute majority of the par value of shares represented at such general meeting of shareholders. A shareholder of a Swiss corporation participating in a statutory merger or demerger pursuant to the Swiss Merger Act (*Loi sur la fusion*) can file a lawsuit against the surviving company. If the consideration is deemed "inadequate," such shareholder may, in addition to the consideration (be it in shares or in cash) receive an additional amount to ensure that such shareholder receives the fair value of the shares held by such shareholder. Swiss law also provides that if the merger agreement provides only for a compensation payment, at least 90.0% of all members in the transferring legal entity, who are entitled to vote, shall approve the merger agreement.
Shareholders' suits	
Class actions and derivative actions generally are available to shareholders of a Delaware corporation for, among other things, breach of fiduciary duty, corporate waste and actions not taken in accordance with applicable law. In such actions, the court has discretion to permit the winning party to recover attorneys' fees incurred in connection with such action.	Class actions and derivative actions as such are not available under Swiss law. Nevertheless, certain actions may have a similar effect. A shareholder is entitled to bring suit against directors, officers or liquidators for breach of their duties and claim the payment of the company's losses or damages to the corporation and, in some cases, to the individual shareholder. Likewise, an appraisal lawsuit won by a shareholder may indirectly compensate all shareholders. In addition, to the extent that U.S. laws and regulations provide a basis for liability and U.S. courts have jurisdiction, a class action may be available. Under Swiss law, the winning party is generally entitled to recover a limited amount of attorneys' fees incurred in connection with such action. The court has discretion to permit the shareholder who lost the lawsuit to recover attorneys' fees incurred to the extent that he or she acted in good faith.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Shareholder vote on board and management compensation	
Under the Delaware General Corporation Law, the board of directors has the authority to fix the compensation of directors, unless otherwise restricted by the certificate of incorporation or bylaws.	Pursuant to the OAEC, the general meeting of shareholders has the non-transferable right, amongst others, to vote separately and bindingly on the aggregate amount of compensation of the members of the board of directors, of the executive committee and of the advisory boards.
Annual vote on board renewal	
Unless directors are elected by written consent in lieu of an annual meeting, directors are elected in an annual meeting of shareholders on a date and at a time designated by or in the manner provided in the bylaws. Re-election is possible. Classified boards are permitted.	The general meeting of shareholders elects the members of the board of directors, the chairperson of the board of directors and the members of the compensation committee individually and annually for a term of office until the end of the following general meeting of shareholders. Re-election is possible.
Indemnification of directors and executive officers and limitation of liability	
The Delaware General Corporation Law provides that a certificate of incorporation may contain a provision eliminating or limiting the personal liability of directors (but not other controlling persons) of the corporation for monetary damages for breach of a fiduciary duty as a director, except no provision in the certificate of incorporation may eliminate or limit the liability of a director for • any breach of a director's duty of loyalty to the corporation or its shareholders • acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; • statutory liability for unlawful payment of dividends or unlawful share purchase or redemption; or • any transaction from which the director derived an improper personal benefit.	Under Swiss corporate law, an indemnification by the corporation of a director or member of the executive committee in relation to potential personal liability is not effective to the extent the director or member of the executive committee intentionally or negligently violated his or her corporate duties towards the corporation (certain views advocate that at least a grossly negligent violation is required to exclude the indemnification). Furthermore, the general meeting of shareholders may discharge (release) the directors and members of the executive committee from liability for their conduct to the extent the respective facts are known to shareholders. Such discharge is effective only with respect to claims of the company and of those shareholders who approved the discharge or who have since acquired their shares in full knowledge of the discharge. Most violations of corporate law are regarded as violations of duties towards the corporation rather than towards the shareholders. In addition, indemnification of other controlling persons is not permitted under Swiss corporate law, including shareholders of the corporation.
A Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any proceeding, other than an action by or on behalf of the corporation, because the person is or was a director or officer, against liability incurred in connection with the proceeding if the director or officer acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the corporation; and the director or officer, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Unless ordered by a court, any foregoing indemnification is subject to a determination that the director or officer has met the applicable standard of conduct • by a majority vote of the directors who are not parties to the proceeding, even though less than a quorum; • by a committee of directors designated by a majority vote of the eligible directors, even though less than a quorum; • by independent legal counsel in a written opinion if there are no eligible directors or if the eligible directors so direct; or • by the shareholders. Moreover, a Delaware corporation may not indemnify a director or officer in connection with any proceeding in which the director or officer has been adjudged to be liable to the corporation unless and only to the extent that the court determines that, despite the adjudication of liability but in view of all the circumstances of the case, the director or officer is fairly and reasonably entitled to indemnity for those expenses which the court deems proper.	The articles of association of a Swiss corporation may also set forth that the corporation shall indemnify and hold harmless, to the extent permitted by the law, the directors and executive managers out of assets of the corporation against threatened, pending or completed actions. Also, a corporation may enter into and pay for directors' and officers' liability insurance, which may cover negligent acts as well.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW

Directors' fiduciary duties

A director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components:

- the duty of care; and
- the duty of loyalty.

The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this

duty, a director must inform himself or herself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction.

The duty of loyalty requires that a director act in a manner he or she reasonably believes to be in the best interests of the corporation. He or she must not use his or her corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties.

Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction and that the transaction was of fair value to the corporation.

The board of directors of a Swiss corporation manages the business of the corporation, unless responsibility for such management has been duly delegated to the executive committee based on organizational rules. However, there are several non-transferable duties of the board of directors:

- the overall management of the corporation and the issuing of all necessary directives;
- determination of the corporation's organization;
- the organization of the accounting, financial control and financial planning systems as required for management of the corporation;
- the appointment and dismissal of persons entrusted with managing and representing the corporation;
- overall supervision of the persons entrusted with managing the corporation, in particular with regard to compliance with the law, articles of association, operational regulations and directives;
- compilation of the annual report, preparation for the general meeting of the shareholders, the compensation report and implementation of its resolutions; and
- notification of the court in the event that the company is over-indebted.

The members of the board of directors must perform their duties with all due diligence and safeguard the interests of the corporation in good faith. They must afford the shareholders equal treatment in equal circumstances.

The duty of care requires that a director act in good faith, with the care that an ordinarily prudent director would exercise under like circumstances.
The duty of loyalty requires that a director safeguard the interests of the corporation and requires that directors act in the interest of the corporation and, if necessarily, put aside their own interests. If there is a risk of a conflict of interest, the board of directors must take appropriate measures to ensure that the interests of the company are duly taken into account.

The burden of proof for a violation of these duties is with the corporation or with the shareholder bringing a suit against the director.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Shareholder action by written consent	
A Delaware corporation may, in its certificate of incorporation, eliminate the right of shareholders to act by written consent.	Shareholders of a Swiss corporation may only exercise their voting rights in a general meeting of shareholders and may not act by written consents. The articles of association must allow for (independent) proxies to be present at a general meeting of shareholders. The instruction of such (independent) proxies may occur in writing or electronically.
Shareholder proposals	
A shareholder of a Delaware corporation has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.	At any general meeting of shareholders any shareholder may put proposals to the meeting if the proposal is part of an agenda item. No resolution may be taken on proposals relating to the agenda items that were not duly notified. Unless the articles of association provide for a lower threshold or for additional shareholders' rights: • shareholders together representing at least 10% of the share capital may demand that a general meeting of shareholders be called for specific agenda items and specific proposals; and • shareholders together representing shares with a par value of at least CHF 1.0 million or 10% of the share capital, whichever is lower, may demand that an agenda item including a specific proposal be put on the agenda for a scheduled general meeting of shareholders, provided such request is made with appropriate lead time.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
	Any shareholder can propose candidates for election as directors or make other proposals within the scope of an agenda item without prior written notice. In addition, any shareholder is entitled, at a general meeting of shareholders and without advance notice, to (i) request information from the board of directors on the affairs of the company (note, however, that the right to obtain such information is limited), (ii) request information from the auditors on the methods and results of their audit, (iii) request that the general meeting of shareholders resolve to convene an extraordinary general meeting, or (iv) request that the general meeting of shareholders resolve to appoint an examiner to carry out a special examination ("contrôle spécial").
Cumulative voting	
Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation provides for it.	Cumulative voting is not permitted under Swiss corporate law. Pursuant to Swiss law, shareholders can vote for each proposed candidate, but they are not allowed to cumulate their votes for single candidates. An annual individual election of (i) all members of the board of directors, (ii) the chairperson of the board of directors, (iii) the members of the compensation committee, (iv) the election of the independent proxy for a term of office of one year (i.e., until the following annual general meeting of shareholders), as well as the vote on the aggregate amount of compensation of the members of the board of directors, of the executive committee and of the members of any advisory board, is mandatory for listed companies. Re-election is permitted.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Removal of directors	
A Delaware corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise.	A Swiss corporation may remove, with or without cause, any director at any time with a resolution passed by a majority of the shares represented at a general meeting of shareholders. The articles of association may require the approval by a supermajority of the shares represented at a meeting for the removal of a director.
Transactions with interested shareholders	
The Delaware General Corporation Law generally prohibits a Delaware corporation from engaging in certain business combinations with an “interested shareholder” for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or group who or which owns or owned 15.0% or more of the corporation’s outstanding voting shares within the past three years.	No such rule applies to a Swiss corporation.
Dissolution; Winding-up	
Unless the board of directors of a Delaware corporation approves the proposal to dissolve, dissolution must be approved by shareholders holding 100.0% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation’s outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.	A dissolution of a Swiss corporation requires the approval by two-thirds of the voting rights represented at the respective general meeting of shareholders as well as the absolute majority of the par value of shares represented at such general meeting of shareholders. The articles of association may increase the voting thresholds required for such a resolution.
Variation of rights of shares	
A Delaware corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise.	The general meeting of shareholders of a Swiss corporation may resolve that preference shares be issued or that existing shares be converted into preference shares with a resolution passed by a majority of the shares represented at the general meeting of shareholders. Where a company has issued preference shares, further preference shares conferring preferential rights over the existing preference shares may be issued only with the consent of both a special meeting of the adversely affected holders of the existing preference shares and of a general meeting of all shareholders, unless otherwise provided in the articles of association. Shares with preferential voting rights are not regarded as preference shares for these purposes.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Amendment of governing documents	
A Delaware corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise.	The articles of association of a Swiss corporation may be amended with a resolution passed by a majority of the shares represented at a general meeting of shareholders, unless otherwise provided in the articles of association. There are a number of resolutions, such as an amendment of the stated purpose of the corporation, the introduction of authorized and conditional capital and the introduction of shares with preferential voting rights that require the approval by two-thirds of the votes and an absolute majority of the par value of the shares represented at such general meeting of shareholders. The articles of association may increase these voting thresholds. The articles of association of a Swiss corporation may be amended with a resolution passed by a majority of the shares represented at a general meeting of shareholders, unless otherwise provided in the articles of association.
Inspection of books and records	
Shareholders of a Delaware corporation, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose and to obtain copies of list(s) of shareholders and other books and records of the corporation and its subsidiaries, if any, to the extent the books and records of such subsidiaries are available to the corporation.	Shareholders of a Swiss corporation may only inspect books and records if the general meeting of shareholders or the board of directors approved such inspection. The information may be refused where providing it would jeopardize the corporation's trade secrets or other interests warranting protection. A shareholder is only entitled to receive information to the extent required to exercise his or her rights as a shareholder, subject to the interests of the corporation. A shareholder's right to inspect the share register is limited to the right to inspect his or her own entry in the share register.
Payment of dividends	
The board of directors may approve a dividend without shareholder approval. Subject to any restrictions contained in its certificate of incorporation, the board may declare and pay dividends upon the shares of its capital stock either: • out of its surplus; or • in case there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. Shareholder approval is required to authorize capital stock in excess of that provided in the charter. Directors may issue authorized shares without shareholder approval.	Dividend payments are subject to the approval of the general meeting of shareholders. The board of directors may propose to shareholders that a dividend shall be paid but cannot itself authorize the distribution Payments out of a corporation's share capital (in other words, the aggregate par value of the corporation's registered share capital) in the form of dividends are not allowed and may be made only by way of a share capital reduction. Dividends may be paid only from the profits of the previous business year or brought forward from previous business years or if the corporation has distributable reserves, each as evidenced by the corporation's audited stand-alone statutory balance sheet prepared pursuant to Swiss law and after allocations to reserves required by Swiss law and the articles of association have been deducted.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Creation and issuance of new shares	
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.	All creation of shares require a shareholders' resolution. The creation of authorized or contingent share capital requires at least two-thirds of the voting rights represented at the general meeting of shareholders and an absolute majority of the par value of shares represented at such meeting. The board of directors may issue shares out of the authorized share capital during a period of up to two years. Shares are created and issued out of contingent share capital through the exercise of options or of conversion rights that the board of director may grant in relation to, e.g., debt instruments or employees.

Certain confidential information contained in this document, marked by [**], has been omitted because SOPHiA GENETIC SA (SOPHiA) has determined that the information (i) is not material and (ii) is the type that SOPHiA customarily and actually treats as private or confidential.

GE Healthcare

MASTER ALLIANCE AGREEMENT

This Master Alliance Agreement ("**Agreement**") is entered into by GE Precision Healthcare LLC ("**GEHC or GE Healthcare**"), and SOPHiA Genetics S.A. ("**Company**" or "**SOPHiA**"), effective as of the last signature date below ("**Effective Date**"). GEHC and COMPANY are each a "**Party**," and collectively "**Parties**."

WHEREAS, GE Healthcare is a leading provider of medical imaging, clinical care, and medical operations solutions, transforming healthcare by delivering better outcomes for providers and patients; and, by harnessing data and analytics across GE Healthcare various healthcare devices and solutions, GE Healthcare is leading the frontier of elevating radiology and oncology care with artificial intelligence applications and solutions;

WHEREAS, COMPANY, is a healthcare technology company dedicated to establishing the practice of data-driven medicine as the standard of care and for life sciences research, with commercial applications for clinical and biopharma markets;

WHEREAS, the Parties share a common vision to develop new AI-powered analytics and workflow solutions to serve both the clinical and biopharma markets for oncology by deploying GE Healthcare's medical imaging, advanced visualization and monitoring capabilities and its Edison platform-enabled data aggregation together with the SOPHiA DDM genomic and radiogenomic AI-powered analytics platform and its related applications through a coordinated marketing and sale of the products and services to achieve the common goal of breaking down the data silos across modalities, instruments and sites, to better targeting and matching of treatments to each patient's genomic profile and cancer type or other diagnosis, and helping to ensure the most effective and personalized treatment.

NOW, THEREFORE, in consideration of the foregoing, and the covenants and promises contained in this Agreement, the Parties agree as follows:

1) **Scope**. The Parties will work together to identify opportunities in the healthcare market where the Parties may engage in jointly identified projects. The Parties will define collaboration initiatives and projects (each, a "**Project**"). The Parties agree to conduct the Projects in accordance with the roadmap, deliverables and budget set forth in each associated statement of work ("**SOW**").

2) **Statement of Work**. For each Project, the Parties or one of their Affiliates will enter into a SOW or a mutually agreed alternative agreement. Each SOW shall incorporate by reference the terms of this Agreement. In the event of any conflict between an SOW and this Agreement and unless expressly stated otherwise in an SOW, the terms of this Agreement shall control. The Parties intend to enter into various SOWs or alternative agreements, including but not limited to the following types:

    a. **SOWs.** The Parties may agree and enter into an SOW for the purpose of collaborating to evaluate, develop, test or commercialize a new Project, which may include but is not limited to a Joint Offering or which would initiate joint development. An SOW may follow the format of **Schedule 1**, **Schedule 2**, or a combination of the two, with additional terms to be mutually agreed as applicable. The Parties intend to negotiate in good faith the SOWs set out in Part I of **Schedule 3**, which may include content as described in Part II of **Schedule 3**.

3) **Governance**.

a. **Joint Governance Board.** Both Parties shall establish a Joint Governance Board related to this Agreement to provide executive leadership and oversight of the activities carried out pursuant to the Agreement. Strategic direction will be set by the Joint Governance Board, and it shall serve as an escalation body for the Joint Steering Committee. The Joint Governance Board shall discuss proposed modifications of Section 4 of this Agreement, including any proposed additions or removals to the lists of companies from whom each Party agrees to refrain from doing certain business, provided that any modification of this Agreement (including Section 4) shall only be by mutual written amendment duly executed by an authorized representative of each Party. The members of the Joint Governance Board shall meet at least [**] to discuss strategy and status of the alliance or any respective SOW. The initial members of the Joint Governance Board shall be (i) for Company, the current Chief Business Officer and current Chief Financial Officer, and (ii) for GEHC, the current Head of Strategy and current Chief Digital Officer. Either Party may replace its member(s) of the Joint Governance Board upon notice to the other Party with a representative of equal or greater authority.

b. **Joint Steering Committee**. Both Parties shall establish a Joint Steering Committee related to this Agreement to provide strategic and operating direction for each Project and reviewing on a periodic basis the overall goals and financial performance of each Project and the alliance as a whole. The members of the Joint Steering Committee shall meet at least [**] to review the alliance and relevant SOWs. The initial members of the Joint Steering Committee shall be (i) for Company, the current VP Business Development; current Chief Architect; current Chief Medical Officer; and current VP, Biopharma; and (ii) for GEHC, the current General Manager Oncology; current Chief Architect; current VP, Strategic Alliances; and current VP, Biopharma Services. Either Party may replace its member(s) of the Joint Steering Committee upon notice to the other Party with a representative of equal or greater authority.

c. **Additional Resources.** Each Party will designate an alliance manager, program manager and other personnel as necessary to perform each SOW within the SOW as appropriate. Each Party will provide the internal resources necessary to perform each SOW, including by providing appropriate access or licenses to their respective platforms, intellectual property and data sets pursuant to the terms of this Agreement and the relevant SOW.

d. **Selection of Projects**. Both Parties agree to use reasonable efforts to work collaboratively with one another in identifying Projects that they believe will support the objectives of the Agreement. In the event the Parties identify a potential Joint Offering, they shall diligently and in good faith discuss for a period of [**] an SOW related to the Joint Offering. During such period, the Parties shall not enter into material discussions or any negotiations or agreements with any third party to work on similar activities related to a Substantially Similar Offering. If after [**] the Parties are unable to reach an agreement on an SOW, each Party shall be free to work on any activities related to a Substantially Similar Offering with any third party.

Joint Offering: means (a) a jointly developed Multimodal product or solution developed or created by both Parties, (b) a joint solution combining, integrating or leveraging both GE and Sophia products, or (c) a joint go to market plan for a jointly developed Multimodal product or solution, or a joint solution combining, integrating or leveraging both GE and Sophia products.

Substantially Similar Solution: means a product or solution which has a substantially similar (a) use case or (b) competitive position in a proposed market segment as a Joint Offering.

Multimodal means genomic analysis combined with, for example, X-ray, PET, CT, Mammography and/or MRI for use in a biopharma or healthcare setting.

e. **Additional Subcommittees.** The Parties may also create additional subcommittees to oversee the activities under this Agreement or any particular Project as needed.

4) **Exclusive Collaboration**.

a. For the six (6) months from the Effective Date of this Agreement, (a) Company shall not (and shall not permit their representatives to), directly or indirectly, through any representative or otherwise, provide information to, solicit or entertain offers from, negotiate with in any manner, announce, encourage, discuss, accept, execute or consider any proposal, term sheet, letter of intent, memorandum of understanding or any other agreement or arrangement in relation to a material collaboration [**] with [**] and (b) GEHC shall not (and shall not permit their representatives to), directly or indirectly, through any representative or otherwise, provide information to, solicit or entertain offers from, negotiate with in any manner, announce, encourage, discuss, accept, execute or consider any proposal, term sheet, letter of intent, memorandum of understanding or any other agreement or arrangement in relation to a material collaboration [**] with [**] . The Parties may extend this exclusivity by a written agreement between the Parities. “Affiliates” means, with respect to any entity, another entity that controls, is controlled by or is under common control with such entity. For the purposes of this definition, the word “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.

b. The Parties agree to terminate Section 2, “Exclusive Dealing” of Part 1 of the Letter of Intent dated July 1, 2021, effective as of the Effective Date.

5) **Fees and Costs**. Unless otherwise set forth in an SOW or other written agreement between the Parties, (i) each Party will be responsible for its own fees or costs incurred under this this Agreement and (ii) no license fees will be paid for the exchange of any Confidential Information or licenses (except software licenses) granted under this Agreement. Any software license fees or costs will be detailed in an SOW.

6) **Sole Discretion**. Subject to Section 4 and any express restrictions contained in an SOW, each Party retains sole discretion to determine design, functionality, development, integration, and release strategy and timing, including whether or not to develop, market, distribute or support a product or solution.

7) **Reserved.**

8) **Confidentiality and Use Restrictions**

a. **Obligations**. In connection with this Agreement, each Party (a “Disclosing Party”) may disclose, make available or provide access to its Confidential Information to the other Party (“Receiving Party”). Receiving Party shall only use Confidential Information or Materials (as defined below) for the limited express purpose of this Agreement. Except as specifically permitted in this Agreement or as required by law (with reasonable prior notice to the Disclosing Party to allow Disclosing Party a reasonable opportunity to seek a protective order or equivalent), Receiving Party shall not disclose any Confidential Information or Materials to any third party without the prior written consent of Disclosing Party. Receiving Party shall at all times keep the Confidential Information and Materials confidential and shall take all reasonable security precautions (and in any event at least as great as the precautions Receiving Party takes to protect its own comparable confidential information) to keep confidential and protect the Confidential Information and Materials from unauthorized access and use. References to Receiving Party or Disclosing Party shall be deemed to include their respective Affiliates. “Confidential Information” means information that the Disclosing Party designates as being confidential or which, under the

circumstances surrounding disclosure, should be treated as confidential by the Receiving Party, and includes, without limitation: (i) information relating to Disclosing Party's current or prospective customers, services, and strategic plans; (ii) Disclosing Party's business policies or practices; (iii) technical, financial, marketing, or other technical or business information or trade secrets of Disclosing Party (whether or not marked as "confidential"); (iv) the Licensed Software, associated documentation and related developments (as defined in the applicable SOW), and any proprietary information associated with such Licensed Software, Documentation and Developments; and (vi) information received from third parties that Disclosing Party is obligated to treat as confidential. Notwithstanding the foregoing, the Receiving Party shall have no obligations with respect to any information which: (i) is or becomes publicly available through no act of the Receiving Party in breach of this Agreement; (ii) was in the possession of the Receiving Party prior to its disclosure or transfer as evidenced by written documentation; (iii) is independently developed by the Receiving Party and the Receiving Party can so prove; or (iv) is received from another source without any restriction on use or disclosure. "Materials" means all tangible or written materials containing Confidential Information, including without limitation, written or printed documents, emails and attachments, electronic files, and computer disks, whether machine or user readable.

b. **Rights and Remedies**. Receiving Party shall notify Disclosing Party immediately upon discovery of any unauthorized use or disclosure of any Confidential Information or Materials, or any other breach of this Agreement, and will cooperate with Disclosing Party in every reasonable way to help Disclosing Party regain possession of the Confidential Information or Materials and prevent their further unauthorized use. At Disclosing Party's request, Receiving Party shall promptly, but in any case within [**] return all originals, copies, reproductions and summaries of Confidential Information or Materials or, at Disclosing Party's option, certify destruction. Receiving Party acknowledges that monetary damages may not be a sufficient remedy for unauthorized disclosure or use of the other party's Confidential Information or Materials and that Disclosing Party shall be entitled, without waiving any other rights or remedies, to seek injunctive or equitable relief as may be deemed proper by a court of competent jurisdiction.

9) **Press Releases, Publications and Disclosure**. The Parties agree that any publication, advertisement, solicitation, or public announcement, including about the existence of this Agreement or the relationship created hereby, including any SOW, must be first approved by both Parties in writing, such approval not to be unreasonably withheld or delayed. The Parties may jointly make press releases or public announcements regarding this Agreement or any matter covered by this Agreement, provided, that neither Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, such permission not to be unreasonably withheld, except as may be required by law or applicable regulations. Notwithstanding the foregoing, each Party reserves the right to publicly disclose the Agreement to satisfy reasonable transparency and disclosure policies and/or reporting obligations.

10) "**Intellectual Property or IP**" means inventions, discoveries, concepts, ideas, data, improvements, combinations, extensions, computer software (source code and object code), methods, processes, machines, manufactures, compositions of matter, algorithms, original works of authorship, designs, prototypes, trademarks, trade secrets, and all related know-how, whether or not protectable under the patent, copyright, and/or trade secret laws of any applicable jurisdiction.

a. **Background IP Rights.** Ownership of background IP rights shall be defined as follows:

i. IP rights related to GEHC products or solutions that are owned by GEHC prior to the Effective Date or developed outside the scope of this Agreement ("**GE Background IP**") shall be owned exclusively by GEHC.

ii. IP rights related to products or solutions that are owned by COMPANY prior to the Effective Date or developed outside the scope of this Agreement ("**COMPANY Background IP**") shall be owned exclusively by COMPANY.

b. **Foreground IP Rights.** Ownership of created foreground IP rights shall be defined as follows, unless otherwise specifically agreed in a SOW:

i. All IP generated or conceived solely by GEHC under this Agreement ("**GE Foreground IP**") shall be owned exclusively by GEHC.

ii. IP developed or conceived solely by Company under the Agreement ("**Company Foreground IP**") shall be owned exclusively by Company.

iii. Except as stated herein or in a related SOW, IP developed jointly by both GEHC and Company under the Agreement ("**Joint Foreground IP**") shall be jointly owned by both Parties. Each SOW anticipating creation of Joint Foreground IP shall include specific rights and responsibilities with respect to the creation, funding, resource allocation, documentation, protection, and defense of such Joint Foreground IP. Except as otherwise agreed herein or in an SOW, each Party shall have the unrestricted, non-exclusive right to make, have made, use, sell, copy, modify, distribute, make derivative works of, sublicense, and otherwise commercialize or exploit Joint Foreground IP, without giving notice to or obtaining consent from the other Party or duty to account to the other Party for any profits that may be derived. The Parties shall work together in good faith and promptly as practicable to protect Joint Foreground IP.

c. **Licensing**. With respect to Background IP or Foreground IP made available by a Party to support activities described in an SOW, each Party grants to the other Party a non-exclusive, royalty-free, fully paid-up, non-assignable, non-transferable, non-sublicensable, non-commercial worldwide license to use such Background IP or Foreground IP solely for the duration of [**] and solely to fulfill its obligations under the SOW. This license shall extend to activity undertaken by the Parties for an identified Joint Offering or an upcoming SOW while the Parties are in good faith negotiations towards an executed SOW. If such good faith negotiations end without the signing of the SOW, the license shall cease, the Parties shall cease all related activity and return all IP of the other Party.

d. **Development Costs.** Unless otherwise agreed in writing, each Party shall bear its own development costs and transactions costs, including, without limitation, the costs and expenses associated with the negotiation and preparation of this Agreement agreements, protection if its IP, and any SOW.

11) **Representations & Warranties**

a. Each Party represents and warrants that:

i. It has the right, power and authority to enter into this Agreement and perform according to its terms; and

ii. The performance of its obligations will not breach any agreements with a third party.

b. Disclaimer. EXCEPT AS PROVIDED HEREIN, THE PARTIES DISCLAIM ALL OTHER EXPRESS, IMPLIED, OR STATUTORY WARRANTIES. THIS INCLUDES THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, AND NON-INFRINGEMENT. THIS ALSO INCLUDES ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING, OR USAGE OF TRADE.

12) **Indemnification**. Each Party (as "Indemnifying Party") will indemnify, defend, and hold harmless the other Party and its officers, directors, employees, contractors, Affiliates, and agents (collectively, the "Indemnified Parties") from and against any and all third-party claims, suits, demands, costs, liabilities, penalties, fines, expenses, and damages (including reasonable attorneys' costs and fees) ("Claims") arising from the Indemnifying Party's (i) breach of this Agreement or, (ii) infringement of any third-party Intellectual Property Rights. The Indemnified Party may participate in the defense of any Claim with its own counsel at its sole expense. The Indemnifying Party will not settle or resolve any such Claims without the prior written consent of the Indemnified Party. Such consent will not be unreasonably withheld.

13) **Limitation of Liability.** To the maximum extent permitted by law, in no event will either Party be liable for any indirect, incidental, consequential, punitive, special, or exemplary damages (including, but not limited to, damages for loss of data, revenue, and/or profits) arising out of or that relate in any way to this Agreement. This exclusion will apply regardless of the legal theory upon which any claim for such damages is based, whether a Party has been advised of the possibility of such damages, whether such damages were reasonably foreseeable, or whether application of the exclusion causes any remedy to fail of its essential purpose.

    a. **Liability Cap.** Except as otherwise stated in an SOW, each Party's total aggregate liability for all claims arising out of or related to any SOW under this Agreement, whether in contract, tort or otherwise, will not exceed the lesser of (i) the sum of the total compensation to be paid under the applicable SOW and (ii) [**].

    b. Each Party's liability for loss or damage of any kind (including loss or damage caused by negligence) to the other is reduced to the extent that the other Party's agents caused or contributed to that loss or damage.

14) **Marketing**. The Parties intend to develop solution(s) using each other's products as components or as co-selling options to customers. As part of the development, the Parties agree to implement a disciplined joint go-to-market (GTM) process and invest in marketing efforts and promotions in support of COMPANY component-based GEHC solutions or component-based SOPHiA solutions. Such go-to-market plans shall be detailed in a SOW substantially in the form attached hereto as **Schedule 2** or as otherwise mutually agreed. With respect to any joint go-to-market plans detailed in such an SOW, the terms in this Section 14 shall apply:

    a. **Marketing Activities**. GEHC and COMPANY will use good faith efforts to market and promote both jointly developed as well as co-marketing solution(s) by engaging in marketing activities mutually agreed upon by the Parties, with marketing materials mutually agreed by the Parties. Except as set forth in Section 9, neither Party will issue any press release or make any public announcement(s) relating to this Agreement without the other Party's prior written consent. Marketing activities may include but not be limited to, efforts for demand generation, sales enablement, sales funnel acceleration, event sponsorship, and thought leadership.

    b. **Go to Market Plan**. Each year, [**], each Party will provide a general view of its marketing plan for the next year to the other Party.

    c. **Marketing and Trademark Usage**. The Parties may collaborate with regard to certain marketing activities if agreed upon on a case-by-case basis. Use of Each Party's Marks and Reservation of Rights: Each Party may, in its sole discretion provide the other Party with electronic files containing the trademarks, logos and trade names of such Party (the "Marks") to be used under this Agreement. Subject to the terms and conditions of this Agreement, each Party hereby grants to the other a non-exclusive, non-assignable, non-sub-licensable, royalty-free, paid up, limited license in the Territory to use and display the other Party's Marks solely as necessary to perform the Party's obligations under this Agreement during the term of the Agreement. Upon termination of the Agreement, any materials containing the other Party's Marks will be returned to their respective holder. A Party may revoke the other Party's ability to use the Party's Marks at any time upon written notice, at its discretion.

d. **Trademark Guidelines** In its use of the Marks of the other Party, each Party will comply with any trademark usage guidelines that the other Party communicates from time to time. Each use of Marks by either Party will be accompanied by the appropriate trademark symbol and a legend specifying such Mark's ownership. Other than the express licenses granted herein with respect to each Party's Marks, nothing herein will grant to the other Party any other right, title or interest in the owner's Marks. Neither Party will (a) modify or create derivative works of the other party's Intellectual Property; or (b) sell, lease, license, sublicense, copy, market or distribute the other party's Intellectual Property except as may be authorized by the owning Party in writing. In no event shall anything in this Agreement or in any Party's conduct or course of dealing convey any license, by implication, estoppel or otherwise, under any patent, copyright, trademark or other intellectual property right not explicitly permitted herein. All rights not expressly granted under this Agreement are reserved by each Party.

15) **Term and Termination**

a. **Term**. The term of this Agreement shall commence upon the Effective Date and shall continue in effect for a period of five (5) years, unless terminated earlier as set forth in this Section 15. The Agreement shall automatically renew for twelve-month terms unless [**] prior to the expiration of the term either Party notifies the other in writing that it will not renew the Agreement. Upon expiration or termination of this Agreement, the terms of this Agreement shall survive for purposes of any SOW that is still in effect, provided that each SOW may be terminated according to its own terms.

b. **Termination for Cause**. In the event of a material breach of this Agreement or a SOW, the non-breaching Party may terminate this Agreement or the SOW, as applicable, upon [**] advance notice, provided that the Agreement or the SOW as applicable, shall not terminate in the event that the breach is cured to the non-breaching Party's reasonable satisfaction during the [**] notice period.

c. **Termination For Business Reasons**. After an initial [**] period, either Party may terminate this Agreement, provided that at the date of notice of termination there are no SOWs in effect. The terminating Party shall give [**] prior written notice to the other Party and the Parties shall meet to discuss the business reasons for termination and any alternative arrangements that can be made within [**].

d. **Termination for Insolvency**. This Agreement may be terminated by either Party immediately in the event: (i) any insolvency proceeding is begun or made by the other Party, including an assignment for the benefit of creditors, (ii) if a receiver, trustee in bankruptcy, or similar officer is appointed to take charge of any or all of the other Party's property, (iii) the other Party files a voluntary petition under federal bankruptcy laws or similar state statutes, or (iv) such a petition is filed against the other Party and is not dismissed within [**].

e. **Effect of Termination**. Upon termination of this Agreement and except as provided in Section 15(f), neither Party shall have any further obligations hereunder except for (i) obligations accruing prior to the date of termination (including payment obligations for work completed through the date of termination), and (ii) obligations, promises, or covenants set forth herein that expressly survive the expiration or termination of this Agreement. Within [**] following the date of termination, each Party shall destroy or return all Confidential Information of the other Party and share with the other Party outputs from uncompleted SOWs in its possession, custody or control. The terms of this Agreement that by their nature are intended to survive expiration or termination of this Agreement will continue in full force and effect after such expiration or termination.

f. **Business Continuity**. For a period of [**] following termination of this Agreement, each Party shall provide to the other Party and its customers, consistent with the terms of any relevant SOW, reasonable support in relation to commercialized Joint Offerings.

16) **Compliance with Laws.**

a. COMPANY and GE shall comply with all laws and regulations to the extent applicable to their respective performance under this Agreement including without limitation the Federal Anti-Kickback Statute ("AKS"), the 1996 Health Insurance Portability and Accountability Act ("HIPAA"), the Federal Food Drug and Cosmetic Act ("FDCA") and the General Data Protection Regulation ("GDPR").

b. COMPANY and GE each affirm neither it nor any of its employees has been excluded from participation in any federally funded healthcare program or convicted of a healthcare-related crime.

c. Nothing in this Agreement is intended to incent or reward either Party for the purchase of any good or service from the other Party, or to require any such purchase in the future.

d. This Agreement does not authorize or require either Party to make any statement or representation about the use of the other Party's technology that is inconsistent with the cleared or approved indications for use for such technology by FDA or other regulatory body (e.g., "off-label" indications).

e. COMPANY agrees to abide with "GE's Integrity Guide for Suppliers, Contractors and Consultants," set out in **Schedule 4**. GEHC agrees to abide with such Integrity Guide, *mutatis mutandis*.

17) **No Guarantee of Success**. Each Party makes no representations, warranties, or promises, express or implied, to the other Party as to the success of the research, development, marketing, or sales efforts pursuant to this Agreement, or with respect to the amount of revenue that may accrue. Except as provided in Section 4, each Party may, at its sole discretion, develop, acquire, market, and provide to its customers products that directly or indirectly compete with, or otherwise offer the same or similar services or functions as those developed pursuant to this Agreement, whether developed internally or by third parties.

18) **Relationship**. The Parties are and will be independent contractors to one another, and nothing herein will be deemed to cause this Agreement to create an agency, partnership, or joint venture between the Parties. Neither Party will provide, or be responsible for, any fringe benefits, including health insurance benefits, paid vacation, or any other employee benefits, for the benefit of the other Party's employees.

19) **No Third-Party Beneficiaries**. Nothing in this Agreement shall be construed to give any person other than the express Parties to this Agreement any benefits, rights, or remedies.

20) **Entire Agreement.** This Agreement, and any schedules hereto, constitutes the complete and exclusive understanding and agreement between the Parties with respect to the subject matter hereof and supersedes all prior discussions between the Parties regarding such subject matter. Any waiver, modification, or amendment of any provision of this Agreement will be effective only by a written agreement dated subsequent to the date of this Agreement and signed by both Parties.

21) **Counterparts**. This Agreement may be executed by in one or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same agreement. Counterpart signature pages may be validly delivered by facsimile or by electronic mail in PDF format and such signature pages shall have the same effect as originals.

22) **Severability**. The provisions of this Agreement are intended to be severable and enforced to the maximum extent permitted by law. If for any reason any provision of this Agreement shall be held invalid, illegal, or unenforceable in whole or in part as applied to any particular circumstance in any jurisdiction, then that provision shall be ineffective only to the extent of the invalidity, illegality, or unenforceability as to that circumstance and in that jurisdiction only, without in any manner affecting the validity, legality or enforceability of that provision as to any other circumstance or of the remaining provisions in that jurisdiction or any provision of the Agreement in any other jurisdiction. The unaffected portion and provisions of the Agreement will be enforced to the maximum extent permitted by law.

23) **Governing Law**. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to any conflict of laws principles.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement to be effective as of the Effective Date.

GE Precision Healthcare LLC

By: /s/ Brian Montgomery

Print name: Brian Montgomery

Title: Head of Strategy

Address: _____

Date: 9/11/2021

SOPHIA GENETICS S.A.

By: /s/ Ross Muken

Print name: Ross Muken

Title: Chief Financial Officer

Address: _____

Date: 9/11/2021

SOPHIA GENETICS S.A.
By: /s/ Daan van Well
Print name: Daan van Well
Title: Chief Legal Officer | General Counsel
Address: _____
Date: 9/11/2021

Contact Information for legal notice:

GE Healthcare Digital	Sophia Genetics
General Counsel	General Counsel
[**]	Rue du Centre 172
[**]	1025 St-Sulpice, Switzerland

Certain confidential information contained in this document, marked by [**], has been omitted because SOPHiA GENETIC SA (SOPHiA) has determined that the information (i) is not material and (ii) is the type that SOPHiA customarily and actually treats as private or confidential.

[Exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. SOPHiA GENETICS SA undertakes to provide a copy of the omitted exhibits to the Securities and Exchange Commission or its staff upon request.]

Certain confidential information contained in this document, marked by [**], has been omitted because SOPHiA GENETICS SA(SOPHiA) has determined that the information (i) is not material and (ii) is the type that SOPHiA customarily and actually treats as private or confidential.

SUPPLY AGREEMENT

This Supply Agreement (this "**Agreement**") is made as of the 4th day of January, 2019 (the "**Effective Date**") by and between New England Biolabs, Inc., a Massachusetts corporation, having a principal place of business at [**] ("**NEB**"), and Sophia Genetics SA, a Swiss corporation, having its principal place of business at Rue du Centre 172, 1025 St-Sulpice, Switzerland ("**Purchaser**"). NEB and Purchaser may each be referred to individually as a "**Party**", or together as the "**Parties**".

RECITALS

WHEREAS, NEB is in the business of the design, development, manufacture and commercialization of life science reagents and kits;

WHEREAS, Purchaser is a health technology company which has developed the SOPHiA Artificial Intelligence genomic analysis software tool; and

WHEREAS, NEB and Purchaser want to enter into a supply agreement under which NEB will supply and Purchaser will buy certain reagent(s), subject to the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The terms defined in this Article 1, wherever used in this Agreement in the singular or the plural, shall have the meanings ascribed to them below.

1.1 "**Affiliate**" means, with respect to a Party, any corporation or other entity that is directly or indirectly controlling, controlled by or under common control of NEB or Purchaser, as the case may be. As used in this definition, the term "control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the stock or other securities having the right to vote for directors thereof.

1.2 "**Applicable Laws**" means all relevant federal, state, local and foreign laws, statutes, rules, regulations and ordinances, as well as industry standards and guidelines issued by any governmental or regulatory authority.

1.3 **"Calendar Year**" means each twelve (12) month period commencing January 1st of each year through the term of this Agreement.

1.4 "**Facility**" means NEB's facility located at [**], as may be modified from time to time by NEB, by providing a [**] prior written notice to Purchaser.

1.5 "**Intellectual Property Rights**" means all rights in patents, copyrights, trade secrets, known-how, trademarks, service marks, trade dress, and other intellectual property rights, current, pending or future, under the laws of any jurisdiction, together with all applications therefor and registrations thereto.

1.6 **Intentionally Left Blank**.

1.7 "**Price**" means the price(s) for the Product(s) set forth in Exhibit A, as updated pursuant to Section 3.1.

1.8 "**Product**" means the product or products described in Exhibit A.

1.9 "**Specifications**" means the specifications and/or similar requirements for each Product set forth in Exhibit B, as may be updated pursuant to Section 4.

1.10 "**Third Party**" means any person or entity other than NEB, NEB's Affiliates, Purchaser or Purchaser's Affiliates.

1.11 Additional Defined Terms. Each of the Following terms will have the meaning described in the section of this Agreement reference below:

Term	**Section Defined**	**Term**	**Section Defined**
Agreement	Introduction	Party / Parties	Introduction
Claim	7.1	Purchase Order	2.3
Confidential Information	9.1	Purchaser	Introduction
Damages	7.1	Receiving Party	9.1
Disclosing Party	9.1	Renewal Term	8.1
Effective Date	Introduction	Required Quantity	2.4
Indemnitee	7.3	Rolling Forecast	2.2
Indemnitor	7.3	Shortage of Supply	2.6
Initial Term	8.1	Term	8.1
NEB	Introduction	TSCA	5.2(b)

Exhibit List

Exhibit A – Price and Products

Exhibit B – Specifications

ARTICLE 2
PRODUCT SUPPLY

2.1 Supply. Subject to the terms and conditions of this Agreement, NEB shall supply the Products to Purchaser, and Purchaser shall purchase the Products from NEB in accordance with the terms of this Agreement.

2.2 Forecasts. Beginning no later than [**] following the Effective Date, and thereafter at least [**] before the first day of [**] of each year, Purchaser shall provide NEB with a written forecast of Purchaser's estimated Product supply requirements for the following twelve (12) month period (each, a "**Rolling Forecast**"). If the supply requirements in the Rolling Forecast are beyond NEB's then-current production capacity, then NEB will notify the Purchaser of this and has the right to reject the Rolling Forecast as proposed. If NEB rejects such Rolling Forecast, NEB and Purchaser shall meet to discuss how to best address this issue and mutually agree on a revised Rolling Forecast. The [**] of each Rolling Forecast will be binding and the remaining [**] will be non-binding and serve only as a good faith estimate to facilitate NEB's production scheduling.

2.3 Purchase Orders. Purchaser shall submit written purchase orders for Products to NEB (each, a "**Purchase Order**") in accordance with the minimum order quantity requirements set out in Exhibit A. Each Purchase Order must specify the quantity of each Product to be delivered as well as the delivery destination(s) and delivery date(s) using delivery schedules and lead times as may be agreed upon by the Parties, *provided* that Purchaser shall not specify lead times that are less than [**] from the date the Purchase Order was received by NEB unless otherwise agreed in writing by NEB. Each Purchase Order will be binding on Purchaser and must be consistent with the binding portion of the Rolling Forecast. NEB shall notify Purchaser within [**] if the Purchase Order has been accepted; *provided* that NEB shall not unreasonably reject any Purchase Order so long as the quantity of Product ordered, cumulatively with all other Purchase Orders submitted to NEB for Product delivery during such [**], is equal to or less than the quantity of Product specified in the binding portion of the then-current Rolling Forecast and the Purchase Order is otherwise compliant with the requirements of this Section 2.3. NEB shall use commercially reasonable efforts to fill Purchase Orders for any quantity of Product that, alone or cumulatively with other Purchase Orders submitted to NEB for Product delivery during such [**], exceeds the amount specified in the binding portion of the then-current Rolling Forecast. Any Purchaser-proposed changes in the quantity, method of shipment, schedule or place of delivery after the submission of a Purchase Order must be provided to NEB in writing and will only be effective if approved in writing by NEB.

2.4 Minimum Purchase Requirements. With respect to [**] and each [**] during the Term thereafter, NEB shall make available to Purchaser, and Purchaser shall purchase from NEB at least the quantity of each of the Product(s) as set forth in Exhibit C (the "**Required Quantity**"). Prior to the start of each Calendar Year, the Required Quantity for each Product for the following Calendar Year shall be agreed upon in good faith by mutual agreement of the Parties. If any NEB products are added to Exhibit A after the Effective Date, the Required Quantity for such products shall be agreed by the Parties and identified in the amendment to add such products to the Agreement

2.5 Shipping. NEB shall deliver the Products ordered by Purchaser in accordance with Section 2.3 to the location specified in the applicable Purchase Order within [**] of the delivery dates specified in the applicable Purchase Order. Subject to the terms of payment for shipping in Article 3, all shipments will be DAP named place of destination (Incoterms 2010). The place of destination shall be Purchaser's offices in Geneva, Chemin des Mines 9, 1202, Geneva, Switzerland **("Sophia Geneva**"). Furthermore, nothing contained herein shall limit the Parties' ability to add or remove places of destination per mutual written agreement. Title to Products will pass to Purchaser at the time of delivery of such Products to named place of destination. NEB shall ship Products in accordance with any agreed-upon shipment specifications or as otherwise agreed in writing by the

Parties and in accordance with this Agreement. Purchaser shall, in accordance with the terms of this Agreement, pay for all Products delivered to it in accordance with a valid and accepted Purchase Order.

2.6 Shortage of Supply. If NEB is unable, or anticipates that it will not be able, to supply Purchaser's requirements for the Product for the binding portion of the Rolling Forecast (a "**Shortage of Supply**"), NEB shall promptly notify Purchaser in writing, and shall include in such notice its estimate of the duration of the delay. NEB shall use its [**] to remedy any Shortage of Supply and resume supplying Product under this Agreement to Purchaser. In the event of a Shortage of Supply, after the expiration of a reasonable period of time [**] during which NEB may remedy the cause of its Shortage of Supply, Purchaser shall be relieved from its obligations to purchase any yet undelivered quantities of Product identified in any outstanding Purchase Order or that are subject to the binding portion of the then current Rolling Forecast, and may cancel such quantities effective upon written notice to NEB. [**].

ARTICLE 3
PRICE AND PAYMENTS

3.1 Price. The Initial Price for each Product sold under this Agreement is set forth in Exhibit A. The Parties agree to discuss in good faith adjusting the Price of a Product in the event of any increase in NEB's documented cost by a minimum of [**] with respect to: (a) labor associated with the manufacture of such Product, or (b) raw materials used in the manufacture of such Product that are purchased from Third Party suppliers. In addition, the effective Prices may be increased [**] by NEB after NEB provides Purchaser with at least [**] prior written notice. Such [**] price increases will not exceed [**] of the prior year Prices.

3.2 Invoice; Payment. NEB shall submit an invoice to Purchaser upon shipment of the Product ordered by Purchaser under this Agreement. The invoice will be sent to the address specified in the Purchase Order, and each invoice will state the Price for the Product in a given shipment, plus any taxes and other costs incident to the purchase or shipment to be paid by Purchaser. Purchaser shall make all payments by direct bank transfer to an account designed in NEB's invoice or by check payable to NEB. Purchaser shall pay in U.S. Dollars within [**] from the date of Purchaser's receipt of an invoice from NEB. If the actual quantity of Products ordered by Purchaser are less than those set forth in the binding portion of the Rolling Forecast, Purchaser nonetheless shall be obligated to pay for the amount of Products set forth in the binding portion of the Rolling Forecast at the price set forth in Exhibit A, which amount will be due and payable within [**] of Purchaser's receipt of NEB's invoice therefor. Purchaser shall also be obliged to pay for the amount, if any, by which the Required Quantity for a Calendar Year exceeds the actual quantity of Products ordered by Purchaser for such Calendar Year, such quantity shortfalls to be paid for at the price set forth in Exhibit C, which amount will be due and payable [**] of Purchaser's receipt of NEB's invoice therefor. NEB may charge interest for late payment at [**]. Payment by Purchaser will not constitute acceptance of any shipment of Product or impair Purchaser's right of inspection and rejection under Article 4 below. In addition to any other remedy that NEB may have at law or equity, NEB may stop shipment of Products without violation of any other Section of this Agreement in the event that Purchaser's payment is past [**] due for any outstanding invoice. Upon payment in full of such outstanding invoices (including applied interest), NEB shall commence shipment of Products hereunder.

3.3 Shipping Charges. Purchaser shall be responsible for all freight, shipping, handling fees, import duties, and related charges for orders shipped outside of the United States. NEB will apply a freight charge of [**] for orders shipped to Sophia Geneva when the total value of a Purchase Order is less than [**]. NEB will not apply a freight charge for orders shipped to Sophia Geneva when

the total value of the applicable Purchase Order is greater than [**]. All shipments will be made DDP named place of destination (Incoterms 2010).

3.4 Taxes. All sales taxes, value added taxes, duties, levies, surcharges or other similar charges and any penalties levied thereon that relate to any amounts paid for the Products hereunder shall be the responsibility of, and paid by, Purchaser. If NEB is required to pay any of these amounts, Purchaser shall reimburse NEB thereafter or provide to NEB an exemption certificate or other document acceptable to the authority that is imposing the payment.

ARTICLE 4
QUALITY; ACCEPTANCE AND REJECTION

4.1 Quality Systems and Assurance. The Quality Management System and standards employed by NEB to manage and monitor Product quality are based upon the latest effective versions of ISO9001 and ISO13485. Prior to each shipment of Product, NEB shall perform quality control procedures reasonably necessary to ensure that the Product to be shipped conforms fully to the Specifications. Each shipment of Product must be accompanied by a certificate of analysis or other such documentation as specified in Exhibit B identifying the Product lot number(s) and describing all current requirements of the applicable Specifications and results of tests performed certifying that the quantities of each Product supplied have been manufactured, controlled and released according to the applicable Specifications.

4.2 Replacement/Refund. Upon delivery of the Product, Purchaser shall have [**] to inspect the Product and shall notify NEB in writing of any defect or non-conformity. Should no such notice be provided by Purchaser, the Products shall be deemed accepted, unless a defect or non-conformity which could not have been reasonably detected upon diligent inspection of the Product is found thereafter, in which case a warranty claim may be made during the applicable valid warranty period pursuant to Section 6.3. Upon a non-conformity or defect being reported, NEB shall organize the replacement of the non-conforming Products, at NEB's expense. The return or destruction of non-conforming Products shall be organized and paid for by NEB and at NEB's discretion. Should the parties disagree on the conformity of a Product with its specifications, the Parties shall hire, upon mutual agreement, an external neutral consultant to assess said Products and their conformity with the required specifications. The findings of such consultant shall be binding upon the Parties and the expenses of the consultant shall be paid by the losing Party, as well as the fees for stocking of the alleged non-conforming Products.

4.3 Recall. If NEB reasonably believes a recall may be necessary with respect to any Product provided under this Agreement, NEB shall promptly notify Purchaser in writing. Each Party shall provide reasonable assistance to the other Party in conducting a recall, including providing each other with all reasonably pertinent records and information. As between Purchaser and NEB, NEB shall be responsible for all Direct Costs of a recall to the extent such recall results from NEB's failure to manufacture Products in accordance with the applicable Specification, or otherwise to the extent such recall is a result of NEB's negligence or willful misconduct. Purchaser shall be responsible for all recall to the extent such recall results from Purchaser's negligence or willful misconduct. In the event that both Parties are liable for the recall, the Parties will agree to share the costs of the recall in such proportions as the Parties deem reasonable given each Party's responsibility for the recall. In the event that the Parties cannot agree on the apportionment of liability, the Parties shall jointly appoint an independent expert whose written determination on the issue shall be final. As used in this paragraph, "Direct Costs" mean reasonable out-of-pocket expenses incurred by a Party as a direct result of a Product recall hereunder, including expenses incurred for customer notifications and destruction or return of recalled Products.

ARTICLE 5
RESTRICTIONS; DISCLAIMERS

5.1 Restricted Use. Purchaser acknowledges that the Products may only be used in the Field, and for and in compliance with the applicable intended use statement, limited use statement or limited label license (if any) set forth in Exhibit A.

5.2 Disclaimers.

(a) The Products were designed for research use only and were not intended for any other purposes including, without limitation, *ex vivo* or *in vivo* therapeutic use, diagnostic use, investigational use in foods, drugs, devices or cosmetics of any kind, or for consumption by or use in connection with or administration or application to humans or animals. Purchaser acknowledges that the Products have not been tested by or for NEB for safety or efficacy. Purchaser is solely (and without assistance from NEB) responsible (i) for confirming that the Products are suitable for Purchaser's intended purpose and use; (ii) for confirming that Purchaser's use complies with Applicable Laws and (iii) for obtaining all necessary approvals, licenses, Third Party Intellectual Property Rights, and permissions needed for such use. Purchaser represents and warrants to NEB that it will properly test, use, and, to the extent authorized, market any Products, and any final articles made from the Products, in accordance with all Applicable Laws.

(b) Purchaser acknowledges that because Products are intended by NEB for research and development purposes, they or one or more of their components may not be on the Toxic Substances Control Act ("**TSCA**") Inventory. Purchaser assumes responsibility to ensure that the Products and the components thereof are in compliance with applicable requirements under TSCA, if applicable, including without limitation, the exemption for research and development, using the Products under the supervision of a technically qualified individual, maintaining all necessary labeling, and providing all necessary notifications. NEB does not and assumes no responsibility or obligation to, conduct research to learn the hazards involved for any of Purchaser's uses of the Products, such uses are at Purchaser's sole risk. Additionally, as between Purchaser and NEB, Purchaser is responsible to warn its customers, employees and any auxiliary personnel (such as freight handlers) of any risks involved in using or handling the Products. Purchaser shall comply with instructions for use of the Products furnished by NEB, if any, and shall not misuse the Products. If the Products are to be repackaged, relabeled or used as starting materials or components of other products, Purchaser will verify NEB's assay of the Products, qualify the Products for such applications, and comply with all Applicable Laws relating to labeling or providing other communications to customers. Purchaser acknowledges that NEB provides material Safety Data Sheets for the Products, and that they are available electronically on NEB's web site at www.neb.com, or by calling NEB at 1-800-632-5227, and that Purchaser is willing and able to access the Safety Data Sheets for the Products by these means. Purchaser also agrees to inform its employees of the risks, if any, involved in using or handling the Products and to train and equip them to handle the Products safely.

ARTICLE 6
REPRESENTATIONS AND WARRANTIES

6.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that (a) the execution, delivery and performance of this Agreement by such Party are within its power and authority and has been duly authorized by all necessary corporate action; (b) this Agreement is legal and valid and the obligations binding upon such Party are enforceable by their terms; and (c) the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound.

6.2 Purchaser Acknowledgement. Nothing in this Agreement will be construed as a representation or warranty that the use of the Products is or will be free from infringement of Third-Party Intellectual Property Rights. Purchaser acknowledges that it is the sole responsibility of Purchaser to determine whether it may be required to obtain any Third-Party Intellectual Property Rights depending upon the particular application in which the Product is used.

6.3 Product Warranty.

(a) NEB warrants that the Products will meet the applicable Specifications until the expiration dates specified on the Product packaging, or if not specified, then [**] from the date that NEB delivers such Product to Purchaser. This warranty shall not be effective if Purchaser has altered or misused the Product or has failed to use or store such Product in accordance with instructions furnished by NEB or the defects to the Product result from negligence, neglect or accident of any party other than NEB or a Party acting on behalf of or mandated by NEB. NEB shall replace the Products that are non-conforming or defective free of charge upon the return of such Product in accordance with NEB's instructions, provided however that the Parties may instead agree on a credit or refund in accordance with Subsection 4.2. This Section 6.3(a) sets out NEB's sole and exclusive liability, and Purchaser's sole and exclusive remedy with respect to a valid warranty claim made pursuant to this Section 6.3.

(b) THE WARRANTY ABOVE EXTENDS ONLY TO PURCHASER, AND PURCHASER CANNOT TRANSFER IT. THE WARRANTY ABOVE IS EXCLUSIVE, AND NEB MAKES NO OTHER WARRANTY WHATSOEVER, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, OF NON-INFRINGEMENT, OR REGARDING RESULTS OBTAINED THROUGH THE USE OF ANY PRODUCT OR SERVICE. IF NEB MANUFACTURES CUSTOM PRODUCTS FOR PURCHASER BASED ON INSTRUCTIONS, SPECIFICATIONS, OR OTHER DIRECTIONS PROVIDED BY PURCHASER, NEB SHALL NOT BE LIABLE FOR THE QUALITY OF THE PRODUCTS TO THE EXTENT ATTRIBUTABLE TO SUCH INSTRUCTIONS, SPECIFICATIONS, OR OTHER DIRECTIONS.

ARTICLE 7
INDEMNIFICATION; LIMITATION OF LIABILITY

7.1 NEB's Indemnity.

(a) General Indemnity. NEB shall indemnify and defend Purchaser, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys' fees and court costs) (collectively, "**Damages**") arising out of any Third Party claim, complaint, suit, proceeding or cause of action against any of them (each, a "**Claim**") resulting from one or more of the following: (a) NEB's gross negligence or intentional misconduct; (b) NEB's breach of its representations and warranties under Section 6.1; or (c) NEB's material breach of any of its obligations under this Agreement. Notwithstanding anything set out in Subsections 7.1(a) or (b), NEB shall have no obligations for any Damages to the extent that they are related to Purchaser's own negligence or willful misconduct.

(b) Infringement Indemnity. NEB will defend and indemnify Purchaser against infringement Damages finally awarded in any legal action brought by a Third Party against Purchaser to the extent that the action is based on a Claim that NEB's manufacture and sale of a Product infringes any valid Intellectual Property Right of such Third Party. This infringement indemnity does not apply to claims that arose based on (a) Purchaser's failure to comply with the Agreement, (b) Purchaser's failure to acquire any applicable rights required for Purchaser's particular use of the Product, (c) Products that NEB made, assembled or labeled in reliance upon Purchaser's

instructions, specifications, or other directions, or (d) Purchaser's use or resale of Products, (e) modifications made by Purchaser or any Third Party.

THE INDEMNITY SET OUT IN THIS SECTION 7.1(b) IS NEB'S ONLY LIABILITY TO PURCHASER, AND PURCHASER'S ONLY REMEDY, FOR ANY INFRINGEMENT OR CLAIMED INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS BY OR INCONNECTION WITH ANY PRODUCT.

7.2 Purchaser's Indemnity. Purchaser shall indemnify, hold harmless, and defend NEB, its directors, officers, employees, agents, successors and assigns from and against any Damages arising out of any Third Party Claims resulting from one or more of the following: (a) Purchaser's gross negligence or intentional misconduct; (b) Purchaser's breach of its representations and warranties under Section 6.1; (c) Purchaser's material breach of any of its obligations under this Agreement; (d) manufacture or sale of a Product to the extent made under Purchaser's instructions, specifications or other directions; or (e) any modification, use or resale of the Product and any final articles made therefrom by Purchaser or its distributors or customers, including without limitation, any Claims related to product liability or infringement of Third Party Intellectual Property Rights. Notwithstanding the foregoing, Purchaser shall have no obligations under this Article 7 for Damages to the extent that they are related to NEB's own negligence or willful misconduct.

7.3 Indemnification Procedure. Any Party seeking indemnification under this Article 7 (the "**Indemnitee**") shall promptly notify the indemnifying Party (the "**Indemnitor**") in writing of any possible Damages or Claim, and the Indemnitor shall assume and have exclusive control over the defense thereof with counsel selected by the Indemnitor that is reasonably satisfactory to the Indemnitee; *provided, however*, that the Indemnitee shall have the right to fully participate in any such action or proceeding and to retain its own (additional) counsel at its own expense (provided that the reasonable fees and expenses of such counsel for the Indemnitee shall be paid by the Indemnitor only if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate under applicable standards of professional conduct due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings). Neither the Indemnitor nor the Indemnitee shall enter into any settlement agreement with any Third Party without the prior written consent of the other Party, which consent will not be unreasonably withheld or delayed, unless such settlement: (i) includes an unconditional release of Indemnitee from all liability arising out of such claim;(ii) does not contain any admission or statement suggesting any wrongdoing or liability on behalf of Indemnitee; and (iii) does not contain any equitable order, judgment or term (other than the fact of payment or the amount of such payment) that in any manner affects, restrains or interferes with the business of Indemnitee. The failure to deliver notice to the Indemnitor within a reasonable time after the commencement of any action, to the extent prejudicial to its ability to defend such action, will relieve the Indemnitor of its obligations under this Article 7, but the failure to deliver notice to the Indemnitor will not relieve the Indemnitor of any obligations that it may have to any Indemnitee hereunder otherwise than as stated in this sentence. The Indemnitee shall, at the reasonable and verifiable out-of-pocket expenses of the Indemnitor, cooperate with the Indemnitor and its legal representatives in the investigation and defense of any Claim covered by this Agreement.

7.4 Product Replacement. If at any time, in NEB's sole opinion, the manufacture or sale of any of the Products may become the subject of a patent infringement claim, NEB may at its sole option: (a) procure for Purchaser the rights to continue using the applicable Product; (b) replace the applicable Products with a reasonable substitute or modify such Products so that the applicable activity is no longer infringing; or (c) stop selling the Product to Purchaser and accept for return any outstanding such Products for a credit. For clarity, none of the actions taken pursuant to this Section 7.4 will be deemed a breach of any other terms of this Agreement, nor will they be deemed an admission of infringement.

7.5 Limitation of Liability. TO THE FULLEST EXTENT ALLOWED BY LAW, IN NO EVENT SHALL EITHER PARTY BE LIABLE UNDER ANY LEGAL THEORY (INCLUDING BUT NOT LIMITED TO CONTRACT, NEGLIGENCE, STRICT LIABILITY IN TORT OR WARRANTY OF ANY KIND) FOR ANY INDIRECT, SPECIAL, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES, OR FOR ANY LOST PROFITS, EVEN IF SUCH PARTY HAD NOTICE OF THE POSSIBILITY OF SUCH DAMAGES OR SUCH DAMAGES ARE FORESEEABLE. SECTIONS 7.1 AND 7.2 SETS FORTH THE ENTIRE LIABILITY AND OBLIGATION OF THE INDEMNIFYING PARTY AND THE SOLE AND EXCLUSIVE REMEDY FOR THE INDEMNIFIED PARTY FOR ANY DAMAGES INDEMNIFIED OR DEFENDED UNDER ARTICLE 7. NEB'S MAXIMUM LIABILITY, IF ANY, UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION CONTRACT DAMAGES AND DAMAGES FOR INJURIES TO PERSONS OR PROPERTY, WHETHER ARISING FROM INDEMNIFICATION OBLIGATIONS HEREUNDER, BREACH OF THESE TERMS AND CONDITIONS, BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY, OR OTHER TORT WITH RESPECT TO THE PRODUCT(S), OR ANY SERVICES IN CONNECTION WITH THE PRODUCT(S), IS LIMITED TO AN AMOUNT NOT TO EXCEED THE AGGREGATE PURCHASE PRICE OF THE PARTICULAR PRODUCT(S) THAT IS THE SUBJECT OF SUCH LIABILITY ACTUALLY PURCHASED HEREUNDER IN THE YEAR IN WHICH THE ACTION OCCURRED. ALL CLAIMS BY PURCHASER FOR BREACH OR DEFAULT UNDER THIS AGREEMENT MUST BE BROUGHT WITHIN ONE (1) YEAR AFTER THE CAUSE OF ACTION INCURRED OR SHALL BE DEEMED WAIVED. NOTHING CONTAINED HEREIN SHALL LIMIT A PARTY'S LIABILITY IN CASE OF GROSS NEGLIGENCE OR WILFULL MISCONDUCT.

ARTICLE 8
TERM AND TERMINATION

8.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue for an initial term of three (3) years ("**Initial Term**"). Thereafter, this Agreement shall automatically renew for successive two (2) year periods (each, a "**Renewal Term**" and the Initial Term together with any and all applicable Renewal Terms, the "**Term**"), unless either Party notifies the other Party in writing at least six (6) months prior to the expiration of the then-current Term that such Party does not wish to continue this Agreement.

8.2 Termination for Breach. Either Party may terminate this Agreement if the other Party commits a material breach of any of its warranties, covenants, conditions, obligations or agreements contained herein, *provided* that such breach continues for a period of [**] after the non-breaching Party provides the breaching Party with written notice thereof. Such termination shall be immediately effective upon the non-breaching Party providing the breaching Party with further written notice of termination after the breaching Party failed to cure such breach within [**] cure period.

8.3 Termination for Bankruptcy. Either Party may immediately terminate this Agreement, upon giving written notice to the other Party, in the event that the other Party is declared bankrupt by a court of competent jurisdiction or is the subject of any reorganization (other than a corporate reorganization effected in the ordinary course of business and not arising out of any insolvency) or winding up, receivership or dissolution, bankruptcy or liquidation proceeding, or any proceeding or action similar to one or more of the above, which proceeding is not dismissed within [**] . The failure of either Party to give notice of termination upon obtaining knowledge of any such event shall not be interpreted as a waiver of such Party's rights under this Section 8.3, and such Party reserves the right to exercise any such rights at any time after the occurrence of any such event.

8.4 Termination by Mutual Agreement. The Parties may terminate this Agreement for any reason at any time by mutual agreement if set forth in writing and executed by an authorized representative of each Party.

8.5 Termination for Stoppage. NEB shall the right to terminate this Agreement with respect to one or more Product(s) after providing at least [**] prior written notice to Purchaser if NEB has determined to cease manufacture and sale of such Product(s).

8.6 Effects of Termination. It is understood that termination or expiration of this Agreement will not relieve a Party from any liability that, at the time of such termination or expiration, has already accrued to the other Party. For clarity, expiration or termination of this Agreement for any reason will not relieve Purchaser's obligation to purchase any Product ordered under any outstanding Purchase Orders or subject to the binding portion of the Rolling Forecast but not yet ordered. The provisions of Articles 1, 5, 7, 8, 9 and 10, and Sections 4.2, 6.2, and 6.3 will survive the expiration or termination of this Agreement for any reason, subject to any time limitations stated therein. All other rights and obligations of the Parties will cease upon termination of this Agreement.

ARTICLE 9
CONFIDENTIALITY; PUBLICITY

9.1 Definitions. "**Confidential Information**" means any information furnished by one Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") pursuant to, and related to the purpose of, this Agreement, whether written or oral, including without limitation any technical, scientific, trade, research, manufacturing, marketing, supplier, business, financial or other information.

9.2 Non-Disclosure and Non-Use. During the Term and for [**] thereafter (unless the Confidential Information constitutes a trade secret under Applicable Laws in which case, until such Confidential Information no longer constitutes a trade secret), the Receiving Party shall (a) keep confidential and not publish or otherwise disclose Confidential Information or use Confidential Information for any purpose other than as permitted under, or required to perform its obligations under, this Agreement; (b) protect the Confidential Information with the same degree of care as it normally uses to preserve and safeguard its own proprietary information of like nature, but not less than a reasonable degree of care; and (c) disclose Confidential Information only to its employees, advisors, agents herein.

9.3 Exclusions. Confidential Information will not include information that the Receiving Party can establish by competent written proof (a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or (e) was independently developed by the Receiving Party without the aid, use or application of the Confidential Information. In addition, disclosure of Confidential Information is not prohibited to the extent required to comply with Applicable Laws or regulations, or with a valid court or administrative order, *provided* that the Receiving Party (i) promptly notifies the Disclosing Party in writing of the existence, terms and circumstances of such required disclosure; (ii) consults with the Disclosing Party on the advisability of taking legally available steps to resist or narrow such disclosure; and (iii) takes all reasonable and lawful actions to obtain confidential treatment for such disclosure.

9.4 Return of Confidential Information. Upon the termination or expiration of this Agreement, at the written request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party or destroy all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of the Receiving Party

(including its employees, advisors, agents and Affiliates); *provided, however*, that one (1) copy of the Confidential Information may be retained by the Receiving Party for the sole purpose of monitoring its ongoing obligations hereunder.

9.5 Publicity. Except as required by Applicable Laws, neither Party shall use the name of the other Party in any publicity or advertising without the prior written approval of the other Party. The Parties agree not to disclose any terms or conditions of this Agreement to any Third Party without the prior written consent of the other Party, except as required by Applicable Laws. Notwithstanding the foregoing, prior to providing any documentation or other materials referring to NEB to, or making any filing referring to NEB with, a regulatory or other government authority or other Third Party, Purchaser shall provide NEB with an advance copy of such documentation with reasonable time to allow NEB to review and comment on such documentation. Further, Purchaser shall incorporate any reasonable changes to language relating to NEB and/or its Products requested by NEB prior to Purchaser's disclosure in the documentation it creates after the notification by NEB. The restrictions on the use of a Party's name in this Section 9.5 shall pertain to the name of the Party and the name of any Affiliates of such Party.

ARTICLE 10
GENERAL PROVISIONS

10.1 Legal Compliance; Export Control. Each Party shall comply in all material respects with all laws, rules and regulations applicable to its conduct pursuant to this Agreement. Without limiting the foregoing, Purchaser acknowledges that the Products are subject to U.S. export control laws and regulations. Purchaser agrees to not, directly or indirectly, (a) sell, export, reexport, transfer, divert, or otherwise dispose of any Products, software, or technology (including products derived from or based on such technology) received from NEB to any destination, entity, or person prohibited by the laws or regulations of the United States, or (b) use the Product for any use prohibited by any Applicable Laws, without obtaining prior authorization from the competent government authorities as required by those laws and regulations.

10.2 Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any provision of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, fire, floods, embargoes, war, acts of war (whether war is declared or not), insurrections, riots, terrorism, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party; *provided, however*, that the Party so affected shall use commercially reasonable efforts to avoid or remove such causes of nonperformance, and shall continue to perform hereunder with reasonable dispatch whenever such causes are removed; *and provided, further*, that in no event shall a Party be required to settle any labor dispute or disturbance. Either Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of *force majeure*. The Parties shall mutually seek a resolution of the delay or the failure to perform as noted above. The Parties shall use their respective reasonable efforts to prevent or mitigate the consequences of such events.

10.3 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; *provided, however*, that each of the Parties may, without such consent, assign this Agreement and its rights and obligations hereunder (a) in connection with the transfer or sale of all or substantially all of the portion of its business to which this Agreement relates; and (b) to its Affiliates. In the event of any assignment, (i) the assigning Party shall deliver written notice of the assignment to the other Party, (ii) the assignee shall agree to be bound to the obligations of the assigning Party, (iii) the assigning Party shall remain liable for the performance of all obligations

under this Agreement as if the assignment did not occur, except in the case of a consolidation or merger where the assigning Party is not the surviving entity, and (iv) in the event the assignee fails to meet its performance obligations under the Agreement the assignee shall be subject to the terms and conditions for breach and termination under this Agreement.

10.4 Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party to circumstance is, to any extent, held to be invalid or unenforceable, then the remainder of this Agreement, or the application of such term, covenant or condition to the Parties or circumstances other than those as to which it is held invalid or unenforceable, will not be affected thereby and each term, covenant or condition of this Agreement will be valid and enforced to the fullest extent permitted by law.

10.5 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties hereto to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery or courier) or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to addressor and shall be effective upon receipt by the addressee.

To NEB:	New England Biolabs, Inc.
	[**]
with a copy to:	New England Biolabs, Inc.
	[**]
To Purchaser:	Sophia Genetics SA
	Rue du Centre 172
	1025 St-Sulpice, Switzerland
	legal@sophiagenetics.com
	Attention: Legal Affairs Office

10.6 Entire Agreement. The terms and provisions contained in the Agreement (including the Exhibits hereto) constitute the entire agreement between the Parties and supersede all previous communications, representations, agreements or understandings, either oral or written, between the Parties with respect to the subject matter hereof. No agreement or understanding varying or extending this Agreement will be binding upon either Party hereto, unless set forth in a writing which specifically refers to the Agreement signed by duly authorized officers or representatives of the respective Parties, and the provisions hereof not specifically amended thereby shall remain in full force and effect. No terms contained in any standard form purchase order, order acknowledgment, invoice, Product warranty literature or Product manuals, or similar standardized form shall be construed to amend or modify the terms of this Agreement and in the event of any conflict, the Agreement shall control, unless the Parties otherwise expressly agree in writing that specifically states an intent to amend the terms of this Agreement and identifies the terms of this Agreement to be so amended.

10.7 Waiver. Except as specifically provided for herein, the waiver from time-to-time by either Party of any of its rights or its failure to exercise any remedy will not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement. No waiver of any breach of a provision of this Agreement will be effective unless made in writing and signed by an authorized representative of the waiving Party. The delay or failure of either Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same.

10.8 Independent Contractors. The relationship of NEB and Purchaser established by this Agreement is that of independent contractors. Nothing in this Agreement shall be construed to create a partnership, joint venture, agency or other fiduciary relationship between Purchaser and NEB. Neither Party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

10.9 Governing Law. This Agreement shall be construed and interpreted in accordance with the laws of the England and Wales, without regard to conflict of law principles.

10.10 Headings. The headings contained in this Agreement are for reference purposes only and are no way intended to describe, interpret, define or limit the scope, extent or intent of this Agreement or any provisions hereof.

10.11 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Supply Agreement as of the Effective Date.

SOPHIA GENETICS SA

By: /s/ Jurgi Camblong
Name: Jurgi Camblong
Title: CEO

By: /s/ Valentin Matillon
Name: Valentin Matillon
Title: CFO

NEW ENGLAND BIOLABS, INC.

By: /s/ Dr. Salvatore V. Russello
Name: Dr. Salvatore V. Russello
Title: Director,
OEM & Customized Solutions

Certain confidential information contained in this document, marked by [**], has been omitted because SOPHiA GENETICS SA(SOPHiA) has determined that the information (i) is not material and (ii) is the type that SOPHiA customarily and actually treats as private or confidential.

[Exhibits to this agreement have been omitted pursuant to Item 601(a)(5) of Regulation S-K. SOPHiA GENETICS SA undertakes to provide a copy of the omitted exhibits to the Securities and Exchange Commission or its staff upon request.]

Exhibit B

[**]

Exhibit 8.1

SUBSIDIARIES

Name of Subsidiary	Jurisdiction of Incorporation
SOPHiA GENETICS S.A.S.	France
SOPHiA GENETICS LTD	United Kingdom
SOPHiA GENETICS, Inc.	Delaware (USA)
SOPHiA GENETICS Intermediação de Negócios EIRELI	Brazil
SOPHiA GENETICS PTY LTD	Australia
SOPHiA GENETICS S.R.L.	Italy

Exhibit 12.1

CERTIFICATION PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jurgi Camblong, certify that:

1. I have reviewed this annual report on Form 20-F of SOPHiA GENETICS SA;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. [reserved];

    c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 15, 2022

/s/ Jurgi Camblong
Name: Jurgi Camblong
Title: Chief Executive Officer

Exhibit 12.2

CERTIFICATION PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ross Muken, certify that:

1. I have reviewed this annual report on Form 20-F of SOPHiA GENETICS SA;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. [reserved];

    c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 15, 2022

/s/ Ross Muken
Name: Ross Muken
Title: Chief Financial Officer

Exhibit 13.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The certification set forth below is being submitted in connection with SOPHiA GENETICS SA's annual report on Form 20-F for the year ended December 31, 2021 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Jurgi Camblong, the Chief Executive Officer of SOPHiA GENETICS SA, certify that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of SOPHiA GENETICS SA.

Date: March 15, 2022

/s/ Jurgi Camblong

Name: Jurgi Camblong
Title: Chief Executive Officer

Exhibit 13.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The certification set forth below is being submitted in connection with SOPHiA GENETICS SA's annual report on Form 20-F for the year ended December 31, 2021 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Ross Muken, the Chief Financial Officer of SOPHiA GENETICS SA, certify that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of SOPHiA GENETICS SA.

Date: March 15, 2022

/s/ Ross Muken

Name: Ross Muken
Title: Chief Financial Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-258121 and No. 333-258122) of SOPHiA GENETICS SA of our report dated March 15, 2022 relating to the consolidated financial statements, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers SA

Lausanne, Switzerland
March 15, 2022