UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended March 31, 2022

OR

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

FOR THE TRANSITION PERIOD FROM_____ TO_____

Commission File Number 001-39587

23ANDME HOLDING CO.

(Exact name of Registrant as specified in its Charter)

Delaware	**87-1240344**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
349 Oyster Point Boulevard **South San Francisco, California**	**94080**
(Address of principal executive offices)	**(Zip Code)**

(650) 938-6300

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, $0.0001 par value per share	**ME**	**The Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, 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. ☐

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 whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the Registrant as of September 30, 2021, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $0.82 billion (based on the last reported sale price of the Registrant's Class A common stock of $9.06 per share on September 30, 2021 on the Nasdaq Global Select Market), excluding only shares of Class A common stock held by executive officers and directors of the Registrant as of such date. The Registrant has no non-voting stock outstanding.

As of May 20, 2022, there were 256,405,630 shares of Class A common stock, $0.0001 par value per share, and 192,767,491 shares of Class B common stock, $0.0001 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement to be delivered to stockholders in connection with the 2022 annual meeting of stockholders are incorporated by reference in response to Part III of this Annual Report on Form 10-K to the extent stated herein. The 2022 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended March 31, 2022 (this "Form 10-K"), including, without limitation, statements under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"). Generally, statements that are not historical facts, including statements concerning 23andMe Holding Co.'s (the "Company," "we," "us," or "our") possible or assumed future actions, business strategies, events, or results of operations, are forward-looking statements. In some instances, these forward-looking statements can be identified by the use of forward-looking terminology, including, without limitation, words like "believes," "estimates," "anticipates," "expects," "intends," "plans," "may," "will," "potential," "projects," "predicts," "continue," or "should," or, in each case, their negative or other variations or comparable terminology. There can be no assurance that actual results will not materially differ from expectations.

The forward-looking statements contained in this Form 10-K are based on our current expectations and beliefs, which we believe to be reasonable, concerning future developments and their potential effects on us. Future developments affecting us may not be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control), and other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, without limitation, those factors described under Part I, Item 1A: "Risk Factors." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. These risks and others described under Part I, Item 1A: "Risk Factors" may not be exhaustive.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition, and liquidity, and developments in the industry in which we operate may differ materially from those made in or suggested by the forward-looking statements contained in this Form 10-K. In addition, even if our results or operations, financial condition, and liquidity, and developments in the industry in which we operate are consistent with the forward-looking statements contained in this Form 10-K, those results or developments may not be indicative of results or developments in subsequent periods.

You should read this Form 10-K and the documents that we reference in this Form 10-K and have filed with the Securities and Exchange Commission as exhibits to this Form 10-K with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

EXPLANATORY NOTE

As previously announced, VG Acquisition Corp. ("VGAC" and, after the Domestication as described below, "23andMe Holding Co."), a Cayman Islands exempted company, entered into that certain Agreement and Plan of Merger, dated February 4, 2021, as amended on February 13, 2021 and March 25, 2021 (the "Merger Agreement"), by and among VGAC, Chrome Merger Sub, Inc., a Delaware corporation and wholly owned direct subsidiary of VGAC (the "Merger Sub"), and 23andMe, Inc., a Delaware corporation.

On June 16, 2021 (the "Closing Date"), as contemplated by the Merger Agreement, VGAC filed a notice of deregistration with the Cayman Islands Registrar of Companies, together with the necessary accompanying documents, and filed a certificate of incorporation and a certificate of corporate domestication with the Secretary of State of the State of Delaware, under which VGAC was domesticated and continued as a Delaware corporation, changing its name to 23andMe Holding Co. (the "Domestication"). As a result of and upon the effective time of the Domestication, among other things, each of the then issued and outstanding Class A and Class B ordinary shares of VGAC automatically converted, on a one-for-one basis, into shares of our Class A common stock, par value $0.0001 per share (the "Class A common stock"). On the Closing Date, VGAC consummated the merger transaction contemplated by the Merger Agreement, whereby the Merger Sub merged with and into 23andMe, Inc., the separate corporate existence of the Merger Sub ceasing and 23andMe, Inc. being the surviving corporation and a wholly owned subsidiary of VGAC, now known as 23andMe Holding Co. (the "Merger"). Prior to the Merger, VGAC's units, public shares, and public warrants were listed on the New York Stock Exchange ("NYSE") under the symbols "VGAC.U," "VGAC," and "VGAC WS," respectively. On June 17, 2021, the Company's Class A common stock and public warrants began trading on The Nasdaq Global Select Market ("Nasdaq"), under the symbols "ME" and "MEUSW," respectively.

In this Form 10-K, 23andMe Holding Co. (together with its subsidiaries) is referred to as the "Company," "we," "us," or "our."

PART I

Item 1. Business

Overview

23andMe Holding Co., formerly known as VG Acquisition Corp., is a mission-driven company dedicated to empowering customers to live healthier lives. The Company's mission is to help people access, understand, and benefit from the human genome. The Company believes that its premier database of genetic and phenotypic information crowdsourced from its millions of customers that separately consent to participate in our research can revolutionize healthcare by enabling us to discover insights into the origins of diseases, to use those insights to prevent, diagnose, and treat diseases, and to speed the discovery and development of novel therapies. The Company is committed to rigorous scientific, ethical, and privacy standards and to being one of the most trusted source for genetic and health information.

We pioneered direct-to-consumer genetic testing, giving consumers unique, personalized information about their genetic health risks, ancestry, and traits. We are the only consumer genetic testing company with multiple Food and Drug Administration ("FDA") authorizations for over-the-counter health and carrier status reports. We were the first company to obtain FDA authorization for a direct-to-consumer genetic test, and we are the only company to have FDA authorization, clearance, or an exemption from premarket notification for all carrier status, genetic health risk, cancer predisposition, and pharmacogenetics reports offered to customers. As of March 31, 2022, over 60 health reports were available to customers in the U.S.

We acquired Lemonaid Health, Inc. ("Lemonaid" or "Lemonaid Health") in November 2021 in an important step to achieve our goal of making personalized healthcare a reality. Lemonaid offers patients affordable and direct online access to medical care, from consultation through treatment, for a number of common conditions, using evidence-based guidelines and up-to-date clinical protocols to deliver quality patient care. When medications are prescribed by our medical professionals, patients can use our convenient online pharmacy for fast and free delivery.

Operating Segments

We operate in two reporting segments: Consumer & Research Services and Therapeutics.

Consumer & Research Services

Our Consumer & Research Services business segment comprises our Personal Genome Service® ("PGS"), our telehealth business, and research services.

PGS

Our PGS service provides customers with a broad suite of genetic reports, including information on customers' genetic ancestral origins, personal genetic health risks, and chances of passing on certain rare carrier conditions to their children, as well as reports on how genetics can impact responses to medications. We believe that by providing customers with direct access to their genetic information, we can empower them to make better decisions by arming them with information about their risks of developing certain diseases or conditions and by highlighting opportunities for prevention and mitigation of disease.

In the U.S., Canada, and the United Kingdom (the "U.K."), we offer two PGS services, and also offer a premium service called 23andMe+. Ancestry + Traits Service is our base service and provides customers information about their genetic ancestral origins and how genetics may influence over 30 traits, such as physical features, sense perceptions, reactions to external stimuli and other traits. The service also includes a tool that enables customers who choose to opt in to connect with genetic relatives that are also customers of the Company. Our Health + Ancestry Service builds upon our Ancestry + Traits Service to also provide reports relating to a customer's health predisposition (including certain cancers and other health risks such as late-onset Alzheimer's disease), carrier status (including for cystic fibrosis and hereditary hearing loss), and wellness (including for deep sleep, lactose intolerance and genetic weight), and carrier status reports. Ancestry + Traits Service customers can upgrade to the Health + Ancestry Service for a fee. We provide customers with an engaging experience, including access to updates to their genetic health and ancestry reports and new product features, and the ability to connect with genetic relatives.

Our 23andMe+ premium subscription service offers customers the Health + Ancestry Service plus pharmacogenetic reports, personalized genetic risk reports based on our research, and advanced ancestry and health features, including insights related to heart, reproductive health and sleep. Our PGS services are available for purchase on our website, 23andMe.com, or mobile app and, in the U.S., the U.K., and Canada, through Amazon. Substantially all of the Company's revenues are derived from the Consumer & Research Services segment, with revenue from PGS representing approximately 75%, 81%, and 89% of our total revenues for the fiscal years ended March 31, 2022, 2021, and 2020, respectively.

Customers have the option to participate in our research programs and over 80% of our customers have chosen to do so. We analyze consenting customers' genotypic data together with phenotypic data they provide to us concerning their health, physical characteristics, family origins, lifestyle, and other habits. We analyze this data using our proprietary machine learning and other analytic techniques in order to discover insights into whether and how particular genetic variants affect the likelihood of individuals developing specific diseases. These insights may highlight opportunities to develop a drug to treat or cure a specific disease, and also provide information that customers can use to enhance their medical care and treatment, including care accessed through our Lemonaid telehealth platform.

Telehealth

The acquisition of Lemonaid provided us with telehealth capabilities and enhances our ability to bring better healthcare and wellness offerings to patients. Our telehealth platform provides patients with easy access to medical consultation and treatment. Within minutes, a patient can interact with one of our affiliated licensed physicians or nurse practitioners via telehealth. If a prescription is warranted, the patient can access our pharmacy services for fast and free delivery. Our pharmacies offer non-controlled medications for prevention and treatment of acute and chronic conditions at affordable prices, and our pharmacists provide ongoing support to ensure proper care by counseling, educating, and following up with patients. Our goal is to make personalized healthcare services affordable and accessible, focusing on both the prevention and treatment of disease. We make telehealth services available in the U.S. and, under a third-party brand, in the U.K.

Affiliated Professional Medical Corporations. Because many states limit the ownership of medical practices to licensed professionals and prohibit corporate ownership of medical practices, we offer medical services through affiliated professional medical corporations ("PMCs") that are owned by a licensed medical provider in the applicable jurisdiction. All of the doctors and nurse practitioners who provide medical services to our patients are employees of the PMCs. Lemonaid, our wholly owned subsidiary, has a management services agreement ("MSA") with each PMC pursuant to which Lemonaid provides business, administrative and non-clinical services to the PMC in exchange for a fixed fee. These services include IT, billing, insurance, tax, accounting and other administrative services, and do not include any clinical, diagnostic or treatment decisions, which are made solely by licensed practitioners based on quality medical care guidelines and protocols. The MSAs are exclusive arrangements, and the PMCs were established specifically to provide medical services through our platform.

Affiliated Pharmacies. Our patients may choose to fill prescriptions provided to them by our affiliated medical professionals by using our pharmacy services. We facilitate the delivery of pharmacy services by our affiliated mail order pharmacy, offering patients affordable, fast and free delivery services throughout the U.S. We also manage an affiliated retail pharmacy that is able to accept insurance from government and commercial providers where applicable. Almost all of our pharmacy services are provided on a self-pay basis and are not covered by third-party payors. We also provide a small number of compounded medications that are fulfilled by a third-party service provider that is not affiliated with us. We manage our affiliated pharmacies under MSAs pursuant to which we provide all administrative services as well as licensed pharmacists, support staff and infrastructure. Our MSAs with our affiliated pharmacies are exclusive arrangements, and the affiliated pharmacies were established specifically to provide prescription medications when patients choose to use our platform to fill prescriptions written by our affiliated licensed medical professionals.

Research Services

Through our research services, we use our vast database of genetic and phenotypic information provided by consenting customers to discover insights into the genetic origins of disease and to identify targets for drug development. These services are performed under agreements with universities, research institutions and pharmaceutical companies, including our multi-year collaboration agreement with an affiliate of GlaxoSmithKline ("GSK"), which was signed in July 2018 (the "GSK Agreement") to leverage genetic insights to validate, develop, and commercialize drugs. The GSK Agreement is expected to identify and prioritize genetically validated drug targets, enable rapid progression of clinical programs, and bring useful new drugs to market. We also provide clinical trial services to accelerate patient recruitment by using our database to identify patients most likely to be eligible for participation in a clinical trial of a new drug. We currently have research programs across several therapeutic areas, including oncology, respiratory, and cardiovascular diseases.

Therapeutics

Our Therapeutics business segment focuses on the use of genetic insights from our vast database of genetic and phenotypic information to develop novel therapies to improve patients' lives. The Therapeutics segment consists of revenues from the out-licensing of intellectual property associated with identified drug targets and expenses related to therapeutic product candidates under clinical development. In addition to our collaboration with GSK, we have several proprietary programs, one of which is being pursued in collaboration with Almirall, S.A.

As of March 31, 2022, two of our programs had entered Phase 1 trials. One is from our proprietary programs, 23ME-00610, previously known as P006, which had started the Phase 1 in patients with advanced solid tumors. 23ME-00610 is a high-affinity humanized monoclonal antibody that is designed to interfere with the ability of CD200R1 to interact with CD200 found on cancer cells. The other one is immuno-oncology program, GSK6097608, led by GSK, an antibody that targets the CD96. CD96 sequesters a shared ligand (CD155) away from the costimulatory receptor (CD226), effectively attenuating T and NK cell anti-tumor immune responses. By blocking CD96, GSK6097608 may allow activation of CD226 and enhance anti-tumor immunity through T and NK cells. If a successful therapy were to be developed and commercialized by GSK using this target, we would be entitled to a royalty under the GSK Agreement.

Business Strategy

- **Building the most trusted brand in the industry.** Our customers and our patients are our partners. We seek to empower them with knowledge that will help them, and ultimately will help everyone, to live happier, healthier and longer lives. They choose how to use the genetic and health information we provide to them. We respect their choices, and we work every day to earn and keep their trust.

- **Revolutionizing healthcare.** Traditional healthcare is impersonal, difficult, and frustrating for consumers, and focuses on treatment and not prevention of disease. We believe that our customer-centric, personalized model has the power to radically shift traditional healthcare to a new focus on individualized care and prevention. We believe that our trusted brand, millions of engaged customers, and unique database of genetic information, combined with our telehealth platform for delivering affordable personalized care efficiently to patients, will provide us with the opportunity to create a new and innovative healthcare model that will drive future growth.
- **Scaling research.** Our research platform is based on a continually growing database of genotypic and phenotypic information. Our database allows us to conduct analyses in a multi-directional fashion, by searching for genetic signatures of particular diseases or the likelihood of a particular genetic variant causing disease in a particular individual or group of individuals who share the same trait. Our platform enables us to rapidly and serially conduct studies across an almost unlimited number of conditions at unprecedented statistical power, yielding insights into the causes and potential treatments of a wide variety of diseases.
- **Efficiently develop novel therapeutics.** We believe that our research platform enables us to rapidly identify drug targets with improved odds of clinical success. With our state-of- the-art bioinformatics capabilities, we analyze the trillions of data points in our database, optimizing the use of our resources, to identify drug targets, inform patient selection for clinical trials and increase the probability of success of our programs. We plan to advance new drugs through the development process by rapidly selecting those with compelling clinical promise.
- **Maximizing our collaborations.** Since inception, we have worked with researchers in academia and in biopharma to demonstrate the quality and power of our database and advance discoveries, resulting in more than 180 published papers. Our collaboration with GSK further validates our drug discovery approach and expands our reach through GSK's size and deep expertise. We plan to continue to leverage synergistic relationships to advance the development of our own, as well as our jointly owned, clinical programs.
- **Dreaming Big.** We have a founder-led, inclusive, entrepreneurially inspired and scientifically rigorous approach to all we do. Our customer-first, patient-focused and data-driven people believe in our vision of "healthy at 100" and are dedicated to our mission of helping people access, understand and benefit from the human genome. Their commitment to our vision and our mission differentiates us from other companies in the healthcare industry.

Acquisitions

VGAC Business Combination

On June 16, 2021, the Company consummated the transactions (the "Merger") contemplated by the Agreement and Plan of Merger, dated February 4, 2021, as amended on February 13, 2021 and March 25, 2021, by and among VG Acquisition Corp., a blank check company incorporated as a Cayman Islands exempted company in 2020 ("VGAC"), Chrome Merger Sub, Inc., a Delaware corporation and wholly owned direct subsidiary of VGAC (the "Merger Sub"), and 23andMe, Inc. In connection with the Merger, VGAC changed its jurisdiction of incorporation from the Cayman Islands to the State of Delaware and changed its name to 23andMe Holding Co. (the "Domestication"). On the closing date, the Merger Sub merged with and into 23andMe, Inc., with 23andMe, Inc. being the surviving corporation and a wholly owned subsidiary of the Company (together with the Merger and the Domestication, the "Business Combination").

Lemonaid Acquisition

We completed our acquisition of Lemonaid on November 1, 2021 (the "Lemonaid Acquisition"). Lemonaid, an on-demand platform for accessing medical care and pharmacy services online, offers telemedicine, lab, and pharmacy services to patients in all 50 states, the District of Columbia, and the U.K. We believe that the addition of Lemonaid's telehealth services to our consumer business will enable us to bring better healthcare to individuals in an affordable and accessible way and offer access to personalized healthcare, based on a patient's wellness, choices, and genetics.

Market Opportunity

Consumer - PGS

We believe that our ability to analyze genetic information and provide personalized reports on genetic variations that are known to be associated with important health conditions empowers our customers. Armed with this personalized information, our customers have the ability to make informed, proactive decisions about their health and their lives. As of March 31, 2022, we had approximately 12.8 million customers.

We expect to continue to develop and provide to our customers new reports, including reports on cancer risk, diet, reproductive health, fitness and injuries, sleep, pharmacogenetics, and autoimmune conditions. Additionally, we believe that direct-to-consumer genetic health testing is gaining wider acceptance by physicians in the U.S., and that we will be able to drive further acceptance through our telehealth platform.

We expect to continue to invest in expanding our PGS offerings and marketing our PGS to customers, and that as we attract more customers, we will benefit from the network effect created by an increasing cohort of customers who recommend our PGS to their families and friends, and who reap health benefits by using their genetic information to help them and their medical providers make better decisions about their care and lifestyle choices.

23andMe+® Subscription Service

The 23andMe+ service is an annual subscription that provides customers with exclusive reports and features not available in the basic Health + Ancestry Service. This subscription is an add-on to our Health + Ancestry Service. 23andMe+ provides customers with additional health reports, including multiple FDA-authorized pharmacogenetics reports, as well as personalized risk score reports based on 23andMe research. These new risk scores can help customers understand certain genetic risks, such as atrial fibrillation, coronary artery disease, high LDL cholesterol, hypertension and migraine, and provide them with information on preventing and managing these conditions. The 23andMe+ subscription also provides customers with advanced ancestry-related features, such as enhanced tools and filters for finding genetic relatives. We are continually investing in new reports and features to provide to subscribers, and expect to add new reports for subscribers based on genetic insights from our research. We believe the 23andMe+ subscription will enhance customer engagement as subscribers receive new content with discoveries about themselves throughout the subscription period and meaningful and customized information to help them lead healthier lives. As of the fiscal years ended March 31, 2022 and 2021, our 23andMe+ membership base had approximately 425,000 and 125,000 subscribers, respectively.

Consumer – Telehealth

Telehealth enables consumers to access healthcare conveniently, from their homes, and to obtain fast and affordable consultation, diagnosis and treatment without the difficulties of scheduling and traveling to physical appointments. By accessing medical consultation and treatment through our telehealth platform, patients are able to take ownership of their health. Support and demand for telehealth services have been increasing due to deregulation and broad societal shifts. We believe that we have the innovative, patient-first care model, the technical platform, the nationwide provider network, and the extensive pharmacy capabilities to be a leading provider of healthcare. Patients can interact with our medical providers through either synchronous or asynchronous consultations, depending on patient's need and applicable regulatory requirements. Our system enables us to deliver convenient, easy-to-access and discrete online care without an appointment. In the future, we plan to offer patients the opportunity to integrate genetic information into their healthcare, which we believe will enhance the ability of our medical providers to offer diagnoses and treatment tailored to our patients' individual needs.

Therapeutics

We believe our research platform can transform the process of drug development. Genetic data can significantly improve our understanding of diseases, their pathways and mechanisms, leading to the design and development of more targeted medicines. Use of genetic data in selecting drug targets can increase both the probability of success in a particular indication and avoid unwanted safety risks. The scale of our database provides us with a unique opportunity to pursue genetically targeted drug discovery by enabling us to:

- Query data that enable us to identify a statistically meaningful number of individuals who report having a particular disease, which we then use to determine whether the presence or absence of a particular genetic variant increases or decreases the likelihood of developing a disease;
- Conduct discovery at scale based on a substantial number of novel associations from a diverse range of people;
- Improve target selection with the aim of discovering safer, more effective "precision" medicines;
- Support identification of patient subgroups that are more likely to respond to targeted treatments; and
- More quickly identify and recruit patients for clinical studies from our re-contactable database.

Competition

Consumer (PGS and Telehealth)

The number of companies entering the personal genetics market with offerings similar to our direct-to-consumer PGS continues to increase. We also face competition from other companies attempting to capitalize on the same, or similar, opportunities as we are, including from existing diagnostic, laboratory services and other companies entering the personal genetics market with new offerings such as direct access and/or consumer self-pay tests and genetic interpretation services. Some of our current and potential competitors have longer operating histories and greater financial, technical, marketing and other resources than we do. These factors may allow our competitors to respond more quickly or efficiently than we can to new or emerging technologies. These competitors may engage in more extensive research and development efforts, undertake more far-reaching marketing campaigns and adopt more aggressive pricing policies, which may allow them to build larger customer bases than we have. Our competitors may develop products or services that are similar to our products and services or that achieve greater market acceptance than our products and services. This could attract customers away from our services and reduce our market share. We believe that our ability to compete successfully will depend on the following factors:

- the size of our customer base;
- the timing and market acceptance of products and services, including the developments and enhancements to those products and services, offered by us or our competitors;
- customer service and support efforts;
- selling and marketing efforts;
- ease of use, performance, price and reliability of solutions developed either by us or our competitors; and
- our brand strength relative to our competitors.

Similarly, the markets for healthcare are intensely competitive, subject to rapid change, and significantly affected by new product and technological introductions and other market activities of industry participants. We compete directly not only with other established telehealth providers but also traditional healthcare providers and pharmacies. Our current competitors include traditional healthcare providers expanding into the telehealth market, incumbent telehealth providers, as well as new entrants into our market that are focused on direct-to-consumer healthcare. Our competitors include enterprise-focused companies that may enter the direct-to-consumer healthcare industry, as well as direct-to-consumer healthcare providers. Many of our current and potential competitors may have greater name and brand recognition, longer operating histories, significantly greater resources than we do, and may be able to offer products and services similar to those offered on our platform at more attractive prices than we can.

Additionally, we believe that the COVID-19 pandemic has introduced many new users to telehealth and further reinforced its benefits to potential competitors. We believe this may drive additional industry consolidation or collaboration involving competitors that may create competitors with greater resources and access to potential patients. The COVID-19 pandemic may also cause various traditional healthcare providers to evaluate and eventually pursue telehealth options that can be paired with their in-person capabilities. These industry changes could better position our competitors to serve certain segments of our current or future markets, which could create additional price pressure. In light of these factors, even if our offerings are more effective than those of our competitors, current or potential patients may accept competitive solutions in lieu of purchasing from us.

Therapeutics

Our therapeutics business faces substantial competition from larger, more established pharmaceutical and biotechnology companies with marketed products that have been accepted by the medical community, patients, and third-party payors, as well as smaller companies in our industry that have successfully identified and developed drugs. Our ability to compete in this industry may be affected by the previous adoption of such products by the medical community, patients, and third-party payors.

We recognize that other companies, including larger pharmaceutical and biotechnology companies, may be developing or have plans to develop drugs that may compete with ours. Many of our competitors have substantially greater financial, technical, and human resources than we have. In addition, many of our competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of drugs, obtaining FDA and other regulatory approvals of drugs for use in healthcare and manufacturing, and marketing and selling approved drugs. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for any drug that we develop.

We anticipate that the competition with our drugs will be based on a number of factors, including product efficacy, safety, availability, and price. The timing of market introduction of any successful drug and competitive drugs will also affect competition among products. We expect the relative speed with which we can develop drugs, complete the clinical trials and approval processes, and supply commercial quantities of such drugs to the market to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, protect our intellectual property, and to secure sufficient capital resources for the period between target identification and commercial sales of the resulting drug.

Seasonality

Historically, our PGS business has been seasonal, with our kit sales being dependent on seasonal holiday demand, variability in our advertising expenditures by season, and the timing of Amazon Prime Day, which has varied in recent years. We generate a significant amount of our PGS revenue during the fourth quarter of our fiscal year, due to seasonal holiday demand and our increased advertising expenditures during the holiday period, which occurs during the third quarter of our fiscal year. Kit orders are recognized as revenue when the customer sends in their kit to the laboratory to be processed and genetic reports are delivered to the customer, which typically for holiday purchases tends to occur in our fourth fiscal quarter. For more information on the potential impacts of seasonality, see “Risk Factors” in Part I, Item 1A of this Form 10-K.

Manufacture/Supply

For our PGS, we do not have in-house manufacturing capabilities and do not plan to develop such capacity in the foreseeable future. We do have a quality system that is compliant to 21 C.F.R. Part 820 for the regulated activities that are performed by us. We rely on third-party suppliers, which we have qualified in accordance with our quality system to provide materials (such as our saliva collection kits, bead chips, reagents or other materials and equipment used in our laboratory operations) and services. Currently, we rely on a sole supplier to manufacture our saliva collection kits. If we were to change the design of certain of the materials which we rely on, such as our bead chip or our saliva collection kit, we may be required to seek additional authorization or clearance from the FDA. Should we seek to utilize additional laboratories, prior to utilizing their services for our U.S. customers the laboratories would need to obtain appropriate Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) certification and state licensure (if required) including the validation of our testing services in accordance with FDA and CLIA regulations and expectations.

For our telehealth services, we operate an affiliated mail order pharmacy licensed in all 50 U.S. states and the District of Columbia. We rely on multiple third-party suppliers for our pharmaceuticals and there is a risk that we may experience supply chain issues that will impact our ability to fulfill prescriptions which would have a material impact on our business.

For Therapeutics, we do not have capability nor do we plan to develop current good manufacturing practices ("cGMP") capacity for the manufacture, or supply of clinical therapeutics for our clinical trials nor for commercialization. We oversee the development of, and rely on third-party suppliers to provide cGMP material for our planned clinical studies and will continue to work with contract manufacturers to improve process requirements to enable continued progress through clinical development to commercial medicines.

COVID-19

The coronavirus ("COVID-19") pandemic has disrupted the Company's general business operations since March 2020. We continue to closely monitor the impact of the COVID-19 pandemic in all aspects of our business. We rely entirely on third-party vendors in our PGS and telehealth supply chain, including our PGS kit and array manufacturers, order fulfillment vendor, our DNA-processing lab vendor, and drug suppliers for our pharmacy business. These vendors have independent responses to managing the effect of the COVID-19 pandemic, and we have not experienced any significant disruptions in our ability to deliver PGS services or fulfill and process telehealth orders to date. If we experience delays or other challenges in obtaining supplies necessary for the production, fulfillment, or distribution of the products or services we offer, it could negatively affect our ability to satisfy our obligations to customers and patients and maintain our operations in a cost-efficient manner, and have a material adverse effect on our business.

With respect to our telehealth services, the COVID-19 pandemic has increased awareness, acceptance, and usage of virtual medical care and pharmacy services, resulting in greater consumer trial and use of telehealth. While we believe that these trends present significant opportunities for our telehealth services, it is uncertain whether the increase in demand caused by COVID-19 will continue.

In our Therapeutics segment, the advancement of our programs requires our scientists to have physical access to our laboratory facilities on a continuing basis, and we have implemented health and safety protocols and procedures to keep our laboratory facilities operating during the COVID-19 pandemic. We also rely on third-party support for manufacturing of cGMP clinical materials for use in studies as well as healthcare institutions and investigators who participate in studies of our programs. We have yet to experience any disruption. Despite our mitigation efforts, we may experience delays or an inability to execute on our clinical and preclinical development plans, reduced revenues or other adverse impacts to our business, which are described in more detail in "Risk Factors" in Part I, Item 1A of this Form 10-K.

We have taken other measures in response to the COVID-19 pandemic, including closing our offices and implementing a work-from-home policy for most of our workforce, and amplifying monitoring of our inventory levels and supply chain. Notwithstanding these measures, the spread of COVID-19 has at certain times impacted our staffing and attendance in our laboratory facilities. We may take further actions that alter our business operations that we determine are in the best interests of our employees, customers, and stockholders or as may be required by federal, state, or local authorities.

To help our customers and others during the pandemic, we created an online COVID-19 Information Center, which contains data from the U.S. Centers for Disease Control and our own COVID-19 research study that evaluated genetic differences in both susceptibility and severity of the disease. The site includes data from both sources, offers people a place to learn more about the virus, and highlights conditions that carry added risks.

Intellectual Property

Since inception, we have considered our intellectual property ("IP") as a critical part of our mission. We make every effort to protect our IP, and as of March 31, 2022, have built an extensive patent estate owned by 23andMe, as summarized below:

Consumer (PGS) Patent Estate

Our PGS patent estate consists of 93 granted U.S. patents, which include 76 utility and 17 design patents that cover technologies that include graphical user interfaces, aspects of algorithms for processing genetic data, computer implemented inventions, bioinformatics, and genotyping. The PGS patent estate includes patents from a third-party patent acquisition that closed in 2021. The acquisition included 34 issued patents and six pending patent applications.

Included in these are patents that relate to the following PGS services: (i) 11 design and 43 utility patents relate to our Ancestry + Traits Service, (ii) 13 design and 43 utility patents relate to our Health + Ancestry Service, and (iii) 11 utility patents relate to our 23andMe+ service. The PGS patent estate also includes 51 pending patent applications, which include two design applications, 39 U.S. utility applications, five Patent Cooperation Treaty ("PCT") applications, two Canadian patent applications, and three European patent applications. Included in these are applications that relate to the following PGS services: (i) two design and 29 U.S. utility applications, three European patent applications, two Canadian patent applications, and four PCT applications relate to our Ancestry + Traits Service, (ii) two design, 30 U.S. utility applications, three European patent applications, two Canadian patent applications, and four PCT applications relate to our Health + Ancestry Service, and (iii) five U.S. utility applications and one PCT application relate to our 23andMe+ service.

Our PGS patent portfolio has expected expiration dates ranging from about 2027 to about 2041.

Therapeutics Patent Estate

Our therapeutics patent estate consists of one granted U.S. patent and one granted Nigerian patent, which includes two utility patents that cover key areas of our past and current therapeutic development candidates. The therapeutics patent estate also includes 49 pending U.S. utility and foreign utility patent applications, which include five U.S. utility applications and 44 foreign utility patent applications, covering key areas of our past and current therapeutic development candidates. These applications include those in the following jurisdictions: the PCT, Gulf Cooperation Council, Argentina, Taiwan, Australia, Brazil, Canada, Chile, China, Colombia, Eurasia, Europe, Hong Kong, India, Indonesia, Israel, Japan, South Korea, Macau, Malaysia, Mexico, New Zealand, Nigeria, Peru, Philippines, Singapore, Thailand, Vietnam and South Africa. The subject matter of the therapeutics patent portfolio relates to our immuno-oncology and inflammatory disease and other therapeutic areas. Our therapeutics patent portfolio has expected expiration dates ranging from about 2039 to about 2043.

Please note that we cannot be sure that patents will be granted with respect to any patent applications we have filed or may file in the future, and we cannot be sure that any patents that have been granted or may be granted to us in the future will not be challenged, invalidated, or circumvented or that such patents will be commercially useful in protecting our technology.

We also appropriately guard our company trade secrets and know-how to maintain our business advantage and seek to identify and obtain third-party licenses where useful. In circumstances where we rely on trade secrets or proprietary know-how to protect our technology, we seek to protect such IP, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators, partners and advisors. We also internally designate levels of sensitive information with certain groups within the Company. We also seek to preserve the integrity and confidentiality of our trade secrets or proprietary know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets or proprietary know-how may otherwise become known or may be independently discovered by competitors. To the extent that our employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology, inventions, improvements and product candidates, please see the section titled "Risk Factors—Risks related to our intellectual property" in Part I, Item 1A of this Form 10-K.

Government Regulation

Consumer (PGS) Business

Our genetic health risk, carrier status, and pharmacogenetic reports are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA") and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, distribution, and export of diagnostic products. The third-party laboratories that we contract with to perform the laboratory portions of our service are subject to oversight by the Centers for Medicare and Medicaid Services ("CMS") pursuant to CLIA, as well as agencies in various states, including New York. We are subject to many other federal, state and foreign laws, including anti-fraud and abuse, anti-kickback and patient privacy. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, exclusion from participation in federal and state healthcare programs, civil money penalties, injunctions, and criminal prosecution.

Regulation of In Vitro ("IVD") Diagnostics and Medical Devices

IVDs are regulated by the FDA in the U.S. as medical devices in accordance with the FDCA and its implementing regulations. The FDCA and its implementing regulations govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of our medical devices.

Medical devices must undergo premarket review prior to commercialization unless the device is exempt from such review or was in commercial distribution prior to May 28, 1976 (referred to as a "pre-amendment" device).

- For devices that require submission of a 510(k) premarket notification, the regulatory process requires the applicant to demonstrate that the device to be marketed is at least as safe and effective as, that is, substantially equivalent to, a legally marketed predicate device. The applicant must submit information that supports its determination that its subject device is substantially equivalent to a legally marketed predicate device. 510(k) premarket notifications do not generally require clinical data. The 510(k) premarket notification pathway generally takes from three to nine months from the date the application is accepted for review but can take longer.
- For devices that require approval of a premarket application ("PMA"), the PMA process requires the applicant to provide clinical and laboratory data that establishes that the new medical device is safe and effective. The FDA will approve the new device for commercial distribution if it determines that the data

and information in the PMA application constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). PMA applications generally require extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. As part of its review of the PMA, the FDA will conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the Quality System Regulation (21 CFR Part 820) ("QSR"), which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny the approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. Once granted, PMA approval may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. The average review time for a PMA application is one to two years, but can take longer.

- Novel device technologies, including novel device changes, that have not been previously classified by the FDA and for which there is no suitable predicate device are considered Class III "by default" under the FDCA and would thus require a PMA. However, if the application of general and/or special controls can provide a reasonable assurance of safety and effectiveness, novel device technologies that are Class III "by default" may be eligible for authorization by the FDA via the De Novo pathway. To obtain marketing authorization via the De Novo pathway, the applicant must show that the subject device is low to moderate risk, such that it can be reclassified as Class I or Class II. The De Novo request pathway usually requires more testing data than a 510(k), and often requires clinical data. The average review time for a De Novo request is nine to 12 months but it can take longer.

Should a company need clinical data to support a premarket application, the FDA regulates clinical investigations through its Investigational Device Exemption ("IDE") regulations 21 C.F.R. Part 812. Clinical investigations of devices that are of a significant risk require pre-approval from the FDA. Investigations of devices that are of a non-significant risk do not require FDA pre-approval; however, an Institutional Review Board ("IRB") must agree that the study is of a non-significant risk. In addition, certain clinical investigations are exempted from IDE regulations including investigations of IVDs so long as certain criteria are met. The IDE regulations place specific requirements on sponsors and investigators of clinical studies including reporting to the FDA certain adverse events and recordkeeping to demonstrate compliance with the regulations. The FDA can conduct periodic, unannounced inspections of sponsors and investigators to evaluate compliance with the IDE regulations. Failure to comply with the IDE regulations can subject the sponsor and investigator to administrative enforcement proceedings, civil penalties, and/or criminal penalties.

We utilized the 510(k) and De Novo pathways to seek authorization from the FDA for those aspects of the PGS products that are medical devices. Specifically, the FDA granted our first De Novo authorization to market our PGS product for Over-the-Counter Carrier testing for Bloom Syndrome in February 2015. Since 2015, we received three additional FDA De Novo Authorizations for Over-the-Counter Genetic Health Risks, BRCA1/BRCA2 Selected Variants and Pharmacogenetic Metabolism Information as well as two FDA 510(k) Clearances for MUTYH and Pharmacogenetic Drug Response Information. The regulations governing our authorizations and clearances place substantial restrictions on how our PGS service is marketed and sold, specifically, requirements on pre-purchase information we must provide to consumers and special controls we must comply with due to the over-the-counter nature of our PGS service. We may develop new diagnostic products and services that are regulated by the FDA as medical devices, or make changes to our medical devices that trigger a premarket submission that requires clinical data. The regulatory review and approval process for medical devices can be costly, timely, and uncertain. This process may involve, among other things, successfully completing additional clinical trials and submitting a premarket 510(k) notice, De Novo submission, or filing a premarket approval application with the FDA. If premarket review is required by the FDA, there can be no assurance that our tests will be cleared, authorized, or approved on a timely basis, if at all. In addition, there can be no assurance that the claims we propose to the FDA for clearance, authorization, or approval will be cleared, authorized, or approved by the FDA.

We consider certain of our Wellness reports and Polygenic Risk Score reports to be either not medical devices under the FDCA or to be medical devices subject to FDA enforcement discretion from compliance with the requirements of the FDCA in accordance with FDA's General Wellness: Policy for Low Risk Devices (issued July 29, 2016 and revised September 27, 2019). It is possible in the future that the FDA may disagree and conclude that some or all of our Wellness reports or Polygenic Risk Score reports are medical devices and not subject to enforcement discretion. As a result, we could be subject to enforcement action and penalties. We consider our COVID-19 Severity Calculator to be a medical device that is subject to FDA enforcement discretion in accordance with FDA's Policy for Device Software Functions and Mobile Medical Applications (issued September 27, 2019). Using a risk-based approach, FDA's policy established a group of software that meets the definition of a medical device but is subject to enforcement discretion from compliance with the requirements of the FDCA. It's possible that the FDA may disagree that our COVID-19 Severity Calculator is subject to enforcement discretion and could thus subject us to an enforcement action and penalties. If this were to occur, we will likely have to utilize the premarket pathways described above or seek FDA authorization through the Emergency Use Authorization ("EUA") pathway in order to market the COVID-19 Severity Calculator. If we utilize the EUA pathway, the authorization to market the software application will terminate once the Secretary of the Department of Health and Human Services ("HHS") declares the COVID-19 emergency over.

Both before and after a medical device is commercially released, we have ongoing responsibilities under FDA regulations which can increase the cost of conducting our business. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices through periodic inspections. Specifically, these inspections evaluate our compliance with its QSR, among other FDA requirements. The QSR includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. Our manufacturing operations, and those of our third-party finished device manufacturers, are required to comply with the QSR. QSR compliance is required for medical devices that are FDA approved and cleared, and generally required for medical devices exempt from FDA pre-market notification. The FDA conducts announced and unannounced periodic and on-going inspections of medical device manufacturers to determine compliance with the QSR. If in connection with these inspections the FDA believes the manufacturer has failed to comply with applicable regulations and/or procedures, it may issue inspectional observations on Form FDA-483 ("Form 483") that would necessitate prompt corrective action. If the FDA determines that our response to the Form 483 is not adequate (e.g., the corrective action plan and/or objective evidence is insufficient), the FDA may issue a warning letter (which would similarly necessitate prompt corrective action) and/or proceed directly to other forms of enforcement action, including the imposition of operating restrictions, a ceasing of operations at one or more facilities, enjoining and restraining certain violations of applicable law pertaining to products, seizure of products, and assessing civil or criminal penalties against our officers, employees or us. The FDA could also require the entry of a consent decree of permanent injunction with us. The FDA may also recommend prosecution to the U.S. Department of Justice ("DOJ"). Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products and could have a material adverse effect on our business, financial condition and results of operations.

Corruption

In situations involving healthcare providers employed by foreign state-funded institutions or national healthcare agencies, violation of the local anti-kickback law may also constitute a violation of the U.S. Foreign Corrupt Practices Act ("FCPA"). The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity from offering or providing, directly or through a third party, including the distributors we 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. In addition, it is illegal for a company that reports to the SEC to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We are also required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions and its anti-bribery provisions.

Laboratory Certification, Accreditation and Licensing

We and our third-party laboratories are also subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. Virtually all clinical laboratories operating in the U.S. must be certified by the federal government or by a federally approved accreditation agency. Federal CLIA requirements regulated by the CMS and laws of certain states, including those of California, New York, Maryland, Pennsylvania, Rhode Island and Florida, impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or require maintenance of certain records. CLIA provides that a state may adopt different or more stringent regulations than federal law and permits states to apply for exemption from CLIA if the state's laboratory laws are equivalent to, or more stringent than, CLIA. For example, the State of New York's clinical laboratory regulations, which have received an exemption from CLIA, contain provisions that are in certain respects more stringent than federal law. Therefore, as long as New York maintains a licensure program that is CLIA-exempt, we will need to comply with New York's clinical laboratory regulations in order to offer our clinical laboratory products and services in New York. Standards for testing under CLIA are based on the complexity of the tests performed by the laboratory, with tests classified as "high complexity," "moderate complexity," or "waived." Laboratories performing high-complexity testing are required to meet more stringent requirements than moderate-complexity laboratories. Laboratories performing only waived tests, which are tests determined by the FDA to have a low potential for error and requiring little oversight, may apply for a certificate of waiver exempting them from most CLIA requirements.

We have current certificates to perform clinical laboratory testing to offer our PGS in all 50 states. Clinical laboratories are subject to inspection by regulators and to sanctions for failing to comply with applicable requirements. The sanctions for failure to comply with CLIA requirements include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business; cancellation or suspension of the laboratory's approval to receive Medicare and/or Medicaid reimbursement; as well as significant fines and/or criminal penalties. States also have licensure requirements and may impose additional sanctions on us. The loss or suspension of a CLIA certification, state license, imposition of a fine or other penalties, or future changes in CLIA and state law/regulations (or interpretation of the law or regulations) could have a material adverse effect on us.

Regulation of Consumer Products

The Federal Trade Commission ("FTC") and U.S. Consumer Product Safety Commission ("CPSC") also have jurisdiction over products offered by PGS (especially those aspects of our products that are not regulated by the FDA). The FTC requires that advertising claims be truthful, non-deceptive, fair, and adequately supported. The CPSC protects the American public from products that may present safety hazards, with labeling requirements, as well as reporting and remedial actions required if certain hazards or events are identified. Failure to comply with FTC and/or CPSC laws and implementing regulations could subject us to enforcement proceedings, including mandatory recalls and penalties that could have a material adverse effect on us.

International

When marketing our PGS health reports outside of the U.S., we are subject to foreign regulatory requirements governing human clinical testing, export of biological or tissue samples, marketing approval for our products and performance and reporting of tests on a local basis. These requirements vary by jurisdiction, differ from those in the U.S. and may require us to perform additional preclinical or clinical testing. Marketing in Europe subjects us to European Union ("EU") medical device oversight. Accordingly, we and certain of our contract manufacturers would be subject to ongoing compliance with various International Organization for Standardization ("ISO") standards and ongoing regulatory oversight and review. These include routine inspections by EU Notified Bodies, which are entities accredited by an EU Member State to assess whether a product to be placed on the market meets certain preordained standards, of our manufacturing facilities and our records for compliance with requirements such as ISO 13485 and ISO 27001, which establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures. Additionally, the EU adopted the IVD Regulation ("IVDR") which will increase the regulatory requirements applicable to IVDs in the EU and would require that we classify and obtain pre-approval for our PGS health reports, which would be subject to the IVDR as of May 25, 2022. If we are not able to obtain and maintain regulatory compliance, we may not be permitted to market our PGS health service and/or may be subject to enforcement by EU Competent Authorities, bodies with authority to act on behalf of the government of the applicable EU Member State to ensure that the requirements of the directive or regulation are met.

As of January 1, 2021, due to the U.K. leaving the EU, the United Kingdom Medicines and Healthcare products Regulatory Agency ("MHRA") began implementation of new requirements for medical devices, including our health reports, marketed in Great Britain. The new regulations require that on or before January 1, 2022, we register with the MHRA, designate a U.K. Responsible Person and prior to June 30, 2023 obtain a United Kingdom Conformity Assessed mark for our health reports, which are Class I In Vitro Diagnostic Devices. Prior to that time, the U.K. will continue to allow marketing of our health reports pursuant to our existing CE mark.

In situations involving healthcare providers employed by state-funded institutions or national healthcare agencies, violation of the local anti-kickback law may also constitute a violation of the FCPA. The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity from offering or providing, directly or through a third party, including the distributors we 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. In addition, it is illegal for a company that reports to the SEC to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We are also required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions and its anti-bribery provisions.

Consumer (Telehealth) Business

The practice of medicine is subject to various federal, state, and local certification and licensing laws, regulations, approvals and standards, relating to, among other things, the qualifications of the provider, the practice of medicine (including specific requirements relating to online or telephone consultations and the provision of remote care), the continuity and adequacy of medical care, the maintenance of medical records, the supervision of personnel, and the prerequisites for the prescription of medication and ordering of tests. Because the practice of telehealth is relatively new and rapidly developing, regulation of telehealth is evolving and the application, interpretation and enforcement of these laws, regulations and standards can be uncertain or uneven. As a result, we must continually monitor legislative, regulatory, and judicial developments regarding the practice of medicine and telehealth in order to support our PMCs.

Physicians, mid-level providers (e.g., physician assistants, nurse practitioners), and behavioral health providers who provide professional clinical services via telehealth must, in most instances, hold a valid license to provide the applicable professional services in the state in which the patient is located. We have established systems to assist the PMCs in ensuring that their providers are appropriately licensed under applicable state law and that their provision of telehealth to our customers occurs in each instance in compliance with applicable rules governing telehealth.

In certain jurisdictions, the corporate practice of medicine doctrine generally prohibits non-physicians from practicing medicine, including by employing physicians to provide clinical services, directing the clinical practice of physicians, or holding an ownership interest in an entity that employs physicians. Other practices, such as professionals splitting their professional fees with non-professional persons or entities, is also prohibited in some jurisdictions. These laws are intended to prevent unlicensed persons from interfering with or unduly influencing a physician's professional judgment. State laws and enforcement activities related to the corporate practice of medicine and fee-splitting vary dramatically. In some states, even activities not directly related to the delivery of clinical services may be considered an element of the practice of medicine. For example, in some states the corporate practice of medicine restrictions may be implicated by non-clinical activities such as scheduling, contracting, setting rates, and the hiring and management of non-clinical personnel.

Because of the restrictions on the corporate practice of medicine doctrine and fee-splitting in various jurisdictions, we do not employ the healthcare providers who provide clinical services on our telehealth platform. Instead, the PMCs provide services on the platform and we contract with but do not own the PMCs. We provide administrative, non-clinical services to the PMCs and bill them a fixed amount for those services, based on what we believe to be the fair market value of the services, pursuant to our contracts. The PMCs and their providers maintain exclusive authority regarding the provision of healthcare services (including consultations that may lead to the writing of prescriptions) and remain responsible for retaining and compensating their providers, credentialing decisions regarding their providers, maintaining professional standards, maintaining clinical documentation within medical records, establishing their own fee schedule, and submitting accurate information to us so that we can bill customers. Despite our care in structuring arrangements with the PMCs, it is possible that a regulatory authority or another party, including providers affiliated with PMCs, could assert that we (or other organizations with similar business models) are engaged in the corporate practice of medicine or that the contractual arrangements with PMCs violate a state's fee-splitting prohibition. Failure to comply with these state laws could lead to materially adverse consequences for the Company.

In response to the COVID-19 pandemic, some state and federal regulatory authorities lowered certain barriers to the practice of telehealth in order to make remote healthcare services more accessible. Due to our business model, these changes did not dramatically change our operations, but these changes did introduce many people to the practice of telehealth. It is unclear whether these changes will have a long-term impact on the adoption of telehealth services by the general public or legislative and regulatory authorities.

Regulation of Pharmacy Services

Our pharmacy services are subject to laws of various state and federal agencies. Our affiliate pharmacies face regulation on a number of issues that vary from state-to-state, including pharmacist-to-technician supervision ratios, practice of pharmacy, quality, sufficiency of facilities and equipment, prescription requirements, patient-friendly medication labeling, controlled substance, scheduled listed chemical, and listed chemical regulation, and ensuring a patient's freedom of choice in selecting their pharmacy, among a number of other requirements. On the federal level, pharmacies must comply with FDA's requirements under the Drug Supply Chain Security Act which are intended to preserve the integrity of the U.S. drug supply chain. The Drug Supply Chain Security Act requires pharmacies and others in the U.S. drug supply chain to comply with requirements for product tracking and tracing, information and pedigree exchange, reporting, investigations, and product quarantine and disposition. Further federal regulations apply to those pharmacies that dispense controlled substances under the Controlled Substance Act, which is implemented by the Drug Enforcement Administration. For our affiliated retail pharmacy that accepts insurance reimbursement from government payors, further federal regulations, such as HIPAA (as defined below), the anti-kickback laws, and the federal False Claims Act apply, as well as regulations from additional state and federal agencies such as the DOJ and Centers for Medicare & Medicaid Services. Furthermore, each pharmacist and technician must also obtain appropriate professional licensure and are subject to upholding state professional standards of conduct and patient privacy laws.

Privacy and Security Regulation

We are engaged in ongoing privacy compliance and oversight efforts, including in connection with the requirements of numerous local, state, federal and international laws, rules, and regulations relating to the privacy and security of directly or indirectly identifiable personal information (collectively, "Data Protection Laws"). Such Data Protection Laws address the collection, storage, sharing, use, disclosure, processing, transferring, and protection of personal information, including genetic information, and evolve frequently in scope and enforcement. There can also be uncertainty, differing interpretations, and contradictory requirements across the privacy and security legal and regulatory landscape. In the U.S., some of the notable Data Protection Laws we are subject to include the California Privacy Rights Act (the "CPRA," previously known as the California Consumer Privacy Act or "CCPA"), the California Genetic Information Privacy Act ("GIPA"), Section 5 of the Federal Trade Commission Act ("FTC Act"), the Telephone Consumer Protection Act of 1991 ("TCPA") and, in the event of a data breach, various data breach laws across the 50 states and territories. Recently, new U.S. state comprehensive Data Protection Laws have developed in response to the CPRA, such as the Colorado Privacy Act ("CPA") and Virginia Consumer Data Protection Act ("VCDPA"). Outside of the U.S., numerous countries have their own Data Protection Laws, including, but not limited to, the Canadian Personal Information Protection and Electronic Documents Act ("PIPEDA") and the EU's General Data Protection Regulation ("GDPR"), now also enacted in the U.K. ("UK GDPR"). 23andMe also expects new Data Protection Laws to be proposed and enacted in the future, particularly in the U.S., and current Data Protection Laws to evolve frequently through new legislation and amendments to existing legislation and changes in enforcement. The effects of such changes may be inconsistent from one jurisdiction to another, and potentially far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. These new or modified Data Protection Laws, and other changes in laws or regulations relating to privacy, data protection and information security, particularly any new or modified laws or regulations that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer or disclosure, could greatly increase the cost of providing our offerings, require significant changes to our operations or even prevent us from providing certain offerings in jurisdictions in which we currently operate and in which we may operate in the future.

Data Protection Laws are enforced by the FTC, government authorities and agencies, including state attorneys general and data protection commissioners. Data Protection Laws require us to publish statements to our customers that describe how we handle personal information and the choices customers have about the way we handle their personal information. If such information that we publish is considered untrue or inaccurate, we may be subject to claims of unfair or deceptive trade practices under Section 5 of the FTC Act or similar laws, which could lead to significant liabilities and consequences.

In the U.S., the CPRA was recently approved by California voters, resulting in a significant modification of the CCPA and additional costs and expenses to our compliance efforts. The CPRA will create additional obligations relating to consumer data, with enforcement beginning on July 1, 2023. The CPRA provides for fines of up to $7,500 per violation and a private right of action in the event of a data breach. Interpretation and enforcement of CPRA, including its current and forthcoming regulatory guidance, remain uncertain. Other states are presenting similar comprehensive privacy laws, some of which are more robust than the CPRA in certain aspects. For example, in 2023 new consumer privacy laws will become effective in Colorado, Virginia, and Utah.

Internationally, we are subject to, among other Data Protection Laws, the GDPR, UK GDPR, and PIPEDA which regulate collection, storage, sharing, use, disclosure, and protection of personal information, and impose stringent requirements with significant penalties and litigation risks for noncompliance. Like the U.S., international Data Protection Laws include national, state or provincial, and local laws, meaning compliance costs increase with every state, province, or locale we ship to. Failure to comply with the GDPR (and the UK GDPR) may result in fines of up to 20 million Euros/£17.5 million or up to 4% of the annual global revenue of the infringer, whichever is greater. It may also lead to civil litigation, with the risks of damages or injunctive relief, or regulatory orders adversely impacting the ways in which our business can use personal information. While Canada's PIPEDA does not have as stringent requirements and fines as the GDPR at this time, Canadian legislators are actively working on reforms to PIPEDA to align it with the GDPR. We anticipate that any reforms to PIPEDA will further increase our compliance costs and liabilities.

Where applicable, we rely on data transfer mechanisms to be able to transfer data between countries freely. We previously relied on the Privacy Shield certification for the purposes of transferring personal information out of the EU. In light of the invalidation of Privacy Shield, we continue to rely on standard contractual clauses to transfer EU/UK personal information outside of the EU/UK, or where applicable derogations provided for by law. These clauses have been being revised, and the process and the implementation of new requirements related to the clauses, such as conducting additional risk assessments and implementing additional safeguards, will increase our costs. On March 25, 2022, the EU and U.S. announced that they had reached an agreement in principle on a new Trans-Atlantic Data Privacy Framework (the "Framework"), which will be translated into legal documents to be adopted in the EU and U.S. to provide a renewed basis for transatlantic data transfers. However, if a new Framework is not adopted and we are unable to continue to rely on the standard contractual clauses or rely upon other alternative means of data transfers from the EU to the U.S., we will likely be unable to offer a number of services in the EU, which would materially and adversely affect our business. Additionally, in the U.S. and internationally, businesses are required to provide notice to affected customers whose personal information has been disclosed as a result of a data breach. Many countries and/or states require businesses to maintain safeguards and take certain actions in response to a data breach and may be required to also notify applicable regulatory authorities. Recently, some states, such as California, have explicitly added genetic information to their breach notification laws, which presents additional liabilities and costs to our business. Some U.S. states go beyond data breach notification and general security safeguards by requiring businesses to maintain specific security safeguards; for example, Massachusetts establishes minimum standards to be met in connection with the safeguarding of personal information contained in both paper and electronic records including maintaining security policies and procedures, security training for employees, regular audits. While many Data Protection Laws rely on regulatory enforcement for non-compliance with security safeguards or data breaches, there may be an increase in legislation like CPRA providing a private right of action for consumers in the event of a data breach. Civil litigation and security compliance present liabilities and costs with respect to maintaining and continually refining security safeguards and incident response processes.

We anticipate changes with Data Protection Laws as countries and states continue to propose comprehensive privacy laws and regulations addressing consumer data protection rights, transparency and cybersecurity. In certain states, these laws are directed specifically to genetic information or genetic testing companies, or more specifically direct-to-consumer genetic testing companies. Data Protection Laws specific to genetic information have recently been enacted in a number of states, including, but not limited to, California, Utah, and Arizona. Many other states are considering similar laws regulating genetic information, some of which include private rights of action for consumers. Such private rights of action present liabilities and costs to our business with respect to implementing and maintaining compliance with such laws, and potentially responding to civil litigation. We have incurred, and expect to continue to incur, significant expenses in an effort to comply with privacy, data protection and information security standards and protocols imposed by Data Protection Laws. With substantial uncertainty over the interpretation and application of these and other laws and regulations (such as CPRA and genetic privacy laws), we may face challenges in addressing their requirements and making necessary changes to our policies and practices, and may incur significant costs and expenses in an effort to do so.

Regulation of our Therapeutics Products and Programs

Government authorities in the U.S. at the federal, state and local level and in other countries regulate, among other things, the research, development, manufacture, testing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, diagnostics, including those we are developing as well as any future drugs. Generally, before a new drug, biologic or diagnostic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved, authorized, or cleared by the applicable regulatory authority. The process of obtaining regulatory approvals and the subsequent compliance with appropriate regional, federal, state, territorial and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, a regulatory agency's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of or debarment from government contracts, FDA debarment, exclusion from federal healthcare programs, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation. Our drugs must be approved by the FDA through either a New Drug Application ("NDA"), or a Biologics License Application ("BLA"), process before they may be legally marketed in the U.S., and by similar processes for other regulatory regions. Moreover, the regulatory requirements governing our business are also evolving and will likely continue to evolve. By example, FDA has issued a number of guidance documents relating to gene therapies. Additionally, in light of the COVID-19 pandemic, FDA has issued a number of guidance documents to assist companies navigating the COVID-19 pandemic. Future changes in legislation may also take place. For example, the Prescription Drug User Fee Act is due for reauthorization by September 2022, which may result in changes to any of the requirements and programs discussed below.

Preclinical Studies

Before testing any drug, biological, or gene therapy candidate in humans, the drug must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess safety and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including Good Laboratory Practice ("GLP") regulations and requirements relating to animal testing. The sponsor submits the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA or other regulatory or oversight committee as part of an IND or Clinical Trial Application ("CTA"). In the U.S., an IND is a request for authorization from the FDA to administer an investigational drug to humans, and must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions and places the study on clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Clinical holds may also be imposed by the FDA during the conduct of trials due to safety or compliance concerns. Some long-term preclinical testing, such as animal tests of reproductive adverse effects and carcinogenicity, may continue after the IND is submitted.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with good clinical practice ("GCP") requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Furthermore, each clinical trial must be reviewed and approved by an IRB/ethics committee for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative as well as other subject communications and must monitor the clinical trial until completed. In the case of certain gene therapy studies, an Institutional Biosafety Committee ("IBC") at the local level may also review and maintain oversight over the particular study, in addition to the IRB.

There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Information about certain clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website or other comparable public trial registries. Sponsors of investigational products for the diagnosis, monitoring, or treatment of one or more serious disease or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access. Investigators must further provide certain information to clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary. The data from the foreign clinical study must also be deemed by FDA to be meaningful to the U.S. population.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the drug. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, dosage tolerance, structure-activity relationships, mechanism of action, absorption, excretion, pharmacokinetics side effect tolerability, and safety of the drug. These trials also sometimes seek to gain an early indication of a product candidate's effectiveness.
- Phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials are adequate and well-controlled studies that involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Additional kinds of data may also help support a BLA or NDA, such as patient experience data and real-world evidence. Real world evidence may also be used to assist in clinical trial design or support an NDA for already approved products. For genetically targeted populations and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was submitted previously to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted drug as the product that is the subject of the application.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the relevant health authorities and IRBs. The sponsor must also notify relevant health authorities and the IRBs of adverse events or other significant safety information within specified timeframes. Certain reports may also be required to be submitted to the IBC. Changes to the enrollment of clinical trials, for example halting enrollment for a clinical safety signal, or completing expected clinical trial accrual may be reported on a clinical trial registration site such as clinicaltrials.gov and may provide publicly available information about the status of an ongoing clinical trial.

Phase 1, Phase 2, Phase 3, and other types of clinical trials may not be completed successfully within any specified period, if at all. The health authority or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB or ethics committee can suspend or terminate approval of a clinical trial at institutions under its jurisdiction if the clinical trial is not being conducted in accordance with their requirements or if the drug or biologic has been associated with unexpected serious harm to patients. IBCs can also require that research activities be ceased if applicable requirements are not being met. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group may monitor the continued safety of the study, provide recommendations on study continuation, and/or provide authorization for whether a trial may move forward at designated check points based on access to certain data from the trial.

The manufacture of investigational drugs and biologics for the conduct of human clinical trials is subject to cGMP requirements. Investigational drugs and biologics and active ingredients and therapeutic substances imported into the U.S. are also subject to regulation by the FDA. Further, the export of investigational products outside the U.S. is subject to regulatory requirements of the receiving country as well as U.S. export requirements.

Concurrent with clinical trials, companies usually complete additional preclinical studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drugs do not undergo unacceptable deterioration over their shelf life.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational drug is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of an NDA or BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The NDA or BLA is a request for approval to market the drug or biologic for one or more specified indications and must contain proof of safety and efficacy for a drug or safety, purity and potency for a biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a drug's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug to the satisfaction of FDA. FDA approval of an NDA or BLA must be obtained before a drug or biologic may be marketed in the U.S.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each NDA or BLA subject to certain exceptions, must be accompanied by a user fee. FDA adjusts the PDUFA user fees on an annual basis. The FDA reviews all submitted NDAs and BLAs before it accepts them for filing and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA or original BLA and respond to the applicant, and six months from the filing date of a new molecular entity NDA or original BLA designated for priority review, which are products that, if approved, would present significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs or BLAs, and the review process is often extended by FDA requests for or a sponsor's submission of additional information or clarification. The FDA also may audit data from clinical trials and clinical trial sites to ensure compliance with GCP requirements. The FDA will also inspect the facilities that manufacture the product candidate and will not approve a marketing application unless the agency confirms the manufacturer's compliance with GMP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee, a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. For product candidates for which no active ingredient has previously been approved, such a referral is mandatory unless FDA issues an action letter summarizing the reasons why it did not require an advisory committee review.

The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates an NDA or BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. If a Complete Response Letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing. Even if such data and information are submitted, the FDA may decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. Even if approval is granted, the FDA may limit the approved product's indications for use, require labeling with significant warnings, limitations, or contraindications, or place other conditions on the approval that restricts the ability to market the product. For instance, FDA may require post-approval testing or surveillance, or impose other restrictions on the product, including distribution restrictions or risk evaluation and mitigation strategies. The FDA may also not approve label statements that are necessary for successful commercialization and marketing.

European Medicines Agency (EMA) Review Process

In the European Economic Area ("EEA"), which is comprised of the 27 Member States of the European Union (including Norway and excluding Croatia), Iceland and Liechtenstein, drugs can only be commercialized after obtaining a marketing authorization ("MA"). Before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy. There are two types of marketing authorizations:

- The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics ("SPC") and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or BLA. If there is another product approved by FDA for the same orphan indication, which FDA deems to be the same as the investigational product, the sponsor of the investigational product must also present a plausible hypothesis of clinical superiority for FDA to grant an orphan drug designation. This hypothesis must be demonstrated to obtain orphan drug exclusivity. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care, or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication. In such cases, the second in time product could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than any orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Moreover, whether a gene therapy product qualifies for orphan designation is an evolving area. FDA issued a final draft guidance document on how the agency will determine gene therapy product "sameness." Pursuant to the guidance, "sameness" will depend on the product's transgene expression, viral vectors groups and variants, and other product features that may have a therapeutic effect. Generally, minor differences between gene therapy products will not result in a finding that two products are different. Any FDA sameness determinations could impact our ability to receive approval and obtain or maintain orphan exclusivity.

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected). In the EU, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following drug approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Expedited Development and Review Programs

A sponsor may seek to develop and obtain approval of its drugs under programs designed to accelerate the development, FDA review and approval of new drugs and biologics that meet certain criteria. For example, the FDA has a fast track program that is intended to expedite review of or facilitate development of new drugs and biologics that are intended to treat a serious or life threatening disease or condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. If fast track designation is obtained, sponsors may be eligible for more frequent development meetings and correspondence with the FDA. For a fast track-designated product, the FDA may consider sections of the NDA or BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application. The sponsor can request the FDA to designate the product for fast track status any time before receiving NDA or BLA approval, but ideally no later than the pre-NDA or pre-BLA meeting. A product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development or review, such as priority review and accelerated approval.

Priority review means that, for a new molecular entity or original BLA, the FDA sets a target date for FDA action on the marketing application at six months after accepting the application for filing as opposed to ten months. A drug is eligible for priority review if it is designed to treat a serious or life-threatening disease condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available drugs. If criteria are not met for priority review, the application for a new molecular entity or original BLA is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

A product may also be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. The product must also provide a meaningful therapeutic benefit to patients over existing treatments. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-approval confirmatory clinical trials. In addition, the FDA requires as a condition for accelerated approval pre-review of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDA may withdraw approval of a drug or indication approved under accelerated approval using a streamlined process if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In recent years, the accelerated approval pathway has come under significant FDA and public scrutiny. Accordingly, FDA may become reluctant in granting accelerated approval or, if granted, may withdraw approval if clinical benefit is not confirmed.

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved drugs on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to help the sponsor design a development program to gather the nonclinical and clinical data necessary for approval as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. The FDA may revoke breakthrough therapy designation if the Agency determines that the product no longer qualifies for this status, for example, if subsequent data does not confirm the clinical efficacy, or if another product addresses the previously serious condition.

Another expedited pathway is the Regenerative Medicine Advanced Therapy ("RMAT") designation. Qualifying products must be a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or a combination of such products, and not a product solely regulated as a human cell and tissue product. The product must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that the product has the potential to address an unmet need for such disease or condition. Advantages of the RMAT designation include all the benefits of the Fast Track and breakthrough therapy designation programs, including early interactions with the FDA. These early interactions may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for full approval.

Pediatric Information and Pediatric Exclusivity

In the U.S., under the Pediatric Research Equity Act ("PREA"), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. PREA does not apply to products that have been granted orphan designation. However, PREA does apply if approval is sought for indications that are broader than or not covered by the orphan designation.

The FDA Reauthorization Act of 2017 introduced an additional provision regarding required pediatric studies. Under this statute, for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, original application sponsors must submit, with the marketing application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals or waivers of some or all of this data, as above. Unlike PREA, orphan products are not exempt from this requirement.

A drug or biologic product can also obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and, for drug products (as opposed to biologic products) any patent terms listed in FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations, which is commonly known as the Orange Book. This six-month exclusivity, which runs from the end of the applicable exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. To qualify for this exclusivity, the study must be completed in accordance with the Written Request and within specified time frames prior to the expiration of the underlying patents or market exclusivity periods that would be extended. The study is not required, however, to show that the product is safe or efficacious in pediatric populations.

In the EEA, MAAs for new drugs must include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when this data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and trial results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse events, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit the change and/or obtain additional regulatory approval, for example, of a new supplementary NDA or BLA, which may require the development of additional data or preclinical studies and clinical trials.

Health authorities may also place other conditions on approvals, either at the time of approval or after, including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS"), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS. The FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, restricted physician prescribing, or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Certain GMP deviations also require reporting to FDA. Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and list the products produced at the facility. There are also continuing program user fees that product sponsors must pay. Recently, the information that must be submitted to FDA regarding manufactured products was expanded through the Coronavirus Aid, Relief, and Economic Security, or CARES, Act to include the volume of drugs produced during the prior year. These facilities are also subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including recall. Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; revisions to promotional material; the provision of corrective information; adverse publicity; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters, untitled letters, or cyber letters, or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals;
- drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties, FDA or contract debarment, refusal of orders under existing governmental contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, corporate integrity agreements and consent decrees, among other consequences described in this filing.

New or modified laws, regulations, and requirements may also be passed that could delay or prevent FDA approval of our product candidates or otherwise negatively impact our commercial prospects. For example, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which includes various provisions regarding FDA drug shortage and manufacturing volume reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. As part of the CARES Act implementation, the FDA issued a guidance on the reporting of the volume of drugs produced, which reporting will require additional administrative efforts by drug manufacturers.

Additional Biological and Gene Therapy Requirements

To help reduce the increased risk of the introduction of adventitious agents, the FDA statutes emphasize the importance of manufacturing controls for products whose attributes cannot be precisely defined and provides FDA with the authority to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the U.S. and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

In addition to the regulations discussed above, there are a number of additional standards that apply to clinical trials involving the use of gene therapy. Certain gene therapy studies are subject to the National Institutes of Health's Guidelines for Research Involving Recombinant DNA Molecules. The FDA has also issued various guidance documents regarding gene therapies, which outline additional factors that the FDA will consider during product development. These include guidance regarding preclinical and clinical studies; chemistry, manufacturing, and controls; the measurement of product potency; how FDA will determine whether a gene therapy product is the same as another product for the purpose of the agency's orphan drug regulations; and long-term patient and clinical study subject follow up and regulatory reporting. FDA has also issued a guidance specific to gene therapy considerations during the COVID-19 pandemic, as well as disease specific guidance.

Biosimilars and Exclusivity

Certain of our drugs may be regulated as biologics. An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 ("BPCI Act") as part of the ACA. This amendment to the PHSA, in part, attempts to minimize duplicative testing. The FDA has also issued a number of guidance documents outlining its approach to the review and approval of biosimilars, including guidance documents on the demonstration of interchangeability and the licensure of biosimilar and interchangeable products for fewer than all of the reference product's licensed conditions of use.

Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, must be shown through analytical studies, animal studies and a clinical trial or trials, absent a waiver from FDA. There further must be no difference between the reference product and a biosimilar in terms of mechanism of action, conditions of use, route of administration, dosage form, and strength. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

A reference biological product is granted twelve years of exclusivity from the time of first licensure of the product, during which time FDA will not approve a biosimilar product. Moreover, FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the U.S. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity, or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor. The BPCI Act also created certain exclusivity periods for biosimilars approved as interchangeable products.

In addition to the above exclusivity periods, the BPCI Act also includes provisions to enable the settlement of potential patent disputes. The biosimilar product sponsor and reference product sponsor may exchange patent and product information to determine whether there should be a patent challenge. The reference product sponsor may be able to bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

The FDA maintains a publicly available online database of licensed biological products, which is commonly referred to as the "Purple Book." The Purple Book lists product names, dates of licensure, and applicable periods of exclusivity. Further, pursuant to an enacted statute to enable biological product patent transparency, the reference product sponsor must provide patent information and patent expiry dates to FDA following the exchange of patent information between biosimilar and reference product sponsors. This information is then published in the Purple Book.

The Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients to the site of action in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA. In an effort to clarify which patents must be listed in the Orange Book, in January 2021, Congress passed the Orange Book Transparency Act of 2020, which largely codifies FDA's existing practices into the FDCA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application approval will not be made effective until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification to the FDA, the applicant must send notice of the certification to the NDA and patent holders. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification, in which case the FDA may not make an approval effective until the earlier of 30 months from the patent or application owner's receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent is favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot accept an ANDA or 505(b)(2) application. The holder of an NDA, including a 505(b)(2) NDA, may obtain five years of exclusivity upon approval of a new drug containing new chemical entities ("NCEs") that have not been previously approved by the FDA. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The Hatch-Waxman Act also provides three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new indication or formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against the FDA making an ANDA and 505(b)(2) NDA approval effective for the condition of the new drug's approval. As a general matter, the three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic or modified versions of the original, unmodified drug product. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Recently, Congress, the Administration, and administrative agencies have taken certain measures to increase drug and biologic competition by facilitating the entry of generic and biosimilar products to the market. For example, measures have been proposed and implemented to facilitate product importation. Congress also passed a bill requiring sponsors of NDA and BLA approved products to provide sufficient quantities of drug product on commercially reasonable market-based terms to entities developing generic, biosimilar, and 505(b)(2) products. This bill also included provisions on shared and individual REMS for generic drug products.

Patent Term Restoration

If approved, drug and biologic products may also be eligible for periods of U.S. patent term restoration. If granted, patent term restoration extends the patent life of a single unexpired patent that has not previously been extended, for a maximum of five years. The total patent life of the product with the extension also cannot exceed fourteen years from the product' approval date. Subject to the prior limitations, the period of the extension is calculated by adding half of the time from the effective date of an IND to the initial submission of a marketing application, and all of the time between the submission of the marketing application and its approval. This period may also be reduced by any time that the applicant did not act with due diligence.

Coverage and Reimbursement

Successful commercialization of new drug products depends in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for 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.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drug products and requiring payment of manufacturer rebates. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the U.S. Certain countries allow companies to fix their own prices for drug products initially, but either assess cost-benefit subsequently or monitor and control company profits. Accordingly, in markets outside the U.S., the reimbursement for drug products may be reduced compared with the U.S.

In the U.S., the principal decisions about reimbursement for new drug products under federal healthcare plans are typically made by CMS, an agency within the HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. New products may not be covered, and coverage and reimbursement levels for drug products can differ significantly from payor to payor.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain, and, in addition, we may be required to pay significant Part D coverage gap discounts on certain Part D utilization. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price ("AMP") and Medicaid unit rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) are not eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid unit rebate data, revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Moreover, multiple federal enactments have established initiatives to compare the effectiveness of different treatments for the same illness. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat are the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

For a drug product to receive federal reimbursement under the Medicaid, the Veterans Health Care Act of 1992 requires, as a condition of payment by certain federal agencies and the Medicaid program, that manufacturers of "covered drugs" (including all drugs approved under an NDA) enter into a Master Agreement and Federal Supply Schedule contract with the Department of Veterans Affairs through which their covered drugs must be offered for sale at a mandatory ceiling price calculated at a statutory discount to certain federal agencies, including the VA and Department of Defense.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any drugs for which we may obtain regulatory approval or the frequency with which any such drug is prescribed or used.

Outside of the U.S., the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular drug to currently available drugs or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

Regulation of Companion Diagnostics/Delivery Devices

We believe that the success of certain of our drug candidates may depend, in part, on the development and commercialization of a companion diagnostic. Companion diagnostics are in vitro diagnostic devices that provide information that is essential for the safe and effective use of a corresponding therapeutic. The use of a companion diagnostic is stipulated in the labeling of both the diagnostic device and the corresponding therapeutic. Companion diagnostics may identify patients who are most likely to benefit from a particular therapeutic product; identify patients likely to be at increased risk for serious side effects as a result of treatment with a particular therapeutic product; or monitor response to treatment with a particular therapeutic product for the purpose of adjusting treatment to achieve improved safety or effectiveness. Companion diagnostics are regulated as medical devices by the FDA. As noted in the "Regulation of In Vitro ("IVD") Diagnostics and Medical Devices" section above, the FDCA and its implementing regulations govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of medical devices which includes companion diagnostics. Unless exempt, companion diagnostics are subject to FDA premarket review before commercialization. Companion diagnostics are generally subject to the 510(k) or PMA regulatory pathways but where appropriate, can be authorized through the De Novo process.

On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for "In Vitro Companion Diagnostic Devices." According to the guidance document, for therapeutic products that depend on the use of a diagnostic test and where the diagnostic device is essential for the safe and effective use of the corresponding therapeutic product, the premarket application for the companion diagnostic device should be developed and approved or cleared via a medical device regulatory pathway contemporaneously with the therapeutic, although the FDA recognizes that there may be cases when contemporaneous development may not be possible. However, in cases where a drug cannot be used safely or effectively without the companion diagnostic, the FDA's guidance indicates it will generally not approve the drug without the approval or clearance of the diagnostic device. The FDA also issued a draft guidance in July 2016 setting forth the principles for co-development of an in vitro companion diagnostic device with a therapeutic product. The draft guidance describes principles to guide the development and contemporaneous marketing authorization for the therapeutic product and its corresponding in vitro companion diagnostic. As noted in the "Regulation of In Vitro ("IVD") Diagnostics and Medical Devices" section above, the companion diagnostic device is subject to FDA's general controls including the QSR, facility registration, device listing, reporting of, adverse events, and reporting of corrections and removals. As a device manufacturer, companion diagnostic makers are subject to periodic FDA inspections. As noted in the "Regulation of In Vitro ("IVD") Diagnostics and Medical Devices" section above, noncompliance with the FDCA and its implementing regulation can subject a manufacturer to enforcement including administrative actions, civil penalties, and criminal penalties.

To the extent a therapeutic drug or biologic product requires a delivery device (e.g., syringe), the delivery device will also be regulated as a medical device. Unless exempt, delivery devices are subject to FDA premarket review before commercialization as outlined in the "Regulation of In Vitro ("IVD") Diagnostics and Medical Devices" section above. In addition to the traditional medical device regulatory pathway, the delivery device could also be authorized as a combination product with the therapeutic drug or biologic product. When authorized as a combination product, medical device quality system and adverse event reporting requirements still apply to the device portion of the combination product. However, the combination product manufacturer may be able to streamline some of these obligations in accordance with 21 C.F.R. Part 4.

Other Laws—Environmental, Occupational Safety and Health

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Human Capital Resources

We believe that our talent is our competitive edge in the global marketplace. We strive to attract and retain a uniquely talented and high performing workforce across all aspects of diversity and aim to foster a team-first culture of innovation.

Workforce

As of March 31, 2022, we employed approximately 768 employees worldwide, of which approximately 728 were full-time employees and approximately 94% were U.S.-based employees.

Diversity, Equity, and Inclusion (DE&I)

We strive to provide opportunity for all: our employees, our community, and our customers. We believe in welcoming and embracing various cultures and backgrounds, as we recognize the value of employing a workforce of unique and varying viewpoints and experiences. Currently, 51% of our U.S. workforce are women. 40% of our Board of Directors identify as people of color and three of our nine directors identify as female.

Our DE&I strategy is focused on workplace, workforce, marketplace and community, and is deeply ingrained in our organizational insights, employee data, and industry research and benchmarks. In fiscal 2022, we achieved the following important milestones of our long-term DE&I strategy:

- Hired a Director of Diversity, Equity and Inclusion to build on the grassroots DEI work that started in 2019;
- Added three new Employee Resource Groups ("ERG") to our existing seven groups to continue to provide a safe space for individuals to discuss issues that impact their shared community;
- Furthered our focus on supplier diversity by developing and implementing a supplier diversity survey to be utilized when sourcing new vendors for the organization;
- Utilize ERG members to make business decisions around product enhancements; and
- Added two additional staff and resources to the DE&I Team.

We aim to grow, learn, and shape our approach to DE&I for the betterment of our workforce and the communities we serve. To that end, we will continue to ensure we are creating an environment that welcomes uncomfortable conversations about issues that impact our workforce, customers and the broader community.

Competitive Compensation and Benefits

We provide all benefit-eligible employees working at least 20 hours per week with a comprehensive benefit and compensation package, which includes:

- Medical, dental, vision care, health savings account plus employer contribution, life insurance plus accidental death and dismemberment (“+ ADD”) coverage, voluntary life + ADD, short-term and long-term disability, a retirement plan with Company match, and a discount employee stock purchase program;
- Healthcare and dependent care flexible spending accounts, commuter benefits plus transit subsidy;
- Discounted gym membership, work-from-home internet stipend plus a one-time work from home office equipment reimbursement, and pet insurance;
- Employee assistance program, precision mental healthcare with free counseling sessions and unlimited digital mental health support, tuition reimbursement and student loan assistance, medical coverage for same and opposite gender domestic partners, company and floating holidays, paid volunteer time off and paid time off;
- Reimbursement of expenses for surrogacy, adoption and infertility;
- Complimentary resource for personal legal questions and personal legal document generation and review, personal financial wellness platform and access to fiduciary financial advisors; and
- 16 weeks of fully paid parental leave following birth, adoption, or surrogacy for both parents.

As a company, we offer postpartum and return-to-work assistance which includes on-site lactation rooms and flexible work hours. For nursing moms who travel for work, we provide reimbursement for the shipment of breast milk back to their homes. We also offer back-up child and elder care. We offer one week of company paid family leave for employees who need to care for a family member who has a serious health condition and provide unlimited sick leave for COVID related illness.

We firmly believe in investing into the health, well-being, and wellness of our employees. We provide complimentary health and fitness classes, including instructor-led yoga, pilates, cardio, strength, and meditation classes. We host individual and team wellness challenges that incorporate mental, emotional, physical, and nutritional elements of a healthy lifestyle. We provide an online navigation and advocacy service to find the right care and deal with medical bills questions.

Talent Development

Employee development is considered to be a strategic priority. We support employee growth and development by offering a variety of benefits. Our focus areas at this time are on leadership development, career development, DE&I and supporting hybrid teams/leadership. Our flagship leadership program is for leaders at all levels (program, project, people, and/or team leaders), which provides employees to be able to lead from any seat. During the fiscal year ended March 31, 2022, over 16% of all employees participated in this 4-month cohort based leadership program. We plan to continue to offer this program and support more employees through their leadership journey.

Other talent development benefits we offer are tuition reimbursement, department learning budgets and internal mentorship programs. We recently launched our Company-wide BestYou@23andMe Framework, a performance management framework designed to support and foster career advancement. BestYou@23andMe encompasses three areas:

- The What - job responsibilities, objectives and key results (OKRs), Goals, DE&I;
- The How - Core Values, DE&I, Team Behaviors; and
- Impact - for DE&I, on the Business, on the Company, for your citizenship.

Our objective is having a clear approach towards career development, programs/benefits allowing employees with healthier lives, and an ability to participate in the community celebrating individuality. Our talent development programs are designed to support a work environment where employees are empowered to promote their unique perspectives.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished to the Securities and Exchange Commission ("SEC") pursuant to Sections 13(a) or 15(d) of the Securities Exchange Act of 1934 are available, free of charge, on the SEC website at www.sec.gov and our Investor Relations website at https://investors.23andme.com as soon as reasonably practicable after we electronically file such materials with, or furnish them to, the SEC. We use our Investor Relations website as a means of disclosing material non-public information. Accordingly, investors should monitor our Investor Relations website, in addition to following our press releases, SEC filings and public conference calls and webcasts.

Our corporate governance materials, including our corporate governance guidelines, the charters of our audit and compensation committees, and our code of business conduct and ethics may also be found under the Investor Relations section of our website at https://investors.23andme.com. A copy of the corporate governance materials is also available upon written request. Additionally, our investor presentations are available under the Investor Relations section of our website at https://investors.23andme.com. These materials are available no later than the time they are presented at investor conferences. Except to the extent expressly stated otherwise, information contained on or accessible from our web site or any other web site is not incorporated by reference into this annual report on Form 10-K and should not be considered part of this report.

Item 1A. Risk Factors

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Cautionary Note Regarding Forward-Looking Statements," you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity, and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described in this Form 10-K are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Unless the context indicates otherwise, references in this "Risk Factors" section to the "Company," "we," "us," "our," and similar terms refer to 23andMe Holding Co., a Delaware corporation formerly known as VG Acquisition Corp., and its consolidated subsidiaries.

Summary of Principal Risk Factors

- The market for personal genetics products and services has experienced a recent overall decline. If this trend continues or worsens, it would adversely affect our business and results of operations.
- If our competitors receive further FDA marketing approval for in vitro diagnostic products, our business could be adversely affected.
- The telehealth market is immature and volatile, and if it does not develop, if it encounters negative publicity, or if the increased use of telehealth solutions as a result of the COVID-19 pandemic does not continue after the pandemic, then the growth of our business and our results of operation will be harmed.
- We rely on key sole suppliers to manufacture and perform services used by customers who purchase our PGS, which could adversely affect our ability to meet customer demand.
- If we are not able to maintain and enhance our brand, our ability to expand our customer base may be impaired and our business and operating results may be harmed.
- If our efforts to attract new customers and patients and engage existing customers and patients with enhanced products and services are unsuccessful or if such efforts are more costly than we expect, our business may be harmed.
- Revenue derived from our kit sales is dependent on seasonal holiday demand and the timing of Amazon Prime Day, which could lead to significant quarterly fluctuations in revenue and results of operations.
- Our pricing strategies may not meet customers' price expectations or may adversely affect our revenue.
- Any significant disruption in service on our website, mobile applications, or in our computer or logistics systems could harm our reputation and may result in a loss of customers.
- If we are unable to deliver a rewarding experience on mobile devices, whether through our mobile website or our mobile application, we may be unable to attract and retain customers and patients.
- We depend on a number of other companies to perform functions critical to our ability to operate our platform, generate revenue from patients.
- If we are unable to attract and retain high quality healthcare providers for our patients, our business, financial condition, and results of operations may be materially and adversely affected.
- If the number of our customers consenting to participate in our research programs declines or fails to grow, our revenue may be adversely affected, and our database may become less effective.

- Our focus on using our genetics-powered platform to discover targets with therapeutic potential may not result in the discovery of commercially viable drug targets for us or our collaborators.
- Media reports on consumer data privacy and security concerns and the use of genetic information may decrease the overall consumer demand for personal genetic products and services, including ours.
- We do not have any experience in successful drug development or commercialization and our failure to execute on successful drug development or commercialization would adversely affect our business and results of operations.
- If we fail to succeed in our drug development efforts, or to develop and commercialize additional products and services, our ability to expand our business and achieve our strategic objectives would be impaired.
- Our Therapeutics business faces substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we can.
- We cannot give any assurance that any of our drugs will receive regulatory approval, which is necessary before they can be commercialized.
- Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect our ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval.
- We may be subject to legal proceedings and litigation, which are costly to defend and could materially harm our business and results of operations.
- Our business and future operating results may be adversely affected by catastrophic or other events outside of our control.
- We may need additional capital, and we cannot be sure that additional financing will be available at acceptable terms or at all.
- We depend on the continued services and performance of our highly qualified key personnel, and we may not be able to attract or retain qualified scientists and other specialized individuals in the future due to the competition for qualified personnel among life science and technology businesses.
- We face risks related to epidemics and other outbreaks of communicable diseases, including the current COVID-19 pandemic.
- Economic uncertainty or downturns, particularly affecting the markets and industries in which we operate, could adversely affect our business, financial condition, and results of operations.
- If we were to enter new business areas, we would likely face competition from entities more familiar with those businesses, and our efforts may not succeed.
- If we, GSK and any future collaborators are unable to successfully complete clinical development, obtain regulatory approval for, or commercialize any drugs, or experience delays in doing so, our business may be materially harmed.
- GSK and any other potential drug discovery collaborators will have significant discretion in determining when to make announcements, if any, about the status of our collaborations.
- We may seek to establish additional collaborations in the future, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.
- Our collaborators may not achieve projected discovery and development milestones and other anticipated key events in the expected timelines or at all, which could have an adverse impact on our business.
- Our products and services are subject to extensive regulation and compliance with existing or future regulations could result in unanticipated expenses, or limit our ability to offer our products and services.
- We will face legal, reputational, and financial damage if we fail to protect our customer and patient data from security breaches or cyberattacks.
- Our ability to meet demand in the Amazon retail channel is dependent upon Amazon's stocking policies.
- If we are unsuccessful in efforts to expand internationally, our business may be harmed.
- If we are unable to protect our intellectual property, the value of our brand and other intangible assets may be diminished, and our business may be adversely affected.

- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- A material weakness in our internal control over financial reporting was identified as of March 31, 2020 and 2021, and remains unremediated at March 31, 2022. If our remediation of this material weakness is not effective, or if we fail to maintain effective internal control over financial reporting in the future, our ability to produce accurate and timely consolidated financial statements could be impaired.
- Our quarterly operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline.
- Our ability to use our net operating loss carryforwards may be subject to limitations.
- We have incurred significant losses since inception, we expect to incur losses in the future, and we may not be able to generate sufficient revenue to achieve and maintain profitability.
- We have incurred and will continue to incur increased costs as a result of being a public company.
- Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the U.S.
- We are subject to changing law and regulations regarding regulatory matters, corporate governance, and public disclosure that have increased our costs and the risk of non-compliance.
- We face additional risks as a result of the acquisition of Lemonaid Health and may be unable to integrate our businesses successfully and realize the anticipated synergies and related benefits, or do so within the anticipated timeframe.

Risks Related to Our Business

Consumer and Research Services Business Risks

The market for personal genetics products and services has experienced a recent overall decline, which corresponds with the recent and significant decreases in our revenues. If this trend continues or worsens, it would adversely affect our business and results of operations.

Our revenue model has historically been derived principally from customers who purchase our PGS services. For the fiscal years ended March 31, 2022, 2021 and 2020, PGS revenue accounted for 75%, 81% and 89% of revenues, respectively. There is no assurance that our business model will be successful or that it will generate increased revenues or become profitable as a result of marketing our current PGS services or any future products or services. We may be forced to make significant changes to our anticipated pricing, sales and revenue model to compete with our competitors' offerings, and even if such changes are implemented, there is no guarantee that they will be successful. If the current market trend continues or worsens, or we are unable to adjust our approach to meet market demands, our revenues and results of operations will be adversely affected.

We operate in highly competitive markets, and competition in the personal genetics and telehealth markets present an ongoing threat to the success of our business.

With respect to our PGS business, the number of companies entering the market with offerings similar to our PGS services continues to increase. We believe that our ability to compete depends upon many factors both within and beyond our control, including the following:

- the size of our customer base;
- the timing and market acceptance of products and services, including the developments and enhancements to those products and services, offered by us or our competitors;
- customer service and support efforts;
- selling and marketing efforts;
- ease of use, performance, price and reliability of solutions developed either by us or our competitors; and
- our brand strength relative to our competitors.

We also face competition from other companies attempting to capitalize on the same, or similar, opportunities as it is, including from existing diagnostic, laboratory services and other companies entering the personal genetics market with new offerings such as direct access and/or consumer self-pay tests and genetic interpretation services. Some of our current and potential competitors have longer operating histories and greater financial, technical, marketing and other resources than we do. These factors may allow our competitors to respond more quickly or efficiently than it can to new or emerging technologies. These competitors may engage in more extensive research and development efforts, undertake more far-reaching marketing campaigns and adopt more aggressive pricing policies, which may allow them to build larger customer bases than we have. Our competitors may develop products or services that are similar to our products and services or that achieve greater market acceptance than our products and services. This could attract customers away from our services and reduce our market share.

Similarly, the markets for healthcare are intensely competitive, subject to rapid change, and significantly affected by new product and technological introductions and other market activities of industry participants. We compete directly not only with other established telehealth providers but also traditional healthcare providers and pharmacies. Our current competitors include traditional healthcare providers expanding into the telehealth market, incumbent telehealth providers, as well as new entrants into our market that are focused on direct-to-consumer healthcare. Our competitors include enterprise-focused companies that may enter the direct-to-consumer healthcare industry, as well as direct-to-consumer healthcare providers. Many of our current and potential competitors may have greater name and brand recognition, longer operating histories, significantly greater resources than we do, and may be able to offer products and services similar to those offered on our platform at more attractive prices than we can.

Additionally, we believe that the COVID-19 pandemic has introduced many new users to telehealth and further reinforced its benefits to potential competitors. We believe this may drive additional industry consolidation or collaboration involving competitors that may create competitors with greater resources and access to potential patients. The COVID-19 pandemic may also cause various traditional healthcare providers to evaluate and eventually pursue telehealth options that can be paired with their in-person capabilities. These industry changes could better position our competitors to serve certain segments of our current or future markets, which could create additional price pressure. In light of these factors, even if our offerings are more effective than those of our competitors, current or potential patients may accept competitive solutions in lieu of purchasing from us.

If our competitors receive further FDA marketing approval for in vitro diagnostic products, our business could be adversely affected.

We were the first direct-to-consumer genetic testing company to include FDA-authorized genetic health risk, carrier status and pharmacogenetic reports. Our competitors had previously released products that were not cleared or approved by the FDA and required partnership with independent physicians, but in August 2020, one of our competitors received premarket notification, also called 510(k) clearance, for their saliva collection kit and one of their genetic health risk reports, and in December 2020 another competitor received a 510(k) clearance for one of their health risk reports. Following these FDA clearances, our competitors can now market those cleared reports directly to consumers rather than relying on clinician network partners. If our competitors receive further FDA approvals, our business could be adversely affected.

The sizes of the markets and forecasts of market growth for the demand of our products and services, including our research services and other key potential success factors are based on a number of complex assumptions and estimates, and may be inaccurate.

We estimate annual total addressable markets and forecasts of market growth for our PGS. We have also developed a standard set of key performance indicators in order to enable us to assess the performance of our business in and across multiple markets, and to forecast future revenue. These estimates, forecasts and key performance indicators are based on a number of complex assumptions, internal and third-party estimates and other business data, including assumptions and estimates relating to our ability to generate revenue from the development of new workflows. While we believe our assumptions and the data underlying our estimates and key performance indicators are reasonable, there are inherent challenges in measuring or forecasting such information. As a result, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors and indicators. Consequently, our estimates of the annual total addressable market and our forecasts of market growth and future revenue from our products and services, including our research services may prove to be incorrect, and our key business metrics may not reflect our actual performance. For example, if the annual total addressable market or the potential market growth for our products and services is smaller than we have estimated or if the key business metrics we utilize to forecast revenue are inaccurate, it may impair our sales growth and have an adverse impact on our business, financial condition, results of operations and prospects.

The telehealth market is immature and volatile, and if it does not develop, if it encounters negative publicity, or if the increased use of telehealth solutions as a result of the COVID-19 pandemic does not continue after the pandemic, then the growth of our business and our results of operation will be harmed.

The telehealth market is relatively new and unproven, and it is uncertain whether it will achieve and sustain high levels of demand, consumer acceptance, and market adoption. The outbreak of the COVID-19 pandemic has increased utilization of telehealth services, but it is uncertain whether such increase in demand will continue. The success of our telehealth business will depend to a substantial extent on the willingness of our patients and members to use, and to increase the frequency and extent of their utilization of, our solution, as well as on our ability to demonstrate the value of telehealth to patients. Negative publicity concerning our telehealth services, or the telehealth market as a whole, could limit market acceptance of our solution. If our telehealth patients and members do not perceive the benefits of our services, then our market may develop more slowly than we expect or not at all. Similarly, individual and healthcare industry concerns or negative publicity regarding patient confidentiality and privacy in the context of telehealth could limit market acceptance of our healthcare services. If any of these events occurs, it could have a material adverse effect on our business, financial condition, and results of operations.

We rely on key sole suppliers to manufacture and perform services used by customers who purchase our PGS. Our reliance on limited contracted manufacturing and supply chain capacity could adversely affect our ability to meet customer demand.

We do not have manufacturing capabilities and do not plan to develop such capacity in the foreseeable future. Accordingly, we rely on third-party suppliers to provide materials (such as our saliva collection kits, bead chips, reagents or other materials and equipment used in our laboratory operations) and services (such as our laboratory processing services). Currently, we rely on a sole supplier to manufacture our saliva collection kits used by customers who purchase our PGS. Change in the supplier or design of certain of the materials which we rely on, in particular the bead chip and saliva collection kit, could result in a requirement that we seek additional premarket review from the FDA before making such a change. We also are required to validate any new laboratory or laboratories in accordance with FDA standards prior to utilizing their services for our U.S. customers. We cannot be certain that we will be able to secure alternative laboratory processing services, materials and equipment, and bring such alternative materials and equipment on line and revalidate them without experiencing interruptions in our workflow, or that any alternative materials will meet our quality control and performance requirements of our contracted laboratory.

Although we maintain relationships with suppliers with the objective of ensuring that we have adequate supply for the delivery of our services, increases in demand for such items can result in shortages and higher costs. Our suppliers may not be able to meet our delivery schedules, we may lose a significant or sole supplier, a supplier may not be able to meet performance and quality specifications and we may not be able to purchase such items at a competitive cost. Further, we may experience shortages in certain items as a result of limited availability, increased demand, pandemics (such as the COVID-19 pandemic) or other outbreaks of contagious diseases, weather conditions and natural disasters, as well as other factors outside of our control. Our freight costs may increase due to factors such as limited carrier availability, increased fuel costs, increased compliance costs associated with new or changing government regulations, pandemics (such as the COVID-19 pandemic) or other outbreaks of contagious diseases and inflation. Higher prices for natural gas, propane, electricity and fuel also may increase our production and delivery costs. The prices charged for our products may not reflect changes in our packaging material, freight, tariff and energy costs at the time they occur, or at all.

In order for other parties to perform manufacturing and participate in our supply chain, we sometimes must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to manufacture and supply sufficient quantities of our products on acceptable terms, or if we should encounter delays or other difficulties with the third parties on which we rely for our supply chain, our business, prospects, operating results, and financial condition may be materially harmed.

Our business significantly depends upon the strength of our brand, and if we are not able to maintain and enhance our brand, our ability to expand our customer base may be impaired and our business and operating results may be harmed.

We believe that the brand identity that we have developed has significantly contributed to the success of our business. We also believe that maintaining and enhancing the "23andMe" brand is a significant factor in expanding our customer base and current and future business opportunities. Maintaining and enhancing our brand may require us to make substantial investments and these investments may not be successful. If we fail to promote and maintain the "23andMe" brand, or if we incur excessive expenses in this effort, our business, operating results and financial condition may be materially and adversely affected. We anticipate that, as our market becomes increasingly competitive, maintaining and enhancing our brand may become increasingly difficult and expensive.

We have a limited history introducing new products and services to our customers and patients. If our efforts to attract new customers and patients and engage existing customers and patients with enhanced products and services, are unsuccessful or if such efforts are more costly than we expect, our business may be harmed.

Our success depends on our ability to attract new customers and patients and engage existing customers and patients in a cost-effective manner. To acquire and engage customers and patients, we must, among other things, promote and sustain our platform and provide high-quality products, user experiences, and service. If customers do not perceive our PGS and PGS reports to be reliable and of high quality, if we fail to introduce new and improved products and services, or if we introduce new products or services that are not favorably received by the market, we may not be able to attract or retain customers and patients.

For example, the increased growth of our subscription service, 23andMe+, depends upon how compelling this offering is to our customers. Many of our 23andMe+ subscribers may initially access the subscription service for a discount. While we strive to demonstrate the value of our subscription service to our customers, and encourage eligible customers to become paid subscribers of 23andMe+, these customers may not convert to a fully paid subscription to 23andMe+ after they take advantage of our promotions. Moreover, if we are unable to keep existing customers engaged, including by their participation in research and responses to questionnaires, our ability to grow our database and discover new insights about the relationship between genetics and disease will be compromised. If we are unable to attract new customers or engage existing customers, including as subscribers of 23andMe+, our revenue and our operating results may grow slower than expected or decline.

Our telehealth business provides patients with access to telehealth-based consultations with healthcare providers and prescription medication services. In order to attract new telehealth patients and members and grow our telehealth business, we need to continue expanding the scope of our products and services and enter into new categories that will provide access to consultation and treatment of additional conditions. It is uncertain whether any such offerings will achieve and sustain high levels of demand and market adoption. Unless we are able to attract new telehealth patients and members and retain existing patients, our business, financial condition, and results of operations may be harmed.

Our marketing efforts currently include various initiatives and consist primarily of digital marketing on a variety of social media channels, such as Facebook, search engine optimization on websites, such as Google, Bing, and Yahoo!, various branding strategies, and mobile “push” notifications and email. During the fiscal years ended March 31, 2022, 2021 and 2020, we spent $100.3 million, $43.2 million and $110.5 million on sales and marketing, representing 37%, 18% and 36% of our revenue, respectively. We anticipate that sales and marketing expenses will continue to represent a significant percentage of our overall operating costs for the foreseeable future. We have historically acquired a significant number of our users through digital advertising on platforms and websites owned by Facebook and Google, which may terminate their agreements with us at any time. Our investments in sales and marketing may not effectively reach potential customers and/or patients, potential customers and/or patients may decide not to buy our products or services, or customer or patient spend for our products and services may not yield the intended return on investment, any of which could negatively affect our financial results.

Many factors, some of which are beyond our control, may reduce our ability to acquire, maintain and further engage with customers and patients, including those described in this "Risk Factors" section and the following:

- system updates to app stores and advertising platforms such as Facebook and Google, including adjustments to algorithms that may decrease user engagement or negatively affect our ability to reach a broad audience;
- consumers opting out of the collection of certain personal information, including opting out of cookies, for marketing purposes;
- consumers opting out of the receipt of promotional emails or text messages;
- federal and state laws governing the use of personal information, including healthcare data, in marketing to potential or existing customers and patients, and the regulation of the use of discounts, promotions, and other marketing strategies in the healthcare industry;
- changes in advertising platforms' pricing, which could result in higher advertising costs;
- changes in digital advertising platforms' policies, such as those of Facebook and Google, that may delay or prevent us from advertising through these channels, which could result in reduced traffic to and sales on our platform, or that may increase the cost of advertising through these channels;
- changes in search algorithms by search engines;
- inability of our email marketing messages to reach the intended recipients' inbox;
- ineffectiveness of our marketing efforts and other spend to continue to acquire new customers and patients and maintain and increase engagement with existing customers and patients;
- decline in popularity of, or governmental restrictions on, social media platforms where we advertise;
- the development of new search engines or social media sites that reduce traffic on existing search engines and social media sites; and
- consumer behavior changes as a result of COVID-19.

In addition, we believe that many of our new customers and patients originate from word-of-mouth and other non-paid referrals from existing customers and patients, including purchases of kits for gift-giving, so we must ensure that our existing customers and patients remain loyal and continue to derive value from our service in order to continue receiving those referrals. If our efforts to satisfy our existing customers and patients are not successful, we may not be able to attract new customers and patients. Further, if our customer base does not continue to grow, we may be required to incur significantly higher marketing expenses than we currently anticipate to attract new customers and patients. A significant decline in our customer base would have an adverse effect on our business, financial condition and results of operations.

Revenue derived from our kit sales is dependent on seasonal holiday demand and the timing of Amazon Prime Day, which could lead to significant quarterly fluctuations in revenue and results of operations.

Our kit sales are dependent on seasonal holiday demand, as well as the timing of Amazon Prime Day, which has varied in recent years. We generate a significant amount of our PGS revenue during the fourth quarter of our fiscal year, due to seasonal holiday demand and to the fact that kits that are ordered during the holiday season (which occurs during the third quarter of our fiscal year) are recognized as revenue when the customer sends in their kit to the laboratory to be processed and genetic reports are delivered to the customer, which typically for holiday purchases tends to occur in the fourth fiscal quarter. For example, in fiscal 2022, 2021 and 2020, fourth quarter PGS revenue represented 36%, 39% and 31% of our total PGS revenue, respectively. Our promotional activity is also higher in the third fiscal quarter, which may reduce gross margin during this period. Purchasing patterns of kit sales are also aligned with other gift-giving and family-oriented holidays such as Mother's Day and Father's Day.

This seasonality causes our operating results to vary considerably from quarter to quarter. Additionally, any decrease in sales or profitability during the fourth quarter of the fiscal year could have a disproportionately adverse effect on our results of operations, which could, in turn, cause the value of our Class A common stock to fluctuate or decrease. This seasonality also could become more pronounced and may cause our operating results to fluctuate more widely.

We also may experience an increase in lab processing times and costs associated with shipping orders due to freight surcharges due to peak capacity constraints and additional long-zone shipments necessary to ensure timely delivery for the holiday season. Such delays could lead to an inability to meet advertised estimated lab processing times, resulting in customer dissatisfaction or reputational damage. If too many customers access our website within a short period of time, we may experience system interruptions that make our website unavailable or prevent us from efficiently fulfilling orders, which may reduce the volume of kits sold. Also, third-party delivery and direct ship vendors may be unable to deliver merchandise on a timely basis.

Our ability to meet demand in the Amazon retail channel is dependent upon Amazon's stocking policies.

We offer for sale both the Health + Ancestry Service kit and the Ancestry + Traits Service kit through Amazon in the US, Canada and the U.K. Demand for our PGS kits through Amazon varies considerably based upon seasonal holiday and other gift-giving and family-oriented holiday demand, as well as the timing of Amazon Prime Day.

Amazon's stocking policies restrict the total number of PGS kits available for shipment to Amazon customers. These policies, including the inventory cap, change frequently, and as a result, our inventory available for shipment through Amazon fluctuates. We may not be able to accurately predict the mix of Health + Ancestry Service kits and Ancestry + Traits Service kits to effectively meet demand for each service type by Amazon customers. We also may experience an increase in costs associated with expedited shipping or use of intermediaries to enable additional stock being made available through Amazon.

We have limited operating experience abroad and may be subject to increased business and economic risks that could impact our financial results.

Our PGS is available in the U.S., Canada, the U.K., and in certain other markets globally, and our telehealth services are available in all 50 states, the District of Columbia, and the U.K. We plan to continue to pursue international expansion of our business operations and we may expand our offering in existing international markets or enter new international markets where we have limited or no experience in marketing, selling and deploying our product and services. If we fail to deploy or manage our operations in these countries successfully, our business and operations may suffer. In addition, we are subject to a variety of risks inherent in doing business internationally, including:

- policies, social and/or economic instability;
- risks related to governmental regulations in foreign jurisdictions and unexpected changes in regulatory requirements and enforcement;
- fluctuations in currency exchange rates;
- higher levels of credit risk and payment fraud;
- enhanced difficulties of integrating any foreign acquisitions;
- burdens of complying with a variety of foreign laws;
- reduced protection for intellectual property rights in some countries;
- difficulties in staffing and managing global operations and the increased travel, infrastructure and legal compliance costs associated with multiple international locations and subsidiaries;
- different regulations and practices with respect to employee/employer relationships, existence of workers' councils and labor unions, and other challenges caused by distance, language, and cultural differences, making it harder to do business in certain international jurisdictions;
- compliance with statutory equity requirements; and
- management of tax consequences and compliance.

If we are unable to manage the complexity of global operations successfully, our financial performance and operating results could suffer.

Our pricing strategies may not meet customers' price expectations or may adversely affect our revenues.

Our pricing strategies have had, and may continue to have, a significant impact on our revenue. From time to time, we offer discounted prices as a means of attracting customers. Such offers and discounts, however, may reduce our revenue and margins. In addition, our competitors' pricing and marketing strategies are beyond our control and can significantly affect the results of our pricing strategies. If our pricing strategies, which may evolve over time, fail to meet our customers' price expectations or fail to result in increased margins, or if we are unable to compete effectively with our competitors if they engage in aggressive pricing strategies or other competitive activities, it could have a material adverse effect on our business.

We depend on our relationships with the PMCs, which we do not own, to provide telehealth consultation services, and our business could be adversely affected if those relationships were disrupted.

In certain jurisdictions, the corporate practice of medicine doctrine generally prohibits non-physicians from practicing medicine, including by employing physicians to provide clinical services, directing the clinical practice of physicians, or holding an ownership interest in an entity that employs or contracts with physicians. Some states have similar doctrines with respect to other professional licensure categories, including behavioral health services and providers. Other practices, such as professionals splitting their professional fees with a non-professional, are also prohibited in some jurisdictions. Many states also limit the extent to which nurse practitioners can practice independently and require that they practice under the supervision of or in collaboration with a supervising physician.

Through our platform, our patients gain access to one or more licensed healthcare providers for telehealth consultations. These providers are employed by or contracted with PMCs, which are professional entities owned by licensed physicians and that engage licensed healthcare professionals, to provide telehealth consultations and related services, including applicable physician supervision of nurse practitioners. We enter into certain contractual arrangements with the PMCs and their provider owners, including an administrative services agreement with each PMC for the exclusive provision by us of non-clinical services and support for the PMCs. While we expect that these relationships with the PMCs will continue, we cannot guarantee that they will. We believe that our arrangements with the PMCs have been structured to comply with applicable law and allow the healthcare providers the ability to maintain exclusive authority regarding the provision of clinical healthcare services (including consults that may lead to the writing of prescriptions), but there can be no assurance that government entities or courts would find our approach to be consistent with their interpretation of, and enforcement activities or initiatives related to, these laws and the corporate practice of medicine doctrine or similar prohibitions. If our arrangements are deemed to be inconsistent with any applicable government entity's interpretation of a law or regulation prohibiting the corporate practice of medicine, a fee-splitting law, or similar regulatory prohibitions, we would need to restructure the arrangements with the PMCs to create a compliant arrangement or terminate the arrangement, and we could face fines or other penalties in connection with such arrangements. A material change in our relationships with the PMCs, whether resulting from a dispute, a change in government regulation, or enforcement patterns, a determination of non-compliance, or the loss of these agreements or business relationships, could impair our ability to provide products and services to our patients and could have a material adverse effect on our business, financial condition, and results of operations. Violations of the prohibition on corporate practice of medicine doctrine, fee-splitting, or similar laws may impose penalties (e.g., fines or license suspension) on healthcare providers, which could discourage professionals from entering into arrangements with the PMCs and using our platform and could result in lawsuits by providers against the PMCs and us. These laws and regulations are subject to change and enforcement based upon political, regulatory, and other influences. More restrictive treatment of healthcare professionals' relationships with non-professionals, such as our Company, in the healthcare services delivery context could have a material adverse effect on our business, financial condition, and results of operations.

We depend on a number of other companies to perform functions critical to our ability to operate our platform, generate revenue from patients.

We depend on the PMCs and their providers and our Affiliated Pharmacies to deliver quality healthcare consultations and pharmacy services through our platform. Any interruption in the availability of a sufficient number of providers or supply from our Affiliated Pharmacies could materially and adversely affect our ability to satisfy our patients and ensure they receive consultation services and prescription medication. If we were to lose our relationship with one of the PMCs, we cannot guarantee that we will be able to ensure access to a sufficient network of providers. Similarly, if we were to lose our relationship with one of our Affiliated Pharmacies, or are unable to obtain access for patients to low-cost pharmaceutical products through such pharmacies, we cannot guarantee that we will be able to find, perform due diligence on, and engage with one or more replacement partners in a timely manner. Our ability to service customer requirements could be materially impaired or interrupted in the event that our relationship with a PMC or Affiliated Pharmacy is terminated or otherwise impaired, which can happen due to a variety of circumstances, including, but not limited to, noncompliance on the part of the third-party entity. We also depend on cloud infrastructure providers, payment processors, and various others that allow our platform to function effectively and serve the needs of our patients. Difficulties with our significant partners and suppliers, regardless of the reason, could have a material adverse effect on our business.

If we are unable to attract and retain high quality healthcare providers for our patients, our business, financial condition, and results of operations may be materially and adversely affected.

Our success is dependent upon our continued ability to maintain a network of qualified telehealth providers. If we are unable to recruit and retain board-certified physicians, pharmacists, and other healthcare professionals, it would adversely affect our business, financial condition, and results of operations and ability to grow. In any particular market, providers could demand higher payments or take other actions that could result in higher medical costs, less attractive service for our patients, or difficulty meeting regulatory or accreditation requirements. The failure to maintain or to secure new cost-effective provider contracts may result in a loss of or inability to grow our membership base, higher costs, less attractive service for our patients, and/or difficulty in meeting regulatory or accreditation requirements, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Any significant disruption in service on our website, mobile applications, or in our computer or logistics systems, whether due to a failure with our information technology systems or that of a third-party vendor, could harm our reputation and may result in a loss of customers.

Customers purchase our PGS and access its services through our website or our mobile applications. We also provide our telehealth services to patients and members through our website and mobile applications. Our reputation and ability to attract, retain and serve our customers, patients, and members is dependent upon the reliable performance of our website, mobile applications, network infrastructure and content delivery processes. Interruptions in any of these systems, whether due to system failures, computer viruses or physical or electronic break-ins, could affect the security or availability of our website or mobile applications, including our databases, and prevent our customers, patients, and members from accessing and using our services.

Our systems and operations are also vulnerable to damage or interruption from fire, flood, power loss, telecommunications failure, terrorist attacks, acts of war, electronic and physical break-ins, earthquake and similar events. For example, our headquarters are located in the San Francisco Bay Area which over the past several years has been subject to planned power outages to reduce the risk of wildfire, and these power outages can last for several days, which may limit or curtail certain operations. In the event of any catastrophic failure involving our website, we may be unable to serve our web traffic. In addition, our Lemonaid pharmacy fulfillment business is processed from a single location, which operations would be materially disrupted in the event any of these events were to occur at such facility. The occurrence of any of the foregoing risks could result in damage to our systems or could cause them to fail completely, and our insurance may not cover such risks or may be insufficient to compensate us for losses that may occur.

Additionally, our PGS business model is dependent on our ability to deliver kits to customers and have kits processed and returned to us. This requires coordination between our logistics providers and third-party shipping services. Operational disruptions may be caused by factors outside of our control such as hostilities, political unrest, terrorist attacks, natural disasters, pandemics (such as COVID-19) and public health emergencies, such as COVID-19, affecting the geographies where our operations and customers are located. We may not be effective at preventing or mitigating the effects of such disruptions, particularly in the case of a catastrophic event. In addition, operational disruptions may occur during the holiday season, causing delays or failures in deliveries of PGS kits. Any such disruption may result in lost revenues, a loss of customers and reputational damage, which would have an adverse effect on our business, results of operations and financial condition.

If we are unable to deliver a rewarding experience on mobile devices, whether through our mobile website or our mobile application, we may be unable to attract and retain customers and patients.

We believe that current and prospective customers and patients are increasingly interested in accessing our PGS and telehealth offerings through mobile devices. We maintain mobile websites and mobile applications for our PGS and telehealth offerings. Developing and supporting a mobile website and mobile application across multiple operating systems and devices requires substantial time and resources. Notwithstanding our efforts to develop mobile solutions, our mobile solutions may fail to meet the needs of our customers and patients or consistently provide rewarding customer and patient experiences. As a result, our ability to attract new customers and patients could be impaired and customers and patients we meet through our mobile websites or mobile applications may not choose to use our offerings at the same rate as customers and patients we meet through our websites.

As new mobile devices and mobile operating systems are released, we may encounter problems in developing or supporting our mobile websites or mobile applications for them. Our ability to offer commercially successful mobile websites and mobile applications could also be harmed by factors outside of our control, such as:

- increased costs to develop, distribute, or maintain our mobile websites or mobile applications;
- changes to the terms of service or requirements of a mobile application store that requires us to change our mobile application development or features in an adverse manner; and
- changes in mobile operating systems, such as Apple's iOS and Google's Android, that disproportionately affect us, degrade the functionality of our mobile websites or mobile applications, require that we make costly upgrades to our technology offerings, or give preferential treatment to competitors' websites or mobile applications.

If our customers or patients experience difficulty accessing or using, or if they elect not to use, our mobile websites or mobile applications, our business and results of operations may be adversely affected.

Use of social media and email may adversely affect our reputation or subject us to fines or other penalties.

We use social media and email as part of our approach to marketing. As laws and regulations rapidly evolve to govern the use of these channels, the failure by us, our employees or third parties acting on our behalf or at our direction to abide by applicable laws and regulations in the use of these channels could adversely affect our reputation or subject us to fines, other penalties, or lawsuits. Although we continue to update our practices as these laws change over time, we may be subject to lawsuits or investigations alleging our failure to comply with such laws. In addition, our employees or third parties acting on our behalf or at our direction may knowingly or inadvertently use social media, including through advertisements, in ways that could lead to the loss or infringement of intellectual property, as well as the public disclosure of proprietary, confidential, or sensitive personal information of our business, employees, customers, patients, members, or others. Any such inappropriate use of social media and emails could also cause reputational damage.

Our customers may engage with us online through social media platforms, including Facebook, Instagram, and Twitter, by providing feedback and public commentary about all aspects of our business. Information concerning us, whether accurate or not, may be posted on social media platforms at any time and may have a disproportionately adverse impact on our brand, reputation, or business. The harm may be immediate without affording us an opportunity for redress or correction and could have a material adverse effect on our business, results of operations, financial condition, and prospects.

Our success depends, in large part, on our ability to extend our presence in the personal genetics market, provide customers with a high level of service at a competitive price, achieve sufficient sales volume to realize economies of scale, and create innovative new features, products, and services to offer to our customers. Our failure to achieve any of these outcomes would adversely affect our business.

Our success depends, in large part, on our ability to extend our presence in the personal genetics market, provide customers with a high level of service at a competitive price, achieve sufficient sales volume to realize economies of scale, and create innovative new features, products and services to offer to our customers. The growth and expansion of our business and service offerings places a continuous significant strain on our management, operational and financial resources. We are required to manage multiple relationships with various strategic suppliers, customers and other third parties, and regulatory agencies and advisors. To effectively manage our growth, we must continue to implement and improve our operational, financial and management information systems and to expand, train and manage our employee base. We further must continue to work to scale our own operations and our supplier operations to meet increases in demand for our services. In the event of further growth of our operations or in the number of our third-party relationships, our supply, systems, procedures, or internal controls may not be adequate to support our operations and our management may not be able to manage any such growth effectively.

Our current and future expense levels are, to a large extent, fixed and are largely based on our investment plans and our estimates of future revenue. Because the timing and amount of revenue from our PGS is difficult to forecast when revenue does not meet our expectations we may not be able to adjust our spending promptly or reduce our spending to levels commensurate with our revenue.

Even if we are able to successfully scale our infrastructure and operations, we cannot ensure that demand for our services will increase at levels consistent with the growth of our infrastructure. If we fail to generate demand commensurate with this growth or if we fail to scale our infrastructure sufficiently in advance to meet such demand, our business, financial condition and results of operations could be adversely affected, which may affect our ability to attract personnel or retain or motivate existing personnel.

Our Consumer and Research Services business relies on the continual growth of our database of information provided by customers who consent to participate in our research. If the number of our customers consenting to participate in our research programs declines or fails to grow, our research services revenue may be adversely affected, and our database may become less effective in facilitating our ability to identify new drug targets and to create new features, products and services to offer to our customers.

Our Consumer and Research Services business is based on our ongoing analysis of the continually growing quantity of data in our proprietary database of genotypic and phenotypic information provided by customers who have consented to participate in our research programs. Over 80% of our customers have consented to participate in our research programs. If this percentage were to decline, or if consenting customers were to decide to opt out of our research programs, such that we cannot continue to grow our research database, the utility and value of our database would be adversely affected.

Our Consumer and Research Services business requires us to continue to improve and develop new data mining technologies and innovations in the use of genotypic and phenotypic data.

Our research services business uses our database and data mining tools and technologies to analyze the impacts of genetics on the sources and risks of disease, and to identify promising drug targets. If we do not continue to improve and develop new data mining technologies and innovations in our use of genotypic and phenotypic data, and to attract and retain skilled scientists to analyze our data, our business would be adversely affected.

Although we believe that our genetics-powered target discovery platform has the potential to identify more promising drugs than traditional methods, our focus on using our genetics-powered platform to discover targets with therapeutic potential may not result in the discovery of commercially viable drug targets for us or our collaborators.

Our scientific approach focuses on using our propriety genotypic and phenotypic database to identify promising drug targets and predict their key properties without conducting time-consuming and expensive physical experiments. Our proprietary data mining techniques underpin, our target identification collaborations and our own internal target identification programs. While we believe that our research platform has been successful to date in identifying promising drug targets, we have no assurance that our early success will continue or lead to future success in identifying such targets.

Media reports have in the past reported on consumer data privacy and security concerns and the use of genetic information accessed from other genetic databases by law enforcement and governmental agencies. These reports may decrease the overall consumer demand for personal genetic products and services, including ours.

We receive a high degree of media coverage. Unfavorable publicity or consumer perception of our product and service offerings, including consumer privacy concerns related to any of our past, existing, or future collaborations, could adversely affect our reputation, resulting in a negative impact on the size of our customer base, the loyalty of our customers, the percentage of our customers that consent to participate in our research program, and our ability to attract new customers.

Therapeutics Business Risks

We expect to make significant investments in our continued efforts to develop new therapies as part of our Therapeutics business; these efforts may not be successful. We do not have any experience in successful drug development or commercialization and our failure to execute on successful drug development or commercialization would adversely affect our business and results of operations.

Drug development is expensive, takes years to complete, and can have uncertain outcomes. Failure can occur at any stage of development. We expect to incur significant expenses to advance our therapeutic development efforts, which may be unsuccessful. Developing new drugs is a speculative, risky, and highly competitive endeavor. Drugs which may initially show promise may fail to achieve the desired results in development and clinical studies and may ultimately not prove to be safe and effective or meet expectations for clinical utility. We may need to alter our offerings in development and repeat clinical studies before we develop a potentially successful drug. If, after development, a drug appears successful, we or our collaborators will still need to obtain FDA and other regulatory approvals before we can market it. The FDA's approval pathways are likely to involve significant time, as well as additional research, development, and clinical study expenditures. The FDA may not approve any drug we develop. Even if we develop a drug that receives regulatory approval, we or our collaborators would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the drug may never be commercially successful. Additionally, development of any product or service may be disrupted or made less viable by the development of competing products or services. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict whether or when our Therapeutics business may successfully commercialize a drug target.

New potential products and services may fail at any stage of development or commercialization and if we determine that any of our current or future products or services are unlikely to succeed, we may abandon them without any return on our investment. If we are unsuccessful in developing additional products or services, our potential for growth may be impaired.

Even if we or our drug discovery collaborators are able to develop drugs that demonstrate potential in preclinical or early stage clinical studies, we or they may not succeed in demonstrating safety and efficacy of drugs in human clinical trials.

Even if we or our drug discovery collaborators are able to develop drugs that demonstrate potential in preclinical or early stage clinical studies, we or they may not succeed in demonstrating safety and efficacy of drugs in human clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drugs performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

If we fail to succeed in our drug development efforts, or to develop and commercialize additional products and services, our ability to expand our business and achieve our strategic objectives would be impaired.

Our Therapeutics business is focused on leveraging our proprietary genotypic and phenotypic database in order to speed the development of successful new drugs. However, we may never succeed in developing a viable drug target. There are many lengthy and complex processes that all must yield successful results in order for us to ultimately succeed in developing and commercializing a drug. There are numerous stages of the drug development process, from initial target identification and validation, through various stages of rigorous preclinical research, to the selection of a lead drug which is suitable for human clinical testing. Once a clinical drug is selected, there are several stages of clinical testing it must undergo, each dependent upon success in the prior stage. This is a long and costly process that will require significant time and resources and, if not successful, for any number of reasons that we cannot anticipate, would have an adverse effect on our business, financial condition and results of operations. In addition, external competition by other therapeutic companies can adversely affect our expected market share and revenues of our drugs.

Developing new products and services requires substantial technical, financial and human resources, whether or not any products or services are ultimately commercialized. We may pursue what we believe is a promising opportunity only to discover that certain of our risk or resource allocation decisions were incorrect or insufficient, or that individual products, services or our science in general has technology or biology risks that were previously unknown or underappreciated. In the event material decisions in any of these areas turn out to be incorrect or sub-optimal, we may experience a material adverse impact on our business and ability to fund our operations.

Our Therapeutics business faces substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we can.

We have not yet developed and commercialized, and may never successfully develop or commercialize, a drug target. Our Therapeutics business faces substantial competition from larger, more established pharmaceutical and biotechnology companies with marketed products that have been accepted by the medical community, patients, and third-party payors, as well as smaller companies in our industry that have successfully identified and developed drugs. Our ability to compete in this industry may be affected by the previous adoption of such products by the medical community, patients, and third-party payors.

We recognize that other companies, including larger pharmaceutical and biotechnology companies, may be developing or have plans to develop drugs and therapies that may compete with ours. Many of our competitors have substantially greater financial, technical, and human resources than we have. In addition, many of our competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of drugs, obtaining FDA and other regulatory approvals of drugs for use in healthcare and manufacturing, and marketing and selling approved drugs. Our competitors may discover, develop, or commercialize drugs or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for any drug that we develop.

We anticipate that the competition with our drugs and therapies will be based on a number of factors, including product efficacy, safety, availability, and price. The timing of market introduction of any successful drug and competitive drugs will also affect competition among products. We expect the relative speed with which we can develop drugs, complete the clinical trials and approval processes, and supply commercial quantities of such drugs to the market to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, and protect our intellectual property, and to secure sufficient capital resources for the period between target identification and commercial sales of the resulting drug product.

Our long-term success will depend, in part, upon our ability to develop, receive regulatory approval for, and commercialize our drugs.

In the U.S., our drugs and the activities associated with their development, including testing, manufacture, recordkeeping, storage and approval, are subject to comprehensive regulation by the FDA. Failure to obtain regulatory approval for a drug will prevent us from commercializing such target. We have limited resources for use in preparing, filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations and consultants to assist us in this process. The FDA and other comparable regulatory agencies in foreign countries impose substantial and rigorous requirements for the development, production, marketing authorization and commercial introduction of drugs. These requirements include pre-clinical, laboratory and clinical testing procedures, sampling activities, manufacturing development, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory authorities, including the FDA evolve in their interpretations and practices and may impose more stringent or different requirements than currently in effect, which may adversely affect our planned and ongoing development and/or our sales and marketing efforts.

Developing and obtaining regulatory approval for drugs is a lengthy process, often taking many years, is uncertain and is expensive. All of the drugs that we are developing, or may develop in the future, require research and development, pre-clinical studies, nonclinical testing, manufacturing development, and clinical trials prior to seeking regulatory approval and commencing commercial sales. In addition, we may need to address a number of technological challenges in order to complete development of our drugs. As a result, the development of drugs may take longer than anticipated or not be successful at all. There can be no assurance that the FDA will ever permit us to market any new drug that we develop. Even if regulatory approval is granted, such approval may include significant limitations on indicated uses, which could materially and adversely affect the prospects of any new therapeutic.

To market any drugs outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional drug testing and validation and additional or different administrative review periods from those in the U.S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

Seeking foreign regulatory approval could result in difficulties and costs and require additional nonclinical studies or clinical trials, which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drugs in those countries. The foreign regulatory approval process may include all the risks associated with obtaining FDA approval. We do not have any drugs approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our drugs will be harmed.

Our drugs are in preclinical or clinical development, which is a lengthy and expensive process with uncertain outcomes and the potential for substantial delays. We cannot give any assurance that any of our drugs will receive regulatory approval, which is necessary before they can be commercialized.

Before obtaining marketing approval from regulatory authorities for the sale of our drugs, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drugs in humans. We have focused our collaborative efforts and significant financial resources on developing new drugs. We cannot be certain that any clinical trials will be conducted as planned or completed on schedule, if at all. Our inability to successfully complete preclinical and clinical development could result in additional costs to us and negatively impact our ability to generate revenue. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize drugs. We currently have no drugs approved for sale and have not generated any revenue from sales of drugs, and we may never be able to develop or successfully commercialize a marketable drug. The results of early-stage clinical trials and preclinical studies may not be predictive of future results. Initial data in clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials.

All our identified drugs require additional development, management of preclinical, clinical, and manufacturing activities, and regulatory approval. In addition, we will need to obtain adequate manufacturing supply, build a commercial organization, commence marketing efforts, and obtain reimbursement before we generate any significant revenue from commercial product sales, if ever. Many of our drugs are in early-stage research or translational phases of development, and the risk of failure for these programs is high. We cannot be certain that any of our drugs will be successful in clinical trials or receive regulatory approval. Further, our drugs may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our drugs, we and our subsidiaries may not be able to continue operations.

If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Our ability to identify and qualify clinical trial participants in an expeditious manner is critical to the success of our clinical development activities. The timing of our clinical studies depends on the speed at which we can recruit trial participants to participate in testing our drugs. Delays in enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drugs. If trial participants are unwilling to participate in our studies because of negative publicity of our trials or other trials of similar drugs, or those related to a specific therapeutic area, or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory approval of potential drugs may be delayed. We also may face delays in enrolling patients and conducting clinical studies, and may need to make adjustments to our development programs as a result of unforeseen global circumstances as a result of the COVID-19 pandemic. Any delays could result in increased costs, delays in advancing our drug development, delays in testing the effectiveness of our drugs, or termination of the clinical studies altogether.

Use of our therapeutic drugs could be associated with side effects, adverse events or other properties or safety risks, which could delay or halt their clinical development, prevent their regulatory approval, cause us to suspend or discontinue clinical trials, abandon a drug, limit their commercial potential, if approved, or result in other significant negative consequences that could severely harm our business, prospects, financial condition, and results of operations.

Undesirable or unacceptable side effects caused by our drugs, including drugs that are part of our collaboration with GSK, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Even if any of our current or future therapeutic drugs receive regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

Our use of third parties to manufacture and develop our drugs for preclinical studies and clinical trials may increase the risk that we will not have sufficient quantities of our drugs, products, or necessary quantities of such materials on time or at an acceptable cost or quality.

We have no experience in drug formulation or manufacturing and we lack the resources and expertise to formulate or manufacture our own therapeutic drugs internally. Therefore, we rely on third-party expertise to support us in this area. We entered into a contract with a third-party manufacturer to manufacture our drugs, and we intend to enter into contracts with third-party manufacturers to supply, store and distribute supplies of our drugs for our clinical trials. If any of our drugs receives FDA approval, we expect to rely on third-party contractors to manufacture our drugs. We have no current plans to build internal manufacturing capacity for any drug, and we have no long-term supply arrangements.

Our reliance on third-party manufacturers exposes us to potential risks, such as the following:

- We may be unable to contract with third-party manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited. Potential manufacturers of any drug that is approved will be subject to FDA compliance inspections and any new manufacturer would have to be qualified to produce our drugs;
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any;
- Our third-party manufacturers may face supply chain issues as a result of global geopolitical events or the COVID-19 pandemic;
- Following submission of a marketing application, our third-party manufacturers may not be inspected on a timely basis by the applicable regulatory authorities;
- Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials through completion or to successfully produce, store and distribute our commercial products, if approved;
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and other government agencies to ensure compliance with cGMP and other government regulations and corresponding foreign standards. We do not have direct control over third-party manufacturers' compliance with these regulations and standards, but we may ultimately be responsible for any of their failures;
- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to such improvements; and
- A third-party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that competes with ours.

If our contract manufacturers or other third parties fail to deliver our drugs for clinical investigation and, if approved, for commercial sale on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend development and commercialization of our drugs. For example, our clinical trials must be conducted with product that complies with cGMP. Failure to comply may require us to repeat or conduct additional preclinical and/or clinical trials, which would increase our development costs and delay the regulatory approval process and our ability to generate and grow revenues. The FDA or other regulatory authorities may also determine that our third-party manufacturers do not maintain quality systems sufficient for product approval and/or may find that the manufacturing data and development does not meet FDA's approval standards.

In addition, any significant disruption in our supplier relationships could harm our business. We source key materials from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There are a small number of suppliers for certain capital equipment and key materials that are used to manufacture our drugs. Such suppliers may not sell these key materials to our manufacturers at the times we need them or on commercially reasonable terms. We do not have any control over the process or timing of the acquisition of these key materials by our manufacturers. Moreover, we currently do not have agreements for the commercial production of a number of these key materials which are used in the manufacture of our drugs. Any significant delay in the supply of a drug or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, drug testing and potential regulatory approval of our drugs. If our manufacturers or we are unable to purchase these key materials for our drugs after regulatory approval, the commercial launch of our drugs could be delayed or there could be a shortage in supply, which would impair our ability to generate revenues from the sale of our drugs, if approved.

Each of these risks, if realized, could delay or have other adverse impacts on our clinical trials and the approval and commercialization of our drugs, potentially resulting in higher costs, reduced revenues or both.

As an organization, we have limited experience designing or implementing clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect our ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs.

The design and implementation of clinical trials is a complex process. We have limited experience designing or implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well-designed, planned or conducted, including with respect to the FDA's GCP requirements, may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the drug on the basis of the study results, or, even if a drug is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed, planned or conducted could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. Failure to comply with the FDA's regulatory requirements for clinical trials can also result in enforcement actions.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any approved drug by a regulatory agency, we may not be successful in commercializing those drugs if and when they are approved.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing drugs. We do not currently have an in-house marketing organization or sales force but may develop such organization and sales force in the future, which will require significant capital expenditures, management resources and time. We will have to compete with other healthcare companies to recruit, hire, train and retain marketing and sales personnel.

In addition to establishing internal sales, marketing, and distribution capabilities, we intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that we will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our drug ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our drugs.

There can be no assurance that we will be able to develop in-house sales, marketing and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the U.S. or overseas.

General Business Risks

We may be subject to legal proceedings and litigation, which are costly to defend and could materially harm our business and results of operations.

We may be party to lawsuits and legal proceedings in the normal course of business. These matters are often expensive and disruptive to normal business operations. We may face allegations, lawsuits, and regulatory inquiries, audits, and investigations regarding data privacy, security, product liability, labor and employment, consumer protection, practice of medicine, and intellectual property infringement, including claims related to privacy, patents, publicity, trademarks, copyrights, open source software, and other rights. A portion of the technologies we use incorporates open source software, and we may face claims claiming ownership of open source software or patents related to that software, rights to our intellectual property or breach of open source license terms, including a demand to release material portions of our source code or otherwise seeking to enforce the terms of the applicable open source license. We may also face allegations or litigation related to our acquisitions, securities issuances or business practices, including public disclosures about our business. Litigation and regulatory proceedings, and particularly the healthcare regulatory and class action matters we could face, may be protracted and expensive, and the results are difficult to predict. Certain of these matters may include speculative claims for substantial or indeterminate amounts of damages and include claims for injunctive relief. Additionally, our litigation costs could be significant. Adverse outcomes with respect to litigation or any of these legal proceedings may result in significant settlement costs or judgments, penalties and fines, or require us to modify our activities or solution or require us to stop offering certain features, all of which could negatively impact our acquisition of customers and revenue growth. Litigation or other proceedings can also have an adverse impact on our therapeutic development program. We may also become subject to periodic audits, which could likely increase our regulatory compliance costs and may require us to change our business practices, which could negatively impact our revenue growth. Managing legal proceedings, litigation and audits, even if we achieve favorable outcomes, is time-consuming and diverts management's attention from our business.

The results of regulatory proceedings, litigation, claims, and audits cannot be predicted with certainty, and determining reserves for pending litigation and other legal, regulatory and audit matters requires significant judgment. There can be no assurance that our expectations will prove correct, and even if these matters are resolved in our favor or without significant cash settlements, these matters, and the time and resources necessary to litigate or resolve them, could harm our reputation, business, financial condition and results of operations.

The U.K.'s withdrawal from the European Union could have an adverse impact on our business.

The changes to the trading relationship between the UK and EU resulting from the UK's exit from the EU on January 31, 2020 (commonly referred to as "Brexit") may result in additional regulatory requirements for us to market our products and services in the UK and an increased cost of goods imported into and exported from the UK. Additional currency volatility could result in a weaker British pound, which increases the cost of goods imported into the UK from sales to UK-based customers and patients. Agreements regarding tariff, trade, regulatory and other aspects of the UK's future relationship with the EU and its member status were reached on December 24, 2020. The agreements came into force on May 1, 2021 following a period of provisional application that began on January 1, 2021. Our business in the UK may be adversely impacted by ongoing uncertainty, fluctuations in currency exchange rates, changes in trade policies, or changes in tax, data privacy or other laws. Any of these effects, among others, could materially and adversely affect our business, results of operations, and financial condition.

Our business and future operating results may be adversely affected by catastrophic or other events outside of our control.

We conduct our research and development in our facilities located in South San Francisco, California and Sunnyvale, California. Any damage to our facilities or the servers we rely on for our database would be costly and could require substantial lead-time to repair or replace. In addition, many of our employees work remotely and would be significantly impacted by any disruption to our servers. Our business and operating results may be harmed due to interruption of our research and development by events outside of our control, including earthquakes and fires. Other possible disruptions may include power loss and telecommunications failures. In the event of a prolonged disruption, we may lose customers and we may be unable to regain those customers thereafter. Our insurance may not be sufficient to cover all our potential losses and may not continue to be available to us on acceptable terms, or at all.

We may need additional capital, and we cannot be sure that additional financing will be available at acceptable terms or at all.

As of March 31, 2022, our principal source of liquidity was cash of $553.2 million, which was held for working capital purposes. On November 1, 2021, we paid approximately $101.9 million in cash consideration for the acquisition of Lemonaid Health (of which approximately $13.0 million was placed in escrow to cover a potential purchase price adjustment and to secure the indemnification obligations of the former equity holders of Lemonaid Health), which decreased our cash reserve. Since our inception, we have generated significant operating losses as reflected in our accumulated deficit and negative cash flows from operations. We had an accumulated deficit of $1,194.7 million as of March 31, 2022.

Although we currently anticipate that our available funds and cash flows from operations will be sufficient to meet our near-term cash needs, we may require additional financing. Our ability to obtain financing may depend on, among other things, our development efforts, business plans, operating performance and condition of the capital markets at the time we seek financing. We cannot assure you that additional financing will be available to us on favorable terms when required, or at all. If we raise additional funds through the issuance of equity, equity-linked or debt securities, those securities may have rights, preferences or privileges senior to the rights of Class A common stock, and our stockholders may experience dilution.

We depend on the continued services and performance of our highly qualified key personnel, and our business and research and development initiatives depend on our ability to attract and retain additional qualified personnel, including highly-skilled scientists and other specialized individuals. We may not be able to attract or retain qualified scientists and other specialized individuals in the future due to the competition for qualified personnel among life science and technology businesses.

We currently depend on the continued services and performance of our highly qualified key personnel, and, in particular, Anne Wojcicki, our CEO and co-founder. The loss of Ms. Wojcicki or other key personnel, including key members of management as well as our research, therapeutics, regulatory, product development, engineering, legal, finance, and other personnel, could disrupt our operations and may significantly delay or prevent the achievement of our business objectives. To retain our key personnel, we use various measures, including an equity incentive program for key executive officers and other employees. These measures may not be enough to retain the personnel we require to operate our business effectively. In addition, volatility in the price of our stock may adversely affect our ability to attract or retain our key personnel, as the fluctuating value of equity-based awards may limit their effectiveness as an employee incentive and retention tool.

The market for qualified personnel in our industry is intensely competitive. Inability to meet the ever-increasing expenses, including salaries, benefits, perks, and technology costs, of attracting and retaining talent may threaten our ability to provide the human resources needed to execute our growth strategy. Many of the companies with which we compete for a relatively limited pool of experienced personnel have greater resources than we have. An inability to attract, retain, and motivate additional highly skilled employees required for the planned expansion of our business could harm our results of operations and impair our ability to grow.

Specifically, our research and development initiatives and Therapeutics business depend on our ability to attract and retain highly-skilled scientists and other specialized individuals and competition for these resources is especially intense. We may not be able to attract or retain qualified scientists and other specialized individuals in the future due to the competition for qualified personnel among life science and technology businesses, particularly near our therapeutics laboratory facilities located in South San Francisco, California. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Recruiting, training and retention difficulties can limit our ability to support our research and development and commercialization efforts. All our employees are at-will, which means that either we or the employee may terminate their employment at any time. In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist it in formulating our research and development, regulatory and commercialization strategy. Our consultants and advisors may provide services to other organizations and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current consultants or advisors could impede the achievement of our research, development, regulatory and commercialization objectives.

Certain other areas of our operations require employing highly specialized individuals, which makes our recruiting efforts more challenging. If we do not succeed in attracting excellent personnel or retaining or motivating existing personnel, we may be unable to achieve our business objectives or grow effectively.

We face risks related to epidemics and other outbreaks of communicable diseases, including the current COVID-19 pandemic, which could significantly disrupt our operations and adversely affect our business and financial condition.

Our operations, business and financial condition could be materially and adversely affected by epidemics and other outbreaks of communicable diseases, including the current COVID-19 pandemic, and by the economic and operational disruptions caused by the attempts of governmental entities to contain or flatten the spread of the disease. The continued spread of COVID-19 in the U.S. and in California, where we are headquartered, could materially and adversely affect our operations, including without limitation, disruptions of our ability to test and process DNA samples, reduced consumer demand for our personal genetic testing services, disruptions in the operations of our suppliers and partners, negative effects on our research and development initiatives and on our recruitment and retention efforts, the continued productivity and health of our employees, and curtailment of business travel and other business activities that may be necessary or helpful to our operations. These factors and resultant uncertainties may have a material adverse effect on our revenue, liquidity and any financing activities that we may undertake. The duration of the COVID-19 pandemic and the impact of the efforts being made to contain it or to flatten the spread of the disease cannot be predicted with any accuracy, and this uncertainty creates additional risk factors affecting the economy generally, as well as our business. Additionally, the presence or absence of government stimulus funding programs has had and may continue to have an impact on consumer discretionary spending and, consequently, purchases of PGS kits. Without timely and robust government stimulus funding programs, consumers may have less money to spend on discretionary items such as our PGS products, which could harm our business and results of operations. Furthermore, our operations, business and financial condition could be materially and adversely affected by a continued economic downturn and its effects on financial markets as well as by the direct impacts of the pandemic on our employees, customers, patients, members, suppliers and other third parties on which we rely.

Economic uncertainty or downturns, particularly affecting the markets and industries in which we operate, could adversely affect our business, financial condition, and results of operations.

In recent years, the United States and global economy has been volatile, and worldwide economic conditions remain uncertain. Economic uncertainty and associated macroeconomic conditions, including market volatility, inflation, and supply chain issues, make it extremely difficult for us, as well as for our collaborators, sales channel partners and suppliers, to accurately forecast and plan future business activities. Supply chain issues could limit the ability of our affiliated pharmacies to purchase sufficient quantities of pharmaceutical products from suppliers, which could adversely affect our ability to fulfill patient orders. In addition, economic uncertainty could cause our customers and patients to slow spending on our PGS and telehealth offerings.

To the extent purchases of our PGS and telehealth offerings are perceived by customers and patients and potential customers and patients as discretionary, our revenue may be disproportionately affected by delays or reductions in Kit purchases and general healthcare spending. Also, competitors may respond to challenging market conditions by lowering prices and attempting to lure away our customers and patients.

We cannot predict the timing, strength, or duration of any economic slowdown or any subsequent recovery generally, or any industry in particular. If the conditions in the general economy and the markets in which we operate worsen from present levels, our business, financial condition, and results of operations could be materially adversely affected.

We may enter new business areas, such as additional primary care services, including diagnostics/behavior modification, where we do not have any experience. If we were to enter new business areas, we would likely face competition from entities more familiar with those businesses, and our efforts may not succeed.

In the future, we may expand our operations into business areas, such as additional primary care services, including diagnostics/behavior modification, where we do not have any experience. These areas would be new to our product development and marketing personnel, and we cannot be assured that the markets for these products and services will develop or that we will be able to compete effectively or will generate significant revenues in these new areas making our success in this area difficult to predict. Many companies of all sizes, including major pharmaceutical companies, specialized biotechnology companies and traditional healthcare providers, are engaged in redesigning approaches to medical care and diagnostic medicine. Competitors operating in these potential new business areas may have substantially greater financial and other resources, larger research and development staff, and more experience in these business areas. There can be no assurances that if we undertake new business areas, that the market will accept our offerings, or that such offerings will generate significant revenues for us.

We may make acquisitions to expand our business, and if any of those acquisitions are unsuccessful, our business may be harmed.

We may choose to expand our current business through the acquisition of other businesses, products or technologies, or through strategic alliances.

Acquisitions involve numerous risks, including the following:

- The possibility that we will pay more than the value we derive from the acquisition which could result in future non-cash impairment charges, and incremental operating losses;
- Difficulties in integration of the operations, technologies and products of the acquired companies, which may require significant attention of our management that otherwise would be available for the ongoing development of our business;
- The assumption of certain known and unknown liabilities of the acquired companies;
- Difficulties in retaining key relationships with employees, customers, collaborators, vendors and suppliers of the acquired company;
- In the case of acquisitions outside of the jurisdictions we currently operate in, the need to address the particular economic, currency, political, and regulatory risks associated with specific countries, particularly those related to our collection of sensitive data, regulatory approvals, and tax management, which may result in significant additional costs or management overhead for our business; and
- Any of these factors could have a negative impact on our business, results of operations or financial position.

Risks Related to Our Collaborations

Our Therapeutics business is substantially dependent on our collaboration with GSK for the development and commercialization of any drugs discovered during the discovery term of the agreement. If we, GSK and any future collaborators are unable to successfully complete clinical development, obtain regulatory approval for, or commercialize any drugs, or experience delays in doing so, our business may be materially harmed. We may engage and depend on other third parties for the development and commercialization of drugs and therapeutic programs discovered following the expiration of the GSK Agreement or outside its scope. If those collaborations are not successful, we may not be able to capitalize on our investment in our Therapeutic business.

In July 2018, we entered into a collaboration agreement with GSK focused on the discovery, development and commercialization of drugs that are identified utilizing our proprietary databases and data mining technologies (the "GSK Agreement"). Under the GSK Agreement, GSK is our exclusive collaborator for drug discovery programs for a four-year period, which has been extended for a fifth year by GSK, pursuant to the terms of the GSK Agreement. Under the GSK Agreement, we and GSK jointly research potential drugs based on reports generated from our proprietary databases and using our proprietary data mining technologies. Once promising drugs are identified through these joint efforts, we and GSK share equally in the costs of discovery, development, and commercialization of any resultant drugs. Both parties have the right to opt out or reduce their share of the funding upon the occurrence of certain specified development milestones, in which case such party would no longer be entitled to share equally in the results of a successful collaboration, but instead would receive certain royalty payments on sales of the resultant drugs, depending on the timing and extent to which such party has reduced its funding or opted out. If GSK were to exercise any of the rights described in the prior sentence, and we elected to continue development, we would be required to supply any necessary funding to continue the development of the applicable drug. In addition, if we were to opt out of a program, GSK has the right to unilaterally decide to terminate the program or fail to develop a drug product, in which case we would not receive any royalty payments. In addition, substantially all our research services revenue is derived from the required payments for research services under the GSK Agreement. When the discovery term of the GSK Agreement terminates, there can be no assurance that we will be able to generate research services revenue from other sources. While the GSK Agreement may not be terminated for convenience, GSK has the ability to terminate the GSK Agreement if certain conditions are met. If GSK were to terminate the GSK Agreement, to reduce its funding or opt out of any drugs thereunder, or to shift its research and development focus so as to deemphasize any programs under the GSK Agreement, our revenues, operating results and our ability to fund and advance drug programs and conduct our Therapeutics business would be adversely affected. We cannot provide any assurance with respect to the success of any research, development or commercialization efforts pursuant to the GSK Agreement.

Our current collaboration with GSK poses, and potential additional collaborations involving drug development activities outside of the GSK Agreement with GSK pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any drugs that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug, repeat or conduct new clinical trials or require a new formulation of a drug for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our drugs;
- drugs discovered in collaboration with us may be viewed by our collaborators as competitive with their own drugs, which may cause collaborators to cease to devote resources to the commercialization of our drug;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a drug candidate or product;
- collaborators are subject to the same risks of drug development as we are and, accordingly, may not ultimately be successful;
- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the drug, or that result in costly litigation or arbitration that diverts management attention and resources;
- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program under such collaboration could be delayed, diminished or terminated;
- collaboration agreements may restrict our right to independently pursue new drugs. For example, under the GSK Agreement, we are prohibited from, directly or indirectly, identifying, developing, manufacturing or commercializing drugs, unless GSK has opted-out of the program or the program pre-existed the date of the Collaboration; and
- collaborations may be terminated by the collaborator, and, if terminated, we may suffer reputational harm, find it more difficult to attract new collaborators and be required to raise additional capital to pursue further development or commercialization of the applicable drugs.

GSK and any other potential drug discovery collaborators will have significant discretion in determining when to make announcements, if any, about the status of our collaborations, including results from clinical trials, and timelines for advancing collaborative programs. As a consequence, the price of our Class A common stock may decline as a result of announcements of unexpected clinical trial results or data relative to our research and development programs.

Our drug discovery collaborators have significant discretion in determining when to make announcements about the status of our collaborations, including about preclinical and clinical developments and timelines for advancing the collaborative programs. While as a general matter we intend to periodically report on the status of our collaborations, our drug discovery collaborators, and in particular, our privately-held collaborators, may wish to report such information more or less frequently than we intend to or may not wish to report such information at all. The price of our Class A common stock may decline as a result of the public announcement of unexpected results or developments in our collaborations, or as a result of our collaborators withholding such information.

We may seek to establish additional collaborations in the future, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our Therapeutics business and the potential commercialization of any drugs will require substantial additional cash to fund expenses. If the GSK Agreement is terminated, or following its expiration, we may decide to collaborate with other pharmaceutical and biotechnology companies for drug development, manufacture and commercialization activities. These collaborations may not be successful, which would adversely impact our business and results of operations.

Under the GSK Agreement, we have granted exclusive rights to GSK with respect to the identification, development and commercialization of drugs until fiscal 2024, subject to certain limited exceptions. During the discovery term of the GSK Agreement, we are restricted from granting similar rights to other parties. This exclusivity currently limits our ability to enter into strategic drug discovery collaborations with other third parties. To the extent we seek additional collaboration opportunities in the future, we will face significant competition. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to successfully enter into collaborations in the future, we may have to curtail our drug discovery and development activities including reducing or delaying individual development programs, potential commercialization plans, or any sales or marketing activities for a drug. We may also have to increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our drugs or bring them to market and generate product revenue.

Our collaborators may not achieve projected discovery and development milestones and other anticipated key events in the expected timelines or at all, which could have an adverse impact on our business.

Our current drug discovery collaborators, from whom we are entitled to receive milestone payments upon achievement of various development, regulatory, and commercial milestones as well as royalties on commercial sales, if any, under the collaboration agreements that we have entered into with them, face numerous risks in the development of drugs, including the conduct of preclinical and clinical testing, obtaining regulatory approval, and achieving product sales. In addition, the amounts we are entitled to receive upon the achievement of such milestones tend to be smaller for near-term development milestones and increase if and as a collaborative drug advances through regulatory development to commercialization and will vary depending on the level of commercial success achieved, if any. We do not anticipate receiving significant milestone payments from many of our drug discovery collaborators for several years, if at all, and our drug discovery collaborators may never achieve milestones that result in significant cash payments to us. Accordingly, our business could be adversely affected if projected discovery and development milestones are not achieved.

Risks Related to Governmental Regulation

Our products and services are subject to extensive regulation by various U.S. federal and state agencies and compliance with existing or future regulations could result in unanticipated expenses, or limit our ability to offer our products and services.

On November 22, 2013, we received a warning letter from the FDA to discontinue marketing our health-related genetic test in the U.S. until we received FDA marketing authorization for the device. We were allowed to continue to offer genetic ancestry services in the U.S.

In June 2014, we submitted a 510(k) seeking premarket clearance for our Bloom Syndrome carrier test. On February 19, 2015, FDA granted marketing authorization pursuant to its de novo review standard for our Bloom Syndrome carrier test. The FDA also determined that certain of our other similar autosomal recessive carrier reports were exempt moderate risk reports, which subject to special controls, could be marketed by us without further premarket review. In October 2015, we began marketing our new Personal Genome Service in the U.S., which includes detailed reports on carrier status, pursuant to our FDA authorization and exemption, as well as research reports and reports on wellness, traits and ancestry, which we believe do not require premarket authorization.

We continued to submit additional requests to the FDA seeking authorization to market certain Genetic Health Risk ("GHR") reports. On April 6, 2017, the FDA granted marketing authorization pursuant to its de novo review standard for our GHR reports for ten disease conditions. The FDA also determined that certain of our other similar genetic health risk reports were exempt low-to-moderate risk reports, which subject to certain special controls, could be marketed by us without further premarket review. On March 6, 2018, the FDA granted marketing authorization pursuant to its de novo review standard for our Genetic Health Risk report for BRCA1/BRCA2 (Selected Variants). On January 22, 2019, we received FDA clearance for a Genetic Health Risk report for MUTYH-associated polyposis (MAP), a hereditary colorectal cancer syndrome. On October 31, 2018, the FDA granted marketing authorization pursuant to its de novo review standard for our Pharmacogenetic reports, including our Pharmacogenetics report for CYP2C19. On August 17, 2020, the FDA granted a 510(k) clearance for our Pharmacogenetics report for CYP2C19, modifying the labeling of the report authorized in 2018 to remove the need for confirmatory testing, allowing us to report interpretive drug information for two medications. On January 10, 2022, the FDA granted a 510(k) clearance for our Genetic Health Risk report for Hereditary Prostate Cancer (HOXB13-Related).

We may be required to seek FDA-premarket review of other products and services, including reports that we do not currently believe require premarket authorization but could be subject to additional regulation including premarket review. The Verifying Accurate Leading-edge IVCT Development Act of 2021 (the "VALID Act of 2021," the "VALID Act" or the "Act") was introduced in both the House and Senate on June 24, 2021 which seeks to regulate laboratory testing and to modernize FDA regulations of diagnostic products and it could increase the types of our reports which are subject to premarket review. For any such review, we are required to conduct extensive analytical validation and user comprehension studies to demonstrate the accuracy of our test results and that they are appropriate for sale directly to consumers. This process will likely be costly, time-consuming and uncertain. Delays in receipt of, or failure to obtain, authorizations or clearances could materially delay or prevent us from commercializing new products and services or result in substantial additional costs. We may not be able to obtain FDA authorization for all our products and services.

We and/or our finished device contract manufacturers may be inspected by the FDA which may result in the issuance of inspectional observations that suggest noncompliance with the FDCA and its implementing regulations (including the QSR). If the FDA determines that we and/or our finished device contract manufacturers are not in compliance with the FDCA, we may have to recall product and/or be subject to an FDA enforcement action. The process for resolving the inspectional observations and/or potential enforcement action could be costly and time-consuming.

We will face legal, reputational, and financial risks if we fail to protect our customer data from security breaches or cyberattacks. Changes in laws or regulations relating to privacy or the protection or transfer of data relating to individuals, or any actual or perceived failure by us to comply with such laws and regulations or any other obligations relating to privacy or the protection or transfer of data relating to individuals, could adversely affect our business.

We receive and store a large volume of personally identifiable information ("PII"), genetic and health information, and other data relating to our customers and patients, as well as other PII and other data relating to individuals such as our employees. Security breaches, employee malfeasance, or human or technological error could lead to potential unauthorized disclosure of our customers' and patients' personal information. Even the perception that the privacy of personal information is not satisfactorily protected or does not meet regulatory requirements could inhibit sales of our solutions and any failure to comply with such laws and regulations could lead to significant fines, penalties or other liabilities.

Increased global IT security threats and more sophisticated and targeted computer crime pose a risk to the security of our systems and networks and the confidentiality, availability, and integrity of our data. There have been several recent, highly publicized cases in which organizations of various types and sizes have reported the unauthorized disclosure of customer or other confidential information, as well as cyberattacks involving the dissemination, theft, and destruction of corporate information, intellectual property, cash, or other valuable assets. There have also been several highly publicized cases in which hackers have requested "ransom" payments in exchange for not disclosing customer or other confidential information or for not disabling the target company's computer or other systems. A security breach or privacy violation that leads to disclosure or unauthorized use or modification of, or that prevents access to or otherwise impacts the confidentiality, security, or integrity of, sensitive, confidential, or proprietary information we or our third-party service providers maintain or otherwise process, could compel us to comply with breach notification laws, and cause us to incur significant costs for remediation, fines, penalties, notification to individuals and governmental authorities, implementation of measures intended to repair or replace systems or technology, and to prevent future occurrences, potential increases in insurance premiums, and forensic security audits or investigations. Additionally, a security compromise of our information systems or of those of businesses with whom we interact that results in confidential information being accessed by unauthorized or improper persons could harm our reputation and expose us to customer and patient attrition, and claims brought by our customers, patients, or others for breaching contractual confidentiality and security provisions or data protection laws. Monetary damages imposed on us could be significant and not covered by our liability insurance. As a result, a security breach or privacy violation could result in increased costs or loss of revenue.

Techniques used by bad actors to obtain unauthorized access, disable or degrade service, or sabotage systems evolve frequently and may not immediately produce signs of intrusion, and we may be unable to anticipate these techniques or to implement adequate preventative measures.

We believe that, because of our operating processes, and except for our affiliated retail pharmacy, which represents a small component of our pharmacy operations, we are not a covered entity or a business associate under HIPAA, which establishes a set of national privacy and security standards for the protection of protected health information 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. However, if the laws change, or to the extent we begin accepting payment from third parties or insurance providers in our telehealth business generally, we may become subject to HIPAA and could face penalties and fines if we fail to comply with applicable requirements of HIPAA and its implementing regulations. Regardless of whether or not we meet the definition of a covered entity or business associate under HIPAA, we voluntarily adhere to certain HIPAA-related requirements.

We have developed and maintain policies and procedures with respect to health information and personal information that we use or disclose in connection with our operations, including the adoption of administrative, physical, and technical safeguards to protect the privacy and security of such information. As our business operations continue to develop, including through the launch of new product offerings or the development of new services, we may collect additional sensitive health and personal information from our customers and patients that could create additional compliance obligations and may increase our exposure to compliance and regulatory risks regarding the protection and dissemination of such information.

In addition to HIPAA, numerous other local, municipal, state, federal, and international laws and regulations address privacy and the collection, storing, sharing, use, disclosure, and protection of certain types of data, including the California Online Privacy Protection Act, the Personal Information Protection and Electronic Documents Act, the Telephone Consumer Protection Act of 1991, or the TCPA, Section 5 of the Federal Trade Commission Act, and effective as of January 1, 2020, the CCPA. These laws, rules, and regulations evolve frequently, and their scope may continually change, through new legislation, amendments to existing legislation, and changes in enforcement, and may be inconsistent from one jurisdiction to another. For example, the CCPA, which went into effect on January 1, 2020, among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of certain sales of personal information. The CCPA provides for fines of up to $7,500 per violation. Aspects of the CCPA and its interpretation and enforcement remain uncertain. The effects of this legislation potentially are far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. The CCPA has been amended on multiple occasions. For example, in November 2020, the CPRA was approved by California voters and significantly modifies the CCPA, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CPRA does not become operative until January 1, 2023 (and then applies only to consumer data collected on or after January 1, 2022, (the "lookback period"), with enforcement beginning July 1, 2023. While the CCPA will remain operative and enforceable from now until July 1, 2023, we will continue to monitor developments related to the CPRA. The effects of this legislation potentially are far-reaching, however, and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. Additionally, many laws and regulations relating to privacy and the collection, storing, sharing, use, disclosure, and protection of certain types of data are subject to varying degrees of enforcement and new and changing interpretations by courts. The CCPA and other changes in laws or regulations relating to privacy, data protection, breach notifications, and information security, particularly any new or modified laws or regulations, or changes to the interpretation or enforcement of such laws or regulations, that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer, or disclosure, could greatly increase the cost of providing our platform, require significant changes to our operations, or even prevent us from providing our platform in jurisdictions in which we currently operate and in which we may operate in the future.

We also are required to comply with increasingly complex and changing data security and privacy regulations in the U.K., the EU and in other jurisdictions in which we conduct business that regulate the collection, use and transfer of personal data, including the transfer of personal data between or among countries. For example, the European Union's GDPR, now also enacted in the U.K. ("U.K. GDPR"), has imposed stringent compliance obligations regarding the handling of personal data and has resulted in the issuance of significant financial penalties for noncompliance. Further, in July 2020, the Court of Justice of the European Union released a decision in the Schrems II case (Data Protection Commission v. Facebook Ireland, Schrems), declaring the EU-US Privacy Shield invalid and calling into question data transfers carried out under the European Commission's Standard Contractual Clauses. As a result of the decision, we may face additional scrutiny from EU regulators in relation to the transfer of personal data from the EU to the US. Noncompliance with the GDPR can trigger fines of up to the greater of €20 million or 4% of global annual revenues. In the U.S., there have been proposals for federal privacy legislation and many new state privacy laws proposed. Since 2021, laws specific to genetic testing companies have passed in California, Utah, Arizona, Maryland, Kentucky and Wyoming and legislation has been proposed in other states. Other countries have enacted or are considering enacting data localization laws that require certain data to stay within their borders. We may also face audits or investigations by one or more domestic or foreign government agencies or our customers or patients pursuant to our contractual obligations relating to our compliance with these regulations. Complying with changing regulatory requirements requires us to incur substantial costs, exposes us to potential regulatory action or litigation, and may require changes to our business practices in certain jurisdictions, any of which could materially adversely affect our business operations and operating results.

Despite our efforts to comply with applicable laws, regulations, and other obligations relating to privacy, data protection, and information security, it is possible that our interpretations of the law, practices, or platform could be inconsistent with, or fail or be alleged to fail to meet all requirements of, such laws, regulations, or obligations. Our failure, or the failure by our third-party providers on our platform, to comply with applicable laws or regulations or any other obligations relating to privacy, data protection, or information security, or any compromise of security that results in unauthorized access to, or use or release of PII or other data relating to our customers and patients, or other individuals, or the perception that any of the foregoing types of failure or compromise have occurred, could damage our reputation, discourage new and existing customers and patients from using our platform, or result in fines, investigations, or proceedings by governmental agencies and private claims and litigation, any of which could adversely affect our business, financial condition, and results of operations. Even if not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition, and results of operations.

We plan to continue to expand operations abroad where we have limited operating experience and we may be subject to increased regulatory risks and local competition. If we are unsuccessful in efforts to expand internationally, our business may be harmed.

Regulations exist or are under consideration in countries outside the U.S., which limit or prevent the sale of direct-to-consumer genetic tests. Some countries, including Australia, require premarket review by their regulatory body similar to that required in the U.S. by FDA. Some countries, including Australia, Germany, France and Switzerland require a physician prescription for genetic tests providing health information, thus limiting our offering in those countries to an ancestry-only test. Other countries require mandatory genetic counseling prior to genetic testing. These regulations limit the available market for our products and services and increase the costs associated with marketing the products and services where we are able to offer our products. Legal developments in the EU have created a range of new compliance obligations regarding transfers of personal data from the European Union to the U.S., including GDPR and U.K. GDPR, which applies to certain of our activities related to services that we offer or may offer to individuals located in the EU. Significant effort and expense will continue to be required to ensure compliance with the GDPR and U.K. GDPR, and could cause us to change our business practices. Moreover, requirements under the GDPR and U.K. GDPR may change periodically or may be modified by the EU/U.K. and/or national law. The GDPR and U.K. GDPR impose stringent compliance obligations regarding the handling of personal data and have resulted in the issuance of significant financial penalties for noncompliance, including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million/£17.5 million (whichever is higher) for the most serious violations.

The EU adopted the IVDR which increased the regulatory requirements applicable to IVDs in the EU and requires that we classify and obtain pre-market approval from an independent certified notified body for our PGS health reports, which will be subject to the IVDR as of May 25, 2022. We must also achieve and maintain International Standards Organization (ISO) certification of our Quality Management Systems. If we are not able to achieve or maintain regulatory compliance, we may not be permitted to market our health reports and/or may be subject to enforcement by EU Competent Authorities, bodies with authority to act on behalf of the government of the applicable EU Member State, or other nations which adopt IVDR standards, to ensure that the requirements of the directive or regulation are met. In October 2021, the European Commission proposed a delay in the implementation of certain requirements of the IVDR due to a shortage of independent notified bodies to provide certification for the volume of products requiring it. The proposal will not be effective unless and until the European Parliament adopts modifications to the IVDR directive.

Additionally, in September 2020 the United Kingdom Medicines and Healthcare Products Regulatory Agency ("MHRA") announced regulations requiring a new United Kingdom Conformity Assessed mark ("UKCA") applicable to medical devices, including testing products and services like our PGS health reports, to be placed on the market beginning January 1, 2021 or for products already on the market, to be maintained on the market after June 30, 2023 which requires that a Declaration of Conformity be obtained based on technical files for all products to which the UKCA applies. Aspects of the UKCA took effect January 1, 2021 and require that medical devices be registered with MHRA. In addition to registration requirements, manufacturers of medical devices based outside of the U.K., including us, must designate a United Kingdom Responsible Person to maintain documents supporting the UKCA and Declaration of Conformity and respond to inquiries from MHRA. If we are not able to achieve or maintain regulatory compliance, we may not be permitted to market our health reports and/or may be subject to enforcement action by MHRA.

If we fail to comply with any of these regulations, we could become subject to enforcement actions or the imposition of significant monetary fines, other penalties, or claims, which could harm our operating results or our ability to conduct our business.

Government regulation of healthcare creates risks and challenges with respect to our compliance efforts and our business strategies, and if we fail to comply with applicable healthcare and other governmental regulations, we could face substantial penalties, our business, financial condition, and results of operations could be adversely affected, and we may be required to restructure our operations.

The healthcare industry is subject to changing political, economic, and regulatory influences that may affect our telehealth business. During the past several years, the healthcare industry has been subject to an increase in governmental regulation and subject to potential disruption due to legislative initiatives and government regulation, as well as judicial interpretations thereof. While these regulations may not directly impact us or our offerings in every instance, they will affect the healthcare industry as a whole and may impact patient use of our services. We currently accept payments only from our patients—not any third-party payors, such as government healthcare programs or health insurers. Because of this approach, we are not subject to many of the laws and regulations that impact many other participants in the healthcare industry.

If the government asserts broader regulatory control over companies like ours or if we determine that we will change our business model and accept payment from and/or participate in third-party payor programs, the complexity of our operations and our compliance obligations will materially increase. Failure to comply with any applicable federal, state, and local laws and regulations could have a material adverse effect on our business, financial condition, and results of operations.

Even within the narrowed band of applicable healthcare laws and regulations, because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our activities could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Although we have adopted policies and procedures designed to comply with these laws and regulations and conduct internal reviews of our compliance with these laws, our compliance is also subject to governmental review. The growth of our business and organization and our future continued expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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 federal, state, and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages and fines, disgorgement, additional reporting requirements and oversight, and imprisonment for individuals, as well as contractual damages and reputational harm. We could also be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Our ability to offer access to telehealth services internationally is subject to the applicable laws governing remote care and the practice of medicine in the applicable jurisdiction. Each country's interpretation and enforcement of these laws is evolving and could vary significantly. We cannot provide assurance that we have accurately interpreted each such law and regulation. Moreover, these laws and regulations may change significantly as this manner of providing products and services evolves. New or revised laws and regulations (or interpretations thereof) could have a material adverse effect on our business, financial condition, and results of operations.

As part of our telehealth business, we provide pharmacy and prescription medication services, which subjects us to additional healthcare laws and regulations and increases the complexity and extent of our compliance and regulatory obligations.

The operations of the Affiliated Pharmacies subjects us to extensive federal, state, and local regulation. Pharmacies, pharmacists, and pharmacy technicians are subject to a variety of federal and state statutes and regulations governing various aspects of the pharmacy business, including the distribution and dispensing of drugs; operation of mail-order pharmacies; licensure of facilities and professionals, including pharmacists, technicians, and other healthcare professionals; packaging, storing, distributing, shipping, and tracking of pharmaceuticals; repackaging of drug products; labeling, medication guides, and other consumer disclosures; interactions with prescribing professionals; compounding of prescription medications; counseling of patients; prescription transfers; advertisement of prescription products and pharmacy services; security; the handling, security, diversion control, dispensing, monitoring, and record keeping of controlled substances, listed chemicals, and scheduled listed chemicals; supply chain security, including requirements related to information exchange, investigations, and reporting; as well as additional requirements of various governmental authorities, including the U.S. Drug Enforcement Agency, the FDA, state boards of pharmacy, the U.S. Consumer Product Safety Commission, and other state enforcement or regulatory agencies. Many states have laws and regulations requiring out-of-state mail-order pharmacies to register with that state's board of pharmacy. The Federal Trade Commission also has requirements for mail-order sellers of goods. The U.S. Postal Service (the "USPS") has statutory authority to restrict the transmission of drugs and medicines through the mail to a degree that may have an adverse effect on our mail-order operations. The USPS historically has exercised this statutory authority only with respect to controlled substances. If the USPS restricts our ability to deliver drugs through the mail, alternative means of delivery are available to us. However, alternative means of delivery could be significantly more expensive. The U.S. Department of Transportation has regulatory authority to impose restrictions on drugs inserted into the stream of commerce. These regulations generally do not apply to the USPS and its operations. Failure or perceived failure by us or our Affiliated Pharmacies to comply with any applicable federal, state, and local laws and regulations could have a material adverse effect on our business, financial condition, and results of operations and may expose us to civil and criminal penalties.

State legislative and regulatory changes specific to the area of telehealth or pharmacy law may present the PMCs and/or Affiliated Pharmacies with additional requirements and state compliance costs, which may create additional operational complexity and increase costs.

The PMCs and their providers' ability to provide telehealth services to patients in a particular jurisdiction is dependent upon the laws that govern the provision of remote care, professional practice standards, and healthcare delivery in general in that jurisdiction. Likewise, the ability of the Affiliated Pharmacies to fulfill prescriptions and distribute pharmaceutical products is dependent upon the laws that govern licensed pharmacies and the fulfillment and distribution of prescription medication and other pharmaceutical products, which include in some cases requirements relating to telehealth. Laws and regulations governing the provision of telehealth services and the compounding, fulfillment, and/or distribution of pharmaceutical products are evolving at a rapid pace and are subject to changing political, regulatory, and other influences. Some states' regulatory agencies or medical boards may have established rules or interpreted existing rules in a manner that limits or restricts providers' ability to provide telehealth services or for physicians to supervise nurse practitioners remotely. Additionally, there may be limitations placed on the modality through which telehealth services are delivered. For example, some states specifically require synchronous (or "live") communications and restrict or exclude the use of asynchronous telehealth modalities, which is also known as "store-and-forward" telehealth. However, other states do not distinguish between synchronous and asynchronous telehealth services. Similarly, the FDA as well as some states' regulatory agencies or pharmacy boards have established rules or interpreted existing rules in a manner that limits or restricts the manner in which prescription medications can be prescribed, dispensed and sold.

Because these are developing areas of law and regulation, we continually monitor our compliance in every jurisdiction in which we operate. However, we cannot be assured that our or the PMCs', providers', or Affiliated Pharmacies' activities and arrangements, if challenged, will be found to be in compliance with the law or that a new or existing law will not be implemented, enforced, or changed in manner that is unfavorable to our business model. We cannot predict the regulatory landscape for those jurisdictions in which we operate and any significant changes in law, policies, or standards, or the interpretation or enforcement thereof, could occur with little or no notice. If there is a change in laws or regulations related to our business, or the interpretation or enforcement thereof, that adversely affects our structure or operations, including greater restrictions on the use of asynchronous telehealth or remote supervision of nurse practitioners, or limitations on the ability to develop or distribute pharmaceutical products, it could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Intellectual Property and Legal Proceedings

If we are unable to protect our intellectual property, the value of our brand and other intangible assets may be diminished, and our business may be adversely affected.

We depend on our proprietary technology, intellectual property and services for our success and ability to compete. We rely and expect to continue to rely on a combination of confidentiality and other agreements with our employees, consultants and third parties with whom we have relationships and who may have access to confidential or patentable aspects of our research and development output, as well as trademark, copyright, patent and trade secret protection laws, to protect our proprietary rights. Although we enter into these confidentiality and other agreements, any of these parties may breach the agreements and disclose information before a patent application is filed and jeopardize our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Since publications in the scientific literature often lag behind the actual discoveries, and patent applications do not publish until 18 months after filing, we are never certain that we are the first to make the inventions claimed in any of our patents or that we are the first to file for patent protection of such patents. We have filed various applications for certain aspects of our intellectual property in the U.S. and other countries. However, third parties may knowingly or unknowingly infringe our proprietary rights, third parties may challenge proprietary rights held by us, pending and future patent, copyright, trademark and other applications may not be approved and we may not be able to prevent infringement without incurring substantial expense. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent, as do the laws of the U.S.

If the protection of our proprietary rights is inadequate to prevent use or appropriation by third parties, the value of our brand and other intangible assets may be diminished and competitors may be able to more effectively mimic our service and methods of operations. Despite our efforts to protect our proprietary rights, attempts may be made to copy or reverse engineer aspects of our products or services, or to obtain and use information that we regard as proprietary. Accordingly, we may be unable to protect our proprietary rights against unauthorized third party copying or use. Furthermore, policing the unauthorized use of our intellectual property would be difficult for us. Litigation may be necessary in the future to enforce our intellectual property rights, to protect our trade secrets or to determine the validity and scope of the proprietary rights of others. Litigation and/or any of the events above could result in substantial costs and diversion of resources and could have a material adverse effect on our business, consolidated financial condition and consolidated results of operations.

We may be unable to obtain and maintain patent protection for therapeutic drugs we develop.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S. and other countries for our proprietary therapeutic drugs and other technologies. Since the development of our therapeutic drugs is at an early stage, our intellectual property portfolio is also at an early stage. We have filed and intend to file patent applications. However, there are no assurances that any such patent application will issue as a granted patent. Any failure to file a non-provisional application within one year of a provisional patent application may cause us to lose the ability to obtain patent protection for the inventions disclosed in the provisional patent application.

In addition, in some cases, we may not be able to obtain issued claims covering compositions relating to our programs and therapeutic drugs, as well as other technologies important to our business. Instead, we may rely on

patent applications covering a method of use and/or method of manufacture for protection of such programs and therapeutic drugs. There is no assurance that any such patent application will issue as a granted patent, and even if they are granted, the claims may not be sufficient to prevent third parties from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our programs and therapeutic drugs could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be unable to obtain sufficiently broad protection, or we may lose patent protection.

As patent prosecution of biotechnology and pharmaceutical companies is highly uncertain, involves complex legal and factual questions, and has been the subject of litigation in recent years, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in granted patents that protect our drugs or technologies which would render us unable to prevent others from commercializing competitive drugs or technologies. The coverage of patent claims may be significantly reduced during patent prosecution before the patent is granted and the scope can also be reinterpreted after grant, which may not provide us meaningful protection, may not allow us to exclude competitors or may not provide us with any competitive advantage.

Litigation with respect to our intellectual property rights or our commercial activities could result in unanticipated expenses and, if resolved unfavorably, could harm our business.

Companies in the genetics, pharmaceutical, medical device, Internet, technology, and online payment industries own large numbers of patents, copyrights, trademarks and trade secrets and frequently enter into litigation based on allegations of infringement or other violations of intellectual property rights. We have, in the past, received notice from patent holders and other parties alleging that we have infringed their intellectual property rights. As we face increasing competition and become increasingly high profile, the possibility of intellectual property rights claims against us grows. Our technologies and services may not be able to withstand any third-party claims or rights against their use. We may in the future be subject to litigation on the foregoing grounds or other grounds. The costs of supporting such litigation are considerable, and there can be no assurances that a favorable outcome will be obtained. We may be required to settle such litigation on terms that are unfavorable to us. Similarly, if any litigation to which we may be a party fails to settle and we go to trial, we may be subject to an unfavorable judgment, which may not be reversible upon appeal. The terms of such a settlement or judgment may require us to cease some or all of our operations or require the payment of substantial amounts to the other party.

With respect to any intellectual property rights claim, we may have to seek a license to continue practices found to be in violation of a third party's rights, which may not be available on reasonable terms and may significantly increase our operating expenses. A license to continue such practices may not be available to us at all. As a result, we may also be required to develop alternative non-infringing technology or practices or discontinue such practices. The development of alternative non-infringing technology or practices could require significant effort and expense. Our business and results of operations could be materially and adversely affected as a result.

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

Filing, prosecuting and defending patents on our products and services in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S., and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Changes in either the patent laws or in interpretations of patent laws in the U.S. or other countries or regions may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In the U.S., prior to March 16, 2013, assuming that other requirements for patentability were satisfied, the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the Leahy-Smith America Invents Act ("America Invents Act"), enacted on September 16, 2011, the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are satisfied, 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. As such, a third party that files a patent application in the USPTO before us could 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. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either file any patent application related to our products or services or 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 will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. 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 business.

Recent U.S. Supreme Court rulings have also narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Issued patents covering our products and services could be found invalid or unenforceable if challenged.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and some of our patents or patent applications, including licensed patents, may be challenged, in courts or patent offices in the U.S. and abroad. We or our collaborators may be subject to a third-party preissuance submission of prior art to the USPTO or be involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference or other similar proceedings challenging our or our collaborators' patent rights. An adverse decision in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our drugs or other technologies and compete directly with us, without payment to us or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Additionally, if we and our licensing partners initiate or become involved in legal proceedings against a third party to enforce a patent covering one of our products or technologies, the defendant could counterclaim that the patent covering our product is invalid or unenforceable. In patent litigation in the U.S., counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In addition, the U.S. now awards patent priority to the first party to file a patent application, and others may submit patent claims covering our inventions prior to us. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. A successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents, which could have a material adverse impact on our business. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products and services.

We may not be aware of all third-party intellectual property rights potentially relating to our drug pipeline, products and services. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO. The outcome of such proceedings is uncertain, and other patent applications may have priority over our patent applications. Such proceedings could also result in substantial costs to us and divert our management's attention and resources.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ, and expect to employ in the future, individuals who were previously employed at universities or other companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products and services, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may not be able to protect and enforce our trademarks.

We have not yet registered certain of our trademarks in all of our potential markets, although we have registered 23andMe, and other 23andMe logos and product and service names in the U.S., the EU and a number of other countries and are seeking to register additional trademarks. As we apply to register our unregistered trademarks in the U.S. and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. In certain countries outside of the U.S., trademark registration is required to enforce trademark rights. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. Ownership disputes may arise, for example, from conflicting obligations of employees, consultants or others who are involved in developing our future products and services.

Litigation may be necessary to defend against these and other claims by a third party challenging inventorship of our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product or services. Alternatively, we may need to obtain one or more additional licenses from the third party which will be time-consuming and expensive and could result in substantial costs and diversion of resources and could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our development and commercialization efforts of our products and services.

There is a substantial amount of litigation, both within and outside the U.S., involving patent and other intellectual property rights in the life sciences, clinical diagnostics and drug discovery industries, including patent infringement lawsuits, declaratory judgment litigation and adversarial proceedings before the USPTO, including interferences, derivation proceedings, ex parte reexaminations, post-grant review and inter partes review, as well as corresponding proceedings in foreign courts and foreign patent offices.

We may, in the future, become involved with litigation or actions at the USPTO or foreign patent offices with various third parties. We expect that the number of such claims may increase as our industry expands, more patents are issued, the number of products or services increases and the level of competition in our industry increases. Any infringement claim, regardless of its validity, could harm our business by, among other things, resulting in time-consuming and costly litigation, diverting management's time and attention from the development of our business, requiring the payment of monetary damages (including treble damages, attorneys' fees, costs and expenses) or royalty payments.

It may be necessary for us to pursue litigation or adversarial proceedings before the patent office to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any such litigation might not be favorable to us, and even if we were to prevail, such litigation could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and expand our products or services offerings, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection.

Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future products, technologies and services may infringe. We cannot be certain that we have identified or addressed all potentially significant third-party patents in advance of an infringement claim being made against us. In addition, similar to what other companies in our industry have experienced, we expect our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products or services infringes these patents. Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products or services and could result in the award of substantial damages against us, including treble damages, attorney's fees, costs and expenses if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties and obtain one or more licenses from third parties, or be prohibited from selling certain products or services. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays in product or service introductions while we attempt to develop alternative products or services to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products or services, and the prohibition of sale of any of our products or services could materially affect our business and our ability to gain market acceptance for our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Class A common stock.

In addition, our agreements with some of our customers, patients, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results or financial condition.

Patent terms may be inadequate to protect our competitive position on our products and services for an adequate amount of time.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products and services are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new products and services, patents protecting such products and services might expire before or shortly after such products and services are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may not obtain patent term extension and data exclusivity for our drugs.

Depending upon the timing, duration and details of any FDA marketing approval of any drugs, our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), which permits a maximum of 5 years of patent term extension to account for patent term lost during FDA regulatory review. The extended patent term must not extend 14 years beyond the date of product approval, and may be used to extend only one patent and may be only used to extend a patent with claims covering the approved drug, a method of using it or a method of manufacturing the drug. Similar extensions are available in other foreign jurisdictions outside of the U.S., such as Supplemental Patent Certificates in Europe. Such extensions may not be granted in situations where there is a failure to exercise due diligence during the testing phase or regulatory review phase, failure to apply within the deadline, failure to apply prior to expiration of the relevant patent, or failure to satisfy the applicable requirements. In addition, the term of patent extension that is granted may be less than is requested. Failure to obtain patent term extension, allows our competitors to obtain approval of competing products following our patent expiration, and may harm our business and financial and growth prospects.

We may not be successful in obtaining, through acquisitions or otherwise, accessory rights to our drugs.

As other biotechnology and pharmaceutical companies and academic entities are competing with us, they may have patents or have filed and are likely filing patent applications potentially relevant to our business. We may find it necessary to obtain licenses to such patents from such third parties to avoid infringing on these third-party patents. The licensing of these third-party patents may be competitive and if we are unable to successfully obtain such rights, we may have to abandon development of the drug which may affect our business and financial and growth prospects.

We utilize open source software, which may pose particular risks to our proprietary software and source code.

We use open source software in our proprietary software and will use open source software in the future. Companies that incorporate open source software into their proprietary software and products have, from time to time, faced claims challenging the use of open source software and compliance with open source license terms. Some licenses governing the use of open source software contain requirements that we make available source code for modifications or derivative works we create based upon the open source software, and that we license such modifications or derivative works under the terms of a particular open source license or other license granting third parties certain rights of further use. By the terms of certain open source licenses, we could be required to release the source code of our proprietary software, and to make our proprietary software available under open source licenses to third parties at no cost, if we combine our proprietary software with open source software in certain manners. Although we monitor our use of open source software, we cannot assure you that all open source software is reviewed prior to use in our software, that our developers have not incorporated open source software into our proprietary software, or that they will not do so in the future. Additionally, the terms of many open source licenses to which we are subject have not been interpreted by U.S. or foreign courts. There is a risk that open source software licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market or provide our proprietary software. 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 proprietary software. If an author or other third party that distributes such open source software were to allege that we have not complied with the conditions of an open source license, we could incur significant legal costs 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 proprietary software. In addition, the terms of open source software licenses may require us to provide software that we develop using such open source software to others on unfavorable license terms. As a result of our current or future use of open source software, we may face claims or litigation, be required to release our proprietary source code, pay damages for breach of contract, re-engineer our proprietary software, discontinue making our proprietary software available in the event re-engineering cannot be accomplished on a timely basis, discontinue certain aspects or functionality of our PGS, or take other remedial action. Any such re-engineering or other remedial efforts could require significant additional research and development resources, and we may not be able to successfully complete any such re-engineering or other remedial efforts. Further, in addition to risks related to license requirements, use of certain open source software can lead to greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or controls on the origin of the software. Any of these risks could be difficult to eliminate or manage, and, if not addressed, could have a negative effect on our business, financial condition and results of operations.

Risks Relating to Financial Reporting and Results of Operations

A material weakness in our internal control over financial reporting was identified as of March 31, 2020 and 2021, and remains unremediated at March 31, 2022. If our remediation of this material weakness is not effective, or if we fail to maintain effective internal control over financial reporting in the future, our ability to produce accurate and timely consolidated financial statements could be impaired. This could adversely affect investor confidence in the Company and, as a result, the value of our Class A common stock.

A material weakness in our internal control over financial reporting was identified as of March 31, 2020 and 2021, and remains unremediated at March 31, 2022. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. The material weakness identified was a lack of sufficient resources in our finance function to meet our financial reporting requirements. This material weakness resulted in insufficient management review of journal entries, account reconciliations, and review of financial statements. Management continues to review and make necessary changes to the overall design of our internal control environment, including implementing additional internal controls over journal entries, account reconciliation and the review of financial statements. We are in the process of adding additional resources to our finance function to enhance the effectiveness of internal controls over financial reporting. The material weakness will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Although we plan to complete this remediation process as quickly as possible, we cannot estimate at this time how long it will take.

Additionally, as discussed elsewhere in this Form 10-K, we completed the Business Combination on June 16, 2021. Prior to the Business Combination, we were a special purpose acquisition company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, recapitalization, reorganization, or similar business combination with one or more businesses. As a result, previously existing internal controls are no longer applicable or comprehensive enough as of the assessment date, as our operations prior to the Business Combination were insignificant compared to those of the consolidated entity post-Business Combination. The design and implementation of internal control over financial reporting post-Business Combinations has required and will continue to require significant time and resources from management and other personnel. Because of this, the design and ongoing development of our framework for implementation and evaluation of internal control over financial reporting is in its preliminary stages. As a result, management was unable, without incurring unreasonable effort or expense, to conduct an assessment of our internal control over financial reporting as of March 31, 2022. Accordingly, we are excluding management's report on internal control over financial reporting pursuant to Section 215.02 of the SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations. See Item 9A, Controls and Procedures, of this Annual Report for more information.

Failure to maintain effective internal control over our financial reporting could have a material and adverse effect. In addition, if we are unable to conclude that we have effective internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an attestation and an unqualified report as to the effectiveness of internal control over financial reporting, investors might lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities.

Our quarterly operating results may fluctuate significantly.

Our quarterly operating results may fluctuate significantly due to seasonality and other factors, some of which are beyond our control, including negative publicity relating to our products and services, changes on customer and patient preferences, and competitive conditions, resulting in a decline in the price of our Class A common stock. Any fluctuation in our operating results, especially if below the expectations of securities analysts, could adversely affect the market price of our securities. Any reduction in the market price of our securities could make it more difficult for us to raise additional funds through future offerings of shares of Class A common stock or other securities.

Our ability to use our net operating loss carryforwards may be subject to limitations.

As of March 31, 2022, we had approximately $1.0 billion of federal net operating loss carryforwards available to reduce future taxable income, which will begin to expire in 2026. Realization of any tax benefit from our carryforwards is dependent on our ability to generate future taxable income and the absence of certain "ownership changes" of our Class A common stock. An "ownership change," as defined in the applicable federal income tax rules, could place significant limitations, on an annual basis, on the amount of our future taxable income that may be offset by our carryforwards. Such limitations, in conjunction with the net operating loss expiration provisions, could effectively eliminate our ability to utilize a substantial portion of our carryforwards. We have conducted a study as of March 31, 2022 and determined that no "ownership change" has occurred.

We have incurred significant losses since inception, we expect to incur losses in the future, and we may not be able to generate sufficient revenue to achieve and maintain profitability.

We have incurred significant losses since our inception. For the fiscal years ended March 31, 2022, 2021 and 2020, we incurred net losses of $217.5 million, $183.6 million and $250.9 million, respectively. As of March 31, 2022, we had an accumulated deficit of $1.2 billion. We expect to incur substantial operating losses in future periods.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue to expand therapeutic research and development efforts, develop drugs with collaborators or on our own, enhance our existing consumer products, services and business model, broaden our customer base, work with the FDA and other regulatory agencies, and hire additional employees to support our growth. Historically, we have devoted most of our financial resources to the research and development of our PGS, as well as our Therapeutics business, which we launched in April 2015. The discovery and development of safe and effective therapies is a complex and uncertain process, which takes many years and involves significant costs. We may not succeed in increasing our revenues, which historically have been reliant on sales of our PGS, in a manner that will be sufficient to offset these higher expenses. Any failure to increase our revenues as we implement initiatives to grow our business could prevent us from achieving profitability. We cannot be certain that we will be able to achieve profitability on a quarterly or annual basis. If we are unable to address these risks and difficulties as we encounter them, our business, financial condition and results of operations may suffer.

We have incurred and will continue to incur increased costs as a result of being a public company.

As a public company, we are subject to enhanced internal controls standards have incurred and will continue to incur increased legal, accounting, insurance and other costs not incurred as a private company. The Sarbanes-Oxley Act and related rules and regulations of the SEC and Nasdaq regulate the corporate governance practices of public companies. Compliance with these requirements has increased and will continue increase our expenses and make some activities more time-consuming than they have been in the past when we were a private company. Such additional costs going forward could negatively affect our financial results.

Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the U.S.

Generally accepted accounting principles in the U.S. are subject to interpretation by the Financial Accounting Standards Board ("FASB"), the American Institute of Certified Public Accountants, the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. Any change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

We are subject to changing law and regulations regarding regulatory matters, corporate governance, and public disclosure that have increased our costs and the risk of non-compliance.

We are subject to rules and regulations by various governing bodies, including, for example, the SEC, which are charged with the protection of investors and the oversight of companies whose securities are publicly traded, and to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in increased general and administrative expenses and a diversion of management time and attention.

Moreover, because these laws, regulations, and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

Risks Related to Acquisitions

We face additional risks as a result of the Lemonaid Acquisition and may be unable to integrate our businesses successfully and realize the anticipated synergies and related benefits of the Lemonaid Acquisition or do so within the anticipated timeframe.

On November 1, 2021, we completed our acquisition of Lemonaid Health. As a result of the Lemonaid Acquisition, we face various additional risks, including, among others, the following:

- difficulties in integrating and managing the combined operations of Lemonaid Health, and realizing the anticipated economic, operational, and other benefits in a timely manner, which could result in substantial costs and delays or other operational, technical, or financial problems;
- disruption to Lemonaid Health's business and operations and relationships with service providers and other third parties;
- loss of key employees of Lemonaid Health and other challenges associated with integrating new employees into our culture, as well as reputational harm if integration is not successful;
- diversion of management time and focus from operating our business to addressing Lemonaid Acquisition integration challenges;
- diversion of significant resources from the ongoing development of our existing products, services, and operations;
- failure to successfully realize our intended business strategy;
- increase in the operating losses that we expect to incur in future periods;
- regulatory complexities of integrating or managing the combined operations or expanding into other industries or parts of the healthcare industry;
- regulatory developments or enforcement trends focusing on corporate practice of medicine;
- greater than anticipated costs related to the integration of Lemonaid Health's business and operations into ours;
- increase in compliance and related costs associated with the addition of a regulated business;
- responsibility for the liabilities of Lemonaid Health, including those that were not disclosed to us or exceed our estimates, as well as, without limitation, liabilities arising out of their failure to maintain effective data protection and privacy practices controls and comply with applicable regulations; and
- potential accounting charges to the extent intangibles recorded in connection with the Lemonaid Acquisition, such as goodwill, trademarks, client relationships, or intellectual property, are later determined to be impaired and written down in value.

Our ability to execute all such plans will depend on various factors, many of which remain outside our control. Any of these risks could adversely affect our business and financial results.

The process of integrating Lemonaid Health's operations into our operations could result in unforeseen operating difficulties and require significant resources.

The following factors, among others, could reduce our revenues and earnings, increase our operating costs, and result in a loss of projected synergies:

- if we are unable to successfully integrate the duties, responsibilities, and other factors of interest to the management and employees of the acquired business, we could lose employees to our competitors, which could significantly affect our ability to operate the business and complete the integration;
- if we are unable to implement and retain uniform standards, controls, policies, procedures, and information systems; and
- if the integration process causes any delays with the delivery of our services, or the quality of those services, we could lose customers, which would reduce our revenues and earnings.

The process of integrating Lemonaid Health and its associated services and technologies involves numerous risks that could materially and adversely affect our results of operations or stock price.

The following factors, among others, could materially and adversely affect our results of operations or stock price:

- expenses related to the acquisition process and impairment charges to goodwill and other intangible assets related to the Lemonaid Acquisition;
- the dilutive effect on earnings per share as a result of issuances of our stock and incurring operating losses;
- stock volatility due to investors' uncertainty regarding the value of Lemonaid Health;
- diversion of capital from other uses;
- failure to achieve the anticipated benefits of the Lemonaid Acquisition in a timely manner, or at all; and
- adverse outcome of litigation matters or other contingent liabilities assumed in or arising out of the Lemonaid Acquisition.

Notwithstanding the due diligence investigation we performed in connection with the Lemonaid Acquisition, Lemonaid Health may have liabilities, losses, or other exposures for which we do not have adequate insurance coverage, indemnification, or other protection.

While we performed significant due diligence on Lemonaid Health prior to signing the Agreement and Plan of Merger and Reorganization (the "Lemonaid Health Merger Agreement"), dated as of October 21, 2021, by and among 23andMe, Life Merger Sub One, Inc., Life Merger Sub Two, Inc., Lemonaid Health, and Fortis Advisors LLC, in its capacity as representative of the Indemnifying Parties (as defined in the Lemonaid Health Merger Agreement), we are dependent on the accuracy and completeness of statements and disclosures made or actions taken by Lemonaid Health and its representatives in connection with our due diligence investigation and our evaluation of the results of such due diligence. We did not control and may be unaware of activities of Lemonaid Health before the Lemonaid Acquisition, including intellectual property and other litigation or disputes, information security vulnerabilities, violations of laws, policies, rules and regulations, commercial disputes, tax liabilities, and other liabilities.

Our post-closing recourse is limited under the Lemonaid Health Merger Agreement.

Our remedies for breaches of representations and warranties under the Lemonaid Health Merger Agreement are limited to recoveries under the representation and warranty policy described below and the indemnification provisions of the Lemonaid Health Merger Agreement. The Indemnifying Parties' (as defined in the Lemonaid Health Merger Agreement) obligations to indemnify us are limited to, among others, breaches of specified representations and warranties and covenants included in the Lemonaid Health Merger Agreement and other specific indemnities as set forth in the Lemonaid Health Merger Agreement. In the event of a breach of a representation or warranty, we cannot recover in respect of a claim for indemnification pursuant to the Lemonaid Health Merger Agreement unless and until the indemnifiable losses exceed $2,000,000 (the "Deductible"), which is the portion of the retention amount under the representation and warranty insurance policy referenced below, for which we are responsible. Additionally, we may not recover losses for breaches of certain representations and warranties from the former stockholders of Lemonaid in excess of $2,000,000 (except as otherwise specified below), which is the portion of the retention amount for which the former stockholders of Lemonaid provide indemnification (the "Cap"). The Deductible and the Cap do not apply to indemnification claims based on breaches of Fundamental Representations or Fraud (each as defined in the Lemonaid Health Merger Agreement) or to other specific indemnities; furthermore, the Cap does not apply to indemnification claims based on breaches of Specified Representations (as defined in the Lemonaid Health Merger Agreement) or to other specific indemnities.

We cannot make an indemnification claim against the Indemnifying Parties for a breach of a representation or warranty after the date that is 18 months after the date of closing of the Lemonaid Acquisition (the "Closing"), other than claims based on breaches of Fundamental Representations, which survive until 6 years after the Closing, and claims based on breaches of Specified Representations, which survive until 30 months after the Closing.

We obtained a representation and warranty insurance policy to insure against certain losses arising from breaches of, or inaccuracies in, the representations and warranties of Lemonaid Health. The policy is subject to a retention amount of $4 million, as referenced above, as well as to exclusions, policy limits, and certain other terms and conditions.

If any issues arise post-closing, we may not be entitled to sufficient, or any, indemnification or recourse from the Indemnifying Parties or pursuant to the representation and warranty insurance policy, which could have a material adverse impact on our business and results of operations.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate headquarters was previously located in Sunnyvale, California and consisted of approximately 154,987 square feet of space under a lease that expires on July 31, 2031. Effective April 1, 2022, we relocated our corporate headquarters to South San Francisco, California. This location consists of approximately 65,340 square feet of space under a lease that expires on January 31, 2025. We use these facilities for communications, engineering, finance, healthcare operations, information technology and security, legal, marketing, human resources, product, research and science, supply chain, and other administrative functions. We also conduct our therapeutics research and development in our laboratory facilities located in the South San Francisco location.

Item 3. Legal Proceedings

From time to time, we are party to litigation and subject to claims incident to the ordinary course of business. As our growth continues, we may become party to an increasing number of litigation matters and claims. The outcome of litigation and claims cannot be predicted with certainty, and the resolution of these matters could materially affect our future results of operations, cash flows, or financial position. We are not presently party to any legal proceedings that, in the opinion of management, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition, or cash flows.

As previously disclosed, on December 10, 2019, Celmatix Inc. ("Celmatix") filed a lawsuit in the Supreme Court of the State of New York against us (Index No. 657329/2019) asserting claims against us for breach of contract and the implied covenant of good faith and fair dealing and tortious interference with contract and prospective economic advantage, alleging damages that, according to the compliant, plaintiff "believed to be in excess of $100 million." On February 14, 2020, we filed its answer, denying all of the material allegations of the complaint and asserting counterclaims against Celmatix for breach of contract. Celmatix amended its complaint on July 13, 2021, asserting an additional claim against us for fraudulent inducement of contract. On July 19, 2021, we filed its answer to the amended complaint, denying all of the material allegations and asserting a counterclaim and an additional defense of fraudulent inducement of contract. On October 29, 2021, both parties made motions for partial summary judgment in their favor. Briefing of the parties' respective motions was completed in December 2021. On March 30, 2022, both parties agreed to a settlement, pursuant to which we made a payment of $10.0 million net of insurance coverage and all claims and counter-claims were released. The parties filed a Stipulation of Dismissal and Discontinuance with Prejudice on April 22, 2022. On April 25, 2022, the presiding judge entered an order noting that the motions for summary judgment are moot, canceling all future appearances and marking the case as disposed.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our Class A common stock is traded on the Nasdaq Global Select Market ("Nasdaq") under the symbol "ME".

Holders

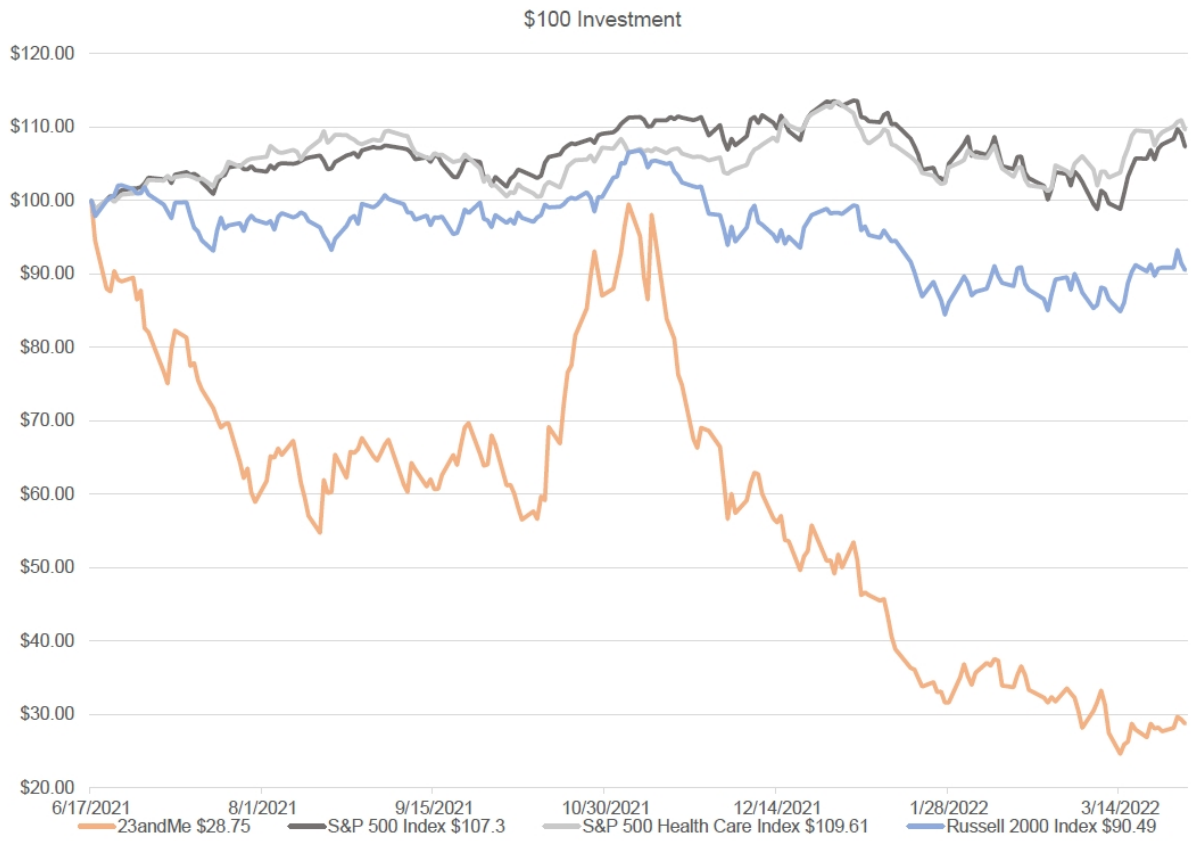
As of May 20, 2022, there were 219 holders of record of our Class A common stock and 140 holders of record of our Class B common stock. Because many of our shares of Class A common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders. However, we believe a substantially greater number of beneficial owners hold shares of Class A common stock through brokers, banks, or other nominees.

Dividends

We have not paid any cash dividends on our Class A common stock to date. The payment of any cash dividends is within the discretion of our Board and our Board does not currently contemplate declaring any dividends in the foreseeable future.

Stock Performance Graph

The following graph compares the cumulative total return to stockholders on our Class A common stock relative to the cumulative total returns of the S&P 500 Index, the S&P 500 Health Care Sector Index, and the Russell 2000 Index. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our Class A common stock and in each index on June 17, 2021, the date our Class A common stock began trading on the Nasdaq, and its relative performance is tracked through March 31, 2022. The returns shown are based on historical results and are not intended to suggest future performance.



Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis provides information that management believes is relevant to an assessment and understanding of our consolidated results of operations and financial condition. You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and accompanying notes included in Part II, Item 8 of this Form 10-K. This section of the Form 10-K generally discusses fiscal 2022 and 2021 items and year-to-year comparisons between fiscal 2022 and 2021, as well as certain fiscal 2020 items. Discussions of fiscal 2020 items and year-to-year comparisons between fiscal 2021 and 2020 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Current Report on Form 8-K filed with the SEC on June 21, 2021, including the audited consolidated financial statements of 23andMe, Inc. as of March 31, 2021 and 2020 filed as Exhibit 99.1 thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included therein.

Unless the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" to the "Company," "we," "us," and "our" refer to 23andMe Holding Co., a Delaware corporation formerly known as VG Acquisition Corp. and its consolidated subsidiaries. References to VG Acquisition Corp. or "VGAC" refer to the Company prior to the consummation of the Business Combination.

Overview

23andMe Holding Co., formerly known as VG Acquisition Corp., is a mission-driven company dedicated to empowering customers to live healthier lives. Our mission is to help people access, understand, and benefit from the human genome.

We pioneered direct-to-customer genetic testing through our PGS products and services. Our PGS business provides customers with a full suite of genetic reports, including information on customers' genetic ancestral origins, personal genetic health risks, and chances of passing on certain rare carrier conditions to their children, as well as reports on how genetics can affect responses to medications. We believe that by providing customers with direct access to their genetic information, we can empower them to make better decisions by arming them with information about their risks of developing certain diseases or conditions and by highlighting opportunities for prevention and mitigation of disease. We provide customers with an engaging experience, including access to frequent updates to their genetic health and ancestry reports and new product features, the ability to connect with genetic relatives, and a subscription option for extended health insights. Customers have the option to participate in our research programs and over 80% of our customers have done so. We analyze consenting customers' genotypic data together with phenotypic data they provide to us concerning their physical characteristics, family origins, lifestyle, and other habits. We analyze this data using our proprietary machine learning and other analytic techniques in order to discover insights into whether and how particular genetic variants affect the likelihood of individuals developing specific diseases. These insights may highlight opportunities to develop a drug to treat or cure a specific disease.

We completed our acquisition of Lemonaid Health on November 1, 2021. Lemonaid Health, an on-demand platform for accessing medical care and pharmacy services online, offers telemedicine, lab, and pharmacy services to patients in all 50 states, the District of Columbia, and the U.K. We believe that the addition of Lemonaid Health's telehealth services to our consumer business will enable us to bring better healthcare to individuals in an affordable and accessible way and offer personalized healthcare, based on a patient's wellness, choices, and genetics.

Our Therapeutics business focuses on the use of genetic insights to validate and develop novel therapies to improve patients' lives. We currently have research programs across several therapeutic areas, including oncology, respiratory, and cardiovascular diseases. In July 2018, we signed an exclusive agreement with GSK to leverage genetic insights to validate, develop, and commercialize promising drugs. This multi-year collaboration is expected to identify and prioritize genetically validated drug targets, enable rapid progression of clinical programs, and bring useful new drugs to market. In addition to our collaboration with GSK, we have several proprietary programs, one of which is being pursued in collaboration with Almirall, S.A.

Our second most advanced program, 23ME-00610, is an antibody that blocks the suppression of T-cells by tumors and reactivates their immune response. 23ME-00610 is wholly owned by the Company, and this program entered Phase 1 clinical trials in January 2022. Following the expiration of the GSK Agreement, we will have the opportunity to collaborate with, or out-license other wholly owned programs to third parties or to develop them independently.

We operate in two reporting segments: Consumer & Research Services and Therapeutics. The Consumer & Research Services segment consists of our PGS and telehealth business, as well as research services that we perform under agreements with third parties, including the GSK Agreement, relating to the use of our genotypic and phenotypic data to identify promising drug targets. The Therapeutics segment consists of revenues from the out-licensing of intellectual property associated with identified drug targets and expenses related to therapeutic product candidates under clinical development. For the fiscal years ended March 31, 2022 and 2021, substantially all our revenues were derived from our Consumer & Research Services segment.

The table below reflects our revenue for the fiscal years ended March 31, 2022 and 2021:

	Year Ended March 31,			
	2022	2021	$ Change	% Change
	(dollars in thousands)			
Consumer & Research Services Revenue	$ 271,893	$ 243,866	$ 28,027	11%
Therapeutics Revenue	—	54	(54)	(100%)
Total Revenue	$ 271,893	$ 243,920	$ 27,973	11%

The table below reflects our two segments' Adjusted EBITDA (as defined below) for the fiscal years ended March 31, 2022 and 2021:

	Year Ended March 31,			
	2022	2021	$ Change	% Change
	(dollars in thousands)			
Consumer & Research Services				
Adjusted EBITDA*	$ (30,112)	$ 12,796	$ (42,908)	(335%)
Therapeutics				
Adjusted EBITDA*	$ (76,944)	$ (58,734)	$ (18,210)	31%

* Adjusted EBITDA is the measure of segment profitability reported to our Chief Executive Officer ("CEO"), who is our chief operating decision-maker ("CODM"). We define Adjusted EBITDA as net income before net interest expense (income), net other expense (income), changes in fair value of warrant liabilities, income tax benefit, depreciation and amortization of fixed assets, amortization of internal use software, amortization of acquired intangible assets, non-cash stock-based compensation expense, acquisition-related costs, litigation settlements not related to normal and continued business activities and expenses related to restructuring and other charges, if applicable, for the period. See "—Adjusted EBITDA" below for a reconciliation of Adjusted EBITDA to net loss.

Key Factors Affecting Results of Operations

We believe that our performance and future success depend on several factors that present significant opportunities for us but also pose risks and challenges, including those discussed below and included (or incorporated by reference) in "Risk Factors" in Part I, Item 1A of this Form 10-K.

New Customer Acquisition

PGS. Our ability to attract new customers is a key factor for the future growth of our PGS business and our database. Our historical financial performance has largely been driven by, and in the future will continue to be affected by, the rate of sales of our PGS kits. Revenue from our PGS business, primarily composed of kit sales, represented approximately, 75% and 81% of our total revenues for the fiscal years ended March 31, 2022 and 2021, respectively. In addition, kit sales are a source of subscribers to our new subscription service. We expect kit sales and our new subscription service to grow as we increase awareness of our current and new offerings in existing markets, expand into new ones, and enhance our subscription service with new features.

Purchasing patterns of our kits are largely influenced by product innovation, marketing spends, and varying levels of price discounting on our products. These promotional windows have typically aligned with gift-giving portions of the year, with an emphasis on the holiday period, other gift-giving and family-oriented holidays such as Mother's Day and Father's Day, and Amazon Prime Day, which may change from year to year. Historically, we have experienced higher revenue in the fourth quarter of the fiscal year compared to other quarters. Over time, we expect the seasonality of our business to continue, with pronounced increases in revenue recognized in the fourth fiscal quarter. We generally incur higher sales and marketing expenses during holiday promotional periods, which have included, among others, Mother's Day, Father's Day, and the November-December holidays.

Telehealth. Our ability to attract new patients and members is a key factor for the future growth of our telehealth business. Revenue from our telehealth business represented approximately 7% of our total revenues for the fiscal year ended March 31, 2022, which included the five month period from the close of the acquisition of Lemonaid Health on November 1, 2021 through March 31, 2022. Telehealth awareness, acceptance, and usage have been positively impacted by the COVID-19 pandemic, leading to increased consumer acceptance of virtual care. While we anticipate continued growth, there are many participants in the telehealth market, including new entrants and traditional health care systems offering virtual care, and competition is intense.

Engagement of Research Participants

Our ability to conduct research and grow our database of genotypic and phenotypic information depends on our customers' willingness to consent to participate in our research. Over 80% of our customers have consented to participate in research. These customers permit us to use their de-identified data in our research and many of them regularly respond to our research surveys, providing us with phenotypic data in addition to the genetic data in their DNA samples. We analyze this genotypic and phenotypic data and conduct genome-wide association studies and phenome-wide association studies, which enable us to determine whether particular genetic variants affect the likelihood of individuals developing certain diseases.

Our customers can withdraw their consent to participate in research at any time. If a significant number of our customers were to withdraw their consent, or if the percentage of consenting customers were to decline significantly in the future, our ability to conduct research successfully could be diminished, which could adversely affect our business.

Drug Target Productivity of Our Genetics Database

Our genetics database underpins our research programs and enables us to identify drug targets with novel genetic evidence. As of March 31, 2022, we have identified over 50 drug targets. We expect the current productivity of our genetics database to continue based on the increasing amounts of data that we expect to result from increased kit sales and customer engagement. Any significant decline in such productivity would have a negative impact on our ability to identify drug targets and ultimately to develop and commercialize new drugs.

Development of Therapeutic Product Candidates

Our ability to successfully identify and develop therapeutic product candidates will determine the success of our Therapeutics business over time. Developing therapeutic product candidates with novel genetic evidence requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. We have over 50 programs in our pipeline in various stages of research and development that have been selected and are being pursued.

We have one therapeutic product candidate, CD96, our joint immuno-oncology antibody program with GSK, in clinical development, for which we have elected to take a royalty option. Our wholly-owned immuno-oncology antibody, 23ME-00610, entered Phase 1 clinical trials in January 2022. Additional programs are in research or preclinical stages of development. We have incurred, and will continue to incur, significant research and development costs for preclinical studies and clinical trials. We expect that our research and development expenses will continue to constitute a significant portion of our expenses in future periods.

Collaborations

Substantially all of our research services revenues are generated from the GSK Agreement. In January 2022, GSK elected to exercise its option to extend the exclusive target discovery period of the ongoing collaboration with the Company for an additional year ending in July 2023. We will receive a one-time payment of $50.0 million to extend the period. In addition, the Company elected to take a royalty option on its joint immuno-oncology antibody collaboration program with GSK targeting CD96 (GSK6097608, a.k.a. GSK'608). GSK will be solely responsible for GSK'608's subsequent development in later-stage clinical trials, including full development costs moving forward. Additionally, all of our Therapeutics revenue for the fiscal year ended March 31, 2021 was derived from our agreements with GSK and Almirall, S.A. There was no Therapeutics revenue for the fiscal year ended March 31, 2022.

Our ability to enter into new collaboration agreements, upon the expiration of the GSK Agreement, will affect our research services revenues. If we are unable to enter into additional collaboration agreements, our future research services revenue may decline.

Ability to Commercialize Our Therapeutics Products

Our ability to generate revenue from our therapeutic product candidates depends on our and our collaborators' ability to successfully complete clinical trials for our therapeutic product candidates and receive regulatory approval, particularly in the United States, Europe, and other major markets.

We believe that our broad portfolio of therapeutic product candidates with novel genetic evidence and validated targets enhances the likelihood that our research and development efforts will yield successful therapeutic product candidates. Nonetheless, we cannot be certain if any of our therapeutic product candidates will receive regulatory approvals. Even if such approvals are granted, we will thereafter need to establish manufacturing and supply arrangements and engage in extensive marketing efforts and expenses prior to generating any revenue from such products. The ultimate commercial success of our products will depend on their acceptance by patients, the medical community, and third-party payors, their ability to compete effectively with other therapies in the market, and the appropriate pricing and reimbursement of the products by third-party payors.

The competitive environment is also an important factor with the commercial success of our therapeutic product candidates, and our ability to successfully commercialize a therapeutic product candidate will depend on whether there are competing therapeutic product candidates in development or already marketed by other companies.

Expansion into New Categories

We launched our 23andMe+ subscription service in October 2020, and through our acquisition of Lemonaid Health, we began providing access to telehealth services in November 2021. We expect to expand into new categories and innovative healthcare models with the goal of driving future growth. Those opportunities include product enhancements, such as our proprietary polygenic risk scores, new product offerings aimed at extending our personalized and customer-centric philosophy to primary healthcare, and potential additional acquisitions of other consumer-oriented healthcare businesses. Such expansion would allow us to increase the number of engaged customers who purchase or subscribe for additional products and services.

Success of our subscription service will depend upon our ability to acquire and retain subscribing customers over an extended period. Retention of customers will be based on the perceived value of the premium content and features they receive. If we are unable to provide sufficiently compelling new content and features, subscribers may not renew.

Similarly, the success of our telehealth business is dependent on our ability to attract and retain patients and members. Category expansion allows us to increase the number of patients to whom we can provide products and services. It also allows us to offer access to treatment of additional conditions that may already affect our current patients. Expanding into new categories will require financial investments in additional headcount, marketing and customer acquisition expenses, additional operational capabilities, and may require the purchase of new inventory. If we are unable to generate sufficient demand in new categories, we may not recover the financial investments we make into new categories and revenue may not increase in the future.

Investments in Growth and Innovation

Our research platform is based on a continually growing database of genotypic and phenotypic information. Our database allows us to conduct analyses in a multi-directional fashion, by searching for genetic signatures of particular diseases or the likelihood of a particular genetic variant causing disease in a particular individual or group of individuals who share the same trait. Our platform enables us to rapidly and serially conduct studies across an almost unlimited number of conditions at unprecedented statistical power, yielding insights into the causes and potential treatments of a wide variety of diseases.

We believe that our research platform enables us to rapidly identify genetically validated drug targets with improved odds of clinical success. With our state-of-the-art bioinformatics capabilities, we analyze the trillions of data points in our database, optimizing the use of our resources, to genetically validate drug targets, inform patient selection for clinical trials, and increase the probability of success of our programs. We plan to advance new drugs through the rapid selection of those with compelling clinical promise.

We expect to continue investing in our business to capitalize on market opportunities and the long-term growth of our company. We intend to make significant investments in therapeutics research and development efforts and in marketing to acquire new customers and drive brand awareness, and also expect to incur software development costs as we work to enhance our existing products, expand the depth of our subscription service, and design new offerings, including additional primary care offerings. In addition, we expect to incur additional expenses as a result of operating as a public company. The expenses we incur may vary significantly by quarter depending, for example, on when significant hiring takes place, and as we focus on building out different aspects of our business.

COVID-19 Impact

We are continuing to closely monitor the impact of the COVID-19 pandemic in all aspects of our business. We rely entirely on third-party vendors in our PGS and telehealth supply chain, including our PGS kit and array manufacturers, order fulfillment vendor, our DNA-processing lab vendor, and drug suppliers for our pharmacy business. These vendors have independent responses to managing the effect of the COVID-19 pandemic, and we have not experienced any significant disruptions in our ability to fulfill and process PGS or telehealth orders to date. If we experience delays or other challenges in obtaining supplies necessary for the production, fulfillment, or distribution of the products or services we offer, it could negatively affect our ability to satisfy our obligations to customers and maintain our operations in a cost-efficient manner and have a material adverse effect on our business.

With respect to our telehealth services, the COVID-19 pandemic has increased awareness, acceptance, and usage of virtual medical care and pharmacy services, resulting in greater consumer trial and use of telehealth. While we believe that these trends present significant opportunities for our telehealth services, it is uncertain whether the increase in demand caused by COVID-19 will continue.

In our Therapeutics segment, the advancement of our programs requires our scientists to have physical access to our laboratory facilities on a continuing basis, and we have implemented health and safety protocols and procedures to keep our laboratory facilities operating during the COVID-19 pandemic. In addition, despite the introduction and continued administration of COVID-19 vaccines, the pandemic remains highly volatile and continues to evolve. We cannot accurately predict the duration or extent of the impact of the COVID-19 virus, including the Omicron, Delta, and other variants and other areas that may affect our business operations. Despite our mitigation efforts, we may experience delays or an inability to execute on our clinical and preclinical development plans, reduced revenues or other adverse impacts to our business, which are described in more detail in "Risk Factors" in Part I, Item 1A of this Form 10-K. The duration of the COVID-19 pandemic and the impact of the efforts being made to contain it or to flatten the spread of the disease cannot be predicted with any accuracy, and this uncertainty could have a material impact on our financial results for the foreseeable future.

We have taken other measures in response to the ongoing COVID-19 pandemic, including closing our offices and implementing a work-from-home policy for most of our workforce, and amplifying monitoring of our inventory levels and supply chain. Notwithstanding these measures, the spread of COVID-19 has at certain times impacted our staffing and attendance in our laboratory facilities. We may take further actions that alter our business operations that we determine are in the best interests of our employees, customers, and stockholders or as may be required by federal, state, or local authorities.

Basis of Presentation

The consolidated financial statements and accompanying notes of the Company included elsewhere in this Form 10-K include the accounts of 23andMe Holding Co. and its consolidated subsidiaries and variable interest entities and were prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP"). As 23andMe, Inc. is considered the Company's accounting predecessor, all historical financial information presented in the consolidated financial statements represents the accounts of 23andMe, Inc. and its wholly owned subsidiary. Certain prior period amounts within the "Results of Operations" section have been reclassified in order to conform with the current year presentation of separately reported research and development expenses and sales and marketing expenses.

As discussed above, we operate in two reporting segments: Consumer & Research Services and Therapeutics. The Consumer & Research Services segment consists of our PGS and telehealth business, as well as research services that we perform under agreements with third parties, including the GSK Agreement, relating to the use of our genotypic and phenotypic data to identify promising drug targets. The Therapeutics segment consists of revenues from the out-licensing of intellectual property associated with identified drug targets and expenses related to therapeutic product candidates under clinical development. Substantially all our revenues are derived from our Consumer & Research Services segment.

Key Business Metrics

We monitor the following key metrics to help us evaluate our business, identify trends, formulate business plans, and make strategic decisions. We believe the following metrics are useful in evaluating our business:

- ***PGS Customers.*** When we refer to our "Customers," this means individuals who have registered a PGS kit and provided their DNA sample. We view Customers as an important metric to assess our financial performance because each Customer has registered a kit and has engaged with us by providing us with their DNA sample. These Customers may be interested in purchasing additional PGS products and services or in becoming subscribers to our new 23andMe+ subscription service, especially if they consent to participate in our research. We had approximately 12.8 million and 11.3 million Customers as of March 31, 2022 and 2021, respectively.

- ***Consenting Customers***. "Consenting Customers" are Customers who have affirmatively opted in to participate in our research program. Consenting Customers are critical to our research programs and to the continuing growth of our database, which we use to identify drug targets and to generate new and interesting additional ancestry and health reports. Moreover, Consenting Customers respond to our research surveys, providing useful phenotypic data about their traits, habits, and lifestyles, which we analyze using de-identified data to determine whether a genetic variant makes an individual more or less likely to develop certain diseases. A Consenting Customer is likely to be more engaged with our brand, which may lead to the purchase of our 23andMe+ subscription service and to participation in further research studies, helping us to advance our research. Over 80% of our Customers are Consenting Customers.

- ***Subscribers.*** This metric represents the number of subscribers who have signed up for our 23andMe+ subscription service, which was launched in October 2020. We believe that 23andMe+ will position us for future growth, as the annual membership model represents a previously untapped source of recurring revenue. We are continually investing in new reports and features to provide to subscribers as part of the 23andMe+ membership, which we believe will enhance customer lifetime value as customers can make new discoveries about themselves. We believe that this, in turn, will help to scale our customer acquisition costs and create expanding network effects. As of March 31, 2022 and 2021, our 23andMe+ membership base had approximately 425,000 and 125,000 subscribers, respectively.

- ***Adjusted EBITDA.*** Adjusted EBITDA is the measure of segment profitability reported to our CEO, the CODM. See "—*Adjusted EBITDA*" below for a reconciliation of Adjusted EBITDA to net loss.

Components of Results of Operations

Revenue

We recognize revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), when we transfer promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

Our consolidated revenue is composed primarily of sales of PGS kits to customers and telehealth services which include online medical visits, pharmacy services, and memberships, as well as revenues from target discovery activities as part of our research collaborations through our Consumer & Research Services segment. Additionally, revenue is generated through our collaboration agreements in our Therapeutics segment primarily as a result of the out-licensing of intellectual property to collaboration partners.

See Note 2 to our accompanying consolidated financial statements for a more detailed discussion of our revenue recognition policy.

Cost of Revenue, Gross Profit, and Gross Margin

Cost of revenue for PGS primarily consists of cost of raw materials, lab processing fees, personnel-related expenses, including salaries, benefits, and stock-based compensation, shipping and handling, and allocated overhead. Cost of revenue for telehealth primarily consists of personnel-related expenses that we incur for medical services, prescription drug costs, packaging and shipping, and amortization of intangible assets. Cost of revenue for research services primarily consists of personnel-related expenses, including salaries, benefits, and stock-based compensation, and allocated overhead. We expect cost of revenue to increase in the foreseeable future in absolute dollars but gradually decrease as a percentage of revenue over the long term.

Our gross profit represents total revenue less our total cost of revenue, and our gross margin is our gross profit expressed as a percentage of our total revenue. Our gross profit and gross margin have been and will continue to be affected by a number of factors, including the volume of PGS kit sales recognized, the prices we charge for our PGS products and research services, the prices we charge for telehealth services (medical visits, pharmacy services, and memberships), the fees we incur for lab processing PGS kits, the costs we incur for medical services and prescription drug costs, and revenues from our collaboration agreements. We expect our Consumer & Research Services gross margin to increase over the long term as subscription revenues become a higher percentage of revenue mix, although our gross margin may fluctuate from period to period. Substantially all our research services revenue is currently derived from the GSK Agreement. If we are unable to add new research services agreements, our research services revenue may decline substantially following the expiration of the GSK Agreement in July 2023.

Operating Expenses

Our operating expenses primarily consist of research and development, sales and marketing, and general and administrative expenses. Personnel-related expenses, which include salaries, benefits, and stock-based compensation, is the most significant component of research and development and general and administrative expenses. Advertising and brand-related spend and personnel-related expenses represent the primary components of sales and marketing expenses. Operating expenses also include allocated overhead costs. Overhead costs that are not substantially dedicated for use by a specific functional group are allocated based on headcount. Allocated overhead costs include shared costs associated with facilities (including rent and utilities) and related personnel, information technology and related personnel, and depreciation of property and equipment.

Research and Development Expenses

Our research and development expenses support our efforts to add new services and new features to our existing services, and to ensure the reliability and scalability of our services across our Consumer and Research Services segment. Research and development expenses also include our efforts to discover and genetically validate new therapeutic product candidates and continue to develop our portfolio of existing therapeutic product candidates, either our own proprietary programs or those in collaboration with partners across our Therapeutics segment. Research and development expenses primarily consist of personnel-related expenses, including salaries, benefits, and stock-based compensation associated with our research and development personnel, collaboration expenses, preclinical and clinical trial costs, laboratory services and supplies costs, third-party data services, and allocated overhead.

We plan to continue to invest in personnel to support our research and development efforts. We intend to make significant investments in therapeutics research and development efforts as we ramp up our clinical trials and the GSK collaboration. This multi-year collaboration with GSK is expected to validate drug targets with novel genetic evidence, enable rapid progression of clinical programs, and bring useful new drugs to market. We expect that research and development expenses will increase on an absolute dollar basis in the foreseeable future as we continue to invest in our products, pipeline, and infrastructure for long-term growth. In addition, our research and development expenses may fluctuate as a percentage of revenue from period to period due to the timing and amount of these expenses.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of advertising costs, personnel-related expenses, including salaries, benefits, and stock-based compensation associated with our sales and marketing personnel, amortization of intangible assets, and outside services. Outside services are primarily related to sales consultants that support sales of PGS kits.

Advertising and brand costs consist primarily of direct expenses related to television and radio advertising, including production and branding, paid search, online display advertising, direct mail, affiliate programs, marketing collateral, market research and public relations. Advertising production costs are expensed the first time the advertising takes place, and all other advertising costs are expensed as incurred. Deferred advertising costs primarily consist of vendor payments made in advance to secure media spots across varying media channels, as well as production costs incurred before the first time the advertising takes place. Deferred advertising costs are expensed on the first date the advertisements occur. In addition, advertising costs include platform fees due to brokers related to our third-party retailers.

We expect our sales and marketing expenses to gradually decrease as a percentage of revenue over the long term, although our sales and marketing expenses may fluctuate as a percentage of revenue from period to period due to promotional strategies that drive the timing and amount of these expenses.

General and Administrative Expenses

General and administrative expenses primarily consist of personnel-related expenses, including salaries, benefits, and stock-based compensation associated with corporate management, including our CEO office, finance, legal, compliance, regulatory, and other administrative personnel. In addition, general and administrative expenses include professional fees for external legal, accounting, and other consulting services, net litigation settlement as well as credit card processing fees related to PGS kit sales and telehealth services.

We expect general and administrative expenses to increase for the foreseeable future as we increase headcount with the growth of our business. We also expect general and administrative expenses to increase in the near term as a result of operating as a public company, including expenses associated with compliance with SEC rules and regulations, and related increases in legal, audit, insurance, investor relations, professional services, and other administrative expenses. However, we anticipate general and administrative expenses to gradually decrease as a percentage of revenue over the long term, although it may fluctuate as a percentage of total revenue from period to period due to the timing and amount of these expenses.

Other (Expense) Income

Other (expense) income includes interest (expense) income, net, change in fair value of warrants liabilities, effects of changes in foreign currency exchange rates, and other (expense) income, net. Interest (expense) income, net primarily consists of interest income earned on our cash deposits. Other (expense) income, net primarily consists of other non-operating income and expenditures.

Benefit for Income Taxes

The income tax benefit primarily consists of a partial release in valuation allowance. Deferred tax assets are reduced by a valuation allowance to the extent management believes it is not more likely than not to be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income. Management makes estimates and judgments about future taxable income based on assumption that are consistent with our plans and estimates.

Results of Operations

Comparisons for years ended March 31, 2022 and 2021

The following table sets forth our consolidated statements of operations for the fiscal years ended March 31, 2022 and 2021, and the dollar and percentage change between the periods:

	Year Ended March 31,			
	2022	2021	$ Change	% Change
	(dollars in thousands)			
Revenue	$ 271,893	$ 243,920	$ 27,973	11%
Cost of revenue[(1)(2)]	138,948	126,914	12,034	9%
Gross profit	132,945	117,006	15,939	14%
Operating expenses:				
Research and development[(1)(2)]	189,377	159,856	29,521	18%
Sales and marketing[(1)(2)]	100,338	43,197	57,141	132%
General and administrative[(1)(2)]	97,383	99,149	(1,766)	(2%)
Total operating expenses	387,098	302,202	84,896	28%
Loss from operations	(254,153)	(185,196)	(68,957)	37%
Other (expense) income:				
Interest (expense) income, net	277	255	22	9%
Change in fair value of warrant liabilities	32,989	—	32,989	100%
Other (expense) income, net	(83)	1,322	(1,405)	(106%)
Loss before benefit for income taxes	(220,970)	(183,619)	(37,351)	20%
Benefit for income taxes	3,480	—	3,480	100%
Net loss	(217,490)	(183,619)	(33,871)	18%

(1) Includes stock-based compensation expense as follows:

	Year Ended March 31,	
	2022	2021
	(in thousands)	
Cost of revenue	$ 4,029	$ 858
Research and development	26,540	21,771
Sales and marketing	5,122	4,081
General and administrative	22,242	59,986
Total stock-based compensation expense	$ 57,933	$ 86,696

(2) Includes stock-based compensation expense related to secondary sale transactions as follows:

	Year Ended March 31,
	2021
	(in thousands)
Cost of revenue	$ 2
Research and development	48
Sales and marketing	9
General and administrative	1,670
Total stock-based compensation expense	$ 1,729

During the fiscal year ended March 31, 2022, there were no secondary sale transactions.

The following table sets forth our consolidated statements of operations data expressed as a percentage of revenue for the periods indicated:

	Year Ended March 31,	
	2022	2021
Revenue	100%	100%
Cost of revenue	51%	52%
Gross margin	49%	48%
Operating expenses:		
Research and development	69%	65%
Sales and marketing	37%	18%
General and administrative	36%	41%
Total operating expenses	142%	124%
Loss from operations	% (93)	(76%)
Other (expense) income:		
Interest (expense) income, net	0%	0%
Change in fair value of warrant liabilities	12%	0%
Other (expense) income, net	% (0)	1%
Loss before benefit for income taxes	% (81)	(75%)
Benefit for income taxes	1%	0%
Net loss	% (80)	(75%)

Revenue

Total revenue increased by $28.0 million, or 11%, for the fiscal year ended March 31, 2022, compared to the fiscal year ended March 31, 2021. The increase was due primarily to an increase of $24.4 million in consumer services revenue, driven mainly by the Lemonaid Acquisition, which resulted in $19.2 million in telehealth services revenue, subscription services revenue of $5.9 million, as well as higher PGS kit sales volume, which resulted from increased marketing spending and growth in consumer demand. The increase was also due to an increase of $3.6 million in research services revenue, driven mainly by an increase in GSK revenue of $6.1 million, partially offset by a decrease of $2.5 million in revenue for other (non-GSK) research services projects. The increase in GSK revenue was primarily attributable to a cumulative revenue adjustment of $9.0 million as a result of a change in estimate related to a change in total project resources resulting in a higher percentage of completion to date and was partially offset by $2.9 million of decreased revenue due to lower project hours incurred during the fiscal year ended March 31, 2022. This change in estimate only impacted the timing of revenue recognition as the total revenue to be recognized for the GSK research services project will remain the same. This change in estimate is discussed further in Note 7 of our consolidated financial statements included in Part II, Item 8 of this Form 10-K.

Cost of Revenue, Gross Profit and Gross Margin

Total cost of revenue increased by $12.0 million, or 9%, for the fiscal year ended March 31, 2022, compared to the fiscal year ended March 31, 2021. The increase in cost of revenue was due primarily to a $10.8 million increase in costs related to consumer services revenue, driven mainly by the addition of $13.1 million in costs associated with telehealth services from the Lemonaid Acquisition, which primarily related to personnel-related expenses, and $1.4 million in amortization expense for developed technology. The foregoing increases in costs related to consumer services revenue was partially offset by a decrease of $2.3 million related to PGS kit sales mainly due to lower lab processing and overhead costs. Additionally, costs associated with research services revenue increased by $1.2 million.

Our gross profit increased by $15.9 million, or 14%, to $132.9 million for the fiscal year ended March 31, 2022 from $117.0 million for the fiscal year ended March 31, 2021. The increase in gross profit was primarily due to the increases in consumer services revenue and research services revenue as discussed above, as well as lower lab processing costs.

Our gross margin improved year over year, from 48% for the fiscal year ended March 31, 2021 to 49% for the fiscal year ended March 31, 2022, due to increased revenue from subscription services, which generates a higher gross margin than our PGS kit sales, operating efficiencies and lower costs in lab processing, slightly offset by telehealth services margin.

Research and Development Expenses

The following table sets forth our research and development expenses for the fiscal years ended March 31, 2022 and 2021, and the dollar and percentage change between the periods:

	Year Ended March 31,			
	2022	2021	$ Change	% Change
	(dollars in thousands)			
Personnel-related expenses	$ 90,563	$ 74,734	$ 15,829	21%
Lab-related research services	40,900	33,258	7,642	23%
Depreciation, equipment and supplies	8,214	10,756	(2,542)	(24%)
Facilities, other overhead allocation, and other	49,700	41,108	8,592	21%
Total research and development expenses	$ 189,377	$ 159,856	$ 29,521	18%

Research and development expenses for the fiscal year ended March 31, 2022 was $189.4 million, compared to $159.9 million for the fiscal year ended March 31, 2021. This increase of $29.5 million, or 18%, is primarily attributable to the increase in personnel-related expenses of $15.8 million, due to growth in headcount and stock-based compensation for new equity awards granted. In addition, facilities, other overhead allocation, and other increased by $8.6 million due to higher allocated overhead costs related to increased research and development headcount, as well as increased personnel-related expenses for shared costs departments and a $2.1 million increase in consulting services during the fiscal year ended March 31, 2022. Lab-related research services related to funding for our programs with GSK and to advancing our Therapeutics portfolio also increased by $7.6 million. These increases were partially offset by a $2.5 million decrease in depreciation, equipment and supplies primarily due to an operating lease amendment to extend the lease term of the Company's facility located in South San Francisco, California, which increased the asset life leasehold improvement assets.

For the fiscal years ended March 31, 2022 and 2021, 53% and 55% of total research and development expenses are attributable to the Consumer and Research Services business, respectively, and 47% and 45% are attributable to our Therapeutics business, respectively. The increase attributable to the Therapeutics business is driven by our continued investment in drug discovery and advancement of ongoing programs.

Sales and Marketing Expenses

The following table sets forth our sales and marketing expenses for fiscal years ended March 31, 2022 and 2021, and the dollar and percentage change between the periods:

	Year Ended March 31,			
	2022	2021	$ Change	% Change
	(dollars in thousands)			
Advertising & brand	$ 65,476	$ 16,227	$ 49,249	304%
Personnel-related expenses	15,653	13,954	1,699	12%
Outside services, equipment and supplies	5,760	5,057	703	14%
Depreciation & Amortization	5,586	—	5,586	100%
Facilities and other overhead allocation	7,863	7,959	(96)	(1%)
Total sales and marketing expenses	$ 100,338	$ 43,197	$ 57,141	132%

Sales and marketing expenses for the fiscal year ended March 31, 2022 amounted to $100.3 million, compared to $43.2 million for the fiscal year ended March 31, 2021, representing an increase of $57.1 million, or 132%. This increase was primarily driven by the $49.2 million increase in advertising and brand-related spend in our marketing programs to grow our consumer business. Depreciation and amortization increased $5.6 million due to amortization of acquired intangible assets from the Lemonaid Acquisition.

General and Administrative Expenses

Total general and administrative expenses decreased by $1.8 million, or 2%, from $99.1 million for the fiscal year ended March 31, 2021 to $97.4 million for the fiscal year ended March 31, 2022. The decrease in general and administrative expenses was due primarily to a $34.6 million decrease in personnel-related expenses, mainly due to a $39.7 million decrease in stock-based compensation expense, offset by a $5.1 million increase in other personnel-related expenses due to increased headcount. The $39.7 million decrease in stock-based compensation expense was attributable to a $51.1 million decrease arising from an option modification that occurred in the prior fiscal year and secondary transactions that also occurred during the prior fiscal year, partially offset by an $11.3 million increase related to new equity award grants, including shares granted in connection with the Lemonaid Acquisition. The foregoing decreases were partially offset by a $21.8 million increase in outside services, mainly attributable to increased advisory, legal and consulting services related to the Business Combination and the Lemonaid Acquisition, integration fees and $10.0 million in net litigation settlement, and a $9.2 million increase in other operating expenses, mainly due to an increase in director and officer insurance as a public company and credit card processing fees related to the increase in PGS kit sales and telehealth services. There was also a $1.9 million increase in facilities expenses and other overhead allocation due to higher allocated overhead costs and increased headcount.

Interest (Expense) Income, Net

Interest (expense) income, net was $0.3 million for both the fiscal years ended March 31, 2022 and 2021, respectively.

Change in Fair Value of Warrant Liabilities

Change in fair value of warrant liabilities increased by $33.0 million, or 100%, from nil for the fiscal year ended March 31, 2021 to $33.0 million for the fiscal year ended March 31, 2022. This increase was due to a reduction in the fair value of the Warrants that were assumed in connection with the Business Combination, which was primarily driven by movements in our stock price and volatility measurements.

As of March 31, 2022, all Warrants were exercised or redeemed. Accordingly, there are no warrant liabilities outstanding.

Other (Expense) Income, Net

Other (expense) income, net decreased by $1.4 million, or 106%, from $1.3 million for the fiscal year ended March 31, 2021 to less than $(0.1) million for the fiscal year ended March 31, 2022. This decrease was primarily due to a lease reassessment that occurred in June 2020, which resulted in a one-time $0.9 million gain during for the fiscal year ended March 31, 2021.

Benefit for Income Taxes

Benefit for income taxes, net increased by $3.5 million, or 100%, from nil for the fiscal year ended March 31, 2021 to $3.5 million for the fiscal year ended March 31, 2022. This increase was primarily due to the partial release of valuation allowance totaling $3.5 million as a result of acquisitions.

Adjusted EBITDA

We evaluate the performance of each segment based on Adjusted EBITDA, which is a non-GAAP financial measure that we define as net income before net interest expense (income), net other expense (income), changes in fair value of warrant liabilities, income tax benefit, depreciation and amortization of fixed assets, amortization of internal use software, amortization of acquired intangible assets, non-cash stock-based compensation expense, acquisition-related costs, litigation settlements not related to normal and continued business activities, and expenses related to restructuring and other charges, if applicable for the period. Adjusted EBITDA is a key measure used by our management and our Board of Directors to understand and evaluate our operating performance and trends, to prepare and approve our annual budget, and to develop short- and long-term operating plans. In particular, we believe that the exclusion of the items eliminated in calculating Adjusted EBITDA provides useful measures for period-to-period comparisons of our business. Accordingly, we believe that Adjusted EBITDA provides useful information in understanding and evaluating our operating results in the same manner as our management and our Board of Directors. Adjusted EBITDA should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. Other companies, including companies in our industry, may calculate similarly-titled non-GAAP financial measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of Adjusted EBITDA as a tool for comparison. There are a number of limitations related to the use of these non-GAAP financial measures rather than net loss, which is the most directly comparable financial measure calculated in accordance with GAAP.

Some of the limitations of Adjusted EBITDA include (i) Adjusted EBITDA does not properly reflect capital commitments to be paid in the future, and (ii) although depreciation and amortization are non-cash charges, the underlying assets may need to be replaced and Adjusted EBITDA does not reflect these capital expenditures. In evaluating Adjusted EBITDA, you should be aware that in the future we will incur expenses similar to the adjustments in this presentation. Our presentation of Adjusted EBITDA should not be construed as an inference that our future results will be unaffected by these expenses or any unusual or non-recurring items. When evaluating our performance, you should consider Adjusted EBITDA alongside other financial performance measures, including our net loss and other GAAP results.

The following tables reconcile net loss to Adjusted EBITDA for fiscal years ended March 31, 2022 and 2021 on a company-wide basis and for each of our segments:

	Year Ended March 31,	
	2022	2021
	(in thousands)	
Segment Revenue		
Consumer & Research Services	$ 271,893	$ 243,866
Therapeutics	—	54
Total revenue	$ 271,893	$ 243,920
Segment Adjusted EBITDA		
Consumer & Research Services Adjusted EBITDA	$ (30,112)	$ 12,796
Therapeutics Adjusted EBITDA	(76,944)	(58,734)
Unallocated Corporate [1]	(43,684)	(30,587)
Total Adjusted EBITDA	$ (150,740)	$ (76,525)
Reconciliation of net loss to Adjusted EBITDA		
Net loss	$ (217,490)	$ (183,619)
Adjustments:		
Interest (income) expense, net	(277)	(255)
Other (income) expense, net	83	(1,322)
Change in fair value of warrant liabilities	(32,989)	—
Income tax benefit	(3,480)	—
Depreciation and amortization	18,899	20,246
Amortization of acquired intangible assets	7,269	—
Stock-based compensation expense	57,933	88,425
Restructuring and other charges	—	—
Acquisition-related costs [2]	9,362	—
Litigation settlement [3]	9,950	—
Total Adjusted EBITDA	$ (150,740)	$ (76,525)

(1) Certain expenses such as Finance, Legal, Regulatory and Supplier Quality, and CEO Office are not reported as part of the reporting segments as reviewed by the CODM. These amounts are included in Unallocated Corporate.

(2) For the fiscal years ended March 31, 2022, acquisition-related costs primarily consisted of advisory, legal and consulting fees related to the Lemonaid Acquisition.

(3) For the fiscal year ended March 31, 2022, litigation settlement is litigation cost net of insurance recoveries, which is not expected to occur on a recurring basis and not part of the Company's normal and continued business activity.

Liquidity and Capital Resources

We have financed our operations primarily through sales of equity securities and revenue from sales of PGS, telehealth, and research services. We received gross proceeds of $309.7 million from the Business Combination and $250.0 million from the PIPE Investment (as defined in Note 3 of our consolidated financial statements included in Part II, Item 8 of this Form 10-K). Our primary requirements for liquidity and capital are to fund operating needs and finance working capital, capital expenditures, and general corporate purposes.

As of March 31, 2022, our principal source of liquidity was our cash balance of $553.2 million, which is held for working capital purposes. We have generated significant operating losses as reflected in our accumulated deficit and negative cash flows from operations. We had accumulated deficit of $1.2 billion and $1.0 billion as of March 31, 2022 and 2021, respectively. As of the date of this Form 10-K, we believe our existing cash resources are sufficient to continue operating activities for the next 12 months.

We expect to continue to incur operating losses and generate negative cash flows from operations for the foreseeable future due to the investments we intend to continue to make in research and development, and additional general and administrative costs we expect to incur in connection with operating as a public company. Cash from operations could also be affected from our customers and other risks detailed in "Risk Factors" in Part I, Item 1A of this Form 10-K. We expect to continue to maintain financing flexibility in the current market conditions. As a result, we may require additional capital resources to execute strategic initiatives to grow our business.

Our future capital requirements will depend on many factors including our revenue growth rate, the timing and extent of spending to support further sales and marketing, and research and development efforts. We may be required to seek additional equity or debt financing. In the event that additional financing is required from outside sources, we may not be able to raise it on terms acceptable to us or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. Future debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be materially and adversely affected.

Cash Flows

The following table summarizes our cash flows for the periods presented:

	Year Ended March 31,	
	2022	2021
	(in thousands)	
Net cash (used in) operating activities	$ (166,828)	$ (74,252)
Net cash (used in) investing activities	$ (108,137)	$ (6,536)
Net cash provided by financing activities	$ 546,004	$ 155,335

Cash Flows from Operating Activities

Net cash used in operating activities of $166.8 million for the fiscal year ended March 31, 2022 was primarily related to a net loss of $217.5 million and changes in fair value of warrant liabilities of $33.0 million, partially offset by non-cash charges for stock-based compensation of $57.9 million, depreciation and amortization of $23.7 million and amortization of internal-use software of $2.4 million. The net changes in operating assets and liabilities of $0.5 million were primarily related to an increase in prepaid expenses and other current assets of $10.1 million primarily due to increases in prepaid insurance and other receivables, a decrease in deferred revenue of $8.8 million primarily due to more kit sales from holiday sales than revenue recognized during the period, a decrease in operating lease liabilities of $7.1 million primarily due to lease payments, an increase in inventories of $4.3 million due to increased purchases aligned with higher forecasted sales, an increase in deferred cost of revenue of $2.2 million primarily due to an increase in PGS kit sales for the holiday season, an increase in other assets of $1.8 million primarily due to an increase in long-term prepaid expenses, and an increase in accounts receivable of $0.9 million primarily attributable to seasonal holiday sales through Amazon.com. These were offset by an increase in accounts payable of $22.9 million primarily due to the timing of payments, an increase in accrued expenses and other current liabilities of $8.3 million primarily due to timing of vendor invoice receipts, a decrease in operating lease right-of-use assets of $7.1 million primarily due to right-of-use assets amortization, and a decrease in other liabilities of $3.6 million mainly related to a deferred income tax benefit recognized for partial release of valuation allowance.

Net cash used in operating activities of $74.3 million for the fiscal year ended March 31, 2021 was primarily related to a net loss of $183.6 million, partially offset by non-cash charges for stock-based compensation of $88.4 million and depreciation and amortization of $18.1 million. The net changes in operating assets and liabilities of $1.5 million were primarily related to a decrease in deferred revenue of $16.2 million as a result of reduced deferred revenue balance related to GSK, and a decrease in operating lease liabilities of $8.5 million primarily due to lease payments. These were offset by a decrease in operating lease right-of-use assets of $10.3 million due to right-of-use assets amortization and adjustment to the carrying amount of the right-of-use assets, a decrease in inventories of $7.9 million due to decreased purchase aligned with lower forecasted sales, a decrease in accounts receivable of $3.9 million, as well as a decrease in deferred cost of revenue of $1.2 million due to decrease in PGS kit sales, and a decrease in prepaid expenses and other current assets of $2.1 million due to decrease in deferred advertising and other receivables.

Cash Flows from Investing Activities

Cash flows from investing activities primarily relate to purchase of property and equipment, prepayments for intangible assets, as well as capitalization of internal-use software costs.

Net cash used in investing activities was $108.1 million for the fiscal year ended March 31, 2022, which consisted of cash paid for acquisitions, net of cash acquired of $94.2 million, purchases of intangible assets of $5.5 million related to a patent rights purchase, capitalization of internal-use software costs of $4.5 million and purchases of property and equipment of $4.0 million.

Net cash used in investing activities was $6.5 million for the fiscal year ended March 31, 2021, which consisted of purchases of property and equipment of $4.0 million and capitalization of internal-use software costs of $3.3 million, partially offset by proceeds from sale of property and equipment of $0.8 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was $546.0 million for the fiscal year ended March 31, 2022, which consisted of $309.7 million in proceeds from the Business Combination, $250.0 million of proceeds from the PIPE Investment, and $17.0 million in proceeds from the exercise of stock options, which were partially offset by $30.6 million in payments of deferred offering costs, and $0.1 million in payments for Warrant redemptions.

Net cash provided by financing activities was $155.3 million for the fiscal year ended March 31, 2021, which consisted of $82.2 million in proceeds from the issuance of convertible preferred stock, net of issuance costs, and $76.2 million in proceeds from the exercise of stock options, which were partially offset by $3.1 million in payments of deferred offering costs.

Contractual Obligations and Commitments

Our lease portfolio includes leased offices, dedicated lab facility and storage space, and dedicated data center facility space, with remaining contractual periods from 1.8 years to 9.3 years. Refer to Note 11 of our consolidated financial statements included in Part II, Item 8 of this Form 10-K for a summary of our future minimum lease obligations.

In the normal course of business, we enter into non-cancelable purchase commitments with various parties for purchases. Refer to Note 11 of our consolidated financial statements included in Part II, Item 8 of this Form 10-K for a summary of our commitments as of March 31, 2022.

Critical Accounting Policies and Estimates

Our consolidated financial statements and the related notes thereto included elsewhere in this Form 10-K are prepared in accordance with GAAP. The preparation of consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations, and cash flows will be affected. We believe the following are the critical accounting policies used in the preparation of our consolidated financial statements, as well as the significant estimates and judgments affecting the application of these policies. This discussion and analysis should be read in conjunction with our consolidated financial statements and related notes included in this report.

Our significant accounting policies are described in Note 2 of our consolidated financial statements included in Part II, Item 8 of this Form 10-K. These are the policies that we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

Revenue Recognition

We generate revenue from our Consumer & Research Services segment, which includes revenue from PGS, telehealth, and research services, and our Therapeutics segment. In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that we expect to receive in exchange for these goods or services.

We sell through multiple channels, including direct-to-consumer via our website and through online retailers. If the customer does not return the Kit, services cannot be completed by us, potentially resulting in unexercised rights ("breakage") revenue. To estimate breakage, we apply the practical expedient available under ASC 606 to assess our customer contracts on a portfolio basis as opposed to individual customer contracts, due to the similarity of customer characteristics, at the sales channel level. We recognize the breakage amounts as revenue, proportionate to the pattern of revenue recognition of the returning kits in these respective sales channel portfolios. We estimate breakage for the portion of Kits not expected to be returned using an analysis of historical data and consider other factors that could influence customer Kit return behavior. We update our breakage rate estimate periodically and, if necessary, adjust the deferred revenue balance accordingly. If actual return patterns vary from the estimate, actual breakage revenue may differ from the amounts recorded. We recognized breakage revenue from unreturned kits of $21.9 million and $24.1 million for the fiscal years ended March 31, 2022 and 2021, respectively.

We generate telehealth revenues from patient fees, pharmacy fees, and membership fees.

In providing telehealth services that include professional medical consultations, we maintain relationships with various affiliated PMCs, which are professional entities owned by licensed physicians and that engage licensed healthcare professionals (each, a "Provider" and collectively, the "Providers") to provide consultation services. We account for service revenue as a principal in the arrangement with our patients.

Additionally, with respect to our telehealth services involving the sale of prescription products, we maintain relationships with affiliated pharmacies (collectively, the "Affiliated Pharmacies") to fill prescriptions that are ordered by our patients. We account for prescription product revenue as a principal in the arrangement with our patients.

Business Combinations

We account for our business combinations using the acquisition method of accounting, which requires, among other things, allocation of the fair value of purchase consideration to the tangible and intangible assets acquired and liabilities assumed at their estimated fair values on the acquisition date. The excess of the fair value of purchase consideration over the values of these identifiable assets and liabilities is recorded as goodwill. The results of businesses acquired in a business combination are included in our consolidated financial statements from the date of acquisition. Acquisition costs, such as legal and consulting fees, are expensed as incurred.

Determining the fair value of assets acquired and liabilities assumed requires management to use significant judgment and estimates, including the selection of valuation methodologies, estimates of future revenue and cash flows, discount rates, and selection of comparable companies. The estimates and assumptions used to determine the fair values and useful lives of identified intangible assets could change due to numerous factors, including market conditions, technological developments, economic conditions, and competition. Our estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. During the measurement period, not to exceed one year from the date of acquisition, we may record adjustments to the assets acquired and liabilities assumed, with a corresponding offset to goodwill if new information is obtained related to facts and circumstances that existed as of the acquisition date. After the measurement period, any subsequent adjustments are reflected in the consolidated statements of operations and comprehensive loss.

When we issue stock-based or cash awards to an acquired company's stockholders, we evaluate whether the awards are consideration or compensation for post-acquisition services. The evaluation includes, among other things, whether the vesting of the awards is contingent on the continued employment of the acquired company's stockholders beyond the acquisition date. If continued employment is required for vesting, the awards are treated as compensation for post-acquisition services and recognized as expense over the requisite service period.

Uncertain tax positions and tax-related valuation allowances are initially established in connection with a business combination as of the acquisition date. We continue to collect information and reevaluate these estimates and assumptions quarterly. We will record any adjustments to our preliminary estimates to goodwill, provided that it is within the one-year measurement period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We have operations primarily within the United States and we are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. We do not believe that inflation has had a material effect on our business, results of operations or financial condition. Nonetheless, if our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs. Our inability or failure to do so could harm our business, results of operations or financial conditions.

Interest Rate Risk

As of March 31, 2022 and 2021, we had cash of $553.2 million and $282.5 million, respectively. Cash consists of cash in banks and bank deposits and is not subject to market risk. A hypothetical 10% change in interest rates during any of the 12-month periods presented would not have had a material impact on our historical consolidated financial statements for the fiscal years ended March 31, 2022, 2021 or 2020.

Foreign Currency Risk

Our results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates. Currently, substantially all our revenue and expenses are denominated in U.S. dollars. Revenue and expenses are remeasured each day at the exchange rate in effect on the day the transaction occurred. Our results of operations and cash flows in the future may be adversely affected due to an expansion of non-U.S. dollar denominated contracts and changes in foreign exchange rates. The effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have a material impact on our historical or current consolidated financial statements. To date, we have not engaged in any hedging strategies. As our international activities grow, we will continue to reassess our approach to manage the risk relating to fluctuations in currency rates.

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
23andMe Holding Co.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of 23andMe Holding Co. and subsidiaries (the Company) as of March 31, 2022 and March 31, 2021, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended March 31, 2022, and the related notes (collectively, 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 March 31, 2022 and March 31, 2021, and the results of its operations and its cash flows for each of the years in the three-year period ended March 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Sufficiency of audit evidence over breakage revenue

As described in Note 2 to the consolidated financial statements, the Company sells its Personal Genomic Service kits through multiple channels, including direct to consumer via the Company's website and through online retailers. In contracts with customers for consumer services, if the customer does not return the kit, services cannot be completed by the Company, potentially resulting in unexercised rights (breakage) revenue. To estimate breakage, the Company assesses customer contracts on a portfolio basis as opposed to individual customer contracts, due to the similarity of customer characteristics, at the sales channel level. The Company recognizes the breakage amounts as revenue, proportionate to the pattern of revenue recognition of the returning kits in these respective sales channel portfolios. The Company estimates breakage for the portion of kits not expected to be returned using an analysis of historical data and considers other factors that could influence customer kit return behavior. The Company updates its breakage estimate rate periodically and, if necessary, adjusts the deferred revenue balance accordingly. If actual return patterns vary from the estimate, actual breakage revenue may differ from the amounts recorded. The Company recognized $21.9 million in breakage revenue in the year ended March 31, 2022.

We identified the evaluation of the sufficiency of audit evidence over breakage revenue related to sales made direct to consumer via the Company's website for sales of the Company's Health & Ancestry and Ancestry & Traits kits as a critical audit matter. Evaluating the sufficiency of audit evidence required a higher degree of auditor judgment due to the volume of historical data required to estimate the portion of kits not expected to be returned and the manual nature of the calculation.

The following are the primary procedures we performed to address this critical audit matter. We applied auditor judgement to determine the nature and extent of procedures to be performed over breakage revenue. We assessed the completeness of the reports used by the Company to estimate the breakage rate by reconciling them to the general ledger and we assessed the accuracy of the reports by comparing them to evidence of cash receipt and third-party invoices for a sample of revenue transactions. In addition, we checked the accuracy of management's calculations. We evaluated the sufficiency of audit evidence obtained by assessing the results of procedures performed.

Valuation of acquired intangible assets in the Lemonaid Health, Inc. business combination

As described in Note 4 to the consolidated financial statements, on November 1, 2021, the Company completed the acquisition of Lemonaid Health, Inc. and subsidiaries for purchase price consideration of $424.7 million. As part of the acquisition, the Company acquired $76 million of intangible assets, including developed technology, trade name, and customer relationships.

We identified the assessment of the valuation of the acquisition date fair value of the developed technology, trade name, and customer relationships intangible assets acquired as a critical audit matter. We performed sensitivity analyses to determine the significant assumptions used to value the acquired intangible assets, individually and in the aggregate. The fair value of these acquired intangible assets were sensitive to possible changes to the following key assumptions, requiring a high degree of auditor judgement and the use of valuation professionals with specialized skills and knowledge:

Developed Technology

- revenue forecasts
- obsolescence rate
- royalty rate
- discount rate

Trade name

- revenue forecasts
- royalty rate
- discount rate

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design of certain internal controls related to the Company's process to value acquired intangible assets. We evaluated the reasonableness of the Company's revenue forecasts by comparing them to historical actual results of the acquired entities and certain peer and market participant data. We also involved valuation professionals with specialized skills and knowledge, who assisted in assessing the appropriateness of:

- the methodologies utilized in determining the valuation of developed technology, customer relationships, and trade name intangible assets
- the royalty rates used to value the developed technology and trade name by comparing them to royalty rates from publicly available industry licensing information
- the discount rate applied by computing an independently developed range using publicly available market data for comparable entities
- evaluating the appropriateness of the guideline comparable companies selected by management's third-party valuation advisor
- the obsolescence rate used to value the developed technology which is estimated as a function of the useful life, corroborated by benchmarking analysis and inquiry of management.

/s/ KPMG LLP

We have served as the Company's auditor since 2020.

Santa Clara, California
May 27, 2022

23ANDME HOLDING CO.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	March 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash	$ 553,182	$ 282,489
Restricted cash	1,599	1,399
Accounts receivable, net	3,380	2,481
Inventories	10,789	6,239
Deferred cost of revenue	7,700	5,482
Prepaid expenses and other current assets	25,139	15,485
Total current assets	601,789	313,575
Property and equipment, net	49,851	60,884
Operating lease right-of-use assets	55,577	63,122
Restricted cash, noncurrent	6,974	6,974
Internal-use software, net	9,635	6,889
Intangible assets, net	73,905	—
Goodwill	351,744	—
Other assets	2,593	654
Total assets	$ 1,152,068	$ 452,098
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable (related party amounts of $12,567 and $4,422 as of March 31, 2022 and 2021, respectively)	$ 37,930	$ 12,271
Accrued expenses and other current liabilities (related party amounts of $5,772 and $7,065 as of March 31, 2022 and 2021, respectively)	44,588	31,953
Deferred revenue (related party amounts of $9,181 and $30,140 as of March 31, 2022 and 2021, respectively)	62,939	71,255
Operating lease liabilities	7,784	6,140
Total current liabilities	153,241	121,619
Operating lease liabilities, noncurrent	78,524	87,582
Other liabilities	4,647	1,165
Total liabilities	$ 236,412	$ 210,366
Commitments and contingencies (Note 11)		
Redeemable convertible preferred stock		
Redeemable convertible preferred stock, $0.0001 par value per share, 10,000,000 shares authorized as of March 31, 2022, and $0.00001 par value per share, 209,512,070 shares authorized as of March 31, 2021; nil and 209,181,855 shares issued and outstanding as of March 31, 2022 and 2021, respectively; aggregate liquidation preference of nil and $874,107 as of March 31, 2022 and 2021, respectively	—	837,351
Stockholders' equity (deficit)		
Common Stock - Class A shares, par value $0.0001, 1,140,000,000 and 390,921,975 shares authorized and 228,174,718 and 20,713,076 shares issued and outstanding as of March 31, 2022 and 2021, respectively; Class B shares, par value $0.0001, 350,000,000 and 380,944,977 shares authorized and 220,637,603 and 103,816,708 shares issued and outstanding as of March 31, 2022 and 2021, respectively; Class C shares, par value $0.0001, nil and 72,276,062 shares authorized and no shares issued and outstanding as of March 31, 2022 and 2021, respectively	45	12
Additional paid-in capital	2,110,160	381,607
Accumulated other comprehensive income	179	—
Accumulated deficit	(1,194,728)	(977,238)
Total stockholders' equity (deficit)	915,656	(595,619)
Total liabilities and stockholders' equity (deficit)	$ 1,152,068	$ 452,098

The accompanying notes are an integral part of these consolidated financial statements.

23ANDME HOLDING CO.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended March 31,		
	2022	**2021**	**2020**
Revenue (related party amounts of $46,064, $39,917 and $26,749 for the years ended March 31, 2022, 2021 and 2020, respectively)	$ 271,893	$ 243,920	$ 305,463
Cost of revenue (related party amounts of $299, $(1,400) and $994 for the years ended March 31, 2022, 2021 and 2020, respectively)	138,948	126,914	168,031
Gross profit	132,945	117,006	137,432
Operating expenses:			
Research and development (related party amounts of $23,954, $18,684 and $19,058 for the years ended March 31, 2022, 2021 and 2020, respectively)	189,377	159,856	181,276
Sales and marketing	100,338	43,197	110,519
General and administrative	97,383	99,149	59,392
Restructuring and other charges	—	—	44,692
Total operating expenses	387,098	302,202	395,879
Loss from operations	(254,153)	(185,196)	(258,447)
Other (expense) income:			
Interest (expense) income, net	277	255	6,244
Change in fair value of warrant liabilities	32,989	—	—
Other (expense) income, net	(83)	1,322	1,340
Loss before income taxes	(220,970)	(183,619)	(250,863)
Benefit from income taxes	3,480	—	—
Net loss	$ (217,490)	$ (183,619)	$ (250,863)
Other comprehensive income	179	—	—
Total comprehensive loss	$ (217,311)	$ (183,619)	$ (250,863)
Net loss per share of Class A and Class B common stock attributable to common stockholders:			
Basic and diluted	$ (0.60)	$ (1.84)	$ (2.84)
Weighted-average shares used to compute net loss per share:			
Basic and diluted	361,528,119	99,660,786	88,201,337

The accompanying notes are an integral part of these consolidated financial statements.

23ANDME HOLDING CO.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share and per share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of March 31, 2019	86,443,341	$ 755,083	41,923,516	$ —	$ 101,474	$ —	$ (542,756)	$ (441,282)
Recapitalization	111,831,592	—	54,236,376	9	(9)	—	—	—
Balance as of March 31, 2019	198,274,933	$ 755,083	96,159,892	$ 9	$ 101,465	$ —	$ (542,756)	$ (441,282)
Issuance of common stock upon exercise of stock options	—	—	5,492,907	—	8,732	—	—	8,732
Vesting of early exercised stock options	—	—	—	—	16,962	—	—	16,962
Stock-based compensation expense	—	—	—	—	45,568	—	—	45,568
Net loss	—	—	—	—	—	—	(250,863)	(250,863)
Balance as of March 31, 2020	198,274,933	$ 755,083	101,652,799	$ 9	$ 172,727	$ —	$ (793,619)	$ (620,883)
Issuance of Series F-1 redeemable convertible preferred stock at $7.56 per share, net of issuance costs of $232	10,906,922	82,268	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	11,768,079	1	29,091	—	—	29,092
Issuance of common stock related to early exercise of stock options	—	—	11,108,906	—	—	—	—	—
Vesting of early exercised stock options	—	—	—	2	91,044	—	—	91,046
Stock-based compensation expense	—	—	—	—	88,745	—	—	88,745
Net loss	—	—	—	—	—	—	(183,619)	(183,619)
Balance as of March 31, 2021	209,181,855	$ 837,351	124,529,784	$ 12	381,607	$ —	(977,238)	$ (595,619)
Preferred stock conversion	(209,181,855)	(837,351)	209,181,855	21	837,330	—	—	837,351
Issuance of common stock upon Merger (net of transaction costs of $33,726)	—	—	46,901,747	5	200,574	—	—	200,579
Issuance of PIPE shares (related party amount of $25,000)	—	—	25,000,000	3	249,997	—	—	250,000

Issuance of common stock upon exercise of stock options	—	—	5,808,526	—	16,831	—	—	16,831
Issuance of common stock for acquisition of business	—	—	30,572,268	3	322,842	—	—	322,845
Issuance of common stock for Class A common stock warrant exercise	—	—	6,016,347	1	42,355	—	—	42,356
Stock-based compensation expense	—	—	—	—	58,624	—	—	58,624
Issuance of common stock upon release of RSUs	—	—	801,794	—	—	—	—	—
Other comprehensive income	—	—	—	—	—	179	—	179
Net loss	—	—	—	—	—	—	(217,490)	(217,490)
Balance as of March 31, 2022	—	$ —	448,812,321	$ 45	$2,110,160	$ 179	$ (1,194,728)	$ 915,656

The accompanying notes are an integral part of these consolidated financial statements.

23ANDME HOLDING CO.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended March 31,		
	2022	**2021**	**2020**
Cash flows from operating activities:			
Net loss	$ (217,490)	$ (183,619)	$ (250,863)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	23,699	18,078	22,249
Amortization and impairment of internal-use software	2,449	2,168	1,040
Stock-based compensation expense	57,933	88,425	44,838
Changes in fair value of warrant liabilities	(32,989)	—	—
Loss on disposal of property and equipment	100	57	6
Gain on lease termination	(15)	(876)	—
Impairment of long-lived assets	—	—	33,213
Changes in operating assets and liabilities:			
Accounts receivable (related party amounts of nil, nil and $2,000 for the years ended March 31, 2022, 2021 and 2020, respectively)	(899)	3,912	4,207
Inventories	(4,262)	7,884	(440)
Deferred cost of revenue	(2,219)	1,163	7,184
Prepaid expenses and other current assets	(10,077)	2,126	3,379
Operating lease right-of-use assets	7,078	10,288	14,557
Other assets	(1,820)	573	480
Accounts payable (related party amounts of $8,145, $191 and $4,231 for the years ended March 31, 2022, 2021 and 2020, respectively)	22,856	137	(29,809)
Accrued expenses and other current liabilities (related party amounts of $ (1,293), $3,517 and $(2,599) for the years ended March 31, 2022, 2021 and 2020, respectively)	8,316	82	4,916
Deferred revenue (related party amounts of $(20,959), $(14,917) and $251 for the years ended March 31, 2022, 2021 and 2020, respectively)	(8,799)	(16,210)	(35,333)
Operating lease liabilities	(7,054)	(8,528)	(5,431)
Other liabilities	(3,635)	88	41
Net cash used in operating activities	(166,828)	(74,252)	(185,766)
Cash flows from investing activities:			
Purchases of property and equipment	(3,968)	(4,054)	(68,371)
Purchases of intangible assets (patents)	(5,500)	—	—
Proceeds from sale of property and equipment	1	838	765
Capitalized internal-use software costs	(4,505)	(3,320)	(5,217)
Cash paid for acquisitions, net of cash acquired	(94,165)	—	—
Net cash used in investing activities	(108,137)	(6,536)	(72,823)
Cash flows from financing activities:			
Proceeds from issuance of redeemable convertible preferred stock	—	82,500	—
Payments for issuance costs of redeemable convertible preferred stock	—	(232)	—
Proceeds from exercise of stock options (related party amounts of nil, $67,359 and nil for the years ended March 31, 2022, 2021 and 2020, respectively)	16,998	76,151	8,830
Payments of deferred offering costs	(30,642)	(3,084)	—
Proceeds from issuance of common stock upon Merger	309,720	—	—
Proceeds from PIPE (related party amounts of $25,000, nil and nil for the years ended March 31, 2022, 2021 and 2020, respectively)	250,000	—	—
Proceeds from exercise of merger warrants	44	—	—

Payment for warrant redemptions	(116)	—	—
Net cash provided by financing activities	546,004	155,335	8,830
Effect of exchange rates on cash	(146)	—	—
Net increase (decrease) in cash and restricted cash	270,893	74,547	(249,759)
Cash and restricted cash—beginning of period	290,862	216,315	466,074
Cash and restricted cash—end of period	561,755	290,862	216,315
Supplemental disclosures of non-cash investing and financing activities:			
Purchases of property and equipment during the period included in accounts payable and accrued expenses	722	535	3,221
Stock-based compensation capitalized for internal-use software costs	1,166	637	792
Reclassification of transaction costs	3,971	—	—
Vesting of related party early exercised stock options	—	91,046	16,962
Assumption of merger warrants liability	75,415	—	—
Deferred offering costs during the period included in accounts payable and accrued expenses	—	887	—
Conversion of redeemable convertible preferred stock to common stock	837,351	—	—
Redemption/exercise of Class A common stock warrants	42,354	—	—
Stock consideration in acquisition of businesses, including fair value of common stock issued and fair value of stock-based awards that were vested	322,842	—	—
Reconciliation of cash and restricted cash within the consolidated balance sheets to the amounts shown in the consolidated statements of cash flows above:			
Cash	553,182	282,489	207,942
Restricted cash, current	1,599	1,399	1,399
Restricted cash, noncurrent	6,974	6,974	6,974
Total cash and restricted cash	$ 561,755	$ 290,862	$ 216,315

The accompanying notes are an integral part of these consolidated financial statements.

23ANDME HOLDING CO.

Notes to Consolidated Financial Statements

1. Organization and Description of Business

23andMe Holding Co. (the "Company") is dedicated to helping people access, understand, and benefit from the human genome. The Company pioneered direct-to-consumer genetic testing through its Personal Genome Service® ("PGS") products and services. Customers receive reports that provide them with information on their genetic health risks, their ancestry, and their traits, based on genetic testing of a saliva sample they send to the Company in an easy-to-use "spit kit" provided by the Company. Customers have the option to participate in the Company's research programs. The Company analyzes consenting customers' genotypic and phenotypic data to discover new insights into genetics. The Company uses these insights to generate new PGS reports, and, through its therapeutics business and collaborations with pharmaceutical companies, nonprofit institutions and universities, to discover and advance new therapies for unmet medical needs. 23andMe, Inc., the Company's accounting predecessor, was incorporated in Delaware in 2006. The Company is headquartered in South San Francisco, California.

On November 1, 2021, the Company completed its acquisition (the "Lemonaid Acquisition") of Lemonaid Health, Inc. ("Lemonaid" or "Lemonaid Health"), pursuant to that certain Agreement and Plan of Merger and Reorganization (the "Lemonaid Health Merger Agreement"), dated as of October 21, 2021. Lemonaid Health offers patients affordable and direct online access to medical care, from consultation through treatment, for a number of common conditions, using evidence-based guidelines and up-to-date clinical protocols to deliver quality patient care. Lemonaid Health's telehealth platform provides patients with easy access to medical consultation and treatment, which enhances the Company's ability to bring better healthcare and wellness offerings to patients. See Note 4, "Acquisitions," for additional details.

On June 16, 2021 (the "Closing Date"), the Company consummated the transactions (the "Merger") contemplated by the Agreement and Plan of Merger, dated February 4, 2021, as amended on February 13, 2021 and March 25, 2021, by and among VG Acquisition Corp., a blank check company incorporated as a Cayman Islands exempted company in 2020 ("VGAC"), Chrome Merger Sub, Inc., a Delaware corporation and wholly owned direct subsidiary of VGAC (the "Merger Sub"), and 23andMe, Inc. (the "Merger Agreement"). In connection with the Merger, VGAC changed its jurisdiction of incorporation from the Cayman Islands to the State of Delaware and changed its name to 23andMe Holding Co. (the "Domestication"). On the Closing Date, Merger Sub merged with and into 23andMe, Inc., with 23andMe, Inc. being the surviving corporation and a wholly owned subsidiary of the Company (together with the Merger and the Domestication, the "Business Combination").

The transaction was accounted for as a reverse recapitalization with 23andMe, Inc. being the accounting acquirer and VGAC as the acquired company for accounting purposes. Accordingly, all historical financial information presented in the consolidated financial statements represents the accounts of 23andMe, Inc. and its wholly owned subsidiary. The shares and net loss per common share prior to the Merger have been retroactively restated as shares reflecting the exchange ratio established in the Merger (each outstanding share of 23andMe, Inc. Class A common stock was exchanged for 2.293698169 shares of the Company's Class A common stock, and each outstanding share of 23andMe, Inc. Class B common stock, including all shares of 23andMe, Inc. preferred stock (which were converted to shares of 23andMe, Inc. Class B common stock immediately prior to the Merger), was exchanged for 2.293698169 shares of the Company's Class B common stock).

Prior to the Business Combination, VGAC's units, public shares, and public warrants were listed on the New York Stock Exchange under the symbols "VGAC.U," "VGAC," and "VGAC WS," respectively. On June 17, 2021, the Company's Class A common stock and public warrants began trading on The Nasdaq Global Select Market ("Nasdaq"), under the symbols "ME" and "MEUSW," respectively. See Note 3, "Recapitalization," for additional details.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principle of Consolidation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiary, and variable interest entities in which it holds a controlling financial interest. All intercompany accounts and transactions have been eliminated in consolidation.

During the fiscal year ended March 31, 2022, the Company's operations were primarily in the United States. Subsequent to the closing of the Lemonaid Acquisition, the Company also had immaterial operations in the U.K.

Fiscal Year

The Company's fiscal year ends on March 31. References to fiscal year 2022, 2021 and 2020, refer to the fiscal years ending and ended March 31, 2022, 2021 and 2020, respectively.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and the related disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period and the accompanying notes. Significant items subject to such estimates and assumptions include, but are not limited to the determination of standalone selling price for various performance obligations; the estimated expected benefit period for the rate and recognition pattern of breakage revenue for purchases where a saliva collection kit ("Kit") is never returned for processing; the capitalization and estimated useful life of internal use software; the useful life of long-lived assets; the incremental borrowing rate for operating leases; the fair value of private warrants; stock-based compensation including the determination of the fair value of stock options, as well as the Company's common stock prior to the Closing Date of the Merger; fair value of intangible assets acquired in business combinations; and the valuation of deferred tax assets and uncertain tax positions. The Company bases these estimates on historical and anticipated results, trends and various other assumptions that it believes are reasonable under the circumstances, including assumptions as to future events. Actual results could differ from these estimates, and such differences could be material to the consolidated financial statements.

During the fiscal year ended March 31, 2022, the Company recorded an adjustment to revenue related to a change in estimate in connection with the collaboration agreement with GlaxoSmithKline plc ("GSK"). The change in estimate was driven by a change in the total project resources resulting in a reduction in the total estimated project hours, which impacted the measurement of progress of the arrangement using the input method. The adjustment increased revenue by $9.0 million, decreased net loss by $9.0 million and decreased the Company's basic and diluted net loss per share by $0.02 for the fiscal year ended March 31, 2022.

The coronavirus ("COVID-19") pandemic has created significant global economic uncertainty and resulted in the slowdown of economic activity. COVID-19 has disrupted the Company's general business operations since March 2020 and the Company expects that such disruption will continue for an unknown period. As the Company continues to closely monitor the COVID-19 pandemic, its top priority remains protecting the health and safety of the Company's employees. Safety guidelines and procedures, including social distancing and enhanced cleaning, have been developed for on-site employees and these policies are regularly monitored. In fiscal year 2020, the Company recorded impairment losses of $12.6 million to operating right-of-use ("ROU") assets associated with the Company's operating lease in Sunnyvale, California, as a result of foreseeable future sublease rental income reduced and delayed by the pandemic. See Note 9, "*Restructuring*," for additional details. The Company is not aware of any specific event or circumstance that would require revisions to estimates, updates to judgments, or adjustments to the carrying value of assets or liabilities. These estimates may change, as new events occur and additional information is obtained, and will be recognized in the consolidated financial statements as soon as they become known. Actual results could differ from those estimates and any such differences may be material to the consolidated financial statements.

Concentration of Supplier Risk

Certain of the raw materials, components and equipment associated with the deoxyribonucleic acid ("DNA") microarrays and Kits used by the Company in the delivery of its services are available only from third-party suppliers. The Company also relies on a third-party laboratory service for the processing of its customer samples. Shortages and slowdowns could occur in these essential materials, components, equipment and laboratory services due to an interruption of supply or increased demand in the industry. If the Company were unable to procure certain materials, components, equipment or laboratory services at acceptable prices, it would be required to reduce its laboratory operations, which could have a material adverse effect on its results of operations.

A single supplier accounted for 100% of the Company's total purchases of microarrays and a separate single supplier accounted for 100% of the Company's total purchases of Kits for the fiscal years ended March 31, 2022, 2021 and 2020. One laboratory service provider accounted for 100% of the Company's processing of customer samples for the fiscal years ended March 31, 2022, 2021 and 2020.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk include cash and accounts receivable. The Company maintains its cash with high-quality financial institutions in the United States, the composition and maturities of which are regularly monitored by the Company. The Company's revenue and accounts receivable are derived primarily from the United States. See Revenue Recognition within Note 2, "*Summary of Significant Accounting Policies*," for additional information regarding geographical disaggregation of revenue. The Company grants credit to its customers in the normal course of business, performs ongoing credit evaluations of its customers and does not require collateral. The Company regularly monitors the aging of accounts receivable balances.

Significant customer information is as follows:

	Year Ended March 31,	
	2022	**2021**
Percentage of accounts receivable:		
Customer G	44%	0%
Customer C	25%	35%
Customer F	19%	0%
Customer D	0%	40%

	Year Ended March 31,		
	2022	**2021**	**2020**
Percentage of revenue:			
Customer C	20%	21%	25%
Customer B	17%	16%	8%

Cash and Restricted Cash

Cash consists of cash in the bank and bank deposits. Cash balances are with U.S. banks and are insured to the extent defined by the Federal Deposit Insurance Corporation. The Company maintains certain cash amounts restricted as to its withdrawal or use. The Company held total restricted cash of $8.6 million and $8.4 million as of March 31, 2022 and 2021, respectively, which are related to letters of credit in connection with operating lease agreements, as well as collateral held against the Company's corporate credit cards.

Fair Value Measurements

Fair value is defined as the exchange price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company measures financial assets and liabilities at fair value at each reporting period using a fair value hierarchy which requires the Company to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's classification within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Three levels of inputs may be used to measure fair value:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Accounts Receivable, Net

Accounts receivable is recorded at the invoiced amount, net of estimated reserves for customer refunds, sales incentives, and bad debt, and is not interest-bearing. Accounts receivable represent amounts billed to the customers for bulk order and retail sales, and amounts billed under research services arrangements. Accounts receivable deemed uncollectable are charged against the estimated reserves when identified. The estimated reserves are based on the Company's assessment of the collectability of accounts. The Company regularly reviews the adequacy of the estimated reserves based on a combination of factors, including an assessment of past collection experience, credit quality of the customer, customer's aging balance, nature and size of the customer, the financial condition of the customer and the amount of any receivables in dispute. The reserves for customer refunds, sales incentives and bad debt were immaterial for all periods presented.

Inventories

Inventories consist primarily of raw material of Kits and DNA microarrays and are stated at the lower of cost or net realizable value. Kits are shipped to and stored at third-party warehouses and retail consignment sites. DNA microarrays are shipped and stored at third-party laboratories. All inventories are expected to be delivered to the Company's customers within a normal operating cycle for the Company, which is 12 months. Accordingly, all the Company's Kits and DNA microarrays are classified as current assets in the consolidated balance sheets. Cost is determined using standard cost, which approximates the average cost of the inventory items, including shipping and taxes. The Company has determined that all of its inventories would be sold above cost, and that no reserve for lower of cost or net realizable value is required for the Company's inventories as of March 31, 2022 and 2021.

Deferred Cost of Revenue

Deferred cost of revenue consists primarily of the purchase costs and shipping and fulfillment costs of Kits that have been shipped to consumers and non-consigned retail sites. Deferred cost of revenue is recognized as cost of revenue when the performance obligation to which it relates is fulfilled, which is when the Kit is processed and initial results are made available to the customer, and the respective deferred revenue is recognized.

Impairment Losses of Deferred Cost of Revenue

The Company recognizes an impairment loss when the costs incurred to date recorded as deferred cost of revenue plus the estimated direct costs to fulfill the performance obligations under the contract exceed the amount of consideration the Company received and expects to receive in the future. For the fiscal years ended March 31, 2022 and 2021, no impairment loss was recorded. For the fiscal year ended March 31, 2020, the Company recorded an impairment loss of $1.3 million.

Property and Equipment, Net

Property and equipment are stated at cost net of accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. Expenditures for maintenance and repairs are expensed as incurred. When property and equipment are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheets, and any resulting gain or loss is reflected in consolidated statements of operations and comprehensive loss in the period realized.

The estimated useful lives of the Company's property and equipment are as follows:

Computer and software	3 years
Laboratory equipment and software	5 years
Furniture and office equipment	5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Internal-Use Software

Costs related to software acquired, developed, or modified solely to meet the Company's internal requirements, with no substantive plans to market such software at the time of development, and certain costs related to the direct development of the Company's customer platform are capitalized. Costs incurred during the preliminary planning and evaluation stage of the project and during the post-implementation operational stage are expensed as incurred. Costs incurred during the application development stage of the project are capitalized and amortized using the straight-line method over the estimated useful life of two to four years. Internal-use software is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an internal-use software asset may not be recoverable.

Goodwill and Intangible Assets

Goodwill amounts are not amortized, but rather tested for impairment at least annually or more often if circumstances indicate that the carrying value may not be recoverable. There were no impairment charges to goodwill during the fiscal years ended March 31, 2022, 2021 and 2020.

Acquired intangible assets consist of identifiable intangible assets resulting from business combinations. Acquired finite-lived intangible assets are initially recorded at fair value and are amortized on a straight-line basis over their estimated useful lives. Amortization expense is recognized within cost of revenue for developed technology, sales and marketing expense for customer relationships, partnerships, and trademark, and general and administrative expense for non-compete agreements, in the consolidated statements of operations and comprehensive loss.

Other intangible assets consist of purchased patents. Intangible assets are carried at cost less accumulated amortization and are amortized over the period of estimated benefit using the straight-line method and their estimated useful lives. Amortization for patents is recognized in research and development and general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Each period the Company evaluates the estimated remaining useful lives of its acquired finite-lived intangible assets and whether events or changes in circumstances warrant a revision to the remaining period of amortization. There were no impairment charges to acquired intangible assets during the fiscal years ended March 31, 2022, 2021 and 2020.

Impairment of Long-Lived Assets

The Company evaluates long-lived assets, which include depreciable tangible assets such as property and equipment, intangible assets, and right of use assets related to operating leases for impairment whenever events or changes in circumstances indicate that the carrying value of long-lived assets may not be recoverable. The recoverability of these assets is measured by comparing the carrying amounts to the future undiscounted cash flows these assets are expected to generate. The Company recognizes an impairment in the event the carrying amount of such assets exceeds the fair value attributable to such assets. During the fiscal year ended March 31, 2020, impairments to long-lived assets of $33.2 million were recorded within restructuring and other charges in the consolidated statements of operations. There was no impairment to long-lived assets during the fiscal years ended March 31, 2022 and 2021.

Leases

The Company's lease portfolio includes leased offices, dedicated lab facility and storage space, and dedicated data center facility space, all of which are accounted for as operating leases. All lease arrangements are recognized at lease commencement. Operating lease ROU assets and operating lease liabilities are recognized at commencement based on the present value of fixed payments not yet paid over the lease term. Operating lease ROU assets represent the Company's right to use an underlying asset during the reasonably certain lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement date, less lease incentives received.

When considering the future lease payments to be included in the measurement of the operating lease liabilities, the Company includes payments to be made in optional renewal periods only if it is reasonably certain to exercise the option, and will include periods covered by a termination option only if it is reasonably certain that it will not exercise such option. In addition, the Company elected not to utilize the hindsight practical expedient to determine the lease term for existing leases at adoption. The Company uses the incremental borrowing rate based on the information available at the commencement date in determining the lease liabilities as the Company's leases generally do not provide an implicit rate. The incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, in an economic environment where the leased asset is located.

Real estate leases of office facilities are the most significant leases held by the Company. For these leases, the Company has elected the practical expedient permitted under Accounting Standards Codification ("ASC") Topic 842, *Leases* ("ASC 842"), to account for the lease and non-lease components as a single lease component. As the Company enters into real estate leases, property tax, insurance, common area maintenance and utilities are generally variable lease payments that do not depend on an index or rate, and therefore, they are excluded from the lease liabilities and expensed as incurred in accordance with ASC 842. The Company reassesses the lease term if and when a significant event or change in circumstances occurs within its control. None of the Company's lease agreements contain significant residual value guarantees, restrictions, or covenants. The Company currently does not have any finance leases.

Revenue Recognition

The Company generates revenue from its Consumer & Research Services segment, which includes revenue from PGS, telehealth, and research services, and its Therapeutics segment. In accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration that the Company expects to receive in exchange for these goods or services.

The Company sells through multiple channels, including direct to consumer via the Company's website and through online retailers. If the customer does not return the Kit, services cannot be completed by the Company, potentially resulting in unexercised rights ("breakage") revenue. To estimate breakage, the Company applies the practical expedient available under ASC 606 to assess its customer contracts on a portfolio basis as opposed to individual customer contracts, due to the similarity of customer characteristics, at the sales channel level. The Company recognizes the breakage amounts as revenue, proportionate to the pattern of revenue recognition of the returning kits in these respective sales channel portfolios. The Company estimates breakage for the portion of Kits not expected to be returned using an analysis of historical data and considers other factors that could influence customer Kit return behavior. The Company updates its breakage rate estimate periodically and, if necessary, adjusts the deferred revenue balance accordingly. If actual return patterns vary from the estimate, actual breakage revenue may differ from the amounts recorded. The Company recognized breakage revenue from unreturned Kits of $21.9 million, $24.1 million and $38.0 million for the fiscal year ended March 31, 2022, 2021 and 2020, respectively.

Fees paid to certain sales channel partners include, in part, compensation for obtaining PGS contracts. Such contracts have an amortization period of one year or less, and the Company has applied the practical expedient to recognize these costs as sales and marketing expenses when incurred.

The Company generates telehealth revenues from pharmacy fees, patient fees, and membership fees.

Pharmacy fees, net – The Company primarily generates revenue through sale and delivery of prescription medications from the Affiliated Pharmacies (as defined below). A contract is entered into with a patient when the patient accepts the Company's terms and conditions, requests a prescription or chooses to refill, and provides access to payment. Revenue is recognized at the point in time in which prescription services are rendered for these transactions. Fees are charged as prescription services are rendered. Revenue is recorded net of refunds and transaction fees.

Patient fees, net – The Company primarily generates revenue through the PMCs (as defined below) from patient visit fees, which include healthcare professional consultations, lab testing, and ordering prescriptions. A contract is entered into with a patient when the patient accepts the Company's terms and conditions and provides access to payment. Revenue is recognized at the point in time in which services are rendered for these transactions. Fees are charged upfront prior to services being rendered and are allocated over the obligation to provide services to the patient. Revenue is recorded net of refunds, transaction fees, and pass-through lab and prescription costs.

Membership fees, net – The Company generates revenue through membership fees from patients, which includes a membership for unlimited medical visits and unlimited prescriptions during the membership period (generally one, three or twelve months). A contract is entered into with a patient when the patient accepts the Company's terms and conditions and makes a pre-payment for the membership term. The Company has determined that access to the services over the membership period qualifies as a series of distinct performance obligations, which is defined as identical distinct services (daily access to the services). As such, revenue is recognized ratably over the respective membership period. The transaction price is determined to be the amount paid by the patient. Revenue is recorded net of refunds. Deferred revenue consists of advance payments from members related to membership performance obligations that have not been satisfied for memberships.

In providing telehealth services that include professional medical consultations, the Company maintains relationships with various affiliated professional medical corporations ("PMCs"), which are professional entities owned by licensed physicians and that engage licensed healthcare professionals (each, a "Provider" and collectively, the "Providers") to provide consultation services. See Note 5, "*Variable Interest Entities*," for additional details. The Company accounts for service revenue as a principal in the arrangement with its patients.

Additionally, with respect to its telehealth services involving the sale of prescription products, the Company maintains relationships with affiliated pharmacies (collectively, the "Affiliated Pharmacies") to fill prescriptions that are ordered by the Company's patients. The Company accounts for prescription product revenue as a principal in the arrangement with its patients.

Disaggregation of Revenue

The following table presents revenue by category:

	Year Ended March 31,					
	2022		2021		2020	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	(in thousands, except percentages)					
Point in Time						
PGS	$ 189,703	70%	$ 191,066	78%	$ 263,679	86%
Telehealth [1]	15,299	6%	—	0%	—	0%
Consumer services	205,002	76%	191,066	78%	263,679	86%
Research services	—	0%	—	0%	—	0%
Therapeutics	—	0%	54	0%	5,556	2%
Total	$ 205,002	76%	$ 191,120	78%	$ 269,235	88%
Over Time						
PGS	$ 12,978	5%	$ 6,459	3%	$ 7,960	3%
Telehealth [1]	3,908	1%	—	0%	—	0%
Consumer services	16,886	6%	6,459	3%	7,960	3%
Research services	50,005	18%	46,341	19%	28,268	9%
Therapeutics	—	0%	—	0%	—	0%
Total	$ 66,891	24%	$ 52,800	22%	$ 36,228	12%
Total Revenue						
PGS	$ 202,681	75%	$ 197,525	81%	$ 271,639	89%
Telehealth [1]	19,207	7%	—	0%	—	0%
Consumer services	221,888	82%	197,525	81%	271,639	89%
Research services	50,005	18%	46,341	19%	28,268	9%
Therapeutics	—	0%	54	0%	5,556	2%
Total	$ 271,893	100%	$ 243,920	100%	$ 305,463	100%

(1) For the year ended March 31, 2022, telehealth revenue included the five month period from the close of the acquisition of Lemonaid Health on November 1, 2021 through March 31, 2022.

Within the Consumer and Research Services segment, substantially all consumer services revenue is recognized at the point in time of the initial transfer of reports to the consumer, the delivery of healthcare services to the patient, or the delivery of prescription medications to the patient. Substantially all research services revenue is recognized over time as services are performed. Substantially all Therapeutics revenue is recognized at the point in time intellectual property is transferred.

The following table summarizes revenue by region based on the shipping address of customers or the location where the services are delivered:

	Year Ended March 31,					
	2022		2021		2020	
	Amount	% of Revenue	Amount	% of Revenue	Amount	% of Revenue
	(in thousands, except percentages)					
United States	$ 192,438	71%	$ 176,120	72%	$ 241,769	79%
United Kingdom	58,477	22%	49,386	20%	41,770	14%
Canada	14,293	5%	12,172	5%	14,481	5%
Other regions	6,685	2%	6,242	3%	7,443	2%
International	79,455	29%	67,800	28%	63,694	21%
Total	$ 271,893	100%	$ 243,920	100%	$ 305,463	100%

Contract Balances

Accounts receivable are recorded when the right to consideration becomes unconditional. Contract assets include amounts associated with contractual rights related to consideration for performance obligations not yet billed and are included in prepaid expenses and other current assets in the consolidated balance sheets. The amount of contract assets was immaterial as of March 31, 2022 and 2021.

Contract liabilities consist of deferred revenue. Revenue is deferred when the Company invoices in advance of fulfilling performance obligations under a contract. Deferred revenue primarily relates to Kits that have been shipped to consumers and non-consigned retail sites but not yet returned for processing by the consumer, as well as research services billed in advance of performance. Deferred revenue is recognized when the obligation to deliver results to the customer is satisfied, and when research services are ultimately performed. Deferred revenue also consists of advance payments from members related to membership performance obligations that have not been satisfied for memberships. Deferred revenue is recognized when the obligation to deliver membership services is satisfied.

As of March 31, 2022 and 2021, deferred revenue for consumer services was $51.3 million and $39.3 million, respectively. Of the $39.3 million, $38.8 million and $74.1 million of deferred revenue for consumer services as of March 31, 2021, 2020 and 2019, respectively, the Company recognized $31.9 million, $34.4 million and $59.9 million as revenue during the fiscal years ended March 31, 2022, 2021 and 2020, respectively.

As of March 31, 2022 and 2021, deferred revenue for research services was $11.6 million and $31.9 million, respectively, including related party deferred revenue amounts of $9.2 million and $30.1 million, respectively. Of the $31.9 million, $48.6 million and $48.7 million of deferred revenue for research services as of March 31, 2021, 2020 and 2019, respectively, the Company recognized $31.4 million, $42.8 million and $28.7 million as revenue during the fiscal years ended March 31, 2022, 2021 and 2020, respectively. Out of the above-mentioned $31.4 million and $42.8 million revenue recognized during the fiscal year ended March 31, 2022 and 2021, respectively, related party revenue amount was $30.1 million and $39.9 million, respectively.

Remaining Performance Obligations

The transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized, which includes deferred revenue and amounts that are expected to be billed and recognized as revenue in future periods. The Company has utilized the practical expedient available under ASC 606 to not disclose the value of unsatisfied performance obligations for PGS and telehealth as those contracts have an expected length of one year or less. As of March 31, 2022 and 2021, the aggregate amount of the transaction price allocated to remaining performance obligations for research services was $67.8 million and $61.9 million, respectively. These amounts are expected to be recognized over a remaining subsequent period of approximately 1 to 2 years from the reporting date.

Cost of Revenue

Cost of revenue for PGS primarily consists of cost of raw materials, lab processing fees, personnel-related expenses, including salaries and benefits and stock-based compensation, shipping and handling, and allocated overhead. Shipping costs for the Kits are incurred prior to fulfillment of consumer services obligations and the corresponding shipping and handling expense is reported in cost of revenue.

Cost of revenue for research services primarily consists of personnel-related expenses, including salaries, benefits and stock-based compensation, and allocated overhead.

Research and Development

Research and development costs primarily consist of personnel-related expenses, including salaries, benefits and stock-based compensation, associated with the Company's research and development personnel, collaboration expenses, laboratory services and supplies costs, third-party data services, and allocated overhead. Research and development costs are expensed as incurred.

Advertising Costs

Advertising costs consist primarily of direct expenses related to television and radio advertising, including production and branding, paid search, online display advertising, direct mail, and affiliate programs. Advertising production costs are expensed the first time the advertising takes place, and all other advertising costs are expensed as incurred. Advertising costs amounted to $54.7 million, $11.2 million and $62.6 million for the fiscal years ended March 31, 2022, 2021 and 2020, respectively, and are included in sales and marketing expense in the consolidated statements of operations and comprehensive loss.

Deferred advertising costs primarily consist of vendor payments made in advance to secure media spots across varying media channels, as well as production costs incurred before the first time the advertising takes place. Deferred advertising costs are not expensed until first used. The deferred advertising costs were $0.7 million as of March 31, 2022 and immaterial as of March 31, 2021. Deferred advertising costs are included in prepaid expenses and other current assets in the consolidated balance sheets.

Stock-Based Compensation

Stock-based compensation expense related to stock-based awards for employees and non-employees is recognized based on the fair value of the awards granted. The fair value of each stock option is estimated on the grant date using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the input of highly subjective assumptions, including the expected term of the stock-based award, the expected volatility of the price of the Company's common stock, risk-free interest rates, and the expected dividend yield of common stock. The fair value of each restricted stock unit ("RSU") is estimated based on the fair value of the common stock on the grant date. Prior to the Merger, the Company determined the fair value of its common stock for financial reporting as of each grant date based on numerous objective and subjective factors and management's judgement. Subsequent to the Merger, the Company determines the fair value using the market closing price of its common stock on the date of grant. The related stock-based compensation expense is recognized on a straight-line basis over the requisite service period of the awards, including awards with graded vesting and no additional conditions for vesting other than service conditions. The Company accounts for forfeitures as they occur.

The Company's Employee Stock Purchase Plan ("ESPP") permits all regular employees, including executive officers, employed by the Company, except for those holding five percent or more of the total combined voting power or value of all classes of the Company's stock, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of the Company's Class A common stock during pre-specified offering periods under the ESPP. Class A common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of the Company's Class A common stock on the first date of an offering, or (ii) 85% of the fair market value of a share of the Company's Class A common stock on the date of purchase. No employee may purchase shares under the ESPP at a rate in excess of $25,000 worth of the Company's Class A common stock based on the fair market value per share of the Company's Class A common stock at the beginning of an offering for each calendar year such purchase right is outstanding. The ability to purchase shares of the Company's common stock for a discount represents an option and, therefore, the ESPP is considered a compensatory plan. Accordingly, stock-based compensation expense is determined based on the option's grant-date fair value as estimated by applying the Black Scholes option-pricing model and is recognized over the requisite service period, which is the withholding period. See Note 14, "*Equity Incentive Plans and Stock-Based Compensation,*" for additional details.

Restructuring Expense

The Company defines restructuring expense to include costs directly associated with exit or disposal activities. Such costs include employee severance and termination benefits, contract termination fees and penalties, impairment associated with long-lived assets, and other exit or disposal costs. In general, the Company records involuntary employee-related exit and disposal costs when there is a substantive plan for employee severance and related costs are probable and estimable. For one-time termination benefits (i.e., no substantive plan) and employee retention costs, expense is recorded when the employees are entitled to receive such benefits and the amount can be reasonably estimated. Contract termination fees and penalties, and other exit and disposal costs are generally recorded as incurred.

Warrant Liabilities

The Company classified the Private Placement Warrants and the Public Warrants (both defined and discussed in Note 13, *"Common Stock and Warrants"* and, collectively, the *"Warrants"*) as liabilities. At the end of each reporting period, changes in fair value during the period were recognized as change in fair value of warrant liabilities within the consolidated statements of operations and comprehensive loss. The Company adjusted the warrant liability for changes in the fair value until the earlier of (a) the exercise or expiration of the Warrants or (b) the redemption of the Warrants, at which time the Warrants were reclassified to additional paid-in capital.

Income Taxes

The Company applies the provisions of ASC Topic 740, *Income Taxes* ("ASC 740"). Under ASC 740, the Company accounts for income taxes using the asset and liability method whereby deferred tax assets and liabilities are determined based on temporary differences between the bases used for financial reporting and income tax reporting purposes. Deferred income taxes are provided based on the enacted tax rates and laws that will be in effect at the time such temporary differences are expected to reverse. A valuation allowance is provided for deferred tax assets if it is more likely than not that the Company will not realize those tax assets through future operations.

The Company also utilizes the guidance in ASC 740 to account for uncertain tax positions. ASC 740 contains a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount which is more likely than not of being realized and effectively settled. The Company considers many factors when evaluating and estimating the Company's tax positions and tax benefits, which may require periodic adjustments, and which may not accurately reflect actual outcomes. The Company recognizes interest and penalties on unrecognized tax benefits as a component of provision for income taxes in the consolidated statements of operations and comprehensive loss. See Note 15, "*Income Taxes,*" for additional details.

Business Combinations

The Company accounts for its business combinations using the acquisition method of accounting, which requires, among other things, allocation of the fair value of purchase consideration to the tangible and intangible assets acquired and liabilities assumed at their estimated fair values on the acquisition date. The excess of the fair value of purchase consideration over the values of these identifiable assets and liabilities is recorded as goodwill. The results of businesses acquired in a business combination are included in the Company's consolidated financial statements from the date of acquisition. Acquisition costs, such as legal and consulting fees, are expensed as incurred.

Determining the fair value of assets acquired and liabilities assumed requires management to use significant judgment and estimates, including the selection of valuation methodologies, estimates of future revenue and cash flows, discount rates, and selection of comparable companies. The estimates and assumptions used to determine the fair values and useful lives of identified intangible assets could change due to numerous factors, including market conditions, technological developments, economic conditions, and competition. The Company's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. During the measurement period, not to exceed one year from the date of acquisition, the Company may record adjustments to the assets acquired and liabilities assumed, with a corresponding offset to goodwill if new information is obtained related to facts and circumstances that existed as of the acquisition date. After the measurement period, any subsequent adjustments are reflected in the consolidated statements of operations and comprehensive loss.

When the Company issues stock-based or cash awards to an acquired company's stockholders, the Company evaluates whether the awards are consideration or compensation for post-acquisition services. The evaluation includes, among other things, whether the vesting of the awards is contingent on the continued employment of the acquired company's stockholders beyond the acquisition date. If continued employment is required for vesting, the awards are treated as compensation for post-acquisition services and recognized as expense over the requisite service period.

Uncertain tax positions and tax-related valuation allowances are initially established in connection with a business combination as of the acquisition date. The Company continues to collect information and reevaluate these estimates and assumptions quarterly. The Company will record any adjustments to its preliminary estimates to goodwill, provided that it is within the one-year measurement period.

Variable Interest Entities

The Company evaluates its ownership, contractual, and other interests in entities to determine if it has any variable interest in a variable interest entity ("VIE") and if it is the primary beneficiary. These evaluations are complex and involve judgment. If the Company determines that an entity in which it holds a contractual or ownership interest is a VIE and that the Company is the primary beneficiary, the Company consolidates such entity in its consolidated financial statements. The primary beneficiary of a VIE is the party that meets both of the following criteria: (i) has the power to make decisions that most significantly affect the economic performance of the VIE, and (ii) has the obligation to absorb losses or the right to receive benefits that in either case could potentially be significant to the VIE. Management performs ongoing reassessments of whether changes in the facts and circumstances regarding the Company's involvement with a VIE will cause the consolidation conclusion to change. Changes in consolidation status are applied prospectively.

Foreign Currency

The reporting currency of the Company is the United States dollar. The Company determines the functional currency of each subsidiary based on the currency of the primary economic environment in which each subsidiary operates. Items included in the financial statements of such subsidiaries are measured using that functional currency. The functional currency of the Company's foreign subsidiary is the British Pound. Foreign currency denominated monetary assets and liabilities are remeasured into U.S. dollars at period-end exchange rates and foreign currency denominated nonmonetary assets and liabilities are remeasured into U.S. dollars at historical exchange rates. Equity transactions are translated using historical exchange rates. Revenue and expenses are translated at the average exchange rates during the period. The resulting translation adjustments are recorded in accumulated other comprehensive income as a component of stockholders' equity (deficit). Foreign currency transaction gains and losses are recognized in other (expense) income, net in the consolidated statements of operations and comprehensive loss, and have not been material for any of the periods presented.

Comprehensive Loss

Comprehensive loss is composed of two components: net loss and other comprehensive income. The Company's changes in foreign currency translation represents the components of other comprehensive income that are excluded from the reported net loss.

Net Loss Per Share Attributable to Common Stockholders

The Company computes net loss per share using the two-class method required for participating securities. The two-class method requires income available to common stockholders for the period to be allocated between common stock and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company determined that it had participating securities in the form of redeemable convertible preferred stock prior to the date of conversion and unvested common stock as holders of such securities had non-forfeitable dividend rights in the event of a declaration of a dividend for shares of common stock prior to the vesting date. These participating securities do not contractually require the holders of such stocks to participate in the Company's losses. As such, net loss for the period presented was not allocated to the Company's participating securities.

The Company's basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration of potentially dilutive securities. The diluted net loss per share is calculated by giving effect to all potentially dilutive securities outstanding for the period using the treasury share method or the if-converted method based on the nature of such securities. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive shares of ordinary shares are anti-dilutive. See Note 16, "*Net Loss Per Share Attributable to Common Stockholders*," for additional details.

Segment Information

The Company currently operates in two reporting segments: Consumer & Research Services and Therapeutics. The Consumer & Research Services segment consists of revenue and expenses from PGS and telehealth, as well as research services revenue and expenses from certain collaboration agreements (including the GSK Agreement (as defined below)). The Therapeutics segment consists of revenues from the out-licensing of intellectual property associated with identified drug targets and expenses related to therapeutic product candidates under clinical development. Substantially all of the Company's revenues are derived from the Consumer & Research Services segment. See Revenue Recognition within Note 2, "*Summary of Significant Accounting Policies*," for additional information regarding revenue. There are no inter-segment sales.

Certain expenses such as Finance, Legal, Regulatory and Supplier Quality, and CEO Office are not reported as part of the reporting segments as reviewed by the CODM (as defined below). These amounts are included in Unallocated Corporate in the reconciliations below. The chief operating decision-maker ("CODM") is the Chief Executive Officer ("CEO"). The CODM evaluates the performance of each segment based on Adjusted EBITDA. Adjusted EBITDA is defined as net income before net interest expense (income), net other expense (income), changes in fair value of warrant liabilities, income tax benefit, depreciation and amortization of fixed assets, amortization of internal use software, amortization of acquired intangible assets, non-cash stock-based compensation expense, acquisition-related costs, litigation settlements not related to normal and continued business activities and expenses related to restructuring and other charges, if applicable for the period.

Adjusted EBITDA is a key measure used by the Company's management and Board of Directors to understand and evaluate the Company's operating performance and trends, to prepare and approve the annual budget, and to develop short- and long-term operating plans. In particular, the exclusion of the items eliminated in calculating Adjusted EBITDA provides useful measures for period-to-period comparisons of the Company's business. Accordingly, Adjusted EBITDA provides useful information in understanding and evaluating the Company's operating results in the same manner as management and the Board of Directors. Adjusted EBITDA should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. Other companies, including companies in the Company's industry, may calculate similarly-titled non-GAAP financial measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of Adjusted EBITDA as a tool for comparison. There are a number of limitations related to the use of these non-GAAP financial measures rather than net loss, which is the most directly comparable financial measure calculated in accordance with GAAP.

Some of the limitations of Adjusted EBITDA include (i) Adjusted EBITDA does not properly reflect capital commitments to be paid in the future, and (ii) although depreciation and amortization are non-cash charges, the underlying assets may need to be replaced and Adjusted EBITDA does not reflect these capital expenditures. In evaluating Adjusted EBITDA, the Company will incur expenses similar to the adjustments in this presentation in the future. The presentation of Adjusted EBITDA should not be construed as an inference that the Company's future results will be unaffected by these expenses or any unusual or non-recurring items. When evaluating the Company's performance, Adjusted EBITDA should be considered alongside other financial performance measures, including net loss and other GAAP results.

The Company's revenue and Adjusted EBITDA by segment is as follows:

	Year Ended March 31,		
	2022	2021	2020
	(in thousands)		
Segment Revenue			
Consumer and Research Services	$ 271,893	$ 243,866	$ 299,907
Therapeutics	—	54	5,556
Total Revenue	$ 271,893	$ 243,920	$ 305,463
Segment Adjusted EBITDA			
Consumer and Research Services Adjusted EBITDA	$ (30,112)	$ 12,796	$ (65,845)
Therapeutics Adjusted EBITDA	(76,944)	(58,734)	(52,883)
Unallocated Corporate	(43,684)	(30,587)	(28,460)
Total Adjusted EBITDA	$ (150,740)	$ (76,525)	$ (147,188)
Reconciliation of net loss to Adjusted EBITDA			
Net Loss	$ (217,490)	$ (183,619)	$ (250,863)
Adjustments:			
Interest (income) expense, net	(277)	(255)	(6,244)
Other (income) expense, net	83	(1,322)	(1,340)
Change in fair value of warrant liabilities	(32,989)	—	—
Income tax benefit	(3,480)	—	—
Depreciation and amortization	18,899	20,246	22,610
Amortization of acquired intangible assets	7,269	—	—
Stock-based compensation expense	57,933	88,425	43,957
Restructuring and other charges [1]	—	—	44,692
Acquisition-related costs [2]	9,362	—	—
Litigation settlement [3]	9,950	—	—
Total Adjusted EBITDA	$ (150,740)	$ (76,525)	$ (147,188)

(1) For the year ended March 31, 2020, restructuring includes $0.9 million of stock-based compensation expense related to restructuring activities.
(2) For the fiscal year ended March 31, 2022, acquisition-related costs primarily consisted of advisory, legal and consulting fees related to the Lemonaid Acquisition.
(3) For the fiscal year ended March 31, 2022, litigation settlement is litigation cost net of insurance recoveries, which is not expected to occur on a recurring basis and not part of the Company's normal and continued business activity.

Customers accounting for 10% or more of segment revenues were as follows:

	Year Ended March 31,					
	2022		2021		2020	
	(in thousands, except percentages)					
Consumer and Research Services Segment Revenue:						
Customer C[1]	$ 53,875	20%	$ 51,786	21%	$ 76,087	25%
Customer B[2]	$ 46,064	17%	$ 39,917	16%	$ 23,768	8%
Therapeutics Segment Revenue:						
Customer B[2]	$ —	0%	$ —	0%	$ 2,981	54%
Customer E[2]	$ —	0%	$ 54	100%	$ 2,575	46%

(1) Customer C revenues are primarily in the United States.
(2) Customer B revenues are in the U.K. and Customer E is in a region other than the United States, U.K., or Canada.

Revenue by geographical region can be found in the revenue recognition disclosures in Note 2, "*Summary of Significant Accounting Policies*." All of the Company's property and equipment, net of depreciation and amortization, was located in the United States during the periods presented. The reporting segments do not present total assets as they are not reviewed by the CODM when evaluating their performance.

Related Parties

A party is considered to be related to the Company if the party, directly or indirectly, controls, is controlled by, or is under common control with the Company, including principal owners of the Company, its management, members of the immediate families of principal owners of the Company and its management, and other parties with which the Company may deal and can significantly influence the management or operating policies to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests. See Note 17, "*Related Party Transactions*," for additional details.

Recently Adopted Accounting Pronouncements

The Company lost its emerging growth company ("EGC") status on March 31, 2022, due to qualifying as a large accelerated filer based on its market capitalization as of September 30, 2021, in accordance with Rule 12b-2 of the Securities Exchange Act of 1934, as amended. Prior to losing its EGC status, the classification allowed the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements were made applicable to private companies, and the Company elected to use adoption dates applicable to private companies. Subsequent to losing its EGC status, the Company adopted all accounting pronouncements previously deferred under the EGC election according to public company standards. The adoption dates for the new accounting pronouncements disclosed below have been presented accordingly.

In January 2017, the FASB issued Accounting Standards Update ("ASU") 2017-04, Intangibles – Goodwill and Other (Topic 350) – *Simplifying the Test for Goodwill Impairment*. ASU 2017-04 simplifies the accounting for goodwill impairments by eliminating the requirement to compare the implied fair value of goodwill with its carrying amount as part of step two of the goodwill impairment test referenced in ASC 350, Intangibles – Goodwill and Other. As a result, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit's fair value. However, the impairment loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The Company adopted ASU 2017-04 as of January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements and related disclosures.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations* (Topic 805), *Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires contract assets and contract liabilities (i.e., deferred revenue) acquired in a business combination to be recognized and measured by the acquirer on the acquisition date in accordance with ASC 606, *Revenue from Contracts with Customers*. The guidance should be applied prospectively to acquisitions occurring on or after the effective date. The guidance is effective for the Company beginning April 1, 2023, and interim periods therein. Early adoption is permitted, including in interim periods, for any financial statements that have not yet been issued. In November 2021, the Company elected to early adopt ASU 2021-08, and the adoption had no material impact on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, to require the measurement of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The guidance also amended the impairment model for available-for-sale debt securities and requires entities to determine whether all or a portion of the unrealized loss on such debt security is a credit loss. The standard is effective for nonpublic entities for annual and interim periods beginning after December 15, 2022, and for public entities for annual and interim periods beginning after December 15, 2019, with early adoption permitted. The Company lost its EGC status on March 31, 2022, and adopted ASU 2016-13 for the year ended March 31, 2022. The adoption did not have a material impact on the consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity, and clarifies the guidance on the computation of earnings per share for those financial instruments. The guidance will be effective for the Company beginning April 1, 2022, and interim periods therein. Early adoption is permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently evaluating the effect that ASU 2020-06 will have on its consolidated financial statements and related disclosures and does not believe the adoption will have a material impact.

3. Recapitalization

As discussed in Note 1, "*Organization and Description of Business*," on the Closing Date, VGAC completed the acquisition of 23andMe, Inc. and acquired 100% of 23andMe, Inc.'s shares and 23andMe, Inc. received gross proceeds of $559.7 million, which includes $309.7 million in proceeds from issuance of common stock upon the consummation of the Merger and $250.0 million in proceeds from the PIPE Investment (as defined below). The Company recorded $33.7 million of transaction costs, which consisted of legal, accounting, and other professional services directly related to the Business Combination. These costs were included in additional paid-in capital on the Company's consolidated balance sheet. The cash outflows related to these costs were presented as financing activities on the Company's consolidated statement of cash flows. These deferred offering costs are offset against proceeds upon accounting for the consummation of the Merger. On the Closing Date, each holder of 23andMe, Inc. Class A common stock received approximately 2.293698169 shares of the Company's Class A common stock, par value $0.0001 per share, and each holder of 23andMe, Inc. Class B common stock received approximately 2.293698169 shares of the Company's Class B common stock, par value $0.0001 per share. See Note 12, *"Redeemable Convertible Preferred Stock"* and Note 13, *"Common Stock and Warrants,"* for additional details of the Company's stockholders' equity prior to and subsequent to the Merger.

All equity awards of 23andMe, Inc. were assumed by the Company and converted into comparable equity awards that are settled or exercisable for shares of the Company's Class A common stock. As a result, each outstanding stock option was converted into an option to purchase shares of the Company's Class A common stock based on an exchange ratio of 2.293698169, and each outstanding restricted stock unit was converted into restricted stock units of the Company that, upon vesting, may be settled for shares of the Company's Class A common stock based on an exchange ratio of 2.293698169.

Each public and private warrant of VGAC that was unexercised at the time of the Merger was assumed by the Company and represented the right to purchase one share of the Company's Class A common stock upon exercise of such warrant.

The Merger was accounted for as a reverse recapitalization with 23andMe, Inc. as the accounting acquirer and VGAC as the acquired company for accounting purposes. 23andMe, Inc. was determined to be the accounting acquirer since 23andMe, Inc.'s stockholders prior to the Merger had the greatest voting interest in the combined entity, 23andMe, Inc.'s stockholders appointed the initial directors of the combined Board of Directors and control future appointments, 23andMe, Inc. comprises all of the ongoing operations, and 23andMe, Inc.'s senior management directs operations of the combined entity. Accordingly, all historical financial information presented in these consolidated financial statements represents the accounts of 23andMe, Inc. and its wholly owned subsidiary. Net assets were stated at historical cost consistent with the treatment of the transaction as a reverse recapitalization of 23andMe, Inc.

Lock-up and Earn-Out Shares

Pursuant to the Company's Bylaws, shares of Class A common stock received as consideration in connection with the Merger (or securities convertible into or exchangeable for shares of Class A common stock) could not be sold or otherwise disposed of or hedged by its stockholders for a period of 180 days after the Closing Date (the "Lock-Up Period"). Except with respect to securities subject to the Sponsor Letter Agreement (as defined below) or as otherwise restricted by applicable securities laws or Company policies, following the expiration of the Lock-Up Period on December 14, 2021, the Company's stockholders were no longer restricted from selling securities held by them.

Pursuant to a Letter Agreement (the "VGAC IPO Letter Agreement") entered into on October 1, 2020 by and among VGAC, VG Acquisition Sponsor LLC (the "Sponsor"), and the then officers and directors of VGAC (collectively, the "VGAC Insiders"), as amended by a Sponsor Letter Agreement (the "Sponsor Letter Agreement"), dated as of February 4, 2021, by and among 23andMe, Inc., VGAC, the Sponsor, the VGAC Insiders and Credit Suisse Securities (USA) LLC as representative of the several underwriters named in the underwriting agreement with respect to the initial public offering of VGAC (the "Underwriters"), the VGAC Insiders agreed to certain transfer restrictions applicable to 12,713,750 of the Class B ordinary shares of VGAC held by the Sponsor and VGAC Insiders (the "Founder Shares"), which were converted in the Business Combination to a like number of shares of Class A common stock of the Company. Pursuant to the VGAC IPO Letter Agreement, as amended by the Sponsor Letter Agreement, 70% of the Founder Shares cannot be transferred (subject to certain limited exceptions) until the earlier to occur of (i) one year after the Closing Date, or (ii) the date following the completion of the Business Combination on which the Company completes a liquidation, merger, share exchange, or other similar transaction that results in all of the stockholders having the right to exchange their ordinary shares for cash, securities, or other property. Notwithstanding the foregoing, if the closing price of the Company's Class A common stock equals or exceeds $12.00 per share (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading-day period commencing at least 150 days after the Business Combination, 70% of the Founder Shares will be released from the lock-up. As of March 31, 2022, the Company did not meet any thresholds for the shares to be released from lock-up. The Founders Shares are issued and outstanding Class A common shares that cannot be forfeited, and as such meet the criteria for equity classification in accordance with ASC 505, *Equity* ("ASC 505").

Following the closing of the Merger, 3,814,125 of the Class B ordinary shares of VGAC held by the Sponsor as of the date of the Sponsor Letter Agreement (the "Earn-Out Shares"), which constitute the remaining 30% of the Founder Shares, and were converted in the Business Combination into a like number of shares of the Company's Class A common stock, are subject to a lock-up of seven years. The lock-up has an early release effective (i) with respect to 50% of the Earn-Out Shares, upon the closing price of the Company's Class A common stock equaling or exceeding $12.50 per share for any 20 trading days within any 30-trading-day period, and (ii) with respect to the other 50% of the Earn-Out Shares, upon the closing price of the Company's Class A common stock equaling or exceeding $15.00 per share for any 20 trading days within any 30-trading-day period; provided that the transfer restrictions applicable to the Earn-Out Shares will terminate on the date following the closing date on which the Company completes a liquidation, merger, amalgamation, capital stock exchange, reorganization, or other similar transaction that results in all of the Company's public stockholders having the right to exchange their shares of Class A common stock for cash, securities, or other property (a "Liquidation Event"), if such Liquidation Event occurs prior to the date that the stock price thresholds referenced in (i) and (ii) are met. As of March 31, 2022, the Company did not meet any earn out thresholds. The Earn-Out Shares are issued and outstanding Class A common shares that cannot be forfeited, and as such meet the criteria for equity classification in accordance with ASC 505.

PIPE Investment

On February 4, 2021, concurrently with the execution of the Merger Agreement, VGAC entered into subscription agreements with certain investors (the "PIPE Investors") to which such investors collectively subscribed for an aggregate of 25,000,000 shares of the Company's Class A common stock at $10.00 per share for aggregate gross proceeds of $250.0 million (the "PIPE Investment"). The Anne Wojcicki Foundation, which subscribed for 2,500,000 shares of the Company's Class A common stock, is affiliated with the Company's CEO and therefore a related party. The PIPE Investment was consummated concurrently with the closing of the Merger.

4. Acquisitions

The Company accounts for acquisitions using the acquisition method with the purchase price being allocated to tangible and identifiable intangible assets acquired and liabilities assumed based on their respective estimated fair values on the acquisition date. The purchase price allocation was prepared as of November 1, 2021 and may be subject to further adjustments for tax and contingent liabilities. The Company has not filed its tax returns or finalized its evaluation of its ability to utilize net operating loss carryforwards which may be subject to annual limitations provided by Section 382 of the Code. The Company may identify liabilities if new information is obtained related to facts and circumstances that existed as of the acquisition date.

Lemonaid Health, Inc.

On November 1, 2021, the Company completed the Lemonaid Acquisition and acquired all of the outstanding equity of Lemonaid Health pursuant to the Lemonaid Health Merger Agreement. The purchase price consideration was $424.7 million, which includes the value of 26,825,241 shares of the Company's Class A common stock valued at $314.4 million as of the closing date, the fair value of the pre-combination service portion of stock-based awards that were vested as of the Lemonaid Acquisition of $8.4 million, and cash payment of approximately $101.9 million (of which approximately $13.0 million was placed in escrow to cover a potential purchase price adjustment and to secure the indemnification obligations of the former equity holders of Lemonaid Health).

The purchase price consideration excludes stock consideration of 3,747,027 shares issued by the Company to certain holders that are subject to vesting restrictions tied to continuing employment with the Company, which is recognized as selling, general, and administrative expenses post-acquisition. See Note 14, "*Equity Incentive Plans and Stock-Based Compensation*," for additional details. The Company also incurred acquisition costs of $9.4 million directly related to the Lemonaid Acquisition, which were recorded within general and administrative expenses on the consolidated statements of operations and comprehensive loss.

The following is an estimate of the allocation of the consideration transferred to acquired identifiable assets and assumed liabilities, net of cash acquired, in the Lemonaid Acquisition as of November 1, 2021:

	Amount (in thousands)
Cash	$ 7,711
Prepaid expenses and other current assets	3,388
Property and equipment, net	1,019
Intangible Assets	
Customer relationships	14,900
Partnerships	23,200
Trademark	11,000
Developed technology	24,100
Non-compete agreements	2,800
Operating lease right-of-use asset	848
Other assumed assets	407
Accounts payable	(3,106)
Accrued liabilities	(4,218)
Operating lease liability	(971)
Deferred tax liability	(6,645)
Other assumed liabilities	(1,311)
Total acquired identifiable assets and liabilities	73,122
Goodwill	351,598
Total consideration transferred	$ 424,720

Identifiable assets and liabilities acquired or assumed are measured separately at their fair values as of the acquisition date. The fair value measurements of the identified intangible assets were based primarily on significant unobservable inputs and thus represent a Level 3 measurement as defined in ASC Topic 820, *Fair Value Measurement* ("ASC 820"). The fair values of the trade name and the developed technology were determined using the relief-from-royalty method under the income approach. This involves forecasting avoided royalties, reducing them by taxes, and discounting the resulting net cash flows to a present value using an appropriate discount rate. Judgment was applied for a number of assumptions in valuing the identified intangible assets, including revenue and cash flow forecasts, survival rates, technology life, royalty rate, obsolescence and discount rate. The fair value of customer relationships were determined using the replacement cost approach. This approach consists of developing an estimate of the current cost of a similar new asset having the nearest equivalent utility to the asset or group of assets being valued and involves the estimation of all the costs incurred and accumulated in the development effort and application of any related obsolescence factors. The fair value of partnerships were determined using the multi-period excess earnings method. This involves forecasting the net earnings expected to be generated by the asset, reducing them by appropriate returns on contributory assets, and then discounting the resulting net cash flows to a present value using an appropriate discount rate. The fair value of the non-compete agreements was determined using the with and without method, a variation of the income approach. The with and without method is based on the difference between cash flows for two different scenarios. For the first scenario, the prospective cash flows for the business are projected assuming the non-compete agreements are in place, and for the second scenario, the prospective cash flows for the business are estimated assuming that the non-compete agreements are not in place.

Amortization expense related to identified intangible assets is recognized on a straight-line basis over the assets' useful lives of two to seven years. Amortization expense is recognized within cost of revenue for developed technology, sales and marketing expense for customer relationships, partnerships and trademark, and general and administrative expense for non-compete agreements, in the consolidated statements of operations and comprehensive loss. Amortization expense for fiscal year ended March 31, 2022 was $7.3 million.

The excess of the consideration paid over the fair value of the net assets acquired is recorded as goodwill. The acquired goodwill of $351.7 million is assigned to the Consumer and Research Services segment and represents future economic benefits expected to arise from synergies from combining operations and commercial organizations to increase market presence and the extension of existing customer relationships. The goodwill recognized upon acquisition is not expected to be deductible for U.S. or U.K. income tax purposes.

As a result of the acquisition and due to basis differences created from the accounting for the combination, the Company acquired a net deferred tax liability of $6.6 million. The Company's deferred tax liabilities are partially offset with 23andMe's deferred tax assets causing a release of the Company's income tax valuation allowance. The release resulted in an income tax benefit of $3.5 million. The Company has a remaining foreign deferred tax liability of $3.1 million.

From the closing of the Lemonaid Acquisition date through March 31, 2022, the Company recognized revenue of $19.2 million and net loss of $22.3 million related to Lemonaid Health. The pro forma financial information in the table below summarizes the combined results of operations for the Company and Lemonaid Health as if the companies had been combined as of April 1, 2019. The pro forma revenue and net loss is presented for informational purposes only and does not purport to be indicative of the results of future operations or the results that would have occurred had the transaction taken place on April 1, 2019.

	Year Ended March 31,		
	2022	2021	2020
	(in thousands)		
Pro forma revenue [1]	$ 295,025	$ 271,532	$ 322,393
Pro forma net loss [1]	$ (241,382)	$ (237,162)	$ (299,199)

(1) As if the acquisition of Lemonaid was consummated on April 1, 2019.

The pro forma financial information includes pro forma adjustments related to the valuation and allocation of the purchase price, primarily amortization of acquired intangible assets, additional stock-based compensation expense related to accelerated vesting of options in connection with the acquisition, additional stock-based compensation expense related to replacement awards issued in connection with the acquisition, amortization of representation and warranty insurance procured in connection with the acquisition, and direct transaction costs reflected in the historical financial statements.

5. Variable Interest Entities

Through the acquisition of Lemonaid Health, Inc. in November 2021, the Company has service agreements with PMCs and Affiliated Pharmacies. In order for customers to obtain a prescription, customers must complete a consultation through the Company's website or app with an appropriately licensed medical provider from one of the PMCs. A customer will receive an electronic prescription that will be sent to an Affiliated Pharmacy, or a pharmacy of the customer's choice, only if the medical provider believes such medical treatment of the customer is safe and appropriate.

The Company provides services pursuant to contracts with the PMCs which employ licensed medical providers to provide telehealth medical services. The PMCs were designed and structured to comply with the relevant laws and regulations governing professional medical practice, which generally prohibit the practice of medicine by lay persons or corporations. To satisfy these regulatory requirements, all of the issued and outstanding equity interests of the PMCs are owned by an appropriately licensed medical professional nominated by the Company (the "Nominee Shareholder"). The Company executes with each PMC a Management Services & Licensing Agreement ("MSA"), which provides for various administrative, technological, and management services to be provided by the Company to the PMCs, licenses certain Company intellectual property to the PMC, and gives the Company rights to impose certain restrictions and conditions of ownership or transfer of the PMC equity by the Nominee Shareholder.

The Company provides all of the necessary capital for the operations of the PMCs through loans to the PMCs. The Company also has exclusive responsibility for the provision of all nonmedical services including operation of all technology platforms used by the PMCs or customers to complete a medical consultation with a Provider, handling all financial transactions and day-to-day operations of each PMC, providing regulatory guidance to the PMCs in establishing telehealth policies and protocols consistent with state and federal law, and making recommendations to the PMCs in establishing the guidelines for employment and compensation of the medical professionals of each PMC. In addition, the MSA provides that the Company has the power and authority to change the Nominee Shareholder upon termination of the MSA, including for convenience upon 180 days prior notice, or other enumerated events, and designate a new Nominee Shareholder, which further constrains the Nominee Shareholder's rights to returns of the PMC. The Nominee Shareholders, notwithstanding their legal form of ownership of equity interests in the PMCs, have no substantive profit-sharing rights in the PMCs.

The Company has also entered into similar MSAs with the Affiliated Pharmacies. The Affiliated Pharmacies are licensed pharmacies primarily responsible for providing prescription fulfillment services to the Company's customers. The Company provides management and administrative services to the Affiliated Pharmacies comparable to the services it provides to the PMCs, except that the Company is the sole provider of professional staffing services required to operate the Affiliated Pharmacies. Under the terms of the MSAs with the Affiliated Pharmacies, the Nominee Shareholders, notwithstanding their legal form of ownership of equity interests in the Affiliated Pharmacies, have no substantive profit-sharing rights in the Affiliated Pharmacies.

Based upon the provisions of these agreements, the Company determined that the PMCs and Affiliated Pharmacies are VIEs due to the respective equity holders having nominal capital at risk, and the Company has a variable interest in each of the PMCs and Affiliated Pharmacies. The Company consolidated the PMCs and Affiliated Pharmacies under the VIE model since the Company has the power to direct activities that most significantly impact the VIEs' economic performance and the right to receive benefits or the obligation to absorb losses that could potentially be significant to the VIEs. Under the VIE model, the Company presents the results of operations and the financial position of the VIEs as part of the consolidated financial statements of the Company.

Furthermore, as a direct result of the financial support the Company provides to the VIEs (e.g. loans), the interests held by holders lack economic substance and do not provide them with the ability to participate in the residual profits or losses generated by the VIEs. Therefore, all income and expenses recognized by the VIEs are allocated to the Company's stockholders.

The aggregate carrying value of total assets and total liabilities included on the consolidated balance sheets for the VIEs after elimination of intercompany transactions were $11.2 million and $13.3 million respectively, as of March 31, 2022. Total revenue included on the consolidated statements of operations and comprehensive loss for the VIEs after elimination of intercompany transactions was $19.4 million for the fiscal year ended March 31, 2022. Net loss included on the consolidated statements of operations and comprehensive loss was $2.1 million for the fiscal year ended March 31, 2022.

6. Fair Value Measurements

Recurring Fair Value Measurements

The fair value of cash, restricted cash, accounts receivable, accounts payable, and accrued liabilities are stated at their carrying value, which approximates fair value due to the short time to the expected receipt or payment date as of March 31, 2022 and 2021. There were no financial assets or liabilities measured at fair value on a recurring basis as of March 31, 2022 and 2021. Identifiable assets and liabilities acquired or assumed are measured separately at their fair values as of the acquisition date. See Note 4, "*Acquisitions,*" for additional detail.

Nonrecurring Fair Value Measurements

Certain items were recorded at fair value on a nonrecurring basis in the Company's financial statements for the fiscal years ended March 31, 2022, 2021 and 2020.

Long-lived assets within an asset group, which included right of use assets, leasehold improvements and property and equipment, were measured at fair value on a nonrecurring basis at March 31, 2020 due to an impairment recognized on those assets at that date (see Note 9, "*Restructuring*"). Fair value of the asset group was estimated as $21.5 million using discounted cash flows under the income approach classified in Level 3 of the fair value hierarchy. Under the income approach, the cash flows were discounted at 9.0% and incorporated assumptions based on the Company's best estimate of future sub-lease income and sub-lease term for a portion of its Sunnyvale, California facility.

For the fiscal year ended March 31, 2022, changes in warrant liabilities were primarily related to Private Placement Warrants and Public Warrants defined and discussed in Note 13, "*Common Stock and Warrants*." The Warrants were measured at fair value on a recurring basis. The Company performs routine procedures such as comparing prices obtained from independent sources to ensure that appropriate fair values are recorded. The Company valued the Private Placement Warrants using a binomial lattice model. Inherent in a binomial lattice model ("lattice model") are assumptions related to expected term, volatility, risk-free interest rate, and dividend yield. The expected term of the Warrants was determined to be equivalent to their remaining contractual term and includes consideration of the redemption features that were incorporated into the binomial lattice model. The Company derived the volatility of its Private Placement Warrants based on an implied volatility that was estimated using an iterative process to calibrate a binomial lattice model to the trading price of the Public Warrant. The risk-free interest rate is based on the U.S. Treasury's rates of U.S. Treasury zero-coupon bonds with a maturity similar to the expected term of the Private Placement Warrants. The dividend rate is based on the historical rate, which the Company anticipates remaining at zero.

On November 22, 2021, the Company called the Public Warrants and the Private Placement Warrants for redemption. The Company valued the Private Placement Warrants on the settlement date of exercise, using the fair market value of the Company's Class A common stock multiplied by the number of shares of Class A common stock to be issued per Warrant, which was determined in accordance with the terms of the warrant agreement and based on the redemption date and the volume weighted average price (the "Redemption Fair Market Value") of the Class A common stock during the ten trading days immediately following the date on which the notice of redemption was sent to holders of Warrants. On a cashless basis exercise, the holder was entitled to receive 0.2516 shares of Class A common stock per Warrant. The Public Warrants were valued using the listed trading price on the relevant settlement date of exercise. Any Warrants not exercised by the redemption date, December 22, 2021, were automatically redeemed by the Company at a price of $0.10 per Warrant. The change in fair value of warrant liabilities was recorded through the date of exercise or redemption within the consolidated statements of operations and comprehensive loss. Since all liability-classified warrants were exercised or redeemed as of March 31, 2022, the associated warrant liabilities were reclassified to additional paid-in capital. As of March 31, 2022, no Warrants were outstanding. See Note 13, "*Common Stock and Warrants,*" for additional detail.

The change in the fair value of warrant liabilities is as follows:

	Warrant Liabilities (in thousands)
Balance at March 31, 2021	$ —
Assumption of Private Placement Warrants and Public Warrants	75,415
Redeemed/exercised warrants	(42,426)
Change in fair value of warrant liabilities	(32,989)
Balance at March 31, 2022	$ —

As of March 31, 2022, the Company had no transfers between levels of the fair value hierarchy of its assets and liabilities measured at fair value. Due to the exercise and redemption of all Public Warrants and Private Placement Warrants during the period, there were no longer any Level 3 Private Placement Warrant liabilities.

7. Collaborations

From time to time the Company enters into collaboration arrangements in which both parties are active participants in the arrangement and are exposed to the significant risks and rewards of the collaboration, in which case the collaboration is within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"). Within such collaborations, the Company determines if any obligations are an output of the Company's ordinary activities in exchange for consideration, and if so, the Company applies ASC 606 to such activities.

For other payments received from the other party for other collaboration activities related to various development, launch and sales milestones of licensed products, or royalties related to net sales of licensed products, the Company analogizes to ASC 606.

Such payments will be recognized when the related activities occur as they are determined to relate predominantly to the license of intellectual property transferred to the other party and therefore have also been excluded from the transaction price allocated to the performance obligations determined under ASC 606. To date, no consideration in this regard has been received under the agreements discussed below.

GlaxoSmithKline Agreement

In July 2018, the Company and an affiliate of GSK entered into a four-year exclusive drug discovery and development collaboration agreement (the "GSK Agreement") for collaboration on identification and development of therapeutic agents with a unilateral option for GSK to extend the term for an additional year. The Company concluded that GSK is considered a customer. Therefore, the Company has applied the guidance in ASC 606 to account for and present consideration received from GSK related to research services provided by the Company. The Company's activities under the GSK Agreement, which include reporting, drug target discovery, and joint steering committee participation, represent one combined performance obligation to deliver research services. In addition, the GSK Agreement, along with subsequent amendments, provided GSK the right to include certain identified pre-existing Company programs in the collaboration at GSK's election, each of which is considered distinct from the research services. The exercise price for the pre-existing program options varied to reflect the respective stage of development of each such program, with up to two such programs being offered for no additional charge. The two programs offered for no additional charge were material rights and therefore also identified as performance obligations within the arrangement.

In addition to cost-sharing during the performance of research services which is recorded within cost of revenue when incurred in the Consumer and Research Services segment, once drug targets have been identified for inclusion in the collaboration, the Company and GSK equally share in the costs of further research, development and commercialization of identified targets, subject to certain rights of either party to opt-out of funding at certain predetermined development milestones. These cost-sharing charges for costs incurred subsequent to the identification of drug targets have been included in research and development expense in the consolidated statements of operations and comprehensive loss during the period incurred. The Company may also share in the net profits or losses of products that are commercialized pursuant to the collaboration or receive royalties on products which are successfully commercialized.

On January 18, 2022, GSK elected to exercise its option to extend the exclusive target discovery period of the ongoing collaboration with the Company for an additional year to July 2023. The Company will receive a one-time payment of $50.0 million to extend the period.

The Company recognizes revenue related to the GSK Agreement as the performance obligation is satisfied using an input method to measure progress. The Company believes that actual hours incurred relative to projected hours is the most accurate measurement of progress for the input method. During the fiscal year ended March 31, 2022, the 23andMe and GSK joint steering committee revised the total project resources, which resulted in a reduction in the total estimated project hours. The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate was recognized as an adjustment to cumulative revenue to reflect the change in estimate. This adjustment increased revenue by $9.0 million, decreased net loss by $9.0 million and decreased the Company's basic and diluted net loss per share by $0.02 for the fiscal year ended March 31, 2022.

During the fiscal years ended March 31, 2022, 2021 and 2020, the Company recognized $46.1 million, $39.9 million and $26.7 million, respectively, of research services and therapeutics revenue related to the GSK Agreement. As of March 31, 2022 and 2021, the Company had current deferred revenue related to GSK of $9.2 million and $30.1 million, respectively. As of March 31, 2022 and 2021, there was no noncurrent deferred revenue related to GSK. As of March 31, 2022 and 2021, there were no receivables and no contract assets recorded in prepaid expenses and other current assets, respectively, related to the GSK Agreement. During the fiscal years ended March 31, 2022, 2021 and 2020, cost-sharing amounts incurred subsequent to the identification of targets, included in research and development expenses, were $24.0 million, $18.7 million and $19.1 million, respectively. During the fiscal years ended March 31, 2022, 2021 and 2020, cost-sharing amounts incurred prior to the identification of targets, included in cost of revenue, were $0.3 million, $(1.4) million and $1.0 million, respectively. As of March 31, 2022 and 2021, the Company had $18.3 million and $11.5 million, respectively, related to balances of amounts payable to GSK for reimbursement of shared costs included within accounts payable and accrued expenses and other current liabilities in the consolidated balance sheets.

8. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consisted of the following:

	March 31,	
	2022	2021
	(in thousands)	
Computer and software	$ 10,573	$ 13,252
Laboratory equipment and software	51,557	48,636
Furniture and office equipment	8,926	8,803
Leasehold improvements	40,566	39,668
Capitalized asset retirement obligations	853	853
Property and equipment, gross	112,475	111,212
Less: accumulated depreciation and amortization	(62,624)	(50,328)
Property and equipment, net	$ 49,851	$ 60,884

Depreciation and amortization expense was $16.1 million, $18.1 million and $22.2 million for the fiscal years ended March 31, 2022, 2021 and 2020, respectively.

Internal-use Software, Net

Internal-use software, net consisted of the following:

	March 31,	
	2022	2021
	(in thousands)	
Capitalized internal-use software	$ 14,804	$ 9,200
Less: accumulated amortization	(5,169)	(2,311)
Internal-use software, net	$ 9,635	$ 6,889

The Company capitalized $5.7 million, $4.0 million and $6.0 million in internal-use software during the fiscal years ended March 31, 2022, 2021 and 2020, respectively. For the fiscal years ended March 31, 2022, 2021 and 2020, amortization expense related to internal-use software was $2.9 million, $2.0 million and $0.4 million, respectively, including approximately $0.5 million, $0.3 million and $0.1 million, respectively, of stock-based compensation expense.

Intangible Assets, Net

Intangible assets, net consisted of the following:

	March 31, 2022			
	Weighted Average Remaining Useful Life-Years	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
		(in thousands, except years)		
Customer Relationships	1.6	$ 14,900	$ (3,104)	$ 11,796
Partnerships	6.6	23,200	(1,558)	21,642
Trademark	4.6	11,000	(917)	10,083
Developed Technology	6.6	24,100	(1,436)	22,664
Non-Compete Agreements	4.6	2,800	(233)	2,567
Patents	6.4	5,500	(347)	5,153
Total intangible assets		$ 81,500	$ (7,595)	$ 73,905

Amortization expense for intangible assets was $7.6 million for the fiscal year ended March 31, 2022. There were no intangible assets as of March 31, 2021.

Estimated future amortization expense of the identified intangible assets as of March 31, 2022, is as follows:

	Estimated Amortization (in thousands)
Fiscal years ending March 31,	
2023	$ 18,209
2024	15,105
2025	10,759
2026	10,759
2027	8,426
Thereafter	10,647
Total estimated future amortization expense	$ 73,905

Accrued Expense and Other Current Liabilities

Accrued expense and other current liabilities consisted of the following:

	March 31,	
	2022	2021
	(in thousands)	
Accrued payables	$ 27,654	$ 19,869
Accrued compensation and benefits	14,898	11,749
Accrued taxes and other	2,036	335
Total accrued expenses and other current liabilities	$ 44,588	$ 31,953

9. Restructuring

In December 2019 and January 2020, the Company approved restructuring plans to achieve its strategic and financial objectives. Restructuring activities included a reduction in workforce, contract terminations related to certain retail and operating lease arrangements, resulting in impairment losses of operating lease ROU assets associated with disposition of the Phoenix, Arizona operating facility and square footage available for sublease at the Sunnyvale, California facility, as well as other exit or disposal costs. The Company recorded restructuring expenses of $44.7 million within restructuring and other charges in the consolidated statements of operations and comprehensive loss during the fiscal year ended March 31, 2020 primarily related to the Consumer & Research Services segment.

During the fiscal year ended March 31, 2020, the Company recorded employee severance and termination benefits expense of approximately $5.5 million within restructuring and other charges in the consolidated statements of operations and comprehensive loss, of which $0.9 million was non-cash stock-based compensation expense. The Company recorded these involuntary employee-related exit and disposal costs when there was a substantive plan for employee severance and related costs were probable and estimable.

The Company ceased use of its Phoenix, Arizona operating facility in January 2020 as part of the Company's restructuring plan. Using the discounted cash flow method, the Company calculated the difference between the present value of the estimated future sublease rental income and the present value of remaining lease obligations, adjusted for the effects of any prepaid or deferred items. The key assumptions used in the Company's discounted cash flow model included the amount and timing of sublease rental receipts and the discount rate. As a result, the Company recognized an impairment loss, which represented the remaining carrying value of the operating ROU asset as of March 31, 2020, of approximately $0.6 million, as well as an impairment loss of $13.0 million associated with property and equipment for this facility and an impairment loss of $0.7 million for capitalized internal use software. The Company also recorded a related liability of $3.0 million for the contractually obligated exit costs associated with this facility as of March 31, 2020. The Company utilized the terms and conditions of the assignment and assumption of lease agreement when evaluating the impairment of the operating lease ROU asset related to the operating lease for the fiscal year ended March 31, 2020. The Company recorded the expenses associated with the Phoenix, AZ facility disposition within restructuring and other charges in the consolidated statements of operations and comprehensive loss. In June 2020, the Company entered into an assignment and assumption of lease agreement with a third-party assignee related to the facility space in Phoenix, Arizona. As part of this agreement, the third-party assignee agreed to assume from the Company all of the rights and remaining obligations under the operating lease, which the Company had previously entered into with the landlord in March 2019 and subsequently amended in June 2019.

In addition, as part of the restructuring plan, the Company made available a significant portion of its Sunnyvale, California facility for sublease. Using the discounted cash flow method, the Company calculated the difference between the present value of the estimated future sublease rental income and the present value of remaining lease obligations, adjusted for the effects of any prepaid or deferred items. As a result, the Company recognized an impairment loss of approximately $12.6 million to reduce the carrying value of the operating ROU asset to fair value, as well as an impairment loss of $7.0 million associated with property, equipment and capitalized asset retirement obligations for this facility within restructuring and other charges in the consolidated statements of operations and comprehensive loss in the fiscal year ended March 31, 2020.

As part of the restructuring activity, the Company also consolidated the sales channel network by terminating certain retail contracts. As a result, the Company recorded $0.8 million return-related fees and $1.5 million inventory write-off within restructuring and other charges in the consolidated statements of operations and comprehensive loss in the fiscal year ended March 31, 2020. Of the $0.8 million of return-related fees incurred during the fiscal year ended March 31, 2020, $0.1 million was paid or adjusted, resulting in an accrued balance of $0.7 million as of March 31, 2020. During the fiscal year ended March 31, 2021, an additional $0.2 million was paid or adjusted, resulting in an accrued balance of $0.5 million as of March 31, 2021. The Company also recorded a refund of the original purchase price related to the return of inventory held by retailers of $5.7 million, which reduced deferred revenue on the consolidated balance sheets as of March 31, 2020.

The following table shows the total amount incurred and accrued related to one-time employee termination benefits:

	One-Time Employee Termination Benefits
	(in thousands)
Accrued restructuring costs as of March 31, 2019	$ —
Restructuring charges incurred during the period	4,633
Amounts paid during the period	(3,580)
Accrued restructuring costs as of March 31, 2020	1,053
Amounts paid during the period	(1,053)
Accrued restructuring costs as of March 31, 2021	$ —

There was no restructuring activity during the fiscal year ended March 31, 2022. The Company does not expect to incur any further expenses in connection with any past restructuring plan.

10. Leases

The Company's lease portfolio includes leased offices, dedicated lab facility and storage space, and dedicated data center facility space, with remaining contractual periods from less than 1.8 years to 9.3 years. For purposes of calculating lease liabilities, lease terms may include options to extend the lease when it is reasonably certain that the Company will exercise those options. In January 2021, the Company entered into an operating lease amendment to extend the lease term of the South San Francisco, California lab facility, which resulted in $12.1 million of non-cancellable future minimum lease payments and a revised lease term through January 2025. For the Company's facility in Sunnyvale, California, there is an option to extend the lease for a period of 7 years. The Company is not reasonably certain that it will exercise this option and therefore it is not included in its rights of use assets and lease liabilities as of March 31, 2022.

The Company incurred total lease costs in its consolidated statements of operations and comprehensive loss. The components of lease cost for operating leases for the fiscal years ended March 31, 2022, 2021 and 2020 were as follows:

	Year Ended March 31,		
	2022	2021	2020
	(in thousands)		
Operating lease cost, net [1]	$ 13,640	$ 13,614	$ 10,999
Variable lease cost	6,425	5,809	4,705
Total lease cost	$ 20,065	$ 19,423	$ 15,704

(1) For the year ended March 31, 2020, included in operating lease cost is a $4.9 million reduction to lease cost related to a lease termination.

Variable lease cost includes property tax, insurance, common area maintenance, and utilities. The following is supplemental balance sheet information as of March 31, 2022 and 2021:

	Year Ended March 31,	
	2022	2021
	(in thousands)	
Reported as:		
Assets:		
Operating lease right-of-use assets	$ 55,577	$ 63,122
Liabilities:		
Operating lease liabilities	7,784	6,140
Operating lease liabilities, noncurrent	78,524	87,582
Total operating lease liabilities	$ 86,308	$ 93,722

Weighted average remaining lease term and discount rate for the Company's operating leases was as follows:

	Year Ended March 31,		
	2022	2021	2020
Weighted-average remaining lease term (in years)	8.4	9.2	10.5
Weighted-average discount rate	7%	7%	8%

Supplemental cash flow information related to operating leases for the fiscal years ended March 31, 2022, 2021 and 2020 was as follows:

	Year Ended March 31,		
	2022	2021	2020
		(in thousands)	
Cash paid for amounts included in the measurement of operating lease liabilities:			
Operating cash flows used in operating leases	$ (13,490)	$ (14,067)	$ (12,520)
Landlord contributions included in the measurement of operating lease ROU assets:			
Operating cash flows provided by operating leases	$ —	$ 3,733	$ 9,940
Supplemental disclosure of non-cash operating lease activities:			
Operating lease ROU assets obtained in exchange for new operating lease liabilities	$ —	$ 12,803	$ 4,769

As of March 31, 2022, the future minimum lease payments included in the measurement of the Company's operating lease liabilities were as follows (in thousands):

Fiscal years ending March 31,	
2023	$ 13,782
2024	14,960
2025	14,464
2026	11,105
2027	11,348
Thereafter	53,095
Total future operating lease payments	118,754
Less: imputed interest	(32,446)
Total operating lease liabilities	$ 86,308

11. Commitments and Contingencies

Non-cancelable Purchase Obligations

In the normal course of business, the Company enters into non-cancelable purchase commitments with various parties for purchases. As of March 31, 2022, the Company had outstanding non-cancelable purchase obligations with a term of 12 months or longer totaling as follows (in thousands):

Fiscal years ending March 31,		
2023	$	22,186
2024		26,977
2025		15,181
2026		728
Total	$	65,072

The amounts purchased under the non-cancelable purchase obligations were $26.3 million, $20.6 million and $32.4 million for the fiscal years ended March 31, 2022, 2021 and 2020, respectively.

Legal Matters

The Company is subject to certain routine legal and regulatory proceedings, as well as demands and claims that arise in the normal course of business. Certain conditions may exist as of the date the consolidated financial statements are issued, which may result in a loss to the Company, but will only be recorded when one or more future events occur or fail to occur. The Company's management assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against and by the Company or unasserted claims that may result in such proceedings, the Company's management evaluates the perceived merits of any legal proceedings or unasserted claims, as well as the perceived merits of the amount of relief sought or expected to be sought.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's consolidated financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, together with an estimate of the range of possible loss if determinable and material, would be disclosed. Loss contingencies considered to be remote by management are generally not disclosed unless they involve guarantees, in which case the guarantee would be disclosed. Legal fees related to potential loss contingencies are expensed as incurred.

On December 10, 2019, Celmatix Inc. ("Celmatix") filed a lawsuit in the Supreme Court of the State of New York against the Company asserting claims against the Company for breach of contract and the implied covenant of good faith and fair dealing and tortious interference with contract and prospective economic advantage, alleging damages that, according to the compliant, plaintiff "believed to be in excess of $100 million." On February 14, 2020, the Company filed its answer, denying all of the material allegations of the complaint and asserting counterclaims against Celmatix for breach of contract. Celmatix amended its complaint on July 13, 2021, asserting an additional claim against the Company for fraudulent inducement of contract. On July 19, 2021, the Company filed its answer to the amended complaint, denying all of the material allegations and asserting a counterclaim and an additional defense of fraudulent inducement of contract. On October 29, 2021, both parties made motions for partial summary judgment in their favor. Briefing of the parties' respective motions was completed in December 2021. On March 30, 2022, the Company and Celmatix agreed to a settlement, pursuant to which the Company made a payment of $10.0 million net of insurance coverage and all claims and counter-claims were released. The parties filed a Stipulation of Dismissal and Discontinuance with Prejudice on April 22, 2022. On April 25, 2022, the presiding judge entered an order noting that the motions for summary judgment are moot, canceling all future appearances and marking the case as disposed. As a result of the settlement, the Company has recorded a net loss on litigation settlement of $10.0 million in general and administrative expenses on the consolidated statements of operations and comprehensive loss.

Indemnification

The Company enters into indemnification provisions under agreements with other companies in the ordinary course of business, including, but not limited to, collaborators, landlords, vendors, and contractors. Pursuant to these arrangements, the Company agrees to indemnify, defend, and hold harmless the indemnified party for certain losses suffered or incurred by the indemnified party as a result of the Company's activities. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the Company believes the fair value of these provisions is not material. The Company maintains insurance, including commercial general liability insurance and product liability insurance, to offset certain potential liabilities under these indemnification provisions. In addition, the Company indemnifies its officers, directors, and certain key employees against claims made with respect to matters that arise while they are serving in their respective capacities as such, subject to certain limitations set forth under applicable law, the Company's Bylaws, and applicable indemnification agreements. To date, there have been no claims under these indemnification provisions.

12. Redeemable Convertible Preferred Stock

The following table is a summary of the Company's redeemable convertible preferred stock as of:

	March 31, 2021			
	Shares	Shares Issued and Outstanding	Carrying Value	Aggregate Liquidation Preference
		(in thousands, except share data)		
Series A	16,330,984	16,330,984	$ 8,815	$ 8,953
Series B	20,754,666	20,754,666	27,643	27,779
Series C	22,703,050	22,703,050	30,961	31,179
Series D	33,110,992	33,110,992	58,274	58,450
Series E	24,414,254	24,414,254	114,936	115,246
Series F	41,300,501	41,300,501	242,168	250,000
Series F-1	50,897,623	50,567,408	354,554	382,500
Total redeemable convertible preferred stock	209,512,070	209,181,855	$ 837,351	$ 874,107

Conversion

Immediately prior to the effective time of the Merger, all series of the redeemable convertible preferred stock of 23andMe, Inc. were converted into shares of Class B common stock of 23andMe, Inc. on a one-for-one basis and then converted to the Company's Class B common stock at an exchange ratio of 2.293698169, and share amounts are presented as having been converted as of March 31, 2021. As of March 31, 2022, no shares of redeemable convertible preferred stock were outstanding.

13. Common Stock and Warrants

Common Stock

Prior to the Merger, 23andMe, Inc. had three classes of authorized common stock: Class A common stock, Class B common stock, and Class C common stock. There were no outstanding shares of 23andMe, Inc. Class C common stock. The rights of the holders of 23andMe, Inc. Class A, Class B, and Class C common stock, respectively, were identical, except with respect to (i) electing members of the Board of Directors, and (ii) voting rights. The outstanding shares of 23andMe, Inc. Class A and Class B common stock, respectively, are presented on the consolidated balance sheets and on the consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit) for the fiscal year ended March 31, 2021.

On the Closing Date and in accordance with the terms and subject to the conditions of the Merger Agreement, each share of 23andMe, Inc. Class A common stock, par value $0.00001 per share, (other than dissenting shares) was canceled and converted into the right to receive the applicable portion of the merger consideration comprised of the Company's Class A common stock, par value $0.0001 per share, as determined in the Merger Agreement (the "Share Conversion Ratio"), each share of 23andMe, Inc. Class B common stock, par value $0.00001 per share (other than dissenting shares) was canceled and converted into the right to receive the applicable portion of the merger consideration comprised of the Company's Class B common stock, par value $0.0001 per share, as determined pursuant to the Share Conversion Ratio. The Share Conversion Ratio was 2.293698169.

On June 16, 2021, in connection with the Merger, the Company amended and restated its certificate of incorporation to authorize 1,490,000,000 shares of common stock, of which 1,140,000,000 shares are designated Class A common stock and 350,000,000 shares are designated Class B common stock. The rights of the holders of Class A common stock and Class B common stock are identical, except with respect to voting and conversion rights. Holders of Class A common stock are entitled to one vote per share and holders of Class B common stock are entitled to ten votes per share. Each share of Class B common stock is convertible into one share of Class A common stock any time at the option of the holder and is automatically converted into one share of Class A common stock upon transfer (except for certain permitted transfers). Once converted into Class A common stock, the Class B common stock will not be reissued. Additionally, pursuant to the Company's amended and restated certificate of incorporation, the Company is authorized to issue 10,000,000 shares of preferred stock having a par value of $0.0001 per share ("Preferred Stock"). The Company's Board of Directors has the authority to issue shares of the Preferred Stock in one or more series and to determine the preferences, privileges, and restrictions, including voting rights, of those shares. As of March 31, 2022, no shares of Preferred Stock were issued and outstanding.

As of March 31, 2022, the Company had authorized 1,140,000,000 and 350,000,000 shares of Class A and Class B common stock, respectively, and the Company had 228,174,718 and 220,637,603 shares of Class A and Class B common stock issued and outstanding, respectively.

Class A Common Stock Warrants

As the accounting acquirer, 23andMe, Inc. is deemed to have assumed 8,113,999 warrants for Class A common stock that were held by the Sponsor at an exercise price of $11.50 (the "Private Placement Warrants") and 16,951,609 Class A common stock warrants held by VGAC's shareholders at an exercise price of $11.50 (the "Public Warrants" and, together with the Private Placement Warrants, the "Warrants"). In accordance with the warrant agreement, the Warrants became exercisable on October 6, 2021. Had the Warrants not expired in connection with the Redemption (as defined below), the Warrants would have expired five years after the completion of the Business Combination.

Subsequent to the Merger, the Private Placement Warrants and Public Warrants for shares of Class A common stock met liability classification requirements since the Warrants were required to be settled in cash under a tender offer. In addition, Private Placement Warrants were potentially subject to a different settlement amount as a result of being held by the Sponsor which precludes the Private Placement Warrants from being considered indexed to the entity's own stock. Therefore, the Warrants were classified as liabilities on the consolidated balance sheets.

Public Warrant Terms

The Public Warrants became exercisable into shares of Class A common stock commencing on October 6, 2021.

Redemption of Warrants When the Price per Class A Common Stock Equals or Exceeds $18.00

Once the Warrants became exercisable, the Company had the right to redeem the outstanding Warrants:

- in whole and not in part;
- at a price of $0.01 per warrant;
- upon not less than 30 days' prior written notice of redemption to each warrant holder; and
- if, and only if, the last reported sale price of the Class A common stock for any 20 trading days within a 30-trading-day period ending three business days before the Company sends the notice of redemption to the warrant holders (which is referred to as the "Reference Value") equals or exceeds $18.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations, and the like).

Redemption of Warrants When the Price per Class A Common Stock Equals or Exceeds $10.00

Once the Warrants became exercisable, the Company had the right to redeem the outstanding warrants:

- in whole and not in part;
- at $0.10 per Warrant upon a minimum of 30 days' prior written notice of redemption, provided that holders will be able to exercise their warrants on a cashless basis prior to redemption and receive that number of shares determined by reference to the table below, based on the redemption date and the "fair market value" of Class A common stock;
- if, and only if, the Reference Value equals or exceeds $10.00 per share (as adjusted per share sub-divisions, share dividends, reorganizations, reclassifications, recapitalizations, and the like); and
- if the Reference Value is less than $18.00 per share (as adjusted for share sub-divisions, share capitalizations, reorganizations, recapitalizations, and the like) the Private Placement Warrants must also be concurrently called for redemption on the same terms as the outstanding Public Warrants, as described above.

The numbers in the fee table of the Registration Statement on Form S-1 filed with the SEC by the Company on July 8, 2021 represent the number of shares of Class A common stock that a warrant holder had the right to receive upon exercise in connection with a redemption by the Company pursuant to this redemption feature, based on the "redemption fair market value" of the Class A common stock on the corresponding redemption date (assuming holders elect to exercise their Warrants on a cashless basis prior to redemption), determined based on the volume-weighted average price for the 10 trading days immediately following the date on which the notice of redemption is sent to the holders of Warrants, and the number of months that the corresponding redemption date precedes the expiration date of the Warrants, each as set forth in such fee table. The Company provided its warrant holders with the redemption fair market value no later than one business day after the 10-trading-day period described above ended.

No fractional shares were issued upon exercise of the Warrants. If, upon exercise of the Warrants, a holder would have been entitled to receive a fractional interest in a share, the Company upon exercise rounded down to the nearest whole number the number of shares of Class A common stock that were issued to the warrant holder.

Private Placement Warrants

The Private Placement Warrants (including the shares of Class A common stock issuable upon exercise of the Private Placement Warrants) were not transferable, assignable, or salable until 30 days after the completion of the Business Combination (except, among other limited exceptions, to VGAC's officers and directors and other persons or entities affiliated with the Sponsor) and they were redeemable by the Company, so long as they are held by the Sponsor, members of the Sponsor, or their permitted transferees under certain specified circumstances. The Sponsor or its permitted transferees had the option to exercise the Private Placement Warrants on a cashless basis. Except as described herein, the Private Placement Warrants had terms and provisions identical to those of the Public Warrants. If the Private Placement Warrants had been held by holders other than the Sponsor or its permitted transferees, the Private Placement Warrants would have been redeemable by the Company and exercisable by the holders on the same basis as the Public Warrants.

Except as described under "—Redemption of Warrants When the Price per Class A common stock Equals or Exceeds $10.00," if holders of the Private Placement Warrants elected to exercise them on a cashless basis, they would have paid the exercise price by surrendering such Warrants for that number of shares of Class A common stock equal to the quotient obtained by dividing (x) the product of the number of shares of Class A common stock underlying the Warrants, multiplied by the excess of the "Sponsor exercise fair market value" of the Class A common stock over the exercise price of the Warrants by (y) the Sponsor exercise fair market value. For these purposes, the "Sponsor exercise fair market value" means the average reported closing price of the shares of Class A common stock for the 10 trading days ending on the third trading day prior to the date on which the notice of warrant exercise was sent to the warrant agent.

Warrant Redemption

On November 22, 2021, the Company issued a redemption notice to warrant holders announcing that all Public Warrants and Private Placement Warrants outstanding on December 22, 2021 at 5:00 p.m. New York City Time (the "Redemption Date") would be redeemed for $0.10 per Warrant, if not earlier exercised on a cash or cashless basis (the "Redemption"). After November 22, 2021 and prior to the Redemption Date, warrant holders were entitled to exercise (i) in cash, at an exercise price of $11.50 per share of Class A common stock, or (ii) on a cashless basis in which the exercising holder was entitled to receive 0.2516 shares of Class A common stock per Warrant. Any Warrants not exercised by the Redemption Date were automatically redeemed by the Company at a price of $0.10 per Warrant.

In connection with the Redemption, approximately 23,901,466 Warrants were exercised, representing approximately 95% of the outstanding Warrants, and 6,016,327 shares of Class A common stock were issued upon exercise of such Warrants. Total cash proceeds generated from exercises of the Warrants were immaterial, and the Company made an immaterial redemption payment to the holders of the 1,164,142 redeemed Warrants. Following the Redemption Date, the Public Warrants stopped trading on Nasdaq and were delisted. No Warrants were outstanding as of March 31, 2022.

The change in fair value of warrant liabilities was recorded through the date of exercise or redemption within the consolidated statements of operations and comprehensive loss. Additionally, the fair value of the warrant liability of $42.4 million was reclassified to additional paid-in capital.

Acquisitions

As part of the Lemonaid Acquisition, the Company issued 26,825,241 shares of Class A common stock and an additional 3,747,027 shares of Class A common stock that are subject to vesting. The shares subject to vesting are considered stock-based compensation as outlined in Note 14, "*Equity Incentive Plans and Stock-Based Compensation*."

Reserve for Issuance

The Company has the following shares of common stock reserved for future issuance, on an as-if converted basis as of the dates indicated:

	March 31,	
	2022	**2021**
Redeemable convertible preferred stock	—	209,181,855
Outstanding stock options	73,609,565	67,377,463
Outstanding restricted stock units	10,676,378	—
Remaining shares available for future issuance under 2006 Equity Incentive Plan	—	2,259,758
Remaining shares available for future issuance under 2021 Equity Incentive Plan	48,895,572	—
Shares available for future issuance under Employee Stock Purchase Plan	11,420,000	—
Total shares of common stock reserved	144,601,515	278,819,076

14. Equity Incentive Plans and Stock-Based Compensation

Equity Incentive Plans

In 2006, 23andMe, Inc. established its 2006 Equity Incentive Plan, as amended (the "2006 Plan"), which provides for the grant of stock options and restricted stock to its employees, directors, officers, and consultants. The 2006 Plan allows for time-based or performance-based vesting for the awards. The 2006 Plan has been amended and restated at various times since its adoption. As of March 31, 2022, there have been no performance-based awards granted under the 2006 Plan.

On June 10, 2021, at an extraordinary general meeting of shareholders of VGAC (the "VGAC Shareholder Meeting"), the shareholders of VGAC approved the 23andMe Holding Co. 2021 Incentive Equity Plan (the "2021 Plan") and reserved 136,000,000 authorized shares of the Company's Class A common stock. In addition, all equity awards of 23andMe, Inc. that were issued under the 2006 Plan were converted into comparable equity awards that are settled or exercisable for shares of the Company's Class A common stock. As a result, each 23andMe, Inc. stock option was converted into an option to purchase shares of the Company's Class A common stock based on an exchange ratio of 2.293698169. As of the effective date of the 2021 Plan, no further stock awards have been or will be granted under the 2006 Plan.

The 2021 Plan authorizes the issuance or transfer of up to 136,000,000 shares of Class A common stock. The number of shares of Class A common stock reserved for issuance under the 2021 Plan will automatically increase on January 1 of each calendar year, starting in 2022, in an amount equal to (i) 22,839,019 shares of Class A common stock, (ii) 3.0% of the aggregate number of shares of Class A common stock and Class B common stock outstanding, or (iii) a lesser number of shares determined by the Company's Board of Directors prior to the applicable January 1. In November 2021, in connection with the Lemonaid Acquisition, the Company registered an additional 2,990,386 shares of Class A common stock issuable under the 2021 Plan, which represent shares of Class A common stock issuable in exchange for outstanding options initially granted under Lemonaid Health's 2014 Equity Incentive Plan, as amended.

Options under the 2021 Plan have a contractual life of up to ten years. The exercise price of a stock option shall not be less than 100% of the estimated fair value of the shares on the date of grant, as determined by the Board of Directors. For Incentive Stock Options ("ISO") as defined in the Internal Revenue Code of 1986, as amended (the "Code"), the exercise price of an ISO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the underlying stock on the date of grant as determined by the Board of Directors. The Company's options generally vest over four years. Under the 2021 Plan, stock option awards entitle the holder to receive one share of Class A common stock for every option exercised.

In connection with the Merger, all of the 23andMe, Inc. option holders received an equivalent award at an exchange ratio of 2.293698169 that vest in accordance with the original terms of the award. The Company determined this to be a Type I modification but did not record any incremental stock-based compensation expense since the fair value of the modified awards immediately after the modification was not greater than the fair value of the original awards immediately before the modification.

In February 2022, the Compensation Committee of the Company's Board of Directors adopted an RSU conversion and deferral program for non-employee directors. The purpose of the program is to provide directors with the option to convert all or a portion of their cash compensation into an RSU award under the 2021 Plan and the opportunity to defer settlement of all or a portion of their RSU awards. As of March 31, 2022, no directors have elected to convert any of their cash compensation or defer settlement of any of their RSU awards under the program.

In March 2022, the Compensation Committee of the Company's Board of Directors adopted an annual incentive plan under the 2021 Plan (the "2022 AIP") effective April 1, 2022. The purpose of the 2022 AIP is to provide an incentive and to reward participants in the plan for achieving certain, pre-established performance targets through RSUs. The performance targets may include the Company-wide objectives and/or individual performance goals.

Stock Option Activity

Stock option activity and activity regarding shares available for grant under the 2021 Plan is as follows:

	Options Outstanding			
	Outstanding Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
	(in thousands, except share, years, and per share data)			
Balance as of March 31, 2021	29,375,026	$ 9.37	7.1	$ 403,498
Recapitalization	38,002,437	$ (5.28)		
Balance as of March 31, 2021	67,377,463	$ 4.09		
Granted	14,968,952	$ 4.37		
Exercised	(5,808,526)	$ 2.90		
Cancelled/Forfeited/Expired	(2,928,324)	$ 4.80		
Balance as of March 31, 2022	73,609,565	$ 4.21	6.9	$ 35,979
Vested and exercisable as of March 31, 2022	42,902,557	$ 3.84	5.6	$ 27,504

The weighted average grant-date fair value of options granted for the fiscal years ended March 31, 2022, 2021 and 2020 was $4.44, $3.02 and $2.73 per share, respectively. The intrinsic value of vested options exercised for the fiscal years ended March 31, 2022, 2021 and 2020 was $25.6 million, $47.6 million and $19.0 million, respectively. As of March 31, 2022, unrecognized stock-based compensation cost related to unvested stock options was $104.1 million, which is expected to be recognized over a weighted-average period of 2.8 years. Due to a full valuation allowance on deferred tax assets, the Company did not recognize any tax benefit from stock option exercises for the fiscal years ended March 31, 2022, 2021 and 2020.

The Black-Scholes assumptions used to value stock options at the grant dates are as follows:

	Year Ended March 31,					
	2022		2021		2020	
	Min	Max	Min	Max	Min	Max
Expected term (years)	3.3	6.1	4.0	6.1	5.0	6.1
Expected volatility	72%	75%	61%	68%	53%	62%
Risk-free interest rate	1.0%	2.5%	0.2%	0.5%	0.6%	2.2%
Expected dividend yield	0%	0%	0%	0%	0%	0%

Restricted Stock Units

Under the 2006 Plan and 2021 Plan, restricted stock units ("RSUs") may be granted to employees, non-employee directors and consultants. The RSUs vest ratably over a period ranging from one to four years and are subject to the participant's continuing service to the Company over that period. Until vested, RSUs do not have the voting and dividend participation rights of common stock and the shares underlying the awards are not considered issued and outstanding.

The following table summarizes the RSU activity under the equity incentive plans and related information:

	RSUs	
	Unvested RSUs	Weighted-Average Grant Date Fair Value Per Share
Balance as of March 31, 2021	—	—
Granted	11,943,645	$ 9.83
Vested	(801,794)	$ 10.90
Cancelled/forfeited	(465,473)	$ 11.08
Balance as of March 31, 2022	10,676,378	$ 9.70

As of March 31, 2022, unrecognized stock-based compensation expense related to outstanding unvested RSUs was $96.0 million, which is expected to be recognized over a weighted-average period of 3.5 years.

Stock Subject to Vesting

In November 2021, the Company granted 3,747,027 shares of Class A common stock subject to vesting with an aggregate grant date fair value of $43.9 million in connection with the acquisition of Lemonaid Health. Vesting of the shares is contingent on each recipient's continued employment, both of whom are part of the management team within the General and Administrative department. Accordingly, the Company has recognized stock-based compensation expense related to these awards of $4.5 million for the fiscal year ended March 31, 2022 within general and administrative expenses. The expense will be recognized over a four-year vesting period with quarterly vesting and no cliff. Unrecognized stock-based compensation expense of $39.4 million will be recognized over a weighted average period of 3.6 years.

Employee Stock Purchase Plan

On June 10, 2021, at the VGAC Shareholder Meeting, the shareholders of VGAC approved the 23andMe Holding Co. ESPP. A total of 11,420,000 shares of the Company's Class A common stock were initially reserved for issuance under the ESPP. The number of shares of the Company's Class A common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2023, by the lesser of (i) an amount equal to one percent (1.0%) of the total number of shares of Class A and Class B common stock outstanding as of the last day of the immediately preceding December 31st, (ii) 5,000,000 shares, or (iii) a lesser number of shares as determined by the Board of Directors in its discretion.

The ESPP provides for concurrent 12-month offerings with purchases each six months commencing on March 1 and September 1 of each year with purchases on August 31 and February 28 of each year. As of March 31, 2022, no shares of the Company's Class A common stock have been purchased under the ESPP. Employees participating in the ESPP commence payroll withholdings that accumulate through the end of the respective offering period. As of March 31, 2022, $0.6 million has been withheld via employee payroll deductions for employees who have opted to participate in the purchase period ending August 31, 2022.

Stock-Based Compensation

The total share-based compensation expense related to stock options by line item in the accompanying consolidated statements of operations and comprehensive loss is summarized as follows:

	Year Ended March 31,		
	2022	2021	2020
		(in thousands)	
Cost of revenue	$ 4,029	$ 858	$ 733
Research and development	26,540	21,771	16,524
Sales and marketing	5,122	4,081	3,988
General and administrative	22,242	59,986	18,932
Restructuring and other charges	—	—	881
Total stock-based compensation expense	$ 57,933	$ 86,696	$ 41,058

Early Exercise of Common Stock Options

The 2006 Plan allows for option awards that include the right to early exercise options for shares of common stock. For the options granted to the CEO (who is a related party), the Company's Board of Directors authorized the CEO to exercise unvested options to purchase shares of common stock. Under the terms of the 2006 Plan, any shares issued as a result of the CEO's early exercise are subject to repurchase, at the option of the Company, at the original issuance price in the event of the CEO's termination of service as a Service Provider (as defined in the 2006 Plan) for any reason, until the options would have been fully vested. In August 2020, the CEO was granted options for 6,881,095 shares, which were eligible for early exercise. In September 2020, the CEO exercised all 6,881,095 unvested stock options. The cash proceeds received for such exercise were $34.7 million. In February 2021, the CEO exercised an option for 11,029,071 shares of Class B common stock, including both vested and unvested shares, for a cash purchase price of $32.6 million. During the fiscal year ended March 31, 2021, the CEO exercised a total of 11,108,906 unvested stock options early for a total of $47.2 million in cash proceeds. There were no early exercises during the fiscal years ended March 31, 2022 and 2020.

In February 2021, the Board of Directors modified option awards granted to the CEO, which accelerated the vesting of all 15,621,041 unvested common shares previously purchased by the CEO. Stock-based compensation expense of $40.4 million was recorded to General and Administrative expenses which represented the recognition of the remaining unrecognized compensation expense associated with these grants as of the date of modification. As a result of the Board-approved accelerated vesting of these early exercised unvested shares, there were no early exercise liabilities as of March 31, 2022 and 2021.

As of March 31, 2022 and 2021, there was no common stock subject to repurchase. As of March 31, 2020, 8,739,945 shares of Class B common stock were subject to repurchase, at a weighted average repurchase price of $11.50 per share.

15. Income Taxes

The Company computes provision for income taxes by applying the estimated annual effective tax rate to year-to-date income from recurring operations and adjust the provision for discrete tax items recorded in the period. The Company's annual estimated effective tax rate differs from the U.S. federal statutory rate primarily as a result of changes in the Company's valuation allowance against its deferred tax assets.

A deferred income tax benefit of $3.5 million was recognized for the fiscal year ended March 31, 2022 related to the partial release of the valuation allowance for deferred tax assets due to the recognition of deferred tax liabilities in connection with the Lemonaid Acquisition (see Note 4, "*Acquisitions*"). Accordingly, this benefit from income taxes is reflected on the consolidated statements of operations and comprehensive loss for the year ended March 31, 2022. The Company continues to maintain a full valuation allowance on the remaining net deferred tax assets of the U.S. entities as it is more likely than not that the Company will not realize the deferred tax assets. For the fiscal years ended March 31, 2021 and 2020, the Company recognized no provision for income taxes. Utilization of net operating loss carryforwards may be subject to future annual limitations provided by Section 382 of the Code and similar state provisions.

The components of the Company's loss before provision for (benefit from) income taxes for the fiscal years ended March 31, 2022, 2021 and 2020 were as follows:

	Year Ended March 31,		
	2022	2021	2020
	(in thousands)		
Domestic	$ (221,212)	$ (183,619)	$ (250,863)
Foreign	242	—	—
Loss before income taxes	$ (220,970)	$ (183,619)	$ (250,863)

There has historically been no federal or state provision for income taxes because the Company has historically incurred operating losses and maintains a full valuation allowance against its net deferred tax assets.

	Year Ended March 31,		
	2022	2021	2020
Statutory federal tax expense rate	21%	21%	21%
Non-deductible stock-based compensation	(3)	(7)	(2)
Fair Market Value adjustment on Warrants	3	—	—
Change in valuation allowance related to acquisition	2	—	—
Change in valuation allowance	(20)	(14)	(19)
Other	(2)	—	—
Effective tax rate	2%	0%	0%

Deferred income taxes result from differences in the recognition of revenue and expenses for tax and financial reporting purposes, as well as operating loss and tax credit carryforwards. The components of net deferred tax assets, as of March 31, 2022 and 2021 consisted of:

	Year Ended March 31,	
	2022	2021
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 248,856	$ 181,020
Accruals and reserves	3,685	3,591
Stock-based compensation	10,000	6,291
Deferred revenue	6,865	17,785
Operating lease liabilities	20,590	23,393
Intangibles	—	355
Other	19	391
Gross deferred tax assets	290,015	232,826
Valuation allowance	(261,795)	(213,267)
Total deferred tax assets	28,220	19,559
Deferred tax liabilities:		
Prepaid expenses	(1,235)	(841)
Intangibles	(15,709)	
Operating lease right-of-use assets	(13,233)	(15,755)
Property and equipment	(1,138)	(2,963)
Gross deferred tax liabilities	(31,315)	(19,559)
Net deferred taxes	$ (3,095)	$ —

As of March 31, 2022 and 2021, the Company had $1.0 billion of federal and $548.5 million state net operating loss carryforwards and $733.3 million of federal and $410.5 million state net operating loss carryforwards, respectively, available to reduce future taxable income, which will begin to expire in 2026 for federal and state tax purposes. As a result of the Tax Cuts and Jobs Act, net operating losses generated after December 31, 2017 have an indefinite life and losses are limited to 80% of taxable income. Included in the $1.0 billion carryover losses is $656.1 million of net operating losses with an indefinite life. The Company does not have any federal and state research and development tax credit carryforwards. The change in the valuation allowance in the current year was an increase of $40.2 million primarily related to the increase of current year losses.

The Tax Reform Act of 1986 and similar California legislation impose substantial limitations on the utilization of net operating loss and tax credit carryforwards, if there is a change in ownership as provided by Section 382 of the Internal Revenue Code and similar state provisions. Such a limitation could result in the expiration of the net operating loss carryforwards and tax credits before utilization. The Company performed a preliminary study for the period through March 31, 2022 and determined that no ownership change exceeding 50 percentage points had occurred subsequent to the date of the Lemonaid Acquisition. The Company's ability to use net operating loss carryforwards to reduce future taxable income and liabilities may be subject to annual limitations as a result of ownership changes in subsequent years.

Significant management judgment is required in determining the provision for income taxes and, in particular, any valuation allowance recorded against the Company's deferred tax assets. The Company determined that, due to the Company's cumulative tax loss history and the difficulty in forecasting the timing of future revenue, it was necessary to maintain a valuation allowance under ASC 740 to the full amount of the deferred tax asset. The Company determined that it was not more-likely-than-not that the deferred tax asset would be utilized.

The Company complies with ASC 740-10, *Accounting for Uncertainty in Income Taxes*, which prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statement of any uncertain tax positions that have been taken or expected to be taken on a tax return. This pronouncement sets a "more likely than not" criterion for recognizing the tax benefit of uncertain tax positions. The Company does not anticipate any significant changes to unrecognized tax benefits in the next 12 months. The Company recognizes interest and

penalties related to uncertain tax positions in income tax expense. As of March 31, 2022 and 2021, there was no unrecognized tax benefits.

A reconciliation of the beginning and ending balance of unrecognized tax benefits is summarized as follows:

	Unrecognized Tax Benefits
	(in thousands)
Balance as of March 31, 2019	$ 282
Decreases in unrecognized tax benefits related to prior year tax positions	—
Increases in unrecognized tax benefits related to current year tax positions	17
Balance as of March 31, 2020	299
Decreases in unrecognized tax benefits related to prior year tax positions	(299)
Increases in unrecognized tax benefits related to current year tax positions	—
Balance as of March 31, 2021	—

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. During the fiscal years ended March 31, 2022, 2021 and 2020, the Company recognized no interest and penalties associated with the unrecognized tax benefits. There are no tax positions for which it is reasonably possible that the total amount of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date. If recognized, there would be no impact on the Company's effective tax rate due to its valuation allowance.

The Company files income tax returns in the U.S. federal jurisdiction, various states, and the U.K. The Company is not currently under examination by income tax authorities in federal, state, or other jurisdictions. All tax returns will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any net operating loss or credits.

16. Net Loss Per Share Attributable to Common Stockholders

Prior to the Merger and prior to effecting the recapitalization, the net loss attributable to common stockholders was allocated based on the contractual participation rights of the 23andMe, Inc. Class A and 23andMe, Inc. Class B common stock. As the liquidation and dividend rights of 23andMe, Inc. Class A and 23andMe, Inc. Class B common stock are identical, the net loss attributable to common stockholders is allocated on a proportionate basis, and the resulting net loss per share is identical for 23andMe, Inc. Class A and 23andMe, Inc. Class B common stock under the two-class method. Earnings per share calculations for all periods prior to the Merger have been retrospectively restated to the equivalent number of shares reflecting the exchange ratio established in the reverse capitalization. Shares issued on early exercise, or issued but subject to vesting, are not included within weighted average shares outstanding for the period.

Subsequent to the Merger, the Company continues to have two classes of common stock: Class A and Class B common stock. Similar to the previous structure, the rights are identical, including liquidation and dividend rights, except the Company's Class B common stock has additional voting rights and is convertible at any time at the option of the holder into Class A common stock, and is automatically converted into Class A common stock upon transfer (except for certain permitted transfers). The net loss attributable to common stockholders is allocated on a proportionate basis, and the resulting net loss per share is identical for Class A and Class B common stock under the two-class method.

No dividends were declared or paid for the fiscal years ended March 31, 2022 and 2021.

The Company's redeemable convertible preferred stock, stock options, early exercised stock options, restricted stock units, and restricted stock awards subject to vesting are considered to be potential common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is antidilutive.

Net loss attributable to common stockholders is equivalent to net loss for all periods presented.

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders for the periods presented:

	Year Ended March 31,					
	2022		2021		2020	
	Class A	Class B	Class A	Class B	Class A	Class B
	(in thousands, except share and per share data)					
Numerator:						
Net loss attributable to common stockholders	$ (68,620)	$ (148,870)	$ (37,070)	$ (146,549)	$ (49,094)	$ (201,769)
Denominator:						
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	114,064,921	247,463,198	20,121,419	79,539,367	17,261,145	70,940,192
Net loss per share attributable to common stockholders, basic and diluted	$ (0.60)	$ (0.60)	$ (1.84)	$ (1.84)	$ (2.84)	$ (2.84)

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive are as follows:

	As of March 31,					
	2022		2021		2020	
	Class A	Class B	Class A	Class B	Class A	Class B
Conversion of redeemable convertible preferred stock	—	—	—	209,181,855	—	198,274,933
Outstanding stock options	73,609,565	—	18,116,302	49,261,103	—	68,392,497
Issuance of common stock upon early exercise of options (unvested)	—	—	—	—	—	8,739,945
Restricted stock units	10,676,378	—	—	—	—	—
Employee Stock Purchase Plan	2,239,756	—	—	—	—	—
Shares subject to vesting	3,512,839	—	—	—	—	—
Total	90,038,538	—	18,116,302	258,442,958	—	275,407,375

17. Related Party Transactions

As described in Note 7, "*Collaborations*," in July 2018, the Company and GSK entered into the GSK Agreement, and there were transactions with GSK during the fiscal years ended March 31, 2022, 2021 and 2020. At the time the GSK Agreement was entered into, GSK also purchased 17,291,066 shares of Series F-1 redeemable convertible preferred stock of 23andMe, Inc. These shares were converted into a like number of shares of 23andMe, Inc. Class B common stock immediately prior to the Merger and were exchanged pursuant to the Share Conversion Ratio into shares of the Company's Class B common stock in the Business Combination. GSK had a 16.3% and 12.6% voting interest in the Company as of March 31, 2022 and 2021, respectively.

As described in Note 3, "*Recapitalization*," in February 2021, concurrently with the execution of the Merger Agreement, VGAC entered into subscription agreements with certain investors to which such investors collectively subscribed for an aggregate of 25,000,000 shares of the Company's Class A common stock at $10.00 per share for aggregate gross proceeds of $250.0 million. The Anne Wojcicki Foundation, which subscribed for 2,500,000 shares of the Company's Class A common stock, is affiliated with the Company's CEO and therefore a related party.

In September 2020 and February 2021, the CEO early exercised unvested options to purchase shares of common stock. In February 2021, the Board of Directors accelerated the vesting of all 15,621,041 unvested shares previously purchased by the CEO, which resulted in stock-based compensation expense of $40.4 million related to recognition of the remaining compensation expense associated with these grants. For further information, see Note 14, "*Equity Incentive Plan and Stock-based Compensation*".

18. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through May 27, 2022, the date at which the consolidated financial statements were available to be issued.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in company reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

We do not expect that our disclosure controls and procedures will prevent all errors and all instances of fraud. Disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable assurance of achieving the desired control objectives. Further, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits must be considered relative to their costs. The design of disclosure controls and procedures also is based partly on 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.

As of March 31, 2022, as required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective.

Management's Report on Internal Controls over Financial Reporting

This Form 10-K does not include a report of management's assessment regarding internal control over financial reporting, or an attestation report of our independent registered public accounting firm, as allowed by the SEC for reverse acquisitions between an issuer and a private operating company when it is not possible to conduct an assessment of the private operating company's internal control over financial reporting in the period between the consummation date of the reverse acquisition and the date of management's assessment of internal control over financial reporting (pursuant to Section 215.02 of the SEC Division of Corporation Finance's Regulation S-K Compliance & Disclosure Interpretations).

As discussed elsewhere in this Form 10-K, we completed the Business Combination on June 16, 2021, pursuant to which we acquired 23andMe, Inc. Prior to the Business Combination, we were a special purpose acquisition company formed for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, recapitalization, reorganization, or similar business combination with one or more businesses. As a result, previously existing internal controls are no longer applicable or comprehensive enough as of the assessment date as our operations prior to the Business Combination were insignificant compared to those of the consolidated entity post-Business Combination. The design of internal control over financial reporting for the Company post-Business Combination has required and will continue to require significant time and resources from management and other personnel. As a result, management was unable, without incurring unreasonable effort or expense, to conduct an assessment of our internal control over financial reporting as of March 31, 2022.

Remediation Efforts to Address the Previously Disclosed Material Weakness

A material weakness in our internal control over financial reporting was identified as of March 31, 2020 and 2021, and remains unremediated at March 31, 2022. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. The material weakness identified was a lack of sufficient resources in our finance function to meet our financial reporting requirements. This material weakness resulted in insufficient management review of journal entries, account reconciliations, and review of financial statements. Management continues to review and make necessary changes to the overall design of our internal control environment, including implementing additional internal controls over journal entries, account reconciliation and the review of financial statements. We are in the process of adding additional resources to our finance function to enhance the effectiveness of internal controls over financial reporting. The material weakness will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. Although we plan to complete this remediation process as quickly as possible, we cannot estimate at this time how long it will take.

As previously disclosed in Part I, Item 9A of VGAC's Annual Report on Form 10-K/A (Amendment No. 1) for the period ended December 31, 2020 filed with the SEC by VGAC on May 4, 2021 (the "VGAC Form 10-K/A"), the management of VGAC, including the principal executive officer and principal financial officer, concluded that VGAC did not maintain effective internal control over financial reporting as of December 31, 2020, due to a material weakness. The material weakness in our internal control over financial reporting led to the Company's restatement of its financial statements to reclassify the Company's Public Warrants and Private Placement Warrants as described in the Explanatory Note to the VGAC Form 10-K/A. In response to this material weakness, our management plans to enhance our processes to identify and appropriately apply applicable accounting requirements to better evaluate and understand the nuances of the complex accounting standards that apply to our financial statements. Our plans include providing enhanced access to accounting literature, research materials, and documents and increased communication among our personnel and third-party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

Changes in Internal Control over Financial Reporting

Other than disclosed above, during the most recently completed fiscal quarter, there has been no change in our internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As a result of the acquisition of Lemonaid, the Company has incorporated internal controls over significant processes specific to the acquisition that it believes to be appropriate and necessary in consideration of the level of related integration. As the post-closing integration continues, the Company will continue to review such internal controls and processes and may take further steps to integrate such controls and processes with those of the Company.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Information required by Items 10, 11, 12, 13, and 14 of Part III is omitted from this Form 10-K and will be filed in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders (the "2022 Proxy Statement") or by an amendment to this Form 10-K not later than 120 days after the end of the fiscal year covered by this Form 10-K.

Item 10. Directors, Executive Officers and Corporate Governance

To the extent applicable, the information called for by this Item 10 will be set forth in the 2022 Proxy Statement under the following captions and is incorporated herein by reference: "Proposal 1 – Election of Directors," "Executive Officers," "Delinquent Section 16(A) Reports," and "Corporate Governance."

Item 11. Executive Compensation

To the extent applicable, the information required by this Item 11 will be set forth in the 2022 Proxy Statement under the following captions and is incorporated herein by reference: "Director Compensation," "Compensation Discussion and Analysis" and the related tabular disclosure, "Compensation Committee Report," "Compensation Risk Assessment," "Policies Prohibiting Hedging, Pledging, and Speculative or Short-Term Trading," and "Compensation Committee Interlocks and Insider Participation."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

To the extent applicable, the information required by this Item 12 will be set forth in the 2022 Proxy Statement under the following captions and is incorporated herein by reference: "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information."

Item 13. Certain Relationships and Related Transactions, and Director Independence

To the extent applicable, the information required by this Item 13 will be set forth in the 2022 Proxy Statement under the following captions and is incorporated herein by reference: "Corporate Governance – Related Person Transactions" and "Corporate Governance –Board Independence."

Item 14. Principal Accounting Fees and Services

Our independent registered public accounting firm is KPMG LLP, Santa Clara, California (Auditor ID: 185).

To the extent applicable, the information required by this Item 14 will be set forth in the 2022 Proxy Statement under the following caption and is incorporated herein by reference: "Audit Fees and Services."

PART IV

Item 15. Exhibits, Financial Statement Schedules

See "Index to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K. Financial statement schedules have been omitted because they are not required or are not applicable or because the information required in those schedules either is not material or is included in the consolidated financial statements or the accompanying notes.

Exhibit Index

Exhibit Number	Description
2.1†	Agreement and Plan of Merger, dated as of February 4, 2021, by and among VG Acquisition Corp., Chrome Merger Sub, Inc., and 23andMe, Inc. (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K (File No. 001-39587), filed with the SEC on February 4, 2021).
2.2	First Amendment to the Merger Agreement, dated as of February 13, 2021, by and among VG Acquisition Corp., Chrome Merger Sub, Inc., and 23andMe, Inc. (incorporated by reference to Exhibit 2.2 to the Registration Statement on Form S-4 (File No. 333-254772), filed with the SEC on May 13, 2021).
2.3	Second Amendment to the Merger Agreement, dated as of March 25, 2021, by and among VG Acquisition Corp., Chrome Merger Sub, Inc., and 23andMe, Inc. (incorporated by reference to Exhibit 2.3 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
2.4	Agreement and Plan of Merger and Reorganization, dated as of October 21, 2021, by and among 23andMe Holding Co., Life Merger Sub One, Inc., Life Merger Sub Two, Inc., Lemonaid Health, Inc., and Fortis Advisors LLC (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K (File No. 001-39587), filed with the SEC on October 22, 2021).
3.1	Certificate of Incorporation of 23andMe Holding Co. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K/A (File No. 001-39587) filed with the SEC on June 21, 2021).
3.2	Amended and Restated Bylaws of 23andMe Holding Co. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K/A (File No. 001-39587) filed with the SEC on June 21, 2021).
4.1*	Description of 23andMe Holding Co.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended.
4.2	Specimen Warrant Certificate (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1 (File No. 333-248844), filed with the SEC on September 16, 2020).
4.3	Warrant Agreement, dated as of October 1, 2020, between VG Acquisition Corp. and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K (File No. 001-39587), filed with the SEC on October 6, 2020).
4.4	Certificate of Corporate Domestication of VG Acquisition Corp. (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K (File No. 001-39587) filed with the SEC on June 21, 2021).
10.1	Sponsor Letter Agreement, dated as of February 4, 2021, by and among 23andMe, Inc., VG Acquisition Sponsor LLC, VG Acquisition Corp., Credit Suisse Securities (USA) LLC as representative of the several Underwriters named therein, the Insiders (as defined therein) and the Holders (as defined therein) (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K (File No. 001-39587), filed with the SEC on February 4, 2021).
10.2	Form of Subscription Agreement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K (File No. 001-39587), filed with the SEC on February 4, 2021).
10.3†	Form of Support Agreement (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K (Registration No. 001-39587), filed with the SEC on February 4, 2021).

10.4	Amended and Restated Registration Rights Agreement, dated as of June 16, 2021, by and among 23andMe Holding Co., VG Acquisition Sponsor LLC, and certain other initial stockholders (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K (File No. 001-39587) filed with the SEC on June 21, 2021).
10.5+	23andMe Holding Co. 2021 Incentive Equity Plan (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K (File No. 001-39587) filed with the SEC on June 21, 2021).
10.6+	23andMe Holding Co. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K (File No. 001-39587) filed with the SEC on June 21, 2021).
10.7+	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.8+	Offer Letter, dated as of February 16, 2014, by and between 23andMe, Inc. and Kathy Hibbs (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.9+	Offer Letter, dated as of February 1, 2019, by and between 23andMe, Inc. and Kenneth Hillan (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.10+	Offer Letter, dated as of October 14, 2010, by and between 23andMe, Inc. and Steve Lemon (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.11+	Offer Letter, dated as of March 27, 2018, by and between 23andMe, Inc. and Steve Schoch (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.12	Consulting Agreement, dated as of April 1, 2019, by and between 23andMe, Inc. and Richard Scheller, Ph.D. (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.13	Amendment No. 1 to Consulting Agreement, dated as of March 30, 2020, by and between 23andMe, Inc. and Richard Scheller, Ph.D. (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.14	Amendment No. 2 to Consulting Agreement, dated as of March 24, 2021, by and between 23andMe, Inc. and Richard Scheller, Ph.D. (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.15+	23andMe, Inc. 2006 Equity Incentive Plan (as Amended and Restated) (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.16+	Form of 23andMe, Inc. 2006 Stock Option Agreement (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.17††	Collaboration Agreement, dated as of July 24, 2018, by and between 23andMe, Inc. and GlaxoSmithKline Intellectual Property (No.3) Limited (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.18††	First Amendment to Collaboration Agreement, dated as of April 8, 2019, by and between 23andMe, Inc. and GlaxoSmithKline Intellectual Property (No.3) Limited (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.19††	Second Amendment to Collaboration Agreement, dated as of January 13, 2021, by and between 23andMe, Inc. and GlaxoSmithKline Intellectual Property (No. 3) Limited (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.20+	Form of 23andMe, Inc. Employee Invention Assignment and Confidentiality Agreement (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).

10.21	Promissory Note dated April 5, 2021, issued by VG Acquisition Corp. to VG Acquisition Sponsor LLC (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-4/A (File No. 333-254772), filed with the SEC on May 13, 2021).
10.22+	Form of 23andMe Holding Co. 2021 Nonqualified Stock Option Grant Agreement (incorporated by reference to Exhibit 10.22 to the Quarterly Report on Form 10-Q, filed with the SEC on August 13, 2021).
10.23+	Form of 23andMe Holding Co. 2021 Restricted Stock Unit Agreement (Employee) (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2021).
10.24+	Form of 23andMe Holding Co. 2021 Restricted Stock Unit Agreement (Non-Employee Director) (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2021).
10.25+	Offer Letter, dated as of October 21, 2021, by and between 23andMe Holding Co. and Paul Johnson (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q, filed with the SEC on February 11, 2022).
21.1*	List of Subsidiaries.
23.1**	Consent of KPMG, independent registered public accounting firm of 23andMe Holding Co.
24.1	Power of Attorney (included in the signature page hereto).
31.1*	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.
31.2*	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.
32.1**	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.
32.2**	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.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL 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)

*	Filed herewith
**	Furnished herewith
+	Indicates management contract or compensatory plan or arrangement
†	Schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.
††	The Registrant has redacted provisions or terms of this Exhibit pursuant to Regulation S-K Item 601(b)(10)(iv). The Registrant agrees to furnish an unredacted copy of the Exhibit to the SEC upon its request.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

23ANDME HOLDING CO.

Date: May 27, 2022

By: /s/ Anne Wojcicki
Name: Anne Wojcicki
Chief Executive Officer
(Principal Executive Officer)

Date: May 27, 2022

By: /s/ Steven Schoch
Name: Steven Schoch
Chief Financial and Accounting Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Anne Wojcicki Anne Wojcicki	Chief Executive Officer and Director (Principal Executive Officer)	May 27, 2022
/s/ Steven Schoch Steven Schoch	Chief Financial and Accounting Officer (Principal Financial and Accounting Officer)	May 27, 2022
/s/ Roelof Botha Roelof Botha	Director	May 27, 2022
/s/ Patrick Chung Patrick Chung	Director	May 27, 2022
/s/ Sandra R. Hernández, M.D. Sandra R. Hernández, M.D.	Director	May 27, 2022
/s/ Evan Lovell Evan Lovell	Director	May 27, 2022
/s/ Neal Mohan Neal Mohan	Director	May 27, 2022
/s/ Valerie Montgomery Rice, M.D. Valerie Montgomery Rice, M.D.	Director	May 27, 2022
/s/ Richard Scheller, Ph.D. Richard Scheller, Ph.D.	Director	May 27, 2022
/s/ Peter Taylor Peter Taylor	Director	May 27, 2022