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 December 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: 001-40592

Rapid Micro Biosystems, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**20-8121647**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1001 Pawtucket Boulevard West, Suite 280 Lowell, MA	**01854**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (978) 349-3200

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, $0.01 par value per share	**RPID**	**The Nasdaq Global Select Market**

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

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 Section 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, a 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statement. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 Class A common stock held by non-affiliates of the registrant computed by reference to the price of the registrant's Class A common stock as of the last business day of the registrant's most recently completed second fiscal quarter (based on the last reported sale price on The Nasdaq Global Select Market as of such date) was 24,145,209.

The number of shares of the registrant's Class A common stock, par value $0.01, outstanding as of March 7, 2023 was 36,635,108.
The number of shares of the registrant's Class B common stock, par value $0.01, outstanding as of March 7, 2023 was 5,553,379.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022 are incorporated herein by reference in Part III.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K may be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "estimates," "forecasts," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements regarding:

- our business strategy for our Growth Direct platform and systems;
- our future results of operations and financial position, including our expectations regarding revenue, gross margin, operating expenses and ability to generate cash flow;
- our expectations and assumptions related to our future funding requirements and available capital resources, which may be impacted by market uptake of our Growth Direct system, our management of inventory and supply chain, our research and development activities and the expansion of our sales, marketing, manufacturing and distribution capabilities;
- our ability to maintain and expand our customer base for our Growth Direct platform and systems;
- our exploration of strategic alternatives for the Company;
- the effectiveness of enhancements of our sales processes;
- the impact of our restructuring on the Company;
- anticipated trends and growth rates in our business and in the markets in which we operate;
- our research and development activities and prospective new features, products and product approvals;
- our ability to anticipate market needs and successfully develop new and enhanced solutions to meet those needs, including prospective products;
- our ability to hire and retain necessary qualified employees to grow our business and expand our operations;
- our expectations regarding the potential impact of the ongoing coronavirus pandemic on our business, operations and the markets in which we and our customers operate;
- our expectations regarding the potential impact of inflation and fluctuations in interest rates on our business and operating costs; and
- our ability to adequately protect our intellectual property.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important

factors discussed in Part I, Item 1A, “Risk Factors” in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed as exhibits with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We caution you not to place undue reliance on forward-looking statements, which speak only as of the date hereof. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

TRADEMARKS

Solely for convenience, our trademarks and trade names in this Annual Report on Form 10-K are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties as part of your evaluation of an investment in our Class A common stock. The principal risks and uncertainties affecting our business include, but are not limited to, the following:

- 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;
- Our limited operating history makes it difficult to evaluate our future prospects and the risks and challenges we may encounter;
- Our success depends on the success of our Growth Direct platform, which may not be achieved or maintained;
- Our operating results have fluctuated significantly in the past and will fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations;
- We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could adversely affect our business, reputation and financial results and cause our stock price to decline;
- If we cannot maintain the level of sales of our Growth Direct systems or the sales of our consumables and service contracts to existing customers declines, our future operating results would be adversely affected;
- We may need to raise additional capital to fund our existing operations, improve our platform or develop and commercialize new products or expand our operations;
- The ongoing coronavirus pandemic has impacted, and may continue to impact, our operations and may materially and adversely affect our business and financial results;
- The continued success of our business relies heavily on establishing and maintaining our position in the market as a leading provider of automated microbial quality control, or MQC, testing;
- It may be difficult for us to implement our strategies for improving growth;
- We may not successfully implement our strategy to expand our Growth Direct platform to customers who manufacture cell and gene therapies;
- The size of the markets and forecasts of market growth for automated MQC testing and other of our key performance indicators are based on a number of complex assumptions and estimates, and may be inaccurate;
- New product development involves a lengthy and complex process and we may be unable to develop or commercialize products on a timely basis, or at all;
- Our customers use our Growth Direct platform as part of their quality-control workflow, which is subject to regulation by the FDA and other comparable regulatory authorities;
- If we are unable to manage our inventory and support demand for the Growth Direct platform, as well as our future product offerings, our business could suffer;

- We have limited experience in marketing and sales, and if we are unable to improve the effectiveness of our marketing and sales organization to adequately expand our business with new and existing customers and address our customers' needs or to expand our customer base, our business may be adversely affected;

- Our organizational restructuring plan, including a reduction in workforce, announced in August 2022, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business;
- We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy;

- If we cannot compete successfully, we may be unable to increase or sustain our revenue, or achieve and sustain profitability;

- We must develop new products, adapt to rapid and significant technological change and respond to introductions of new products by competitors to remain competitive;

- Due to the significant resources required to enable access in new markets, we must make strategic and operational decisions to prioritize certain markets, products and services. We may expend our resources to access markets and develop products and services that do not yield meaningful revenue or we may fail to capitalize on markets, products or services that may be more profitable or with a greater potential for success;

- The Growth Direct platform may contain undetected errors or defects and may not meet the expectations of our customers, which means our business, financial condition, results of operations and prospects could suffer;

- Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop;

- If we lose key management, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may be materially harmed;

- If our sole manufacturing and development facility becomes damaged or inoperable or we are required to vacate our existing facility, our ability to conduct and pursue our manufacturing and development efforts will be jeopardized;

- Our manufacturing operations are dependent upon third-party suppliers, including single-source suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business;

- If we are unable to obtain and maintain sufficient intellectual property protection for our technology, including the Growth Direct platform, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired;

- Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time;

- The market price of our Class A common stock has been and may continue to be volatile and fluctuate substantially, which could result in substantial losses for our stockholders; and

- If our Class A common stock is delisted from the Nasdaq Global Select Market, the liquidity of our Class A common stock would be adversely affected and the market price of our common stock could decrease.

- We have been, and may continue to be, subject to the actions of activist shareholders, which could cause us to incur substantial costs, divert management's and the board's attention and resources, and have an adverse effect on our business and stock price.

PART I

Item 1. Business.

Defining the future of pharmaceutical quality control

We are leading a global transformation toward fully automated microbial quality control within pharmaceutical manufacturing. Our products safeguard the most complex and critical bioprocessing workflows in the industry, enabling faster, safer, and higher capacity drug production. Through our unique expertise at the intersection of microbiology, robotic systems, and advanced vision algorithms, we are setting the foundation for end-to-end quality control automation to enable the future of advanced pharmaceutical manufacturing.

Overview

We are an innovative life sciences technology company providing mission critical automation solutions to facilitate the efficient manufacturing and fast, safe release of healthcare products such as biologics, vaccines, cell and gene therapies, and sterile injectables. Our flagship Growth Direct platform automates and modernizes the antiquated, manual microbial quality control, or MQC, testing workflows used in the largest and most complex pharmaceutical manufacturing operations across the globe. The Growth Direct platform brings the quality control lab to the manufacturing floor, unlocking the power of MQC automation to deliver the faster results, greater accuracy, increased operational efficiency, better compliance with data integrity regulations, and quicker decision making that our customers rely on to ensure safe and consistent supply of important healthcare products.

Our Growth Direct platform is the only fully automated, high-throughput and secure MQC solution. Developed with over 15 years of active feedback from our customers, Growth Direct was purpose-built to meet the MQC challenges posed by the increasing scale, complexity, and regulatory scrutiny confronting global pharmaceutical manufacturers. Our platform delivers the robust and scalable automation necessary to support rapidly expanding demand for novel and complex therapeutic modalities, such as biologics, vaccines, cell and gene therapies, and sterile injectables. Our systems are designed to absorb and automate the vast majority of daily MQC test volume in any pharmaceutical manufacturing facility and can be operated in networked fleets of multiple systems per facility or campus to scale up with high-volume manufacturing.

MQC is a ubiquitous and critical testing process, executed daily at massive scale globally, that ensures pharmaceutical manufacturing facilities and products are free of microbial contamination from exogenous microorganisms such as bacteria, mold, and other foreign substances. MQC ensures the safety of final drug products released for patient use, via the

constant testing for microbial contamination of raw materials, production environments, personnel, and in-process and final sterility testing for drug products. A single drug production facility may conduct anywhere from tens of thousands to over one million MQC tests per year to ensure product quality. This testing is mandated and closely monitored by the U.S. Food and Drug Administration, or the FDA, and other global regulatory agencies to ensure the safety of all pharmaceutical products, with serious regulatory and financial consequences for lack of compliance.

The traditional method of MQC testing, or the traditional method, also known as the compendial method, involves detection of viable, potentially contaminating organisms by a process known as "growth promotion." In this method, samples are manually collected on media plates, hand labeled and inventoried, physically transported to a centralized lab, and incubated at various temperatures for days to weeks. MQC specialists then visually inspect these plates manually, counting colonies of microbial organisms and recording their counts of thousands of plates by hand, which is a repetitive process predisposed to operator miscounts. In total, the traditional method can require 15 individual processing steps per sample. The benefit of this long-standing method is that it is trusted—a colony growing on media strongly implies the existence of viable, potentially contaminating organisms growing in the location or sample from which the assay was collected.

However, the manual traditional MQC method has become antiquated and is unable to match the growing scale of global pharmaceutical manufacturing—especially complex bioprocessing of biologics, cell, and gene therapies—principally because the process is slow to deliver results, entirely dependent on human labor, subject to technician fallibility and error, unsecured, and non-compliant with data integrity regulations. In time-sensitive, highly regulated pharmaceutical manufacturing operations, these process vulnerabilities can expose organizations to significant operational, financial, and reputational risks, including loss of valuable product batches, reduced manufacturing capacity, lengthy regulatory investigations, costly enforcement actions, and delayed release of life-saving products.

Our Growth Direct platform improves the traditional MQC process, maintaining the fundamental trusted method of growth promotion, but applying advanced robotic automation, powerful optical imaging, algorithmic vision analysis, and data management to render it more scalable and efficient for the future of advanced pharmaceutical manufacturing. Our proprietary technology works by replacing human counting of growing colonies with software and algorithm detection and counting based on image analysis. We exploit the natural autofluorescent properties of microbial organisms to count microcolonies by detecting minute changes to their brightness over time using proprietary vision algorithms, without any new reagents or additional sample prep. Our system wraps this core detection technology with fully automated, high-volume, walk-away robotic sample handling and incubation, locked behind a secured interface that enables compliance with data integrity regulations.

We believe the MQC market is poised for disruption and modernization via the widespread deployment of our Growth Direct platform, and we have embarked on the mission of transforming the MQC test market to standardize on our fully automated solution.

The Growth Direct platform fully automates and digitizes the process of pharmaceutical MQC and enables our customers to perform this critical testing process more efficiently, accurately, and securely. Our platform comprises the Growth Direct system, proprietary consumables, lab information management system, or LIMS, connection software, and comprehensive customer support and validation services. Our Growth Direct system is a fully automated, high throughput instrument for daily processing of MQC samples on our proprietary consumables—a microbiology quality control lab in a box. We have achieved an automated method that is faster and produces more accurate, reliable and accessible data than the traditional method. The Growth Direct platform delivers faster results in half the time, and with its higher testing throughputs and capacity can absorb the vast majority of daily MQC testing in any facility. Our system increases accuracy and efficiency through full automation of the MQC process. Customers depend on Growth Direct's robust security, connectivity, and data integrity capabilities, reinforced by its high reliability.

We believe we are the first company to solve the existing barriers to MQC automation. Our product platform reflects our expertise at innovating and integrating across multiple technology disciplines, including systems design, robotic

handling, microbiology, optical imaging, software image analysis, data management and security, and process automation. Our business was specifically built to meet the needs of pharmaceutical manufacturing and has developed a track record of delivering reliable results for our customers, which is why we believe we are the trusted standard in microbial automation.

We employ direct commercial and service teams that drive the adoption of our products globally. We create a superior user experience from pre-sales, to onboarding, consultative validation services, onsite technical training, and continued customer support throughout our relationship. We have a scalable commercial infrastructure including a direct sales force in North America and Europe. This is supplemented with an extensive and highly specialized customer service and validation infrastructure. This infrastructure ensures successful on-boarding of the Growth Direct through both initial validation and follow-on purchases throughout the entire customer site network, where the highest volume sites may require dozens of Growth Direct systems. We currently have customers across approximately 75 sites in 14 countries and the majority of our customers have multiple Growth Direct systems and have deployed Growth Direct across multiple facility locations.

We launched our current, second generation Growth Direct system in 2017 and have placed 125 systems and sold over 3 million consumables globally. Our customer base includes over half of the top twenty largest pharmaceutical companies as measured by revenue and the manufacturers of 25% of globally approved cell and gene therapies, including approximately 60% of approved gene-modified autologous CAR-T cell therapies. Once installed and validated in our customers' facilities, Growth Direct provides for recurring revenues through ongoing consumables and service contracts.

We seek to establish Growth Direct as the trusted global standard in automated MQC by delivering the speed, accuracy, security, and data integrity and regulatory compliance that our customers depend on to ensure patient safety and consistent drug supply.

Industry background and challenges

MQC overview

MQC is the principal method by which pharmaceutical manufacturers ensure the ongoing sterility of their facilities and finished products by detecting and stopping contamination from any outside microorganisms, such as bacteria, mold, and other foreign substances. MQC is a critical component of the bioprocess and pharmaceutical production process and is regulated and mandated by the FDA under current good manufacturing practice, or cGMP, and by other international regulatory agencies. Current MQC testing methods are manual, laborious, have lacked innovation over the past several decades.

To guarantee the quality of the end products and the safety of patients who receive them, manufacturers must ensure that their products are free of potentially harmful microbial contamination. This requirement creates a considerable operational challenge, as the natural environment is rife with microorganisms that could pose serious risk to patients should they transit into these clean rooms and contaminate any aspect of the manufacturing process. Consequently, pharmaceutical companies must maintain strict sterility control in their manufacturing facilities by vigilantly monitoring their sites, equipment, and finished drugs, and responding quickly to any microbial contamination. This is accomplished through MQC testing, which generally encompasses four specific applications for testing of microbial contamination:

- **Environmental Monitoring (EM)**—tests the manufacturing environment, including circulating air, exposed surfaces, and personnel, and represents approximately 65-70% of global MQC test volume;
- **Water (W)**—tests any purified water used at any stage of the drug production process, including water for injection, or WFI, and represents approximately 15% of global MQC test volume;
- **In-Process Bioburden (BB)**—tests raw materials, drug substance and in-process product, and represents approximately 15% of global MQC test volume; and

- **Sterility Release (ST)**—final testing of finished product to ensure sterility before the product is released for commercial sale, and represents less than 5% of global MQC test volume.

MQC testing occurs at high volumes due to its importance across all dimensions of a pharmaceutical manufacturing operation and must be executed daily and implemented across all production lines. As a result, pharmaceutical manufacturing facilities may conduct as many as tens of thousands to over one million tests per year.

Legacy MQC techniques and key challenges

The traditional method of MQC testing involves detection of viable organisms by a process known as "growth promotion." In this process, samples are collected from a manufacturing site (e.g., on equipment, water, raw materials) and deposited by various methods onto plates with a matrix (typically agar) containing growth media with nutrients that encourage microbial growth. These plates are hand-labeled, inventoried, and physically transported to a centralized MQC lab. The plates are incubated under various conditions favorable for microbial growth; a manufacturing operation may simultaneously maintain multiple different incubation conditions and processes. If the original sample is contaminated with microbial organisms, the transferred organisms will divide and expand on the test plate, eventually forming visible colonies on the surface of the growth media. Technicians inspect these plates manually, counting colonies and recording their counts by hand. Visualization of colonies indicates the original presence of viable—that is, living—organisms from the sampled location or substance, and a likely microbial contamination for investigation and remediation.

A typical MQC testing process using the traditional testing method involves 15 or more manual steps per sample, including sample collection, labeling, transport, inventory, incubation, multiple reading and re-incubation steps, final counting, data recording, and data entry. The process is inherently inefficient, with some of the early sample collection steps occurring inside the manufacturing suites spread across a campus, and others centralized in campus MQC labs, requiring sample transport. The manual handling aspect of the traditional method makes it more prone to human error than an automated alternative and can lead to extensive labor and other direct and indirect costs given the thousands to millions of MQC tests required annually per manufacturing facility.

The traditional method poses several operational problems:

- **Delayed results** — Colonies must grow to a certain size, typically 10 million cells, before the human eye is able to detect them. Across the range of organisms and incubation protocols that facilities handle, this growth time can range from 5-14 days. Until then, no definitive result can be determined, which delays any dependent processes.

- **Test subjectivity** — Once growth has occurred, a human operator will count the colonies and decide whether the number of colonies meets or exceeds their organization's threshold for remediation. However, colonies can grow together or overlap completely, or can be mistaken for other artifacts, confounding operators' ability to generate an accurate, subjective count, especially given the fact that human operators can only check plates a few times during the incubation cycle.

- **Vulnerability to errors** — Operators must manually categorize, label, track and manage numerous plates through a complex multi-step, multi-day process of incubation and analysis, risking the loss or mishandling of samples. Manual analysis of samples also requires human data collection and entry, introducing risk of mistakes during recording and transcription of data.

- **Lack of data integrity and audit controls** — The manual, traditional method of data handling faces challenges in meeting the current regulatory standards requiring data integrity. Current processes, which are often paper based, introduce risk of erroneous or fraudulent data as critical data entry points are reliant on the experience, state of mind, and motives of the individual recording them.

- **Laborious process** — Manual growth promotion is a labor-intensive, multi-step process that requires operators to cycle samples through incubators multiple times per day as they check for growth and often requires physical transport from a manufacturing facility to a centralized lab.

Lapses in traditional MQC processes and potential contamination have resulted in increased regulatory scrutiny and organizational risk, leading to lengthy regulatory investigations and costly enforcement actions in addition to product loss and resulting lost revenue. The risks and costs of inadequate traditional MQC testing include:

- **Global data integrity risk** — 40-50% of all warning letters issued globally contain a data integrity component.

- **Lengthy regulatory investigations** — The time to resolution of FDA 483s and warning letters is approximately 6-24 months, and even longer in some cases.

- **FDA enforcement action risk** — Risk of significant and costly FDA enforcement actions, up to and including consent decrees.

- **Significant product loss** — Up to $100 million annual product loss per company due to MQC failures has been observed in recent years.

- **Shareholder value destruction** — Potential shareholder value destruction in the hundreds of millions to billions of dollars due to MQC issues, resulting product and financial issues, potential customer concerns, and impact from negative press.

In the last several years alone, there have been numerous publicized incidents involving leading pharmaceutical companies that highlight the risk of poorly controlled, manual MQC testing and protocols, resulting in lengthy site closures, CRLs, and delays to product approvals.

Furthermore, regulatory compliance pressures in the pharmaceutical industry have generally increased over the past decade. More specifically, the proportion of FDA warning letters containing a data integrity complaint has risen in recent years, as the agency devotes greater attention to that topic. We expect there to be continued regulatory scrutiny as the industry shifts to more complex biological manufacturing and manufacturing returns domestically.

Key MQC automation growth drivers

We believe several industry trends are driving the need for MQC automation, including:

- **Increasing regulatory scrutiny** — Regulatory compliance pressures in the pharmaceutical industry have increased over the past decade, as mentioned above.

- **Increasing data integrity scrutiny and need for remote, real-time monitoring of facilities** — Facing increased data integrity scrutiny from regulatory authorities in their quality control lab and manufacturing areas, pharmaceutical manufacturers must focus on meeting these regulatory requirements as defined by the FDA and other international regulatory bodies.

- **Expansion of high growth biologics and advent of new, more complex therapeutic modalities such as cell and gene therapies** — The global prescription drug market is large and growing, driven in part by the rise in the burden of chronic diseases and the growing demand for innovative therapies such as biologics and cell and gene therapies. Biologics, cell, and gene therapies require complex multi-step manufacturing processes which demand efficient automated MQC processes.

- **Greater efficiency and focus on six sigma lean manufacturing principles** — The pharmaceutical industry is under significant pressure to commercialize products faster in order to maximize their patent life. There is

continued focus on concepts such as lean manufacturing and six sigma to drive efficiencies in the manufacturing process and a greater emphasis on automating MQC testing to reduce errors and decrease manufacturing lead times and inventory requirements in supply chains.

- **Rebuilding of domestic growth supply chain / increasing scrutiny of outsourced materials with focus on reshoring drug development process** — We believe the reshoring of manufacturing operations will further necessitate the need for efficient automated MQC testing.

- **Labor shortages** — With labor shortages facing many companies in the global pharmaceutical industry, we believe that automated MQC processes can not only make their manufacturing processes more efficient and cost-effective but also help mitigate worker scarcity.

Market opportunity

Our core market of MQC testing encompasses a ubiquitous and high-volume testing process deployed across all pharmaceutical manufacturing operations.

Our core total addressable market

We are especially focused on serving the high-growth biologics, cell, and gene therapy markets, which have the highest MQC testing intensity per batch of manufactured product. We seek to drive substantial growth by establishing Growth Direct as the standard for MQC automation in advanced bioprocessing for biologics, cell, and gene therapies.

The Growth Direct platform

Our proprietary Growth Direct platform fully automates and digitizes the trusted growth-based method of MQC and enables customers to perform this critical testing process more efficiently, accurately, and securely. Our platform comprises the Growth Direct system, proprietary consumables, LIMS connection software, and comprehensive customer support and validation services. The platform's suite of products reflects our expertise at innovating and integrating across multiple technology disciplines, including systems design, robotic handling, microbiology, optical imaging, image analysis, data management and security, and process automation, and is supported by our unwavering commitment to the highest level of customer support.

Our technology

To date, prior technology products have not succeeded in automating MQC workflow at scale, due to a combination of insufficient platform throughput, lack of full automation, and non-viable technology approaches. Most testing solutions on the market that seek to replace the traditional method diverge from directly measuring microbial growth, using alternative analytical technologies that often require additional reagent preparation and that do not deliver the same results as the existing traditional method. These methods are difficult to validate relative to the traditional method and have therefore seen low adoption across the industry.

Growth Direct method

The Growth Direct method relies on a fundamental property of all microorganisms—they contain cellular components required for growth, called flavins and flavoproteins, that autofluoresce, or glow, without the addition of reagents under certain frequencies of light. Our proprietary system detects microcolonies of microorganisms by illuminating them with blue-spectrum light and directing the resulting green-spectrum signal onto a Charged-Coupled Device, or CCD, chip—an array of independent photosensitive pixel elements. Our image analysis software interprets these light signals and counts the clusters of illuminated pixels representing each microcolony. The end result is an automated method that is faster and produces more reliable and accessible data than the traditional method. Our Growth Direct platform accelerates time to results by several days, a 50% improvement over the traditional method, and reduces MQC testing to a simple two-step

workflow, eliminating up to 85% of the manual steps of traditional MQC, generating significant time, operational, and cost savings for our customers.

Core detection technology

Our system illuminates samples using an array of high-intensity blue LED lights, which causes microcolonies to autofluoresce without destroying them. All microbial cells autofluoresce in the green-spectrum when illuminated with blue LED light. A CCD chip captures images with illuminated pixels wherever autofluorescence from microbial cells is detected. Our software detects and registers the clusters of illuminated pixels that represent underlying microcolonies. The system generates a time series of images as the sample incubates and is imaged every four hours. Finally, vision analysis software continuously evaluates the time series for evidence of growing colonies, represented by increasing signal intensity and size of illuminated groups of pixels.

A key feature of detection via imaging of autofluorescence is that this approach does not harm cells, and as such is a non-destructive method. This provides several benefits, including ensuring that detected colonies represent actual viable microbial contaminations, and permitting detected microcolonies to grow into visible colonies for use in subsequent microbial identification for root cause investigation follow-up.

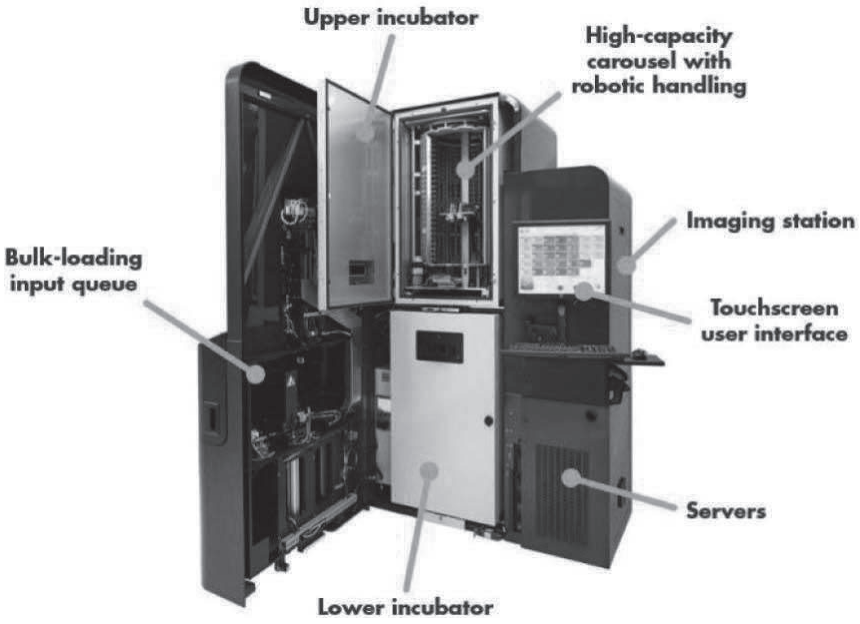
Our platform can detect microorganism growth at the microcolony stage at approximately 100 cells, which typically occurs in half the time required for visual plate counting to detect visible colonies by eye at approximately 10 million cells.

System components and workflow

The Growth Direct system comprises two automated and temperature-controlled incubators, robotic sample transport systems, an advanced imaging system, two servers (one for system control, the other for image analysis) and associated hardware and staging required for the handling of up to 700 of our consumables.

The overall workflow of the automated Growth Direct method mirrors the traditional visual plate counting assays, allowing for operator familiarity of use, ease of integration into existing MQC protocols, and a streamlined regulatory validation process.

Growth Direct system components



The Growth Direct workflow begins when microbial organisms are collected on proprietary growth media plates using the same collection methods as the traditional method—via direct contact, air settling or air filtration for environmental monitoring testing, or via funnel filtration of liquid samples onto the membrane of the consumable for water or bioburden testing. For ease of use, our consumables are compatible with existing hardware, such as active air samplers or liquid filtration systems, and are supplied by us with identical nutrient agar media as traditional media plates.

A Growth Direct operator loads the system in bulk using two carriers designed to hold up to 60 of our consumables each. A key benefit of the Growth Direct is that the system can be placed directly in a production area, compared to the traditional method which often requires transporting samples to a centralized lab for testing. Our consumables are pre-labeled with unique bar codes for forensic trail identification, management and to enable data integrity compliance. Every consumable bar code contains a unique serial number that allows traceable information to be captured by two bar code scanners on the Growth Direct system. That allows metadata such as sample location, time, type, test protocol, and operator to be captured and associated with each consumable result. Intake sensors within the system automatically read, identify, and catalog the bar-coded samples, after which the samples are transferred from the loading queue to one of two independently controlled incubators, which together have a capacity of 700 of our consumables, and which support the operation of multiple custom incubation protocols. Once loaded into the system, consumables cannot be removed or tampered without generating an auditable record of actions by an operator.

During the incubation phase, the Growth Direct captures images of each consumable at intervals of four hours. To perform the imaging, the system transfers consumables from the incubator to the imaging chamber, illuminates them using a blue-spectrum light and captures autofluorescence signals in a high-resolution image using the CCD camera. Samples are returned to the incubators to continue their incubation protocols. Automated sample handling means no sample is ever missed for testing or replaced into the wrong incubator or accidentally discarded.

Over the course of the incubation protocol, the system's image analysis software uses proprietary algorithms to analyze the behavior of autofluorescent objects over an accumulating time series of images, enabling the Growth Direct to identify and count growing microcolonies and distinguish them from non-living debris.

After the image analysis is complete, the system reports the number of growing colonies found on the surface of the consumable. The result data can be printed or transmitted to LIMS via our LIMS connection software for storage and user review. When a sample demonstrates growth that exceeds the threshold for contamination set by the organization, automatic email alerts notify quality personnel of a possible contamination before the end of the incubation period. A powerful yet intuitive user interface allows the operator to track the consumables in the system throughout the testing process and monitor the results in real time, which offers a significant advantage to the manual and traditional method that has to wait to the end of the incubation before counting. After results are reviewed, the consumable can either be unloaded to a carrier for further microbiological identification or automatically discarded as waste at the operator's discretion.

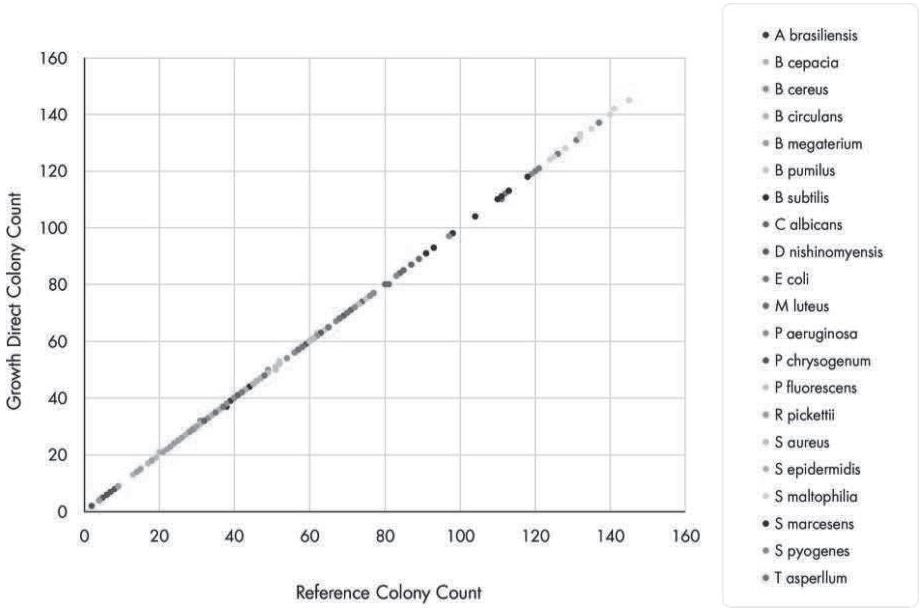
Validation framework

We have demonstrated the accuracy, speed, and reliability of detecting microcolonies using the Growth Direct's automated image analysis compared to conventional methods through numerous scientific studies.

Accuracy. The Growth Direct is highly accurate when compared to traditional methods. Studies of the Growth Direct comparing its vision-based detection and enumeration of colonies against the MQC gold-standard USP <61> benchmark reference set of micro-organisms demonstrate that the Growth Direct delivers the same results or better as traditional, manual verification of colonies.

The figure below demonstrates the accuracy of the Growth Direct imaging and analysis technology compared to a reference count produced by an analyst interpreting the image data created by the software. A wide range of organism types—both mandated by the United States Pharmacopeia, or USP, and those commonly found in pharmaceutical facilities—were evaluated.

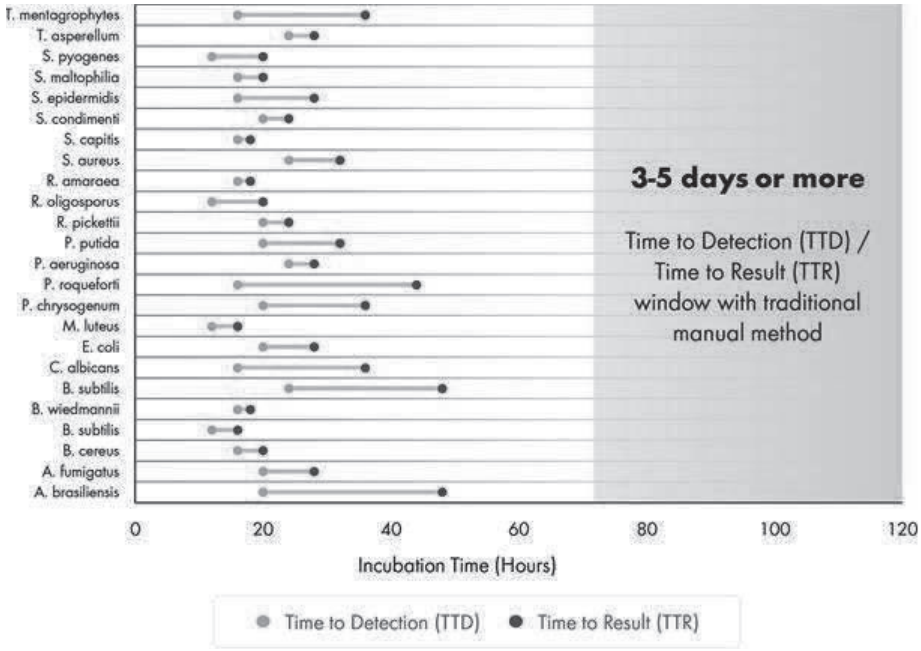
Growth Direct colony count accuracy vs. standard reference



Speed. The Growth Direct is faster than the traditional method. Across a range of organisms of interest, the Growth Direct detects colonies in half the time or faster.

The figure below shows the time to detection, or TTD, and time to result, or TTR, in hours for a wide range of pharma lab-relevant microorganisms using the Environmental Modeling, or EM, application on the Growth Direct system compared to the time to detection / time to result window using traditional manual tests (72+ hours).

Growth Direct time to result vs. traditional method

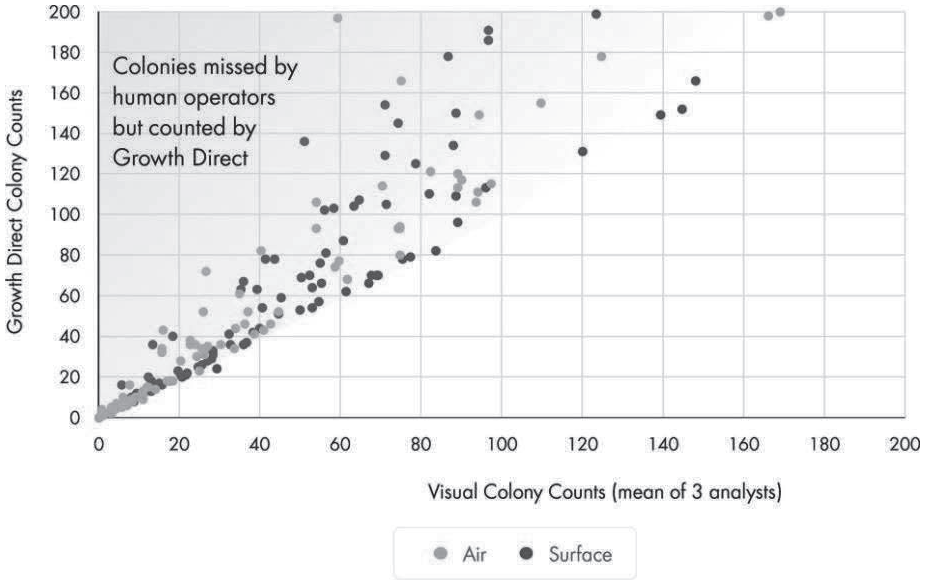


Our value proposition by stakeholder is described below:

Reliability. The Growth Direct is more reliable than the traditional method for accuracy of organism enumeration. In studies of environmental monitoring plates incubated for five days, which compared Growth Direct's vision-based

detection and enumeration to visual counting conducted by technicians, the Growth Direct regularly identified and counted colonies that technicians missed, as shown by the counts in the shaded area in the figure below.

Growth Direct colony detection reliability vs. traditional method



Our Growth Direct platform

We pioneered the Growth Direct platform—a combination of our novel Growth Direct system, proprietary consumables, LIMS connection software, and comprehensive customer support and validation services—to fully automate and digitize the process of MQC in the sterile manufacturing of important health care products.

The Growth Direct system

Our current, second-generation Growth Direct system, launched in 2017, reflects our deep experience with delivering automation to the MQC market. The Growth Direct system is a fully automated, high throughput system for processing MQC samples—a microbiology quality control lab in a box. The Growth Direct system contains two high-capacity incubators, an advanced imaging system and internal robotics for sample handling. The system enables walk-away bulk sample loading, holding 700 of our consumables per system. Its dual, independently controlled incubators automatically manage multi-temperature incubation protocols. Onboard imaging and vision software detects and counts microbial growth, delivering test results in half the time of the manual method. The system's compact 57" x 39" x 95" size delivers these benefits in a footprint that allows customers to place the Growth Direct system directly in manufacturing suites of various sizes compared to the traditional method, where samples are often required to be transferred to a centralized lab. Co-location in manufacturing minimizes delays to incubation and errors introduced by sample transfer to the quality control lab. The Growth Direct system brings the lab to the manufacturing floor, for automated MQC testing, anywhere in the facility or manufacturing campus.

Proprietary consumables

We offer two proprietary consumables plates to capture test samples for analysis on the Growth Direct: (1) an Environmental Monitoring, or EM, consumable and (2) a Water / Bioburden, or W/BB, consumable. Both types are custom-designed proprietary consumables with specific mechanical and optical features to facilitate automated handling and image processing within our Growth Direct system and have bar codes for tracking and data integrity. Two bar codes are used—one applied during our manufacturing process to define the media type and expiration dates, and a second that is generated by the Growth Direct system at time of testing that defines the sample ID and LIMS number. The consumables incorporate multiple standard media for each application as both products are based on the traditional growth method.

In addition, we are developing a growth-based rapid automated sterility test for use on the Growth Direct system. Rapid sterility tests are utilized for final release testing in any facility that manufactures sterile products such as biologics and sterile injectables, as a final quality check before shipment. The traditional sterility test utilizes a growth method that requires at least 14 days to deliver final results, during which time dependent manufacturing steps are paused or proceed at risk, or final products are held in inventory. Similarly, autologous cell therapies require collection of patient tissue, ex vivo manipulation of these cells, and delivery via reinjection into patients — all steps which must be conducted within approximately two weeks, which the traditional method of sterility testing exceeds, causing delays or requiring release of the product at risk.

We began beta testing of our rapid sterility test with one of our existing global customers in 2022. When commercialized, we expect our rapid sterility test will reduce the traditional method's 14-day time to results by at least 50%, permitting faster final release, with the goal of speeding critical drugs and vaccines to market. When released, we expect our rapid sterility test will also deliver the other benefits of the Growth Direct platform, including increased efficiency, reduced risk of errors, and enabling data integrity compliance. Our development program was supported by contract funding from U.S. Department of Health and Human Services Biomedical Advanced Research & Development Authority, or BARDA, which is supporting the development of improvements in vaccine production methods that accelerate the availability of vaccines against viruses with pandemic potential.

Growth Direct LIMS connection software

Our Growth Direct software allows for two-way integration to LIMS, enabling a fully paperless workflow. The bi-directional LIMS connection uses the widely supported comma-separated values, or CSV, file format to communicate, delivering compatibility with all existing LIMS. The connection supports the use of LIMS for Growth Direct created barcodes that are applied to our consumables. After sampling, the consumables are loaded into the Growth Direct system, which performs the incubation, detection and enumeration of colonies. Final results are automatically uploaded to the LIMS. This eliminates the risk of human error that could arise from manually entering the results, while improving efficiency. Moreover, the LIMS connection eliminates the need to use paper in the lab and delivers information to stakeholders in a secure manner, designed to enable compliance with data integrity regulations.

Our service team works directly with customers' IT teams to help integrate Growth Direct software into their LIMS for seamless connectivity.

Validation services

As part of our customer support experience, we offer full validation support to ensure customer success with the Growth Direct platform. This offering helps our customers validate their Growth Direct system for full routine use faster, typically in just three to nine months, and develops confidence in the operation of our platform.

Support begins prior to system purchase when our sales representative brings in a validation expert for consultation about specific application requirements. The validation teams offer a complete array of documents and services to support validation efforts, including:

- Installation Qualification
- Operational Qualification
- Performance Qualification
- Time-To-Results Qualification
- 21 CFR Part 11 Assessment
- Method Qualification/Method Suitability

Once initial systems are validated, our customized validation approach allows customers to quickly validate follow-on systems through a Technical Transfer Method, facilitating faster adoption throughout their site network.

Customer support

We offer full 24/7 maintenance support via our annual service contract. Purchase of the Growth Direct system comes with a one-year warranty, after which customers may purchase annual service contracts. Our maintenance support package offers access to a staffed online and phone help desk with knowledge base, remote management and troubleshooting, and a 24-hour response time from our on-site field service engineer team.

Key advantages of our Growth Direct platform

We believe that several factors differentiate our technology and will continue to be significant drivers of customer adoption of Growth Direct:

- **Faster Results at Higher Testing Throughputs and Capacity** — The Growth Direct platform uniquely combines superior detection and enumeration capabilities—translating to a 50% reduction in detection time compared to the traditional method—with a high-throughput, 700-sample total capacity form factor. This allows Growth Direct to offer a large volume automated testing solution that allows for fewer investigations, more targeted interventions, and more uptime for manufacturers, therefore saving time and money.

- **Increased Accuracy through Automation** — The automation of both sample handling and enumeration virtually eliminates human errors from the MQC process. Samples are transferred automatically at the right time, reducing the risk of sample loss, misplacement or mislabeling. The Growth Direct platform also more reliably distinguishes distinct colonies, hence avoiding the subjectivity that human operators introduce through visual inspection of plates.

- **Increased Process Efficiency** — Faster time to results means faster decision-making and intervention in the event of contamination, preventing production of contaminated batches, and reducing waste and overproduction. Meanwhile, elimination of unnecessary manual labor allows skilled MQC specialists to spend time on test design, interventions, standard operating procedure, or SOP, updates and other critical tasks.

- **Robust Security and Connectivity** — The Growth Direct platform can integrate with existing LIMS, allowing for seamless data transfer from the system to the LIMS. This connection not only makes it easier for quality control personnel to handle and process their testing data, but it also allows other stakeholders to instantly access information critical to continued production.

- **Superior Data Integrity** — By maintaining accurate, complete, and intact records within their original context, the Growth Direct platform is designed to ensure the trustworthiness of data. Moreover, data reside in permanent form for the lifetime of the record, easily accessible to authorized users, which allows operators to analyze trends over time for timely, cost-saving decision-making. The system is designed to enable compliance with industry data integrity standards such as 21 CFR Part 11, which set forth the FDA's standards for electronic records and electronic signatures.

- **High Reliability with Clear Path to Validation** — The Growth Direct platform delivers the reliability that customers need for their mission-critical manufacturing processes, with a consistent record of uptime in live production use. Our platform's reliability is further supported by our 24/7 support infrastructure and extensive regulatory validation services to ensure quick and seamless integration with customer's facilities and IT systems.

Competitive strengths

We believe our continued growth will be driven by the following competitive strengths.

- **Our proprietary technology platform offering best-in-class automated and secure MQC testing** — Our platform was purpose built to meet the growing demands posed by the increasing scale, complexity, and regulatory scrutiny of global pharmaceutical manufacturing. We believe that our Growth Direct platform leads the industry in throughput, accuracy, reliability, security, and data integrity. Compared to the traditional method, our Growth Direct platform accelerates time to results by several days, a 50% improvement over the traditional method, and reduces MQC testing to a simple two-step workflow, eliminating 85% of the manual steps of traditional MQC, generating significant time, operational, and cost savings for our customers. The Growth Direct platform is backed by our comprehensive validation and value-added service offerings, which create a continuous, positive touch point with our customers. Altogether, we believe our technology and service platform best address the growing needs of our customers.

- **Our investment and patent-protected innovation across multiple technology disciplines** — Our platform reflects our expertise at innovating and integrating across multiple technology disciplines, including systems design, robotic handling, microbiology, optical imaging, software image analysis, data management and security, and process automation. Through multiple years of development and investments from both investors and institutional partners, such as BARDA, we have amassed a set of technologies that form the foundation of our growing suite of products and solutions. We also believe that our first mover advantage in automated MQC testing reinforces our growing position in this market, with over 15 years of customer development and feedback, technical development, advocacy, and customer success. We continue to focus on investing in our business and have a well-defined product roadmap which includes development of new, innovative products, as well as advancements to our existing suite of technologies. Moreover, we have a strong intellectual property portfolio, including at least eighty-five granted and pending patents globally with eight unexpired U.S. granted patents and ten U.S. pending patent applications as of December 31, 2022.

- **Top-tier customer partners establishing Growth Direct as an industry standard globally** — We have cultivated long-standing and collaborative relationships with our significant and growing customer base. We originally developed our platform in close collaboration with our customers, and our customers' success in validating our technology constitutes a major driver for platform deployment. Moreover, our comprehensive validation, value-added service, and customer support offerings create a continuous touch point with our customers, cementing the value and integration of our products. Through these efforts, we deliver high quality experiences at every step of the customer journey which creates and strengthens our customer loyalty.

- **Deep integration into heavily regulated pharmaceutical manufacturing processes** — Our products are entrenched within our customers' workflow and the majority of our customers have purchased multiple systems and at multiple locations. For every drug product manufactured or in development, our customers are required to establish a validated QC process that they can execute consistently and reliably. Customers typically dismantle manual testing infrastructure after switching to our platform, creating enormous switching costs that get amplified by the network effect of linked systems and data aggregation across customer sites. Since initial installation, our relentless focus on providing robust validation support ensures assimilation of our platform into our customers' standard operating procedures, further contributing to customer captivity. We believe that our first mover advantage has further enabled us to become deeply rooted within our customer's facilities and provide for ongoing opportunity with our existing customer base.

- **Our highly attractive business model that leverages our growing installed base of systems to generate persistent recurring revenues through consumables and service contracts** — Once embedded and validated in our customers' facilities, our Growth Direct provides for recurring revenues through ongoing consumables and service contracts. When our customers invest in our technology, they commit to a long-term

use of our products. Our customers regularly purchase our proprietary consumables to perform MQC testing and maintain their systems via annual service contracts. Our products are used daily in our customer's facilities and their key workflows, reinforced by regulatory requirements that are driving the industry towards further automation. Once validated, additional systems can be deployed to absorb the majority of test volume in a facility. Moreover, once a Growth Direct system is installed within a customer's facility, it provides for an opportunity to place additional systems in existing and new facilities, which can be installed and validated in a faster, more efficient manner given the comprehensive validation process for the initial system.

- **Ability to leverage our extensive regulatory expertise to better serve our customers' needs** — We believe we are a thought-leader with respect to regulatory requirements. We have a long history engaging with the major regulatory bodies in our industry, such as the FDA and the European Medicines Agency, or the EMA, some of whom are also our customers. Our regulatory strategy has benefited our business in several ways, including: 1) by achieving the definition of the Growth Direct Technology as an "automated compendial validation" in key trade group and regulatory issuances, such as the Parenteral Drug Association, or PDA, Technical Report 33, and USP chapter <1223>; 2) by working with industry and regulatory forums to define a fast validation strategy that allows a short timeline routine testing implementation; 3) and by helping our customers obtain regulatory acceptance from the EMA and the FDA for the use of our technology and validation strategy for new drug applications with the Bioburden application (environmental modeling and water do not need regulatory license change). Our technology has also been audited regularly by regulatory inspectors as part of routine audits of customer sites, with no citations received to date. We have also succeeded in securing a substantial long-term government contract from BARDA to support development of new products as part of an ongoing partnership concerning areas of shared strategic interest regarding accelerated pandemic vaccine release.

- **Our experienced management team and workforce with deep domain knowledge** — Our management team combines strong subject matter expertise with a demonstrated history of commercial and operational execution. Moreover, our workforce has deep domain knowledge across a range of healthcare, technology and business disciplines, which we believe drives our continued commercial success. We have supplemented our diverse technical experience by assembling an operational team with expertise in manufacturing, legal, sales, marketing, customer service and finance. We believe this confluence of talent from multiple disciplines allows us to stay ahead of our competitors by identifying highly impactful opportunities and building products and solutions that address these opportunities.

Our growth strategy

We aim to position the Growth Direct platform as the industry standard for automated MQC testing. We believe we can achieve this through the following key growth strategies.

Reorganize to achieve growth and profitability — In August 2022, our management team endeavored to reorganize the company into a leaner, lower cost organization focused on a path to growth and profitability. As of December 31, 2022, we reduced our workforce by approximately 20%, including employees, contractors and temporary employees, in connection with an organizational restructuring plan. We will continue to invest in key growth initiatives including enhancing commercial execution and key product development programs that are expected to drive future revenue growth.

Leverage our first-mover advantage and our industry leadership to cement Growth Direct as the new standard of MQC automation in the rapidly growing bioprocessing market, including biologics, cell, and gene therapy manufacturing — Our MQC process automation platform is particularly well-suited to the manufacturing of biologics, cell, and gene therapies. These products are manufactured in a highly modularized fashion where each manufacturing batch often represents an individual dose to a specific patient. These therapies are therefore exceedingly valuable, and the manufacturing methods to produce them are time-sensitive and exposed to outsized risk of contamination given the amount of material handling and process change-over. We have demonstrated the value of our platform in cell and gene therapy

manufacturing with our early success in converting customers in this segment. Furthermore, companies in this space are developing new approaches to manufacture these complex products, including novel facility layouts, new processes and workflows, and new quality and risk management frameworks. We intend to capitalize on our first-mover advantage to define the standard of MQC automation in this growing market by moving upstream in the cell and gene therapy manufacturing design practice, creating thought leadership on MQC automation in cell and gene therapy manufacturing, partnering with facility design firms who specialize in manufacturing infrastructure for these modalities, and targeting CDMOs, contract manufacturing organizations, or CMOs, and contract research organizations, or CROs, with significant exposure to this segment.

Drive new customer adoption of the Growth Direct platform by converting the leading manufacturers in our core markets, including but not limited to top 50 pharmaceutical companies and leading CDMOs — With the launch of our latest generation Growth Direct in 2017, approximately 40 global customers have adopted the Growth Direct platform to automate MQC testing in over 75 manufacturing facilities. We intend to drive global adoption by broadly seeking new customers in our core pharmaceutical manufacturing end markets. Our initial focus is on influential high-volume top 50 pharmaceutical companies as measured by revenue and global contract manufacturing organizations, which provide manufacturing services directly to pharmaceutical companies. Our existing customer base includes over 50% of the top twenty global pharmaceutical companies by revenue. Our target geographies include North America and Europe and we are expanding our direct and indirect sales teams to access new customers in other geographic territories, such as Asia.

Expand implementation of the Growth Direct platform within our existing customer base by deploying additional systems across their global manufacturing site network and driving increased application utilization and consumable pull through on a system-by-system basis — We pursue a land-and-expand strategy to drive broad global adoption of our systems. Our approach begins by placing initial systems within our customers' global manufacturing network. The majority of our customers, which comprise over 50% of the top twenty global pharmaceutical companies as measured by revenue, have global operations with multiple manufacturing facilities. We guide these initial sites as they gain experience with the Growth Direct, assisting their validation of initial applications, proving the value of our systems, and establishing a relationship as a trusted and reliable vendor. Our system is specifically designed to absorb the daily MQC testing volume at our customer's facilities. We then successfully sell additional systems to support additional suites at existing sites as well as leverage our high customer satisfaction at existing facilities to drive adoption at new sites within our customers' global manufacturing network. The majority of our customers have multiple Growth Direct systems per site and across different facility locations. We accomplish this expansion via direct peer-to-peer selling facilitated by our commercial team, and by partnering with executive decision makers to execute global customer rollout agreements. We simultaneously drive increased utilization on a system-by-system basis by providing our customers our full suite of applications that can be validated and used on the Growth Direct platform. Moreover, our customers' strong desire to globally standardize and harmonize their MQC operations provides us a direct opportunity to grow with them, and after validating their first system we are able to install and validate more systems globally for them in a much faster time period given the initial validation process.

Increase the value of our platform by innovating and launching new applications, hardware, and software products that deliver the power of integrated automation across our customers' QC workflows — We believe the depth, scalability and robust capabilities of our Growth Direct platform allow us to address key challenges facing MQC testing in the pharmaceutical industry. As an innovative leader in automatic MQC testing, we intend to invest in further enhancements in our existing platform as well as end-to-end workflow solutions in our core market. We have a well-defined roadmap for our existing products, which includes new consumables to expand our platform's MQC testing applications, such as in sterility testing; improvements to on-board algorithms that enable greater insight from our image analysis, such as our RMBNucleus™ Mold Alarm software; additional imaging modalities to unlock new testing functionality; additional system formats to accommodate new customer use cases; and new software to enable fleet management and analytics. Our product roadmap also includes new products to automate upstream and downstream workflow elements, such as microbial identification and automated sample collection, and data-rich products including data management, fleet integration, and predictive analytics. By expanding and continuously enhancing the Growth Direct platform, we believe we can drive incremental revenue from existing clients as well as broaden the appeal of our solutions to potential new customers.

Pursue opportunistic strategic investments, partnerships, and acquisitions — Our strong growth to date has been entirely organic as we continue to add customers to our growing install base of Growth Direct users, while also expanding our consumables and product offering to those customers. At the appropriate stage we may consider opportunistic investments, partnerships, and acquisitions which may strengthen our product platform, allow us to enter new markets, and enhance our growth profile.

Commercial

We launched the latest generation of the Growth Direct platform in 2017, which includes the Growth Direct system and consumables for three applications: environmental monitoring, water, and bioburden testing. Our principal commercial strategy since launch has been to focus on converting customers among the top fifty global pharmaceutical companies. Our land-and-expand approach concentrates on placing initial systems at leading pharmaceutical manufacturers, validating our products, driving high customer satisfaction, and then expanding throughout our customer's network of sites with more systems and applications. We have simultaneously and opportunistically pursued other important customer types outside of top fifty global pharmaceutical companies, such as CDMOs, CMOs, CROs, vaccine manufacturers, pharmacy compounders (503Bs), among others.

With this approach, we have substantially grown our customer base to approximately 35 global customers and have placed 125 systems and sold over 3 million consumables globally. We have customers across approximately 75 sites in 14 countries and the majority of our customers have multiple Growth Direct systems per site and across different facility locations. Our customer base includes manufacturers of biologics, including cell and gene therapies, sterile injectables, small molecule pharmaceutical manufacturers, and CDMOs, among others. We have sold to over half of the top twenty global pharmaceutical companies as measured by revenue. Moreover, we serve customers who operate some of the most complex manufacturing modalities in the world; for example, we support the manufacturers of 25% of globally approved cell and gene therapies, including over 60% of approved gene-modified autologous CAR-T cell therapies. Many of our customers purchase multiple Growth Direct systems at the same time and we expect them to use these systems for many years before needing to purchase new systems. As a result, a significant portion of our annual sales currently comes from the purchase of our Growth Direct system by a small number of different customers each year. We are working to expand our new customer base and sales within existing customers' organizations to provide a steady stream of sales of our systems and to grow our recurring sales stream from consumables and service contracts.

We have a global commercial team that includes direct sales, commercial operations, validation, field services, strategic marketing, marketing communications and product management. This staff is primarily located in North America and Europe, and we also maintain direct customer support teams providing both validation and field service capabilities in the same territories. We intend to expand our sales, support, and marketing efforts in the future by expanding our direct footprint in North America and Europe as well as developing a comprehensive distribution and support network in Asia where new market opportunities exist.

We increase awareness of our products among our target customers through direct sales calls, trade shows, seminars, academic conferences, web presence, social media and other forms of internet marketing. We supplement these traditional marketing efforts by fostering an active community of users of our products through user groups, customer advisory board meetings, forums and blogs with internally generated and user-generated content.

We employ a high-touch, customer-centric commercial approach focused on maximizing customer success. After a system sale is closed, our team works closely with customers to install systems and provide on-site validation and training support. We focus on supporting our customer's transition to an automated MQC protocol and aim to ensure customer success in routine use. We maintain high customer satisfaction through a robust service and maintenance offering, including an online phone and help desk, remote support and on-site field service.

Manufacturing and supply

Our primary manufacturing facility is located in our headquarters in Lowell, Massachusetts. The facility has over 52,000 square feet, with 20,000 square feet of manufacturing floor space that houses multiple manufacturing spaces and functions, including assembly of Growth Direct systems, an ISO-8 cleanroom with ISO-5 laminar flow hoods for consumable manufacturing, dedicated areas for media preparation. The facility has robust quality control from materials receiving to product distribution. We are working to complete a back-up manufacturing facility for consumables in Lexington, Massachusetts, which we expect to be completed in the first half of 2023.

We believe that our manufacturing capacity is sufficient to meet our near-term growth targets for both systems and consumables. Our consumables manufacturing operation, in particular, is designed to meet the demands of high-volume media supply necessary to serve our market. It is centered around a state-of-the-art automated production line that we believe has enough capacity to support near and medium-term growth. To support continuous supply for our customers, we have manufacturing redundancies and maintain inventory in multiple locations, including our Lowell headquarters, a second redundant storage location in the metropolitan Boston area, and at our third-party logistics, or 3PL, warehouses in Schiphol, Netherlands and Frankfurt, Germany.

Our manufacturing strategy includes direct manufacturing of certain products, and third-party outsourcing for certain components and subassemblies. We obtain components and subassemblies for our Growth Direct systems from multiple third-party suppliers and contract manufacturers. While some of these components are sourced from a single supplier, we have qualified second sources for several of our critical parts. We believe that having dual sources for our critical components helps reduce the risk of a production delay caused by a disruption in the supply of a critical component. We perform final assembly, commissioning, and inspection of the systems in our Lowell facility before shipping to customers. Our consumable plate assemblies and lids are manufactured to our specifications by manufacturing partners. We procure media from third-party suppliers and fill and assemble the final consumables in our Lowell facility. We contract with third party vendors to sterilize our consumables before shipping to customers.

We continue to invest in our manufacturing capabilities to increase capacity ahead of future growth, to ensure continuity of supply, and to make order fulfillment consistent and convenient for our customers. Our future manufacturing plans may include expansion of our existing facilities, additional global sites, additional automation lines, and further manufacturing redundancy plans. We are continually evaluating our supply chain and may proactively optimize certain aspects of our manufacturing and supply chain footprint to meet our business objectives.

License agreement

License agreement with Thermo Fisher

In May 2013, we entered into a patent license agreement, or the Thermo Fisher license agreement, with Thermo CRS, Ltd., or Thermo Fisher, pursuant to which we obtained a non-exclusive, worldwide, royalty-bearing, non-sublicensable license under Thermo Fisher's patent rights relating to robotic devices. Pursuant to the Thermo Fisher license agreement, we paid Thermo Fisher one-time fees in the aggregate of $125,000 and are also obligated to pay royalties at a fixed dollar amount ranging from the low to mid four figures for our sale of each system containing the licensed products, subject to increase or decrease upon certain events. The Thermo Fisher license agreement will remain in effect until the last to expire of the licensed patent rights.

Intellectual property

Our success depends in part on our ability to obtain and maintain intellectual property protection for our products and technology, including by seeking and maintaining patent protection, protecting our trade secrets and other proprietary information, obtaining and maintaining our licenses to use intellectual property owned by third parties, and continually evaluating third-party technologies for further licensing opportunities. We also seek trademark protection where appropriate to protect the names that identify us as the source of our products and services.

We own certain patents, patent applications and intellectual property and license certain patents and other intellectual property from third parties. We have also entered into certain supply and commercial agreements with various vendors and suppliers under which we receive rights to their intellectual property for use in our products. Our material license agreement with Thermo Fisher is described in more detail above.

As of December 31, 2022, we own eight granted unexpired patents in the United States, forty issued patents in foreign jurisdictions, including Australia, Canada, China, countries in Europe, India, Japan and Mexico, and ten pending patent applications in the United States. Our issued patents and pending patent applications cover our technologies and products, including machines, manufactures, compositions of matter, and methods of use with respect thereto, related to the Growth Direct platform. Additionally, as of December 31, 2022, we license three issued patents in the United States, Canada and Europe from Thermo Fisher relating to a robotic carousel workstation. The issued patents that we own or that we in-license from Thermo Fisher and any patents that may issue from pending applications that we own have expiration dates or, in the case of patent applications, projected statutory expiration dates, between 2023 and 2042, excluding, with respect to patents that may be issued from our patent applications, any additional term for patent term adjustments or patent term extensions, if applicable.

Competition

As a life sciences technology company, we face competition from a wide array of companies in the pharmaceutical manufacturing industry. This competition includes both small companies and large companies with greater financial and technical resources and longer operating histories than our own.

Our competitors may have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, and sales and marketing than we do. These competitors also compete with us in recruiting and retaining qualified engineering, sales, marketing and management personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly if they establish collaborative arrangements with large companies.

The key competitive factors affecting the success of the products that we develop are likely to be the continued growth of our market position, our ability to expand our integration with existing customers, our ability to develop new products and improve our existing products, and our ability to grow our sales and marketing capabilities. Our commercial opportunity for any of our products could be reduced or eliminated if our competitors develop and commercialize products that are more effective, are more convenient, or are less expensive than our products, or if they are able to more effectively integrate their systems with customers before we do.

We primarily compete with established manufacturers of traditional MQC testing products, such as petri dishes, incubators, and other manual testing equipment, which our products aim to displace. These companies include bioMerieux, Becton Dickinson, Charles River Labs, Merck Millipore and Thermo Fisher. We also compete with a limited number of companies that have or are attempting to enter the MQC testing market with alternative automated solutions, such as Interscience, which has developed a partially-automated system for MQC testing. There are also several established companies in the bioprocessing technology market with whom we do not currently compete, but that could develop products that will compete with us in the future. Many of the established companies have substantially greater financial and other resources than us, including larger research and development teams or more established marketing and sales and commercial teams.

Seasonality

Our revenues vary from quarter to quarter as a result of factors such as our customers' budgetary cycles and extended summer vacation periods that can impact our ability to deliver products and provide onsite services to our customers during those periods. We expect this volatility to continue for the foreseeable future, which may cause fluctuations in our operating results and financial metrics. In addition, trends may vary in the future as our revenue mix shifts from non-recurring to recurring revenues.

Government regulation

We provide products and services used for quality-control testing in pharmaceutical product and medical device manufacturing. Although our Growth Direct platform is not directly subject to regulation by the FDA, our customers' products and product candidates are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. In the United States, many of our customers' products are regulated as either medical devices or drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations, or as biological products under the FDCA and the Public Health Service Act, or the PHSA, and their implementing regulations, each as amended and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices, drugs and biological products to ensure that such products distributed domestically are safe and effective for their intended uses and otherwise meet the applicable requirements of the FDCA and the PHSA. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity.

The manufacture of our Growth Direct system and our consumables is subject to compliance with regulatory systems, standards, guidance and other requirements, as appropriate, including, but not limited to, laws and regulations for safe working conditions and certifications from the International Organization for Standardization. Our products are also subject to various federal, state, local, and foreign laws, regulations and recommendations, relating to the safe and proper use, transportation and disposal of hazardous or potentially hazardous substances. In addition, U.S. and international import and export laws and regulations, including those enforced by the U.S. Departments of Commerce, State and Treasury and OFAC, require us to abide by certain standards relating to the cross-border transit of finished goods, raw materials and supplies and the handling of related information. Our logistics activities must comply with the rules and regulations of the Department of Transportation, the Department of Homeland Security, Department of Commerce, Department of Defense, and the Federal Aviation Administration and similar foreign agencies. We are also subject to various other laws and regulations concerning the conduct of our foreign operations, including the Foreign Corrupt Practices Act and other anti-bribery laws as well as laws pertaining to the accuracy of our internal books and records. We also contract and may in the future contract with the U.S. government. As such, we are subject to certain laws and regulations applicable to companies doing business with the government, as well as with those concerning government contracts, including being subject to potential investigation for compliance with government contract regulations.

Human capital resources

Our key human capital objectives in managing our business include attracting, developing and retaining top talent while integrating diversity, equity and inclusion principles and practices into our core values.

Employees

As of December 31, 2022, we had 177 full-time employees across the globe, of which 39 were engaged in sales and marketing, 32 in research and development, 76 in manufacturing and service, and 30 in general and administrative. None of our employees are covered by a collective bargaining agreement. We consider our relationships with our employees to be good.

Talent Recruitment and Retention

We strive to attract a pool of diverse and exceptional candidates and support their career growth once they become employees. In 2022, we hired an employee experience manager to foster and enrich employee experience from initial onboarding to retirement.

We emphasize in our evaluation and career development efforts internal mobility opportunities to drive professional development for every employee, which we believe also drives our retention efforts. We strive to provide learning opportunities for all our employees through the development of new learning paths, technical on-the-job training, and leadership training. We also provide our employees career development and career paths through internal promotional opportunities, tuition reimbursement and annual performance management processes. For our global managers and directors, we offer training in leadership essentials.

We provide our employees with a competitive employment opportunity through market-based compensation, equity ownership at all levels across the Company, competitive health and welfare benefits including: short-term disability, long-term disability insurance, 401k, ESPP, pet insurance and paid time off.

Diversity and Inclusion

We value diversity at all levels and continue to focus on expanding our diversity and inclusion initiatives from candidate attraction, employee onboarding and employee experience.

As part of our commitment to diversity and inclusion, RMB proudly supports employee-initiated and led employee resource groups, or ERGs, to provide business insights, solve unique business problems, build leadership skills, and represent the company within the communities we serve. For example, the RMB Women's ERG was established in 2021 and focuses on the engagement, empowerment, and elevation of women within the company. Membership is open and encouraged for all employees and grew more than 200% in its first year. Examples of program content organized by this ERG include professional career panel discussions with company leaders, attendance sponsorship to leadership conferences such as Massachusetts Conference for Women, company-wide charity drives for local Women's shelters, and celebration of global events such as International Women's Day.

Additional information

Rapid Micro Biosystems, Inc., a Delaware corporation, was incorporated in December 2006. We completed our initial public offering of our Class A common stock in July 2021.

Our Internet address is *www.rapidmicrobio.com*. On our Investor Relations website, *investors.rapidmicrobio.com*, we make available free of charge a variety of information for investors, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file that material with or furnish it to the Securities and Exchange Commission, or SEC. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at *www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

Our business involves significant risks. Stockholders should carefully consider the risks and uncertainties described below and the other information in this Annual Report on Form 10-K. Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our Class A common stock could decline and stockholders could lose all or part of their investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain important factors, including those set forth below.

Risks Related to Our Financial Position and Need for Capital

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 years ended December 31, 2022 and 2021, we incurred net losses of $60.8 million and $73.5 million, respectively. As of December 31, 2022, we had an accumulated deficit of $375.9 million. We expect that our operating expenses will continue to increase as we grow our business. Since our inception, we have financed our operations primarily from private placements of our convertible preferred stock, the incurrence of indebtedness, our initial public offering, and to a lesser extent, revenue derived from our Growth Direct platform and non-commercial contracts. We have devoted substantially all of our resources to the development and commercialization of our Growth Direct platform and to development activities related to advancing and expanding our technological capabilities. We will need to generate significant additional revenue to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. We may never be able to generate sufficient revenue to achieve or sustain profitability and our recent and historical growth should not be considered indicative of our future performance.

Our limited operating history makes it difficult to evaluate our future prospects and the risks and challenges we may encounter.

We were established in 2006 and launched our current second-generation Growth Direct platform in 2017 for which we are continuing to grow our manufacturing and sales and marketing capabilities. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. While our product and services revenue has increased, if our growth strategy is not successful, we may not be able to continue to grow our revenue or operations. Our limited operating history, evolving business and rapid growth make it difficult to evaluate our future prospects and the risks and challenges we may encounter, and we may not continue to grow at or near historical rates.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We are transitioning to a company capable of supporting commercial manufacturing, sales and marketing at scale. We may not be successful in such a transition and, as a result, our business may be adversely affected.

Our success depends on the success of our Growth Direct platform, which may not be achieved or maintained.

Our ability to achieve and maintain commercial market acceptance of our Growth Direct platform will depend on a number of factors, including:

- significant acceptance by drug manufacturers of automated microbial quality control, or MQC, testing;
- our ability to increase awareness of the capabilities of automated MQC testing and our technology and solutions;

- our customers' willingness to adopt new technologies and workflows;
- our ability to integrate our platform with our customers' existing workflows, including related to regulatory validation processes;
- whether our platform reliably provides advantages over the conventional, manual method of MQC testing and other automated technologies and is perceived by customers to be cost effective;
- the continued growth of the pharmaceutical and biopharmaceutical industry, in particular biologics, cell and gene therapies;
- our ability to execute on our business strategy, including continuing to expand in the market for cell and gene therapies;
- the rate of adoption of our platform and solutions by drug manufacturers;
- prices we charge for our systems and consumables;
- the relative reliability and robustness of our platform as a whole and the components of our platform;
- our ability to develop new products for existing customers and to expand our capabilities within the MQC testing workflow;
- our ability to expand the use of our platform with existing customers;
- other competitive automated MQC testing platforms; and
- the impact of our investments in product innovation and commercial growth.

We cannot assure our stockholders that we will be successful in addressing each of these criteria or other criteria that might affect the market acceptance of our products. If we are unsuccessful in achieving and maintaining commercial market acceptance of our Growth Direct platform, our business, financial condition, results of operations and prospects could be adversely affected.

Our operating results have fluctuated significantly in the past and will fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results have fluctuated significantly in the past and may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- our customers' tendency to purchase our Growth Direct system, including multiple systems, in a single transaction, resulting in significant variations in sales of our systems over time;
- the level of demand for our platform and solutions, which may vary significantly;
- the length of time of the sales cycle for purchases of our systems;
- seasonality in our business due to our customers' budgetary cycles and time off during the summer vacation;
- lead time needed for validation prior to our customers' using and purchasing our consumables;
- changes in demand for our consumables;

- the timing and cost of, and level of investment in, technology development and commercialization activities, which may change from time to time;
- the start and completion of manufacturing runs;
- system repairs or replacements that may impact our customers' confidence in us and our products and our reputation in the market;
- the relative reliability and robustness of our platform;
- the introduction of new products or product enhancements by us or others in our industry;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- expenditures involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- future accounting pronouncements or changes in our accounting policies;
- the ability of our sales organization to design and execute effective sales processes; and
- general market conditions and other factors, including factors, such as inflation, unrelated to our operating performance or the operating performance of our competitors.

The effect of one of the factors discussed above, or the cumulative effects of a combination of factors discussed above, could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. We may continue to experience fluctuations in our operating results as a result of these factors.

We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could adversely affect our business, reputation and financial results and cause our stock price to decline.

From time to time, we release earnings guidance in our quarterly and annual earnings conference calls, quarterly and annual earnings releases, or otherwise, regarding our future performance that represents our management's estimates as of the date of release. This guidance includes forward-looking statements based on projections prepared by our management. Projections are based upon a number of assumptions and estimates that are based on information known when they are issued, and, while presented with numerical specificity, are inherently subject to significant business, economic, and competitive uncertainties and contingencies relating to our business, many of which are beyond our control and are based upon specific assumptions with respect to future business decisions, some of which will change. These assumptions are inherently difficult to predict. It can be expected that some or all of the assumptions underlying any guidance furnished by us will not materialize or will vary significantly from actual results. From time to time, we provide possible outcomes as high and low ranges, but these are not intended to imply that actual results could not fall outside of the suggested ranges.

Our actual business results may vary significantly from such guidance due to a number of factors, many of which are outside of our control, including our customers' demand for our Growth Direct systems, the length of the sales cycle for purchases of our systems, customer site readiness and the lead time needed for validation of our systems prior to customers using and purchasing our consumables, as well as the impact of global economic uncertainty and financial market conditions, geopolitical events, such as the conflict in Ukraine, rising inflation, rising interest rates, and the coronavirus pandemic, all of which could adversely affect our business and future operating results. There are no comparable recent events that provide insights on the probable effects of the coronavirus pandemic and current macro-economic uncertainty, and, as a result, the ultimate impacts of the coronavirus pandemic and/or the current macro-economic environment are

highly uncertain and subject to change. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors, or other interested parties, we may experience adverse effects on our business and reputation and the price of our common stock could decline.

In January 2022, we announced that our actual commercial revenue for the fiscal year ended December 31, 2021 was below our previous guidance, and in August 2022, we announced a downward revision in our commercial revenue guidance for the fiscal year ended December 31, 2022. Given the uncertainty surrounding our ability to design and execute more effective sales processes, generate and convert sufficient sales leads with new customers and place additional systems with existing customers, we may continue to fail to meet our publicly announced guidance in the future. Guidance is necessarily speculative in nature, and it can be expected that some or all of the assumptions underlying the guidance furnished by us will not materialize or will vary significantly from actual results. Accordingly, our guidance is only an estimate of what management believes is realizable as of the date of release. Actual results may vary from our guidance and the variations may be material. Investors are urged to exercise caution when using our guidance in making an investment decision regarding our common stock. Any failure to successfully implement our business strategy or the occurrence of any of the events or circumstances set forth in this Risk Factors section in this Annual Report on Form 10-K could result in the actual operating results being different from our guidance, and the differences may be adverse and material.

If we cannot maintain the level of sales of our Growth Direct systems or the sales of our consumables and service contracts to existing customers declines, our future operating results would be adversely affected.

In the years ended December 31, 2022 and December 31, 2021, 22.8% and 16.7% of our revenue was generated from one customer, respectively. The revenue generated from these customers was derived from sales of our Growth Direct system, consumables and service contracts. Many of our customers purchase multiple Growth Direct systems at the same time and we expect them to use these systems for many years before needing to purchase new systems. Our ability to generate revenue depends on our ability to sell our Growth Direct system to new customers or expand the use of our system by existing customers. As a result, in the near term, we expect a significant portion of our revenue to primarily be generated from a small number of different customers each year. We also rely on consumables and service contracts as a source of recurring revenue from our existing customers. These consumables and service contracts are purchased on an as-needed basis and, as a result, revenue from these sources may be subject to change, as customers' purchasing practices and policies change or their demand for our consumables and service contracts change. If we are unable to sell our Growth Direct system to new customers, if our existing customers do not expand their use of our system, or if our existing customers decide to purchase fewer of our consumables and service contracts or terminate their relationships with us, our revenue could significantly decrease, which would have an adverse effect on our financial condition and results of operations and could adversely impact our ability to execute on our growth strategy.

We may need to raise additional capital to fund our existing operations, improve our platform or develop and commercialize new products or expand our operations.

We expect to spend significant amounts to expand our existing operations, to continue to improve our Growth Direct platform and to develop new products and consumables. Based upon our current operating plan, we believe our existing cash, cash equivalents, and investments of $138.4 million, and anticipated cash flow from operations, will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months following the date these consolidated financial statements were issued. This estimate and our expectation regarding the sufficiency of our existing cash, cash equivalents, and investments are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Until such time, if ever, as we can generate sufficient cashflow, we may finance our cash needs through a combination of equity offerings and debt financings or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

- our ability to achieve revenue growth;
- the cost of expanding our operations, including our manufacturing facilities, and our offerings, including our sales and marketing efforts;
- our rate of progress in launching and commercializing new products, and the cost of the sales and marketing activities associated with, establishing adoption of our Growth Direct system;
- our rate of progress in, and cost of research and development activities associated with, products in research and development;
- the effect of competing technological and market developments;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- costs related to domestic and international expansion.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or products or grant licenses on terms that may not be favorable to us. Furthermore, any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to advance product development activities. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate product development or commercialization efforts.

Repair or replacement costs due to warranties we provide on our Growth Direct system could have a material adverse effect on our business, financial condition and results of operations.

We provide a one-year limited assurance warranty on Growth Direct systems, which is included in the sales price. Existing and future warranties place us at the risk of incurring future repair or replacement costs. We establish our accrual for estimated warranty expenses based on historical information, current cost data and future forecasts. We exercise judgment in determining the expected product warranty costs, using estimated material, labor and other costs. While we believe that historical experience provides a reliable basis for estimating such warranty cost, unforeseen quality issues or component failure rates could result in future costs in excess of such estimates. As of December 31, 2022, we had an amount reserved for warranty costs of $0.9 million. Substantial amounts of warranty claims could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Business and Strategy

The ongoing coronavirus pandemic has impacted, and may continue to impact, our operations and may materially and adversely affect our business and financial results.

Since late 2019, the coronavirus pandemic has spread globally, including to the Boston, Massachusetts area, where our primary offices and manufacturing facility are located. Although the U.S. government has announced that the public health emergency related to the coronavirus pandemic will end in May 2023, our business has been, and may continue to be, affected by the continuing effects of the coronavirus pandemic. The coronavirus pandemic continues to evolve, and has led

to the implementation of various responses, including government-imposed, shelter-in-place orders, quarantines, travel restrictions and other public health safety measures. In response to the spread of coronavirus, and its variants, and in accordance with direction from state and local government authorities, we have restricted access to our facilities mostly to personnel and third parties who must perform critical activities that must be completed on-site, limited the number of such personnel that can be present at our facilities at any one time, and requested that most of our personnel work remotely. In the event that government authorities modify current restrictions, our employees conducting development or manufacturing activities may not be able to access our manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

Any of these factors could severely impact our development activities, business operations and sales, or delay necessary interactions with manufacturing sites and other important contractors and customers. For example, we experienced a disruption in receiving supplies from third parties and a decrease in installations as a result of the shutdown of our customers' businesses. In addition, our sales and service processes have been significantly disrupted by our customers' coronavirus-related restrictions and staffing shortages, which have impacted our customer site access and delayed systems placement timelines. These and other factors arising from the coronavirus pandemic could worsen in countries that are already afflicted with coronavirus, and its variants, could continue to spread, or could return to countries where the pandemic has been partially contained, and could further adversely impact our ability to conduct our business generally and have a material adverse impact on our operations and financial condition and results.

The extent to which the outbreak may negatively impact our operations and results of operations or those of our third party manufacturers, suppliers, collaborators or customers will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate duration of the pandemic, subsequent waves of infection or variant strains, including the impact of the Delta and Omicron variants, the timing, availability, and effectiveness of vaccines as well as vaccination rates among the population, travel restrictions, and additional or modified government actions and private sector actions to contain the spread of coronavirus or treat its impact, such as social distancing, quarantines, lock-downs or business closures.

The continued success of our business relies heavily on establishing and maintaining our position in the market as a leading provider of automated MQC testing.

Our future profitability will depend on our ability to successfully execute and maintain a sustainable business model and generate continuous streams of revenue. Our business model is premised on the fact that we are and will continue to be a leader in automated MQC testing and the competitive advantages our position creates. Our Growth Direct platform, among other things, is designed to reduce the amount of time for MQC testing and the opportunity for human error in what we believe is a more cost-effective manner than traditional MQC testing. However, if competitors develop and commercialize an automated MQC testing platform that is comparable to ours and are able to obtain traction with customers, we may not be able to maintain our lead position and execute our business strategy, which could adversely affect our financial position and prospects. If we are unable to expand or continue to expand our customers in new areas of drug manufacturing, such as cell and gene therapies, continue to grow market adoption of our Growth Direct platform, and maintain our position as the industry leader in automated MQC testing, our business, prospects, financial condition and results of operation could be adversely affected.

It may be difficult for us to implement our strategies for improving growth.

Our success will depend on our ability to expand our business with existing customers and to target new drug manufacturing customers to capture a greater share of the MQC testing value chain. Our ability to grow our business with existing customers will depend on our ability to broaden the application of our automated MQC testing to a larger portion of the MQC testing workflow and to increase the number of Growth Direct systems in their manufacturing facilities. Our ability to expand our business will also depend on our ability to attract new customers and to integrate our platform with new methods of manufacturing, such as cell and gene therapies. Future revenue growth will also depend on our ability to develop and market new products, technologies and solutions to meet our customers' evolving needs, as well as our ability

to identify new applications and customers for our technology in additional industries beyond the drug manufacturing industry.

As we continue to scale our business, we may find that certain of our products, certain customers or certain industries may require a dedicated sales force or sales personnel with different experience than those we currently employ. Identifying, recruiting and training additional qualified personnel would require significant time, expense and attention. If we are unable to drive new customer conversion to automated MQC and our Growth Direct platform, expand adoption of our Growth Direct platform into new industries and markets, or increase the usage and value of our platform to our customers, then our business, financial condition, results of operations and prospects could be adversely affected.

We may not successfully implement our strategy to expand our Growth Direct platform to customers who manufacture cell and gene therapies.

Our ability to execute our growth strategy to expand our Growth Direct platform to customers who manufacture cell and gene therapies depends upon our ability to integrate our platform with the novel manufacturing processes being developed for these therapies. Companies that manufacture cell and gene therapies are developing new approaches to handle this manufacturing method, including novel facility layouts, new processes and workflows, and new quality and risk management frameworks. Unlike traditional "small molecule" drug manufacturing, the manufacture of biologics, such as cell and gene therapies, is more time sensitive and subject to increased risk of contamination due to material handling and process change-over. There are also currently a small number of cell and gene therapies approved by the FDA. While we have experience providing automated MQC testing for customers that manufacture a number of these approved therapies, we may encounter challenges or unexpected issues as we apply our Growth Direct platform to testing a greater number of therapies as they are approved in future. We cannot be certain that we will be able to successfully or consistently integrate our platform with this novel manufacturing process. If we are unable to successfully expand our Growth Direct platform into this growing segment of therapeutic manufacturing, our business and financial position may be adversely affected.

The size of the markets and forecasts of market growth for automated MQC testing and other of our key performance indicators 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 Growth Direct platform. 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 market studies, and other business data, including assumptions and estimates relating to our ability to generate revenue from the expansion of our platform into new drug manufacturing areas and new industries. 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. As a result, our estimates of the total addressable market and our forecasts of market growth for our current or future products may prove to be incorrect, and our key performance indicators may not reflect our actual performance. If the total addressable market or the potential market growth for our platform is smaller than we have estimated or if the key performance indicators 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.

New product development involves a lengthy and complex process and we may be unable to develop or commercialize products on a timely basis, or at all.

Products from our development programs will take time and considerable resources to develop, and may include improvements or changes to our systems, software and consumables. We may not be able to complete development and commercialize them on a timely basis, or at all. There can be no assurance that our development programs will produce

commercial products and solutions and before we can commercialize any new products, we will need to expend significant funds in order to:

- conduct substantial research and development, which may include validation studies;
- further develop and scale our engineering and manufacturing processes to accommodate different products;
- further develop and scale our infrastructure to be able to analyze increasingly large amounts of data; and
- utilize data and analytical insights generated from existing Growth Direct platform in our research and development programs in order to advance these programs.

Our product development processes involve a high degree of risk, and these efforts may be delayed or fail for many reasons, including:

- failure of the product to perform as expected;
- higher costs than anticipated; and
- failure to reliably demonstrate the advantages of our products.

In addition, if we are unable to generate additional data and insights from our existing Growth Direct platforms, then we may not be able to advance these programs as quickly, or at all, or without significant additional investment, all of which could have a material adverse effect on our product development efforts.

Even if we are successful in developing new products, it will require us to make significant additional investments in marketing and selling resources in order to commercialize any such products. As a result, we may be unsuccessful in commercializing new products that we develop, which could adversely affect our business, financial condition, results of operations and prospects.

Our customers use our Growth Direct platform as part of their quality-control workflow, which is subject to regulation by the FDA and other comparable regulatory authorities.

We provide products and services used for quality-control testing in pharmaceutical product manufacturing. Our customers are subject to extensive regulations by the FDA and similar regulatory authorities in other countries, including, for example, cGMP regulations and associated requirements to validate the methods used to manufacture their products. To meet their regulatory compliance requirements, our customers have implemented quality-control workflows to monitor for microbial growth and contamination. While our Growth Direct platform is not regulated directly by the FDA or other comparable authorities and we have not verified our Growth Direct platform for compliance with such regulations, we have designed our platform to be integrated as part of a compliant quality-control workflow. If our Growth Direct platform is unable to meet regulatory standards for compliance or we are unable to update our platform to meet new regulatory requirements, we will lose customers and our business will be adversely affected. While under our agreements with our customers we are not liable for non-compliance of our Growth Direct platform, if a customer experienced a compliance failure due to our Growth Direct platform, or that the customer attributes to our Growth Direct platform, our reputation could be harmed and our business prospects adversely affected.

If we are unable to manage our inventory and support demand for the Growth Direct platform, as well as our future product offerings, our business could suffer.

As the number of customers using the Growth Direct platform grows and our volume of installed systems increases, we will need to continue to increase our capacity for customer service and support, including maintenance services of our systems, and expand our manufacturing capabilities. As a result, we will also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate, and increase our personnel levels to meet

increased demand. Additionally, we maintain certain levels of inventory to support future manufacturing efforts. If our inventory should exceed our customer demand, then it may not be sold at a pace that keeps up with the development of our technology and may therefore become obsolete or no longer competitive in the marketplace. There is no assurance that any of these measures taken with respect to scale, expansion of personnel, equipment, manufacturing or services will be successfully implemented, or that we will have adequate space, including in our manufacturing facility, to accommodate such required expansion.

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

We have limited experience in marketing and sales, and if we are unable to improve the effectiveness of our marketing and sales organization to adequately expand our business with new and existing customers and address our customers' needs or to expand our customer base, our business may be adversely affected.

We have limited experience in marketing and selling our products and we currently rely on a small team to make direct sales in countries around the world. There are significant risks involved with relying on our own marketing and sales capabilities, including our ability to design and execute effective sales processes, generate and convert sufficient sales opportunities into new customers and place additional systems with existing customers. We are implementing improved sales processes, and there can be no assurance that those efforts will be successful.

Furthermore, in order to support our planned growth, we will need to increase our sales and marketing team. Competition for employees capable of selling expensive instruments within the drug manufacturing industry is intense. There are significant expenses and risks involved with having our own sales and marketing team, including our ability to hire, train, retain, and appropriately incentivize a sufficient number of qualified individuals, generate sufficient sales leads and provide our sales and marketing team with adequate access to customers who may want to purchase our products, effectively manage a geographically dispersed sales and marketing team, and other unforeseen costs and expenses. We may not be able to attract and retain personnel or be able to build an efficient and effective sales organization, which could negatively impact sales and market acceptance of our products and limit our revenue growth and potential profitability. Following the departure of our Chief Commercial Officer in August 2022, our Chief Executive Officer has assumed leadership responsibility over the commercial organization and is expected to continue in this capacity until a new commercial leader is hired. In addition, the time and cost of establishing a specialized sales, marketing and service force for a particular product or service may be difficult to justify in light of the revenue generated or projected. Our sales processes may also be disrupted by our announced organizational restructuring plan.

We may engage distributors or other strategic partners for the sale of our products. We would exert limited control over these distributors, and if their sales and marketing efforts for our products are not successful, our business would be materially and adversely affected. We may not be successful in locating, qualifying and engaging distributors with local industry experience and knowledge, or we may not be able to enter into arrangements with them on favorable terms. Even if we are successful in identifying distributors, such distributors may engage in sales practices that violate local laws or our internal policies. Furthermore, sales practices utilized by any such distributors that are locally acceptable may not comply with sales practices standards required under U.S. laws that apply to us, which could create additional compliance risk.

Any of these issues could impair our ability to successfully place our Growth Direct systems and meet our revenue expectations. If we are unable to improve our sales processes and expand our marketing and sales organization,

whether independently or with third parties, then our business, financial condition, results of operations and prospects will be materially adversely affected.

Our organizational restructuring plan, including a reduction in workforce, announced in August 2022, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

On August 12, 2022, we announced an approximately 20% reduction in our workforce, including employees, contractors and temporary employees, in connection with an organizational restructuring plan. We may not realize, in full or in part, the anticipated benefits and cost savings from our cost reduction efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies, improved commercial execution and cost savings from the restructuring, our operating results and financial condition could be adversely affected. If future results of operations lag our expectations, we may undertake additional workforce reductions or restructuring activities.

Our restructuring and any additional measures we might take to reduce costs could divert the attention of management, yield attrition beyond our intended reduction in workforce, reduce employee morale, or cause us to delay, limit, reduce or eliminate certain product development plans, each of which could have an adverse impact on our business, operating results and financial condition. This organizational restructuring plan may also reduce our existing customers' confidence in us, disrupt our sales initiatives for new system placements, and negatively impact our customer service operations. Our failure to adequately address any of these issues could have a material adverse effect on our business, operating results and financial condition.

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

We have experienced volatility in our revenue, however, given our recent efforts to streamline our business operations and refocus our personnel strategy, we anticipate resumed growth in our business operations. The volatility in our growth has required significant time and attention from our management, and placed strains on our operational and manufacturing systems and processes, financial systems and internal controls and other aspects of our business. We expect to continue to increase headcount and to hire more specialized personnel in the future as we grow our business. We will need to continue to hire, train and manage additional qualified engineers, client and account services personnel and sales and marketing staff and improve and maintain our technology to properly manage our growth. We may also need to hire, train and manage individuals with expertise that is separate, supplemental or different from expertise that we currently have, and accordingly we may not be successful in hiring, training and managing such individuals. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees, or if we are not successful in retaining our existing employees, our business may be harmed. In addition, our compensation arrangements, such as our equity award programs, may not always be successful in attracting new employees and retaining and motivating our existing employees. We may need to issue additional equity securities to attract job candidates or issue additional securities and reprice existing options to retain personnel. In making employment decisions, job candidates and existing personnel often consider the value of the equity awards they would receive in connection with their employment and fluctuations in our stock price, or a perception that the market price of our stock may not increase or may increase more slowly than stock prices at other companies, may make it more difficult to attract, retain, and motivate employees.

Developing and launching new products and innovating and improving our existing products have required us to hire and retain additional engineering, sales and marketing, software, manufacturing, distribution and quality assurance personnel. As we have grown, our employees have become more geographically dispersed. We serve customers located in multiple countries and plan to continue to expand to new countries as part of our growth strategy, which will lead to increased dispersion of our employees, including sales employees and employees who are in our service and support groups. We may face challenges integrating, developing and motivating our rapidly growing and increasingly dispersed employee base.

We may not be able to maintain the quality, reliability or robustness of our platform, or the expected turnaround times of our services and support, or to satisfy customer demand as it grows. Our ability to manage our growth properly will

require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. To effectively manage our growth, we must continue to improve our operational and manufacturing systems and processes, our financial systems and internal controls and other aspects of our business and continue to effectively expand, train and manage our personnel. The time and resources required to improve our existing systems and procedures, implement new systems and procedures and to adequately staff such existing and new systems and procedures is uncertain, and failure to complete such activities in a timely and efficient manner could adversely affect our operations and negatively impact our business and financial results.

If we cannot compete successfully, we may be unable to increase or sustain our revenue, or achieve and sustain profitability.

We currently primarily compete with established companies that provide consumables for MQC testing and with a limited number of established and early-stage companies that have automated MQC testing systems. In addition, our customers may also elect to continue to use the traditional MQC testing method rather than our platform and may decide to stop using our platform.

Our competitors and potential competitors may enjoy a number of competitive advantages over us, including:

- longer operating histories;
- larger customer bases;
- greater brand recognition and market penetration;
- greater financial resources;
- greater technological and research and development resources;
- better system reliability and robustness;
- greater selling and marketing capabilities; and
- better established, larger scale and lower cost manufacturing capabilities.

As a result, our competitors and potential competitors may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their platforms or instruments than we can or sell their platforms or instruments, or offer services competitive with our platform and services at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations.

In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies. Certain of our competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing policies and devote substantially more resources to product development than we can. Further, competition in the automated MQC testing market, while currently limited, may increase in future, and we may not be able to maintain our leading position in the industry as a result. If we are unable to compete successfully, we may be unable to increase market adoption and sales of our platform, which could prevent us from increasing our revenue or achieving profitability.

We must develop new products, adapt to rapid and significant technological change and respond to introductions of new products by competitors to remain competitive.

We sell our products in industries that are characterized by significant enhancements and evolving industry standards. As a result, our customers' needs are rapidly evolving. If we do not appropriately innovate and invest in new technologies, our products and services may become less desirable in the markets we serve, and our customers could move to new technologies offered by our competitors or decide to revert to the traditional MQC testing method. Though we believe customers in our markets display a significant amount of loyalty to their supplier of a particular product, we also believe that because of the initial time investment required by many of our customers to reach a purchasing decision for a new product, it may be difficult to regain that customer once the customer purchases a product from a competitor. Without the timely introduction of new products, services and enhancements, our offerings will likely become less competitive over time, in which case our competitive position and operating results could suffer. Accordingly, we focus significant efforts and resources on the development and identification of new technologies, products and markets to further broaden our offerings. To the extent we fail to timely introduce new and innovative products or services, adequately predict our customers' needs or fail to obtain desired levels of market acceptance, our business may suffer and our operating results could be adversely affected.

Due to the significant resources required to enable access in new markets, we must make strategic and operational decisions to prioritize certain markets, products and services. We may expend our resources to access markets and develop products and services that do not yield meaningful revenue or we may fail to capitalize on markets, products or services that may be more profitable or with a greater potential for success.

We believe our platform has potential applications across a wide range of markets and we have targeted certain markets in which we believe our technology has significant advantages or a higher probability of success or greater revenue opportunity, such as the manufacture of cell and gene therapies. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between advancing near-term opportunities and exploring additional markets for our platform. However, due to the significant resources required for the development of products and services for new markets, we must make decisions on which markets to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular markets, products or services may not lead to the development of any viable product or service and may divert resources away from better opportunities. Similarly, we may choose to pursue certain markets, which may not be as profitable as other markets that we did not pursue due to our limited resources. As a result, our business, financial condition, results of operations and prospects could be adversely impacted.

The Growth Direct platform may contain undetected errors or defects and may not meet the expectations of our customers, which means our business, financial condition, results of operations and prospects could suffer.

Our Growth Direct platform includes the Growth Direct system, proprietary consumables and our LIMS connection software. While we rigorously test our platform and its components, there could be undetected errors or defects. Disruptions or other performance problems with our platform or with the components that comprise our platform may adversely impact our customers' manufacturing process, compliance workflow or business, harm our reputation and result in reduced revenue or increased costs associated with repairs or replacements. If that occurs, we may also incur significant costs, the attention of our key personnel could be diverted, or other significant customer relations problems may arise. We may also be subject to warranty claims or breach of contract for damages related to errors or defects in our products. Additionally, we may be subject to legal claims arising from any defects or errors in our platform, and in the systems, consumables and software that comprise our platform. In the past, we have repaired, and in exceptional cases, replaced Growth Direct systems under warranty. Our failure to adequately address any of foregoing risks related to errors or defects with our platform could have a material adverse effect on our business, operating results and financial condition.

Our success depends on, among other things, the market's confidence that the Growth Direct platform is capable of substantially enhancing quality control in the conduct of manufacturing activities as compared to the traditional method of

MQC testing and will enable more efficient or improved drug manufacturing. Pharmaceutical companies and contract manufacturing organizations, or CMOs, are likely to be particularly sensitive to defects and errors in the use of our platform, including if our platform fails to deliver meaningful improvements in MQC testing with results at least as good as the results generated using the traditional method of MQC testing. There can be no guarantee that our platform will meet the expectations of these companies or CMOs.

The complexity of our products and the amount of lead time required to deliver products to our customers have caused in the past, and may cause in the future, delays in releasing new products and workflows. In addition, we have experienced in the past, and may experience in the future, challenges with respect to the reliability of our systems. If there are delays in delivering our products to our customers, or if our products fail to perform as well as or better than traditional MQC testing or fail to generate reliable results for our customers, our revenue could be reduced or delayed, which could adversely affect our business, financial condition, results of operations and prospects.

These complexities also require that we train our customers to operate our Growth Direct platform, which is expensive and time consuming. Any misuse of our products, including as a result of inadequate training, could cause our products not to perform as expected or to fail to demonstrate the process advantages of our products. The training requirement may also deter some customers from utilizing our products. Any of these results could adversely affect our business, financial condition, results of operations and prospects.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of any product we may develop and the sale of any products exposes us to the risk of product liability claims. Product liability claims might be brought against us by pharmaceutical companies, CMOs or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of customers;
- significant costs to defend the litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to claimants;
- inability to commercialize a product;
- product recalls or withdrawals;
- decreased market demand for any product; and
- loss of revenue.

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operation and business, including preventing or limiting the commercialization of any products we develop.

If we lose key management, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may be materially harmed.

We are highly dependent on our management and directors, including our Chief Executive Officer, Robert Spignesi, among others. Due to the specialized knowledge each of our officers and key employees possesses with respect to our products and services and our operations, the loss of service of any of our officers or directors could delay or prevent the successful sales and expansion of our platform. We do not carry key person life insurance on our Chief Executive Officer or our other officers or directors. In general, the employment arrangements that we have with our executive officers do not prevent them from terminating their employment with us at any time.

In addition, our future success and growth will depend in part on the continued service of our directors, employees and management personnel and our ability to identify, hire and retain additional personnel. If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult or costly and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, market and sell our products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or effectively incentivize these additional key personnel on acceptable terms given the competition among numerous technology companies for similar personnel. In addition, we rely on consultants and advisors to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

In August 2022, we implemented our organizational restructuring plan to reduce our operating expenses. In addition, we announced plans to explore strategic alternatives. These actions, and any future related actions or announcements, may make it increasingly difficult for us to hire and retain our executive officers, key employees, consultants and advisors. If we are unable to attract qualified personnel and retain our current employees, our ability to develop and sell our products could be limited and our business and customer relationships could be materially harmed.

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

We depend on information technology and telecommunications systems for significant elements of our operations, including our knowledge management system, our customer reporting, our platform, advanced automation systems, and advanced application and LIMS connection software. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including for example, systems handling human resources, financial controls and reporting, contract management, compliance and other infrastructure operations. These implementations can be expensive and require significant time and effort. These information technology and telecommunications systems support a variety of functions, including manufacturing operations, data analysis, quality control, customer service and support, billing, research and development activities, and general administrative activities.

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious software, bugs or viruses, human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our reputation.

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

In the ordinary course of our business, we collect and store sensitive data, including personal information, intellectual property and proprietary business information owned or controlled by ourselves or our employees, customers and other

parties. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. These applications and data encompass a wide variety of business-critical information, including research and development information, customer information, commercial information and business and financial information. We, like all companies storing business-critical information, face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, unauthorized access or exfiltration, inappropriate modification, inappropriate destruction, and the risk of our being unable to adequately monitor and audit and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may still be vulnerable to, and we have in the past experienced, attacks by hackers or viruses or breaches due to employee error, malfeasance or other malicious or inadvertent disruptions. Further, attacks upon information technology systems, including those involving system disrupting ransomware and digital extortion, are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives, capabilities, and expertise. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. While we have measures in place to identify, detect and mitigate security threats and incidents, they are not failproof, so we may also experience security incidents that may remain undetected for an extended period. Any such incident could result in the compromise of our information systems, and the data stored there could be accessed, encrypted, corrupted, modified, publicly disclosed, lost or stolen. Any such incident could result in legal claims or proceedings, including for breaches of confidential information obligations with contractual counterparties, and liability under federal or state laws that protect the privacy of personal information, and regulatory penalties. Notice of breaches may be required to affected individuals, customers, or other state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. Although we have implemented security measures to prevent, detect and respond to security incidents, our data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access to our information systems, and the loss, destruction or, dissemination of data stored within them could also disrupt or halt our operations and damage our reputation, any of which could adversely affect our business.

We are currently subject to, and may in the future become subject to additional, U.S., state, federal, and foreign laws and regulations imposing obligations on how we collect, store and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, various federal and state regulators, including governmental agencies like the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act, or CCPA, which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. In 2020, the California residents voted the California Privacy Rights Act or the CPRA into law. The CPRA, which entered into force on January 1, 2023, amends the CCPA and imposes additional data protection

obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. Similar laws have passed in Connecticut, Colorado, Utah and Virginia and other states have also proposed broad consumer privacy laws. Such laws may have potentially conflicting requirements that would make compliance challenging.

A number of other states have proposed their own comprehensive privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country could make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personally identifiable information has been disclosed as a result of a data breach.

Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, the EU General Data Protection Regulation, or EU GDPR, has extraterritorial reach and adds a broad array of requirements for handling personal data. EU and the European Economic Area, or EEA, member states are tasked under the EU GDPR to enact, and have enacted, certain implementing legislation that adds to and/or further interprets the EU GDPR requirements and potentially extends our obligations and potential liability for failing to meet such obligations. In particular, the EU GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the European Economic Area, security breach notifications and the security and confidentiality of personal data. The EU GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater.

Further, from January 1, 2021, following Brexit, companies handling personal data of individuals in the UK have to comply with the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the EU GDPR in UK national law. The UK GDPR mirrors the fines under the EU GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The EU GDPR and the UK GDPR are largely aligned, but it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

We may evaluate strategic alternatives for our business, including through acquisitions, joint ventures or investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

We may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our technology and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic partnerships. We may not be able to find suitable collaborators or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. The competition for collaborators or acquisition candidates may be intense, and the negotiation process will be time consuming and complex. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, these acquisitions may not strengthen our competitive position, the transactions may be viewed negatively by customers or investors, we may be unable to retain key employees of any acquired business, relationships with key suppliers, manufacturers or customers of any acquired business may be impaired due to changes in management and ownership, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. We cannot guarantee that we will be able to fully recover the costs of any acquisition. Integration of an acquired company also may disrupt ongoing

operations and require management resources that we would otherwise focus on developing our existing business. We may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture. We also may experience losses related to investments in other companies, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our Class A common stock is low or volatile, we may not be able to acquire companies or fund a joint venture project using our stock as consideration.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter and our policies have limits and significant deductibles. Some of the policies we currently maintain include general liability, property, umbrella and directors' and officers' insurance.

Any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. A successful product liability claim or series of claims in which judgments exceed our insurance coverage could adversely affect our business, financial condition, results of operations and prospects, including preventing or limiting the commercialization of any products we develop.

Operating as a public company makes it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage, seek alternative insurance options or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

We currently have limited international operations, but our business strategy incorporates potentially significant international expansion. We currently maintain a small sales force internationally and engage one distributor. We also have relationships with customers outside of the United States and may in the future expand our international customer base. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, tariffs, economic sanctions and embargoes, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain approvals to conduct our business in various countries;
- differing intellectual property rights;
- complexities and difficulties in obtaining intellectual property protection, enforcing our intellectual property and defending against third-party intellectual property claims;
- difficulties in staffing and managing foreign operations;

- logistics and regulations associated with shipping systems and parts and components for systems and consumables, as well as transportation delays;

- travel restrictions that limit the ability of marketing, presales, sales, services and support teams to service customers;

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;

- international trade disputes that could result in tariffs and other protective measures;

- natural disasters, the severity and frequency of which may be amplified by global climate change, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

- regulatory and compliance risks, including severe penalties such as criminal and civil penalties, disgorgement and other remedial measures, that relate to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our business, financial condition, results of operations and prospects. In addition, certain international markets are subject to significant political and economic uncertainty, including for example the effect of the withdrawal of the United Kingdom from the European Union. Significant political and economic developments in international markets for which we intend to operate, or the perception that any of them could occur, creates further challenges for operating in these markets in addition to creating instability in global economic conditions.

Certain legal and political risks are also inherent in foreign operations. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong collaborators and customers for operations outside the United States who will comply with the high legal and regulatory standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition or results of operations.

Rising inflation rates could negatively impact our revenues and profitability if increases in the prices of our Growth Direct systems or a decrease in consumer spending results in lower sales. In addition, if our costs increase and we are not able to pass along these price increases to our customers, our net income would be adversely affected, and the adverse impact may be material.

Inflation rates, particularly in the United States, increased significantly in 2022. Increased inflation may result in decreased demand for our products and services, increased operating costs (including our labor costs), reduced liquidity, and limitations on our ability to access credit or otherwise raise debt and equity capital. In addition, the United States Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may have the effect of further increasing economic uncertainty and heightening these risks. In an inflationary environment, we may be unable to raise the sales prices of our products and services at or above the rate at which our costs increase, which could/would reduce our profit margins and have a material adverse effect on our financial results and net income. We also may experience lower than expected sales and potential adverse impacts on our competitive position if there is a decrease in consumer spending or a negative reaction to our pricing. A reduction in our revenue would be detrimental to our profitability and financial condition and could also have an adverse impact on our future growth.

In operating our business, we may experience inflationary pressures on significant cost categories including labor, materials and freight. An inflationary environment, including factors such as tight labor markets and increasing freight and materials prices, could make it more costly for us to do business. In order to meet the compensation expectations of our prospective and current employees due to inflationary factors, we may be required to increase our labor costs, including wages and employee benefits, or risk losing skilled workers to competitors. In addition, changes in global shipping capacity and demand as well as the cost of raw materials and commodities such as oil (including derivative products including fuel and plastics) could negatively impact our freight and materials costs. If we see additional pressure on our labor, materials and freight costs, we could see negative effects on our results of operations (including product costs), cash flows and overall financial condition.

Global economic and political instability and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions and geopolitical conflicts, such as the conflict between Russia and Ukraine. While we do not have any customer or direct supplier relationships in either country at this time, the current military conflict, and related sanctions, as well as export controls or actions that may be initiated by nations including the United States, the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.) and other potential uncertainties could adversely affect our business and/or our supply chain, business partners or customers, and could cause demand for our products to be volatile, cause abrupt changes in our customers buying patterns, interrupt our ability to supply products, limit customers' access to financial resources and ability to satisfy obligations to us, or otherwise adversely impact our ability to place our Growth Direct systems. In the event geopolitical tensions fail to abate or deteriorate further, additional governmental sanctions may be enacted adversely impacting the global economy, its banking and monetary systems, markets or customers for our products.

Our employees, consultants and collaborators may engage in misconduct or other improper activities.

We are exposed to the risk of fraud or other misconduct by our employees, consultants and collaborators. Misconduct by these parties could include intentional failures to comply with the applicable laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. These laws and regulations may restrict or prohibit a wide range of pricing, discounting and other business arrangements. Such misconduct could result in legal or regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct, and any precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits

stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, we could be subject to significant civil, criminal and administrative penalties, which could have a material adverse impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse impact on our business.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with applicable laws and regulations, our policies and other legal or contractual requirements, which may give rise to regulatory enforcement action, liability, lead to the loss of trade secrets or other intellectual property or result in public exposure of personal information of our employees, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results and financial condition and could adversely affect the price of our Class A common stock.

Increasing attention to environmental, social and governance matters may impact our business, financial results or stock price.

Companies across all industries are facing increasing scrutiny from stakeholders related to their environmental, social and governance (ESG) practices and disclosures, including practices and disclosures related to climate change, diversity and inclusion and governance standards. Investor advocacy groups, certain institutional investors, lenders, investment funds and other influential investors are also increasingly focused on ESG practices and disclosures and in recent years have placed increasing importance on the implications and social cost of their investments. In addition, government organizations are enhancing or advancing legal and regulatory requirements specific to ESG matters. The heightened stakeholder focus on ESG issues related to our business requires the continuous monitoring of various and evolving laws, regulations, standards and expectations and the associated reporting requirements. A failure to adequately meet stakeholder expectations may result in noncompliance, the loss of business, reputational impacts, diluted market valuation, an inability to attract customers and an inability to attract and retain top talent. In addition, our adoption of certain standards or mandated compliance to certain requirements could necessitate additional investments that could impact our profitability.

Risks Related to Manufacturing and Supply

If our sole manufacturing and development facility becomes damaged or inoperable or we are required to vacate our existing facility, our ability to conduct and pursue our manufacturing and development efforts will be jeopardized.

We currently conduct our development and manufacturing at a single facility located in Lowell, Massachusetts. Our facility and equipment could be harmed or rendered inoperable or inaccessible by natural or man-made disasters, the severity and frequency of which may be amplified by global climate change, or other circumstances beyond our control, including fire, power loss, communications failure, war or terrorism, or another catastrophic event, such as a pandemic or similar outbreak or public health crisis, which may render it difficult or impossible for us to support our customers and develop products. The inability to manufacture our systems and consumables could develop if our facility is inoperable or suffers a loss of utilization for even a short period of time and may result in the loss of customers or harm to our reputation. Furthermore, our facility and the equipment we use to perform our manufacturing and development could be unavailable or costly and time consuming to repair or replace. It would be difficult, time consuming and expensive to rebuild our facility, to locate and qualify a new facility or license or transfer our proprietary technology to a third party. Even in the event we are able to find a third party to assist in manufacturing and development efforts, we may be unable to negotiate

commercially reasonable terms to engage with the third party. Although we are working to complete a back-up manufacturing facility in Lexington, Massachusetts, it is not complete and these risks are not yet mitigated.

We also store a certain amount of inventory of components of our products at our Lowell, Massachusetts facility.

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

Our manufacturing operations are dependent upon third-party suppliers, including single-source suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

We source the components of our Growth Direct system and consumables from third-party suppliers. We do not have supply agreements with most of our suppliers beyond purchase orders and, although we maintain an inventory of components, forecasted amounts may be inaccurate and we may experience shortages as a result of serious supply problems with these suppliers. There can be no assurance that our supply of components will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. For example, we experienced disruptions to our supply chain as a result of the coronavirus pandemic and may experience additional disruptions in the future.

Certain critical components of our Growth Direct system and consumables we obtain from single suppliers and the loss of supply from any of these suppliers could materially adversely affect our business. To protect against such loss, we maintain, or are working to obtain, sufficient inventory of these components to allow us to continue to manufacture our systems and consumables during the period required to qualify a new supplier. For example, the manufacturer of the camera used in our Growth Direct system intends to discontinue production of the camera, and we have obtained a supply we believe is sufficient to allow us to qualify a new camera supplier. While we believe we have, or will have, sufficient inventory to provide protection against changes in our sole suppliers, our estimates of the length of time required to qualify a new supplier or inventory level required to manufacture our systems and consumables during that time may be incorrect, and we may run out of inventory sooner than we anticipate. In addition, we have not obtained sufficient inventory for all of our single-source components and we may not be able to do so in the amounts we predict will be required. In addition, any change to a new supplier will require us to devote substantial time and resources, result in additional costs, and could involve a period in which our products might not be produced in a timely or consistent manner. We may also be unable to enter into agreements with new suppliers on commercially reasonable terms or at all. The occurrence of any of these events could adversely affect our business and customer relationships. In addition, loss of any critical component provided by a single-source supplier could require us to change the design of our manufacturing process based on the functions, limitations, features and specifications of the replacement components.

Several other non-critical components and materials that comprise our Growth Direct platform are currently manufactured by a single supplier or a limited number of suppliers. In many of these cases, we have not yet qualified alternate suppliers and rely upon purchase orders, rather than long-term supply agreements. A supply interruption or an increase in demand beyond our current suppliers' capabilities could harm our ability to manufacture our products unless and until new sources of supply are identified and qualified. Our reliance on these suppliers subjects us to a number of risks that could harm our business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;

- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- a modification or change in a manufacturing process or part that unknowingly or unintentionally negatively impacts the operation of our products;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers prioritizing other customer orders over ours;
- damage to our brand reputation caused by defective components produced by our suppliers;
- increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

Any interruption in the supply of components or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers, which would have an adverse effect on our business.

We forecast sales to determine requirements for components and materials used in our products, and if our forecasts are incorrect, we may experience delays in shipments or increased inventory costs.

To manage our operations with our third-party suppliers, we forecast anticipated product orders and material requirements to predict our inventory needs and enter into purchase orders on the basis of these requirements. Our limited historical commercial experience and recent growth may not provide us with enough data to consistently and accurately predict future demand. If our business expands and our demand for components and materials increases beyond our estimates, we or our suppliers may be unable to meet our demand. In addition, if we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay, or prevent delivery of our products to our customers. By contrast, if we overestimate our component and material requirements, we may have excess inventory, which would increase our expenses. Any of these occurrences would negatively affect our financial performance and business results.

Shipping is a critical part of our business and any changes in our shipping arrangements or damages or losses sustained during shipping could adversely affect our business, financial condition, results of operations and prospects.

Shipments of our products are subject to various regulations in the various countries in which we provide our products. For example, shipments of our growth media consumables may be required to comply with the shipping requirements promulgated by the U.S. Department of Transportation and the U.S. Federal Aviation Administration, as well as shipment rules established by the International Air Transport Association. If we are unable to comply with any of these rules or regulations, our ability to deliver our products in a timely manner may be adversely affected. In addition, even if we are able to comply with these rules and regulations, compliance can result in increased costs. In either event, our financial results and condition may be adversely affected.

We also currently rely on third-party vendors for our shipping. If we are not able to negotiate acceptable pricing and other terms with these entities or they experience performance problems or other difficulties, it could negatively impact our operating results and our customers' experience. Our products could sustain serious damage or be lost in transit. If a product is damaged in transit, including damage due to consumable temperature excursion, it may result in a substantial delay in the fulfillment of the customer's order, and depending on the type and extent of the damage and whether the incident is covered by insurance, it may result in a substantial financial loss. If our products are not delivered in a timely

fashion or are damaged or lost during the delivery process, our customers could become dissatisfied and cease using our products or services, which would adversely affect our business, financial condition, results of operations and prospects.

We use biological and hazardous materials that require considerable expertise and expense for handling, storage and disposal and may result in claims against us.

We work with materials, including chemicals, biological agents and compounds that could be hazardous to human health and safety or the environment. Our operations also produce hazardous and biological waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. We are subject to periodic inspections by federal, state and local authorities to ensure compliance with applicable laws. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental laws and regulations may restrict our operations. If we do not comply with applicable regulations, we may be subject to fines and penalties. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes, which could cause an interruption of our commercialization efforts, research and development programs and business operations, as well as environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations. In the event of contamination or injury, we could be liable for damages or penalized with fines in an amount exceeding our resources and our operations could be suspended or otherwise adversely affected. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our technology, including the Growth Direct platform, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to maintain, protect or enforce our intellectual property, third parties may be able to compete more effectively against us. In addition, we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

As is the case with other technology companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, particularly patents, in the United States and other countries with respect to our products and technologies. We apply for patents covering our products and technologies and their uses, as we deem appropriate. However, obtaining and enforcing patents in our industry is costly, time consuming and complex, and we may fail to apply for patents on important products, services and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights. We may not be able to patent the technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our products, or to block competitor products that are similar or adjacent to ours. Our earliest patent filings have been published. A competitor may review our published patents and arrive at the same or similar technology advances for our products as we developed. If the competitor files a patent application on such an advance before we do, then we may no longer be able to protect the technology, we may require a license from the competitor, and if the license is not available on commercially-viable terms, then we may not be able to launch our product. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties.

Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products or services, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies.

The patent positions of technology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions that may affect the patentability of certain inventions or discoveries. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our products is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our products. Depending on future actions by the U.S. Congress, the U.S. courts, the United States Patent and Trademark Office, or USPTO, and the relevant law-making bodies in other countries, 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.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications (including licensed patents) may be challenged in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which could harm our business. In addition, in patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on certain aspects of our platform technologies. In addition, 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. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all).

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

Patents have a limited lifespan. In the United States, 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 are obtained, once the patent life has expired, we may be open to competition from competitive products. If one of our products requires extended development or testing, patents protecting such products might expire before or shortly after such products are commercialized. For example, while our patents and, if issued, our patent applications have terms that will expire through 2042, certain of our unexpired U.S. patents covering the Growth Direct system and its use are scheduled to expire in 2023 and 2024. Although we own other patents with later expiration dates that cover various improvements and consumables for the Growth Direct platform, these other patents may not provide the same protection as the earliest-filed patents. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which would have a material adverse effect on our business.

The United States government may exercise certain rights with regard to certain of our inventions developed using government funding.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. Certain of our inventions for which we have pursued, and in some cases obtained, patent protection were developed using federal funding from BARDA. As a result, the U.S. government may have certain rights, including so-called march-in rights, to any patent rights that were funded in party by the U.S. government and any products or technology developed from such patent rights. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a nonexclusive license authorizing the U.S. government to use the invention for non-commercial purposes. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or to allow third parties to use our licensed technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the U.S. government of such rights could harm our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business could be harmed.

We rely heavily on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, including parts of our technology platform, and to maintain our competitive position and we expect our reliance to increase in the near term as the terms for certain of our patents expire. For example, while our patents and, if issued, our patent applications have terms that will expire through 2042, some of our unexpired U.S. patents covering the Growth Direct system and its use are expected to expire in 2023 and 2024. Once these patents expire, we may have to rely more heavily on trade secrets to maintain our competitive advantage. Any disclosure, either intentional or unintentional, by our employees, consultants and vendors that we engage to perform research or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our products, we may, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, advisors, collaborators and customers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure, which could materially adversely impact our business and financial position. If we are required to assert our rights against such a party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, if we choose to go to court to stop a third party from using any of our trade secrets, it may result in a public disclosure of our

trade secrets and corresponding loss of rights, which could have a material adverse effect on our business. In addition, courts outside the United States may be less willing to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor or other third party, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If any of our trade secrets were to be disclosed to, or independently discovered by, a competitor or other third party, it could harm our business, financial condition, results of operations and prospects.

We rely on in-licenses from third parties. If we lose these rights, our business may be materially adversely affected, our ability to develop improvements to our Growth Direct platform and to develop new technologies may be negatively and substantially impacted, and if disputes arise, we may be subjected to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technology covered by these license agreements.

We are party to a non-exclusive, royalty-bearing license agreement with Thermo CRS, Ltd., or Thermo Fisher, that grants us rights to exploit certain patent rights that are related to our Growth Direct platform. We may need to obtain additional licenses from others to advance our research, development and commercialization activities. These and other intellectual property license agreements that we enter into with third parties may impose various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations on us. Our rights to use the technology we license are subject to the continuation of and compliance with the terms of these agreements. If we fail to comply with our obligations under these agreements (including as a result of coronavirus, and its variants, impacting our operations), we use the licensed intellectual property in an unauthorized manner or we are subject to bankruptcy-related proceedings, the terms of the licenses may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate their respective agreement with us, which could limit our ability to implement our current business plan and materially adversely affect our business, financial condition, results of operations and prospects.

In some cases, we may not control the prosecution, maintenance or filing of the patents to which we hold licenses, or the enforcement of those patents against third parties. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Further, we may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control, and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

In spite of our efforts to comply with our obligations under our in-license agreements, disputes may arise with respect to our licensing agreements and/or our licensors might conclude that we have materially breached our obligations under our license agreements and might therefore, terminate the relevant license agreement, thereby removing or limiting our

ability to develop and commercialize products and technology covered by these license agreements. If any such in-license agreement is terminated, or if the licensed patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to market or develop products similar to ours. In addition, absent the rights granted to us under such license agreements, we may infringe the intellectual property rights that are the subject of those agreements, we may be subject to litigation by the licensor, and if such litigation by the licensor is successful we may be required to pay damages to the licensor, or we may be required to cease our development and commercialization activities that are deemed infringing, and in such event we may ultimately need to modify our activities or products to design around such infringement, which will consume time and resources and may not be ultimately successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. In particular, if our license with Thermo Fisher is terminated, we may suffer the foregoing consequences with respect to our business.

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, 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 some or all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest thereby harming our competitive position.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks or trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. We have not yet registered certain of our trademarks in all of our potential markets. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademarks. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such objections. In addition, at the USPTO and at comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

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

We or our licensors 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. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to defend against these and other claims challenging inventorship of our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such 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 products. 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, and certain customers or partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We may be involved in litigation claiming that we have infringed on a third party's intellectual property, which could be time consuming and costly and may adversely affect our business, financial condition, results of operations and prospects.

We may be involved with litigation or actions at the USPTO or foreign patent offices with various third parties that claim we or our collaborators or customers using our solutions and services have infringed, misappropriated or misused other parties' intellectual property rights. We expect that the number of such claims may increase as the number of our products grows, we expand our market share and the level of competition in our markets increases. Moreover, as the automated MQC testing industry expands and more patents are issued, the risk increases that our products may be subject to claims of infringement of the patent rights and other proprietary rights of third parties. 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 the business, requiring the payment of monetary damages (including treble damages, attorneys' fees, costs and expenses) or royalty payments, or result in potential or existing customers delaying purchases of our products or entering into engagements with us pending resolution of the dispute.

As we move into new markets and applications for our platform, 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. Our competitors and others have significantly larger and more mature patent portfolios than we currently have. 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. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties, or the invalidity of such patents or proprietary rights.

There can be no assurance that we will prevail in any suit initiated against us by third parties, successfully settle or otherwise resolve patent infringement claims. Third 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, attorneys' 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 and incur significant costs, in product or service introductions while we attempt to develop alternative products or services, or redesign our products or services, to avoid infringing third party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses or to develop a workaround could prevent us from commercializing products or services, and the prohibition of sale or the threat of 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. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Further, even if we were successful in defending against a

lawsuit, such a defense would distract our management team from our operations, which could have an adverse effect on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, our agreements with some of our customers, 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, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful.

Third parties, including our competitors, could be infringing, misappropriating or otherwise violating our intellectual property rights. Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we seek to analyze our competitors' products and services, and may in the future seek to enforce our rights against potential infringement, misappropriation or violation of our intellectual property. However, the steps we have taken to protect our proprietary rights may not be adequate to enforce our rights against such infringement, misappropriation or violation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products and services.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. If we do not prevail in such legal proceedings, we may be required to pay damages, we may lose significant intellectual property protection for our products or services, such that competitors could copy our products or services and we could be forced to cease commercialization of certain of our products or services. Even if resolved in our favor, any award of monetary damages or other remedy we receive may not be commercially valuable.

Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, financial condition, results of operations and prospects. In any lawsuit we bring to enforce our intellectual property rights, a court may refuse to the stop the other party from using the technology at issue on grounds that our intellectual property rights do not cover the technology in question. Further, in such proceedings, the defendant could counterclaim that our intellectual property is invalid or unenforceable and the court may agree, in which case we could lose valuable intellectual property rights. The outcome in any such lawsuits are unpredictable. Even if we do prevail in any future litigation related to intellectual property rights, the cost and time requirements of the litigation could negatively impact our financial results. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel using an outside service to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse, including due to the effect of the coronavirus pandemic on us or our vendors, can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business.

Our use of open-source software could compromise our ability to offer our services and subject us to possible litigation.

We use open-source software licensed to us by third-party authors under "open source" licenses in connection with our products and services. Use and distribution of open-source software may entail greater risks than use of third-party commercial software, as open-source licensors generally do not provide support, warranties, indemnification or other contractual protections regarding infringement claims or the quality of the code.

Further, some open-source software licenses require users who distribute software containing open-source software to publicly disclose all or part of the source code to the licensee's software that incorporates, links or uses such open-source software, and make available to third parties for no cost, any derivative works of the open source code created by the licensee, which could include the licensee's own valuable proprietary code. While we monitor our use of open-source software and try to ensure that none is used in a manner that would require us to disclose our proprietary source code or that would otherwise breach the terms of an open source agreement, such use could inadvertently occur, or could be claimed to have occurred, in part because open source license terms are often ambiguous. Despite our efforts to monitor our use of open-source software to avoid subjecting our platform to conditions we do not intend, there is a risk that open source licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to provide or distribute our platform. Additionally, we may from time to time face claims from third parties claiming ownership of, or seeking to enforce the terms of, an open source license, including by demanding release of source code for the open-source software, derivative works or our proprietary source code that was developed using, or that is distributed with, such open-source software. These claims could also result in litigation and could require us to make our proprietary software source code freely available, require us to devote additional research and development resources to change re-engineer our platform, seek costly licenses from third parties or otherwise incur additional costs and expenses, any of which could result in reputational harm and would have a negative effect on our business and operating results. There is little legal precedent in this area and any actual or claimed requirement to disclose our proprietary source code or pay damages for breach of contract could harm our business and could help third parties, including our competitors, develop products and services that are similar to or better than ours.

In addition, if the license terms for the open-source software we utilize change, we may be forced to re-engineer our platform, incur additional costs to comply with the changed license terms or replace the affected open-source software. Although we have implemented policies to regulate the use and incorporation of open-source software into our platform and solutions, we cannot be certain that that such policies will be effective and that we have not incorporated open-source software in our platform and solutions in a manner that is inconsistent with such policies.

Risks Related to Our Common Stock

The market price of our Class A common stock has been and may continue to be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

The market price of our Class A common stock has been and may continue to be volatile. The stock market in general and the market for smaller technology companies in particular has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their Class A common stock at or above the price they paid for them. The market price for our Class A common stock may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results;
- the introduction of new products or product enhancements by us or others in our industry;
- variances in product and system reliability;
- overall conditions in our industry and the markets in which we operate;
- disputes or other developments with respect to our or others' intellectual property rights;
- actual or anticipated changes in our operating results or growth rate as a result of our competitors' operating results;
- our ability to develop and market new and enhanced products and expand into new markets on a timely basis;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- product liability claims or other litigation;
- announcement or expectation of additional financing effort;
- sales of our common stock by us or our stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- media exposure of our products or of those of others in our industry;
- changes in earnings estimates or recommendations by securities analysts;
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and
- the other factors described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K.

If our Class A common stock is delisted from the Nasdaq Global Select Market, the liquidity of our Class A common stock would be adversely affected and the market price of our common stock could decrease.

Our Class A common stock is currently listed on the Nasdaq Global Select Market and closed at $1.40 on March 7, 2023. The Nasdaq Stock Market LLC, or Nasdaq, has minimum requirements that a company must meet in order to remain listed on Nasdaq markets, including that we maintain a minimum closing bid price of $1.00 per share for our Class A common stock. If we fail to maintain such minimum requirements, then Nasdaq will issue a notice that we are not in

compliance and we will need to take corrective actions in order to not be delisted. Such corrective actions could include a reverse stock split or a buyback of shares of our Class A common stock, which may adversely affect the liquidity of our Class A common stock or our cash balance, respectively. There is no way to guarantee that either measure, if implemented, would help us regain compliance with the minimum bid price requirement or maintain compliance with other Nasdaq listing rules. If Nasdaq were to make a final determination that our Class A common stock must be delisted, the liquidity of our Class A common stock would be adversely affected and the market price of our Class A common stock could decrease. Our failure to be listed on Nasdaq or another national securities exchange would have a material adverse effect on the value of your investment in us.

An active trading market for our Class A common stock may not be sustainable.

It is possible that an active or liquid market for our Class A common stock may not be sustainable. In the absence of an active trading market for our Class A common stock, it may be difficult for stockholders to sell our shares without depressing the market price for the shares, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of Class A common stock as consideration.

Our executive officers, directors and principal stockholders, if they choose to act together, will have the ability to control all matters submitted to stockholders for approval.

Following our IPO, based on the number of shares of Class A common stock outstanding as of December 31, 2022, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before the IPO and their respective affiliates hold, in the aggregate, a majority of our outstanding voting stock. The holders of shares of our Class B common stock have the ability to convert any portion of their Class B common stock into Class A common stock. Our Class B common stock cannot be converted if, immediately following such conversion, the holder would beneficially own more than 4.9% of the issued and outstanding Class A common stock. Due to this conversion right, holders of our Class B common stock could, at any time, increase their voting control of us. As a result of their combined voting power, if our executive officers, directors and stockholders who own more than 5% of our outstanding common stock choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

The dual class structure of our common stock and the option of the holders of shares of our Class B common stock to convert into shares of our Class A common stock may limit our Class A stockholders' ability to influence corporate matters.

Our Class A common stock has one vote per share, while our Class B common stock is non-voting. Nonetheless, each share of our Class B common stock may be converted at any time into one share of issued and outstanding Class A common stock at the option of its holder, subject to the limitations provided for in our restated certificate of incorporation that prohibit the conversion of our Class B common stock into shares of Class A common stock to the extent that, upon such conversion, such holder would beneficially own in excess of 4.9% of our Class A common stock. Consequently, if holders of Class B common stock exercise their option to make this conversion, such exercise will have the effect of increasing the relative voting power of those prior holders of our Class B common stock (subject to the ownership limitation described in the previous sentence) and increasing the number of outstanding shares of our voting common stock, and correspondingly decreasing the relative voting power of the current holders of our Class A common stock, which may limit our current Class A stockholders' ability to influence corporate matters.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our Class A common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of the IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in the previous three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and from providing the pay ratio between our Chief Executive Officer and employees; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We cannot predict whether investors will find our Class A common stock less attractive if we rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We intend to utilize the extended transition period and, as a result, we will not be required to comply with new or revised accounting standards on the same time line as other public companies.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our Class A common stock less attractive to investors.

We are a "smaller reporting company" and are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as presenting two years of audited financial statements in our annual Form 10-K or reduced disclosure requirements for executive compensation. This reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our Class A common stock less attractive because we may rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock prices may be more volatile.

If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered accounting firm. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and

our consolidated financial statements may be materially misstated. We will need to maintain and enhance the systems, processes and documentation necessary to comply with Section 404 of the Sarbanes-Oxley Act as we grow, and we will require additional management and staff resources to do so.

Additionally, even if we conclude our internal controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls, in which case our management will be unable to conclude that our internal control over financial reporting is effective. Our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting following the date we are no longer an emerging growth company. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may in the future conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We are continuing to refine our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected, which could have a material adverse effect on investors' confidence in our reporting and the price of our Class A common stock.

Provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Class A common stock, thereby depressing the market price of our Class A common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;

- the required approval of the holders of at least two-thirds of the shares entitled to vote thereon to (i) effect a reorganization, recapitalization, share exchange, share classification, consolidation, conversion or merger, (ii) sell, lease, exchange, transfer or otherwise dispose of all or substantially all of our assets, or (iii) dissolve our company or revoke a dissolution of our company;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, on August 11, 2022, we adopted a stockholder rights agreement, or the Rights Agreement, that could discourage potential acquisition proposals and could delay or prevent a change in control of the Company or a change in our management or board of directors, even in situations that may be considered beneficial by some of our shareholders. For additional information regarding risks associated with the Rights Agreement, see below risk entitled "Our Rights Agreement could make it more difficult for a third party to acquire control of incorporation designates specific courts as the exclusive forum for certain litigation Company, which could have a negative effect on the price of our common stock."

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

We have been, and may continue to be, subject to the actions of activist shareholders, which could cause us to incur substantial costs, divert management's and the board's attention and resources, and have an adverse effect on our business and stock price.

From time to time, we may be subject to proposals by shareholders urging us to take certain corporate actions. For example, in June 2022, we received an unsolicited, non-binding proposal from a shareholder to acquire all of our

outstanding common stock for $5.00 per share in cash. We rejected the shareholder's offer in August 2022 and commenced a process to review our strategic alternatives, which concluded in December 2022. If activist shareholder initiatives ensue, our business could be adversely affected, as responding to such actions can be costly and time-consuming, disrupt our operations and divert the attention of management and our board of directors. For example, we retained the services of various advisors, including legal, financial, and communications professionals, to advise us in considering the shareholder's proposal and during our review of strategic alternatives, the costs of which negatively impacted our financial results, and we may be required to retain such services in the future, which could have a further negative impact on our financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of new activist shareholder initiatives may result in the loss of potential business opportunities, harm our ability to attract new investors, customers, and employees, and cause our stock price to experience periods of volatility or stagnation.

Our restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation described above; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

These provisions may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents and result in additional litigation costs in pursuing any such claims. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations. The choice of forum provision contained in our restated certificate of incorporation may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Our Rights Agreement could make it more difficult for a third party to acquire control of incorporation designates specific courts as the exclusive forum for certain litigation Company, which could have a negative effect on the price of our common stock.

On August 11, 2022, we adopted the Rights Agreement that could discourage potential acquisition proposals and could delay or prevent a change in control of the Company or a change in our management or board of directors, even in

situations that may be considered beneficial by some of our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. The Rights Agreement may substantially dilute the stock ownership of a person or group that attempts to acquire a large interest. These deterrents could also adversely affect the price of our Class A common stock. The Rights Agreement will automatically expire on the day after our 2023 Annual Meeting of Stockholders, unless approved by our stockholders at the 2023 Annual Meeting of Stockholders, in which case it will expire in one year, on August 11, 2023.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be stockholders' sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain all available funds and future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be the sole source of gain on an investment in our common stock for the foreseeable future.

Our ability to use our net operating losses and research and development tax credits to offset future taxable income or income tax liabilities may be subject to certain limitations.

As of December 31, 2022, we had U.S. federal and state net operating loss, or NOL, carryforwards of $189.3 million and $87.1 million, respectively, which may be available to offset future taxable income, if any, that begin to expire in 2038 and 2032, respectively. Additionally, we had federal NOLs of $176.6 million generated since 2018 that will not expire. The Tax Cuts and Jobs Act (TCJA) enacted on December 22, 2017 limits a taxpayer's ability to utilize NOL deduction in a year to 80% taxable income for federal NOL arising in tax years beginning after 2017. In addition, we had federal and state research and development tax credits of $1.5 million and $2.9 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2038 and 2024, respectively.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change by value in its equity ownership by one or more stockholders or groups of stockholders owning at least 5% of the corporation's stock over a rolling three-year period, is subject to limitations on its ability to utilize its pre-ownership change NOLs and tax credits to offset future taxable income or income tax liabilities for U.S. federal income tax purposes. Similar rules may apply under state tax laws. The Company has completed a Section 382 study through July 31, 2020 to assess the limitations on use of NOLs and research and development credits due to changes in control. The study determined that ownership changes materially limited the NOL carryforwards and research and development tax credits available to offset future tax liabilities and the limitations have been reflected in the amounts of NOL carryforwards, research and development tax credits, and deferred tax assets disclosed above. The Company has not completed a Section 382 study for post July 31, 2020 transactions which could create an additional limitation although materially all of the current federal NOL carryforwards can be carried forward indefinitely. We have in the past experienced, and we may in the future experience ownership changes, some of which are outside our control. For these reasons, we are not able to utilize a material portion of the NOLs and tax credits even if we attain profitability. For additional information on our use of NOLs, see the section entitled "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Components of results of operations—Income tax (benefit) expense*" and Note 14—*Income taxes* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

General risk factors

Changes in tax laws may impact our future financial position and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made, and changes are likely to continue to

occur in the future. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, our suppliers or our customers, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline, even if our business is doing well.

The trading market for our Class A common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, or our stock performance, or if our product development or marketing and sales results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A common stock.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A common stock.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because early-stage technology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal office is located in Lowell, Massachusetts, where we lease 67,663 square feet of office, laboratory, manufacturing and inventory-storage space. We lease this space under a lease agreement, as amended, which expires in July 2029. In June 2021, we entered into a sublease agreement for 33,339 square feet of office and back-up manufacturing space in Lexington, Massachusetts, which expires in June 2029. Further, we maintain inventory at storage a warehouse in Noord-Brabant, Netherlands as well as various offsite warehouses in the United States and Europe. We believe that our facilities are sufficient to meet our current needs.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

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

On July 15, 2021, our Class A common stock began trading on the Nasdaq Global Select Market under the symbol "RPID." Prior to that time, there was no public market for our common stock. There is no established public trading market for our Class B common stock.

Holders

As of March 7, 2023, there were 34 holders of record of our Class A common stock and 2 holders of record of our Class B common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for the operation and expansion of our business and do not anticipate declaring or paying any dividends in the foreseeable future.

Recent Sales of Unregistered Securities; Purchases of Equity Securities by the Issuer or Affiliated Purchaser

Other than as disclosed in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, the Company did not sell any equity securities during the years ended December 31, 2021 and 2022 that were not registered under the Securities Act. On July 16, 2021, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our Class A common stock subject to outstanding options and all shares of our Class A common stock otherwise issuable pursuant to our equity compensation plans.

Use of Proceeds

On July 14, 2021, the registration statement on Form S-1 (File No. 333-257431) relating to our IPO was declared effective by the SEC. There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act and other periodic reports previously filed with the SEC.

Item 6. Reserved

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are an innovative life sciences technology company that enables the safe and efficient manufacture of pharmaceutical products through our rapid automated microbial quality control, or MQC, detection platform. We develop, manufacture, market and sell the Growth Direct system and related proprietary consumables, and value-added services to enable rapid MQC testing in the manufacture of biologics, cell and gene therapies, vaccines, sterile injectables, and other healthcare products. Our system delivers the power of industrial automation to bioprocessing and pharmaceutical manufacturing firms by modernizing and digitizing their MQC operations. Our Growth Direct platform, developed with over 15 years of active feedback from our customers, was purpose-built to meet the growing demands posed by the increasing scale, complexity, and regulatory scrutiny confronting global pharmaceutical manufacturing. Our Growth Direct platform comprises the Growth Direct system, optional laboratory information management system, or LIMS, connection software (which the majority of our customers purchase), proprietary consumables, and comprehensive field service, validation services and post-warranty service contracts. Once embedded and validated in our customers' facilities, our Growth Direct platform provides for recurring revenues through ongoing sales of consumables and service contracts.

Our technology fully automates and digitizes the process of pharmaceutical MQC and is designed to enable our customers to perform this critical testing process more efficiently, accurately, and securely. Our Growth Direct platform accelerates time to results by several days, a 50% improvement over the traditional method, and reduces MQC testing to a simple two-step workflow, eliminating up to 85% of the manual steps of traditional MQC, generating significant time, operational, and cost savings for our customers. We seek to establish the Growth Direct as the trusted global standard in automated MQC by delivering the speed, accuracy, security, and data integrity compliance that our customers depend on to ensure patient safety and consistent drug supply.

Since inception, we have devoted a majority of our resources to designing, developing, and building our proprietary Growth Direct platform and associated products, launching our Growth Direct platform commercially, expanding our sales and marketing infrastructure to grow our sales, building a global customer support team to deliver our value-added services, investing in robust manufacturing and supply chain operations to serve our customers globally, and providing general and administrative support for these operations. Prior to our IPO, we funded our operations primarily with proceeds from sales of preferred stock, borrowings under loan agreements and product and service sales as well as our cost-reimbursement contract with the U.S. Department of Health and Human Services Biomedical Advanced Research & Development Authority, or BARDA. All funding under this contract was fully earned by the fourth quarter of 2021.

On July 19, 2021, we closed an initial public offering of our Class A common stock, or the IPO, which resulted in the sale of 7,920,000 shares of our Class A common stock at a public offering price of $20.00 per share, before underwriting discounts. The IPO resulted in gross proceeds of $158.4 million and net proceeds of approximately $143.8 million after deducting underwriting discounts, commissions and estimated offering expenses payable by us. Additionally, on August 4, 2021, the underwriters exercised their overallotment option in part and purchased 1,086,604 shares of Class A common stock at the initial public offering price of $20.00 per share less discounts and commissions. The overallotment option exercise resulted in net proceeds of approximately $20.2 million. Immediately prior to the completion of the IPO, all of the outstanding shares of our Series A1, Series B1, Series C1 and Series D1 preferred stock converted into 24,200,920 shares

of Class A common stock and all of the outstanding shares of our Series C2 and Series D2 converted into 6,903,379 shares of Class B common stock. As of December 31, 2021, no shares of our preferred stock remained outstanding.

On August 11, 2022, our board of directors approved an organizational restructuring plan, or the Restructuring Plan, to right-size our cost structure based on our lowered 2022 outlook. The Restructuring Plan involved an approximately 20% reduction in our workforce, including employees, contractors and temporary employees, which was focused on non-commercial functions. We recorded a restructuring charge of $1.1 million in the third quarter of 2022 primarily related to severance, employee benefits, outplacement and related costs under the Restructuring Plan. When it was announced, we expected the Restructuring Plan to result in approximately $8.0 - $9.0 million in annualized cost savings by year end in 2023, with cost savings beginning in the first quarter of 2023. We are investing, and expect to continue to invest, a portion of these savings in key growth initiatives including enhancing commercial execution and key product development programs that are expected to drive future revenue growth.

On August 12, 2022, we announced our board of directors' decision to reject an unsolicited, non-binding proposal we received from a shareholder to acquire all of our outstanding common stock for $5.00 per share in cash and to commence a process to review our strategic alternatives. On December 1, 2022, we announced the conclusion of our strategic alternative review process. As a result of the process, our board of directors determined that the best path to deliver shareholder value is for us to continue executing our strategy to improve our commercial execution to drive system placement growth, advance our new product development programs and expand the market for our Growth Direct system.

Since our inception, we have incurred net losses in each year. We generated revenue of $17.1 million and $23.2 million for the years ended December 31, 2022 and 2021, respectively, and incurred net losses of $60.8 million and $73.5 million for those same years. As of December 31, 2022, we had an accumulated deficit of $375.9 million. We expect to continue to incur net losses in connection with our ongoing activities, including:

- growing sales of our products in both the United States and international markets by further expanding our sales and marketing capabilities;
- scaling our manufacturing and supply chain processes and infrastructure to meet growing demand for our products;
- investing in research and development to develop new products and further enhance our existing products;
- protecting and building on our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Until such time as we can generate revenue sufficient to achieve profitability, we expect to finance our operations through a combination of equity offerings and debt financings. If we are unable to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue our expansion plans including the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations.

We believe that our cash, cash equivalents and investments as of December 31, 2022 will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months following the date these consolidated financial statements were issued. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “Liquidity and Capital Resources.”

Coronavirus update

In response to the coronavirus pandemic and various resulting government directives, we took proactive measures to protect the health and safety of our employees, customers, and partners, while maintaining our ability to supply and service our customers. We continue to monitor the implications of the ongoing coronavirus pandemic on our business, as well as

our customers' and suppliers' businesses.

As access to customer sites and in-person engagement continued to gradually improve in the second half of 2022, we gained deeper insight into the challenges the pandemic created for our customers in advancing capital purchasing decisions. As a result, we took actions to improve aspects of our sales process and sales team training, which we expect to enhance the consistency and effectiveness of our sales team.

While disruptions due to coronavirus, and its variants, are currently expected to be temporary, there is considerable uncertainty around their duration. We expect these disruptions to continue to impact our operating results. However, the related financial impact and duration of these disruptions cannot be reasonably estimated at this time.

Effects of inflation and interest rates

The current inflationary environment and rising interest rates could have a negative impact on our results of operations, cash flows and overall financial condition. We may experience inflationary pressures on significant cost categories including labor, materials and freight. We continue to monitor the impact of inflation on these costs in order to minimize its effects through productivity improvements and cost reductions. There can be no assurance, however, that our operating results will not be affected by inflation in the future. In addition, inflation and increased interest rates may decrease demand for our Growth Direct systems, as our customers may face economic uncertainty or higher cost of capital as a result. A decrease in demand for our products or increases in our costs, as well as any steps we may take to mitigate changes, could impact our overall growth. However, the related financial impact cannot be reasonably estimated at this time.

Factors affecting our performance

We believe that our financial performance has been, and in the foreseeable future will continue to be, primarily driven by multiple factors as described below, each of which presents growth opportunities and challenges for our business. Our ability to successfully address these opportunities and challenges is subject to various risks and uncertainties, including those described under the heading "Risk Factors."

New customer adoption of the Growth Direct platform

Our financial performance has largely been driven by, and a key factor to our future success will be, our ability to increase the global adoption of our Growth Direct platform in our key markets. We plan to drive global customer adoption through both direct and indirect sales and marketing organizations in North America, Europe, Asia, and Australia.

Our focus is on enhancing customer engagement and experience and improving the efficiency and effectiveness of our sales team. We are making targeted investments in these organizations and expect to continue to do so in the future. Examples of these investments include new tools and training for the sales organization, targeted marketing, expanding lead generation capabilities and hosting customer-related Growth Direct demonstrations.

Expansion within our existing customer base

There is an opportunity to increase broader adoption and utilization of our Growth Direct platform throughout our existing customers' organizations by existing customers purchasing more systems. These additional systems will allow our existing customers to convert more of their test volume at existing locations, to support multiple locations, to meet redundancy requirements, or to increase capacity. As of December 31, 2022, approximately 45% of our customers have purchased Growth Direct systems for multiple sites, and approximately 55% of our customers have purchased multiple Growth Direct systems. Increased utilization amongst existing customers can also occur as customers advance through the Growth Direct platform adoption cycle from early validation of initial applications to validation and conversion of multiple applications on the Growth Direct platform or as the result of increasing manufacturing volumes.

Innovating and launching new products on the Growth Direct platform

We believe the depth, scalability and robust capabilities of our Growth Direct platform allow us to address key opportunities and challenges facing MQC testing in the pharmaceutical industry. As an innovative leader in automated MQC testing, we intend to invest in further enhancements in our existing Growth Direct platform as well as end-to-end workflow solutions in our core market. We plan to further invest in research and development to support the expansion of our Growth Direct platform through development and launch of new applications to capture greater share of customer testing volume, new product formats to broaden our ability to serve different market segments and launch of new products and technologies to address adjacent segments of the overall MQC workflow. We plan to continue to hire employees with the necessary scientific and technical backgrounds to enhance our existing products and help us introduce new products to market. We expect to incur additional research and development expenses as a result. By expanding and continuously enhancing the Growth Direct platform, we believe we can drive incremental revenue from existing clients as well as broaden the appeal of our solutions to potential new customers.

Revenue mix

Our revenue is derived from sales of our Growth Direct systems, our LIMS connection software, proprietary consumables, services and our cost-reimbursement contract with BARDA. Growth Direct system revenue involves a capital selling process and tends to be somewhat concentrated within a small (but varied) group of customers each year, so it is subject to variability from quarter to quarter. As our base of validated Growth Direct systems continues to grow, we expect our recurring revenue (consumables and service contracts) to grow at a faster rate than our non-recurring revenues (Growth Direct systems, validation and other services), which we expect to drive variability and longer-term trends in our revenue mix.

Our non-commercial revenue has historically been generated from long-term contracts with BARDA. All funding awarded to-date under our contract with BARDA was fully earned by the fourth quarter of 2021. We are now in the process of closing out our BARDA contract, which includes a true-up of actual reimbursable costs to those previously billed at provisional rates for each year of performance. Once the amount of each annual true-up is determined and approved by BARDA and they identify available funds to reimburse us for that amount, we expect to enter into a contract modification and invoice BARDA for the true-up amount, at which point we will recognize corresponding incremental non-commercial revenue in that amount. Based on the above and our current expectations for the timing of the true-up process. We anticipate recognizing the annual true-ups as non-commercial revenue as outlined above, which we currently expect to take place after over a period of up to several years.

Key business metrics

We regularly review the following key business metrics to evaluate our business, measure our performance, identify trends affecting our business, formulate financial projections and make strategic decisions. We believe that the following

metrics are representative of our current business; however, we anticipate these may change or be substituted for additional or different metrics as our business grows and evolves.

	Year Ended December 31,		Change Amount	%
	2022	2021		
	(dollars in thousands)			
Systems placed:				
Systems placed in period	9	29	-20	(69.0%)
Cumulative systems placed	125	116	9	7.8%
Systems validated:				
Systems validated in period	19	33	-14	(42.4%)
Cumulative systems validated	103	84	19	22.6%
Product and service revenue — total	$ 17,133	$ 21,637	$ (4,504)	(20.8%)
Product and service revenue — recurring	$ 10,983	$ 7,819	$ 3,164	40.5%

Growth Direct system placements

We consider a Growth Direct system to be "placed" upon transfer of control of the system to the customer, at which point the revenue for that system is recognized. We regularly review the number of Growth Direct systems placed and cumulative Growth Direct system placements in each period as a leading indicator of our business performance. Our revenue has historically been driven by, and in the future will continue to be impacted by, the rate of Growth Direct system placements as a reflection of our success selling and delivering our products. We expect our Growth Direct system placements to continue to grow over time as we increase penetration in our existing markets and expand into new markets.

The number of Growth Direct system placements and rate of growth varies from period-to-period due to factors including, but not limited to, Growth Direct system order volume and timing, and access to customer sites (including coronavirus related restrictions and the timing of customer site construction activities). As a result, we expect to experience continued variability in our period-to-period number of Growth Direct system placements due to the aforementioned factors.

Validated systems

We regularly review the number of Growth Direct systems validated and cumulative Growth Direct systems validated in each period as indicators of our business performance. Management focuses on validated Growth Direct systems as a leading indicator of likely future recurring revenue as well as a reflection of our success supporting our customers' validating placed systems. We expect our validated Growth Direct systems to continue to grow over time as we increase our base of cumulative systems placed and then validate those systems. After a Growth Direct system is placed with a customer and installed, we work with the customer to validate the system, which typically takes anywhere from three to nine months. Once a validation has been completed, we generally expect our customers to transition from their legacy manual method to our automated method and begin regular utilization of consumables over a period of up to three months after we complete our validation. However, the timeline for such transition may be longer depending on the needs of individual customers.

The number of validated Growth Direct systems and rate of growth varies from period-to-period due to factors including, but not limited to, Growth Direct system order volume and timing, whether customers have previously validated Growth Direct systems within their site or network, access to customer sites (including as a result of coronavirus related restrictions), customer site readiness and the time to install and validate each individual system. As a result, we expect to experience continued fluctuations in our period-to-period number of Growth Direct systems validated due to the aforementioned factors.

Product and service revenue

We regularly assess trends relating to our combined product and service revenue as an indicator of our business performance. Product and service revenue represents all of our commercial revenue for the business. It excludes non-commercial revenue, which typically supports other business functions such as research and development and is, by its nature, subject to significant variability.

Recurring revenue

We regularly assess trends relating to recurring revenue, which is the revenue from consumables and service contracts, based on our product offerings, our customer base and our understanding of how our customers use our products. Recurring revenue was 64.1% and 33.7% of our total revenue for the years ended December 31, 2022 and 2021, respectively. Our recurring revenue as a percentage of the total product and service revenue will generally vary based upon the number of Growth Direct systems placed and the cumulative number of systems validated in the period, as well as other variables such as the volume of tests being conducted, and the test application(s) being used on those Growth Direct systems. As our base of validated systems continues to grow, we expect our recurring revenue streams to grow at a faster rate than our non-recurring revenue streams and that this will ultimately result in our recurring revenue constituting the majority of our revenue over the longer term.

Components of results of operations

Revenue

We generate revenue from sales of our Growth Direct system (including our LIMS connection software), consumables, validation services, service contracts and field service as well as our contractual arrangement with BARDA, which we completed in the fourth quarter of 2021. We primarily sell our products and services through direct sales representatives. The arrangements are noncancellable and nonrefundable after ownership passes to the customer.

	Year Ended December 31, 2022	Percentage of total revenue	Year Ended December 31, 2021	Percentage of total revenue
	(in thousands)		(in thousands)	
Product revenue	$ 11,056	64.5 %	$ 15,512	66.8 %
Service revenue	6,077	35.5 %	6,125	26.4 %
Non-commercial revenue	—	— %	1,595	6.9 %
Total revenue	$ 17,133	100.0 %	$ 23,232	100.0 %

Based on the significant value that our Growth Direct platform provides to our customers, we have historically experienced strong organic commercial revenue growth, including in 2021, when commercial revenue of $21.6 million and increased 53.6% compared to $14.1 million in 2020. While commercial revenue subsequently declined 20.8% to $17.1 million in 2022 due mainly to lower system placements as a result of impacts from the coronavirus pandemic and commercial execution challenges, combined product and service recurring revenues still increased by 40.5% to $11.0 million compared to $7.8 million in 2021. We expect to return to commercial revenue growth and to continue growing our recurring revenues in 2023.

Product revenue

We derive product revenue primarily from the sale of our Growth Direct systems and related consumables as well as our LIMS connection software, which the majority of our customers purchase. As of December 31, 2022, we had placed 125 Growth Direct systems to over thirty-five customers globally, including over half of the top twenty pharmaceutical companies as measured by revenue and the manufacturers of 25% of globally approved cell and gene therapies.

Growth Direct systems

Growth Direct system revenue is a non-recurring product revenue stream that we recognize as revenue upon transfer of control of the system to the customer. The Growth Direct system is fully functional for use by the customer upon delivery as we do not require our customers to use our installation and validation services, however it is unusual for our customers to not purchase those services. As such, transfer of control occurs at shipment or delivery depending on contractual terms. We expect our Growth Direct system revenue to continue to grow over time as we increase system placements in our existing customers and markets and expand into new customers and markets.

Consumables

Our consumable revenue is a recurring product revenue stream composed of two proprietary consumables to capture test samples for analysis on the Growth Direct system, an Environmental Monitoring, or EM, consumable, and a Water/Bioburden consumable, or W/BB, consumable. Both proprietary consumables support the growth-based compendial method for MQC testing mandated by global regulators and provide results that are comparable to traditional consumables. Our consumables are designed with features that enable automation on the Growth Direct system, with bar coding for tracking and data integrity, and physical characteristics for robotic handling, to support vision detection, and to prevent counterfeiting.

We expect consumable revenue to increase in future periods as our base of cumulative validated Growth Direct systems grows and those systems utilize our consumables on a recurring, ongoing basis.

LIMS Connection Software

Our LIMS connection software is a non-recurring product revenue stream. Although optional, the majority of our customers elect to purchase this software, which allows Growth Direct systems to export result reports and securely link to a customer's two-way LIMS connection software to completely eliminate manual data entry and drive productivity.

Service revenue

We derive service revenue from validation services, field service including installations, and service contracts sold to our customers. Revenue from validation services and field service are non-recurring service revenue streams, while revenue from service contracts is a recurring service revenue stream.

We offer our customers validation services (including related documentation) that enable them to replace their existing manual testing method and utilize their Growth Direct systems in compliance with relevant MQC regulations. Validation services are recognized as revenue over time as these services are provided to the customer.

We offer our customers service contracts that can be purchased after the expiration of the one-year assurance warranty that all of our customers receive with the purchase of a Growth Direct system. Under these contracts, they are entitled to receive phone support, emergency on-site maintenance support and two preventative maintenance visits per year. These service contracts generally have fixed fees and a term of one year. We recognize revenue from the sale of service contracts over time as these services are provided over the respective contract term.

We also offer our customers field service which primarily consists of services provided by our field service engineers to install Growth Direct systems at customer sites. We recognize revenue from field service over time as these services are provided to the customer.

We expect service revenue to increase in future periods as the number of placed and validated Growth Direct systems grows and we are able to generate increasing non-recurring revenue from validation services and field service for newly placed systems and increasing recurring revenue from service contracts for validated systems.

Non-commercial revenue

We have generated non-commercial revenue from long-term contracts with governmental agencies and third parties. To date, our non-commercial revenue has been derived from contracts with BARDA and was fully earned by the fourth quarter of 2021. We are now in the process of closing out our BARDA contract, which includes a true-up of actual reimbursable costs to those previously billed at provisional rates for each year of performance. Once the amount of each annual true-up is determined and approved by BARDA and they identify available funds to reimburse us for that amount, we expect to enter into a contract modification and invoice BARDA for the true-up amount, at which point we will recognize corresponding incremental non-commercial revenue in that amount. We anticipate recognizing the annual true-ups as non-commercial revenue as outlined above, which we currently expect to take place over a period of up to several years.

Costs and operating expenses

Costs of revenue

Cost of product revenue primarily consists of costs for raw material parts and associated freight, shipping and handling costs, salaries and other personnel costs including stock-based compensation expense, contract manufacturer costs, scrap, warranty cost, inventory reserves, royalties, depreciation and amortization expense, allocated information technology and facility-related costs, overhead and other costs related to those sales recognized as product revenue in the period.

Cost of service revenue primarily consists of salaries and other personnel costs including stock-based compensation expense, travel costs, materials consumed when performing installations, validations and other services, allocated information technology and facility-related costs, costs associated with training, and other expenses related to service revenue recognized in the period.

Cost of non-commercial revenue primarily consists of salaries and other personnel costs including stock-based compensation expense, consulting expense, materials, travel and other costs related to the revenue recognized as non-commercial revenue during the period. Our contract with BARDA is subject to the Federal Acquisition Regulation, or FAR and is priced based on estimated or actual costs of producing goods or providing services. The FAR provides guidance on the types of costs that are allowable in establishing prices for goods or services provided under U.S. government contracts.

Research and development

Research and development expenses consist primarily of costs incurred for our research activities, product development, hardware and software engineering and consultant services and other costs associated with our technology Growth Direct platform and products, which include:

- employee-related expenses, including costs for salaries, bonuses and other personnel costs including stock-based compensation expense, for employees engaged in research and development functions;
- the cost of developing, maintaining and improving new and existing product designs;
- the cost of hardware and software engineering;
- research materials and supplies;
- external costs of outside consultants engaged to conduct research and development associated with our technology and products; and
- allocated information technology and facility-related costs, which include direct and allocated expenses for rent, maintenance of facilities and insurance as well as related depreciation and amortization.

Our research and development costs are expensed as incurred. We believe that our continued investment in research and development is essential to our long-term competitive position, and we expect these expenses to increase in future periods.

Sales and marketing

Sales and marketing expenses consist primarily of salaries, commissions, benefits and other personnel costs including stock-based compensation expense as well as costs relating to travel, consulting, public relations and allocated information technology and facility-related costs for our employees engaged in sales and marketing activities. We expect sales and marketing expenses to increase in future periods as the number of sales and marketing personnel grows and we continue to expand our geographic reach and capabilities, broaden our customer base and introduce new products.

General and administrative

General and administrative expenses consist primarily of salaries, bonuses and other personnel costs including stock-based compensation expense for our finance, legal, human resources and general management employees and most of our executive leadership team, as well as professional fees for legal, patent, accounting, audit, corporate governance, investor relations, recruiting, consulting and other services. General and administrative expenses also include direct and allocated information technology and facility-related costs. General and administrative expenses are expected to increase in future periods as the number of administrative personnel grows to support increasing business size and complexity. Since our IPO in July 2021, we have also incurred incremental accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor relations expenses associated with operating as a public company.

Additionally, during the year ended December 31, 2022, we incurred incremental legal, investment banking and other expenses associated with an unsolicited, non-binding proposal we received from a shareholder to acquire all of our outstanding common stock and our strategic alternatives review process. This process was concluded during the fourth quarter of 2022.

Other income (expense)

Interest income (expense), net

Interest income (expense), net is comprised of interest income from investments as well as costs associated with outstanding borrowings under our loan and security agreements, amortization of deferred financing costs and debt discounts associated with such arrangements.

Change in fair value of preferred stock warrant liability

In connection with the May 2020 term loan facility that we entered into with a lender, or the 2020 Term Loan, we issued 1,195,652 warrants to purchase shares of Series C1 Preferred Stock at an exercise price of $1.15 per share. These warrants were immediately exercisable and expire 10 years after the issuance date. We also have other outstanding warrants to purchase preferred stock issued in connection with previous financing arrangements.

We classified all of our warrants to purchase preferred stock as a liability on our consolidated balance sheets until our IPO because the warrants are freestanding financial instruments that may require us to transfer assets upon exercise. The liability associated with each of these warrants was initially recorded at fair value upon the issuance date and was subsequently remeasured to fair value at each reporting date. The resulting change in the fair value of the preferred stock warrant liability was recorded as a component of other income (expense) in our consolidated statements of operations. We continued to recognize changes in the fair value of this preferred stock warrant liability at each reporting period until the IPO, when the preferred stock warrants were converted into common stock warrants that are equity classified.

In connection with the IPO, the preferred stock warrants were automatically converted to Class A common stock warrants. We determined the event resulted in equity classification of the Class A common stock warrants and derecognized the fair value of the preferred stock warrant liability as of the IPO date and reclassified to equity.

Loss on extinguishment of debt

Loss on extinguishment of debt recognized during the year ended December 31, 2021 includes a loss from the repayment of the 2020 Term Loan as well as unamortized issuance costs, unamortized prepaid commitment fees, and early payment fees associated with that repayment.

Other income (expense), net

Other income (expense), net primarily consists of other miscellaneous income and expense unrelated to our core operations.

Income tax (benefit) expense

We generated significant taxable losses during the years ended December 31, 2022 and 2021, and, therefore, have not recorded any U.S. federal or state income tax expense during those periods. However, we did record an immaterial amount of foreign income tax expense during each of those periods. Additionally, as a result of a favorable outcome related to the tax examination for our German subsidiary, Rapid Micro Biosystems Europe GmbH, we recorded an income tax benefit of $0.6 million during the year ended December 31, 2022.

We have not recorded any U.S. federal or state income tax benefits for the NOLs we have incurred in each year or for the research and development tax credits we generated in the United States. As of December 31, 2022, we had U.S. federal and state NOL carryforwards of $189.3 million and $87.1 million, respectively, which may be available to offset future taxable income and begin to expire in 2038 and 2032, respectively. Additionally, we had a federal NOL carryforward of $176.6 million generated since 2018 that will not expire. As of December 31, 2022, we also had U.S. federal and state research and development tax credit carryforwards of $1.5 million and $2.9 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2038 and 2024, respectively. Utilization of the U.S. federal and state NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation due to ownership changes that have occurred previously or that could occur in the future.

We completed a Section 382 study through July 31, 2020 to assess whether a change of control has occurred or whether there have been multiple changes of control. The study determined that ownership changes materially limited the NOL carryforwards and research and development tax credits available to offset future tax liabilities and the limitations have been reflected in the amounts of NOL carryforwards, research and development tax credits, and deferred tax assets disclosed above. We have not completed a Section 382 study for post July 31, 2020 transactions which could create an additional limitation although materially all of the current federal NOL carryforwards can be carried forward indefinitely.For additional information, see the risk factor entitled "*Our ability to use our net operating losses and research and development tax credits to offset future taxable income or income tax liabilities are subject to certain limitations*" and Note 14—*Income taxes* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date because of uncertainty about future taxable income to permit use of the assets.

Results of operations

Comparison of the years ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended		Change	
	December 31, 2022	December 31, 2021	Amount	%
	(dollars in thousands)			
Revenue:				
Product revenue	$ 11,056	$ 15,512	$ (4,456)	(28.7)%
Service revenue	6,077	6,125	(48)	(0.8)%
Non-commercial revenue	—	1,595	(1,595)	(100.0)%
Total revenue	17,133	23,232	(6,099)	(26.3)%
Costs and operating expenses:				
Cost of product revenue	18,477	23,434	(4,957)	(21.2)%
Cost of service revenue	7,196	5,922	1,274	21.5 %
Cost of non-commercial revenue	—	1,617	(1,617)	(100.0)%
Research and development	12,866	9,781	3,085	31.5 %
Sales and marketing	14,994	11,815	3,179	26.9 %
General and administrative	26,819	17,895	8,924	49.9 %
Total costs and operating expenses	80,352	70,464	9,888	14.0 %
Loss from operations	(63,219)	(47,232)	(15,987)	33.8 %
Other income (expense):				
Interest income (expense), net	1,778	(2,608)	4,386	(168.2)%
Change in fair value of preferred stock warrant liability	—	(19,643)	19,643	(100.0)%
Loss on extinguishment of debt	—	(3,100)	3,100	(100.0)%
Other income (expense), net	59	(850)	909	(106.9)%
Total other income (expense), net	1,837	(26,201)	28,038	(107.0)%
Loss before income taxes	(61,382)	(73,433)	12,051	(16.4)%
Income tax (benefit) expense	(576)	91	(667)	(733.0)%
Net loss	$ (60,806)	$ (73,524)	$ 12,718	(17.3)%

Revenue

Product revenue decreased by $4.5 million, or 28.7%, with the decrease attributable to volume of $3.9 million as a result of fewer Growth Direct system placements partially offset by higher consumable shipment volumes due to an increase in cumulative validated Growth Direct systems. The mix of consumable products sold negatively impacted revenue by $0.6 million.

Service revenue remained relatively consistent, decreasing 0.8%. The slight decrease in service revenue was primarily due to a $1.2 million decrease in validation and installation revenue due to fewer Growth Direct systems placed during 2022. Recurring service contract revenue increased $1.2 million as a result of the increase in cumulative Growth Direct systems validated and placed under service contracts.

Non-commercial revenue decreased by $1.6 million, or 100.0%. All funding under our most recent contract with BARDA was fully earned by the fourth quarter of 2021.

During the years ended December 31, 2022 and 2021, restrictions on travel and access to customer sites related to coronavirus, and its variants, negatively impacted our ability to sell, ship, install and validate systems, as well as train customers in certain geographies. Although travel restrictions have gradually eased in many geographies by the second half of 2022, the impact of previous travel restrictions negatively impacted our product and service revenue in the period. While we expect these disruptions may continue to impact our operating results, the related financial impact and duration of these disruptions cannot be reasonably estimated at this time.

Costs of revenue

Cost of product revenue decreased by $5.0 million, or 21.2%. The decrease was driven by $2.1 million in costs related to fewer placements of Growth Direct systems, partially offset by the increase in consumables sold. Direct labor cost decreased $1.3 million due to a combination of reduced headcount spend in systems as well as increased absorption due to higher production volumes and related absorption in consumables. In addition, material and production costs favorably impacted cost of product revenue by $1.0 million due to manufacturing efficiencies and other improvements partially offset by material cost increases as well as $0.3 million in other costs. Also, overhead related costs decreased $0.7 million primarily due to a reduction in headcount partially offset by an increase in freight costs, while warranty-related costs increased by $0.4 million.

Cost of service revenue increased by $1.3 million, or 21.5%. This increase was primarily due to higher employee-related costs of $0.7 million due to increases in headcount in the latter part of 2021 and 2022. We also incurred additional travel costs of $0.3 million and increased material cost of $0.5 million due to the higher number of Growth Direct systems under service contracts. These increases were offset by a decrease in other costs of $0.2 million.

Cost of non-commercial revenue decreased by $1.6 million, or 100.0%. All funding under our most recent BARDA contract was fully earned by the fourth quarter of 2021.

Research and development

	Year Ended December 31,		Change	
	2022	2021	Amount	%
	(dollars in thousands)			
Research and development	$ 12,866	$ 9,781	$ 3,085	31.5 %
Percentage of total revenue	75.1 %	42.1 %		

Research and development expenses increased by $3.1 million, or 31.5%. This increase was primarily due to an increase of $2.2 million in employee-related costs due primarily to higher headcount to support increased new product development activities. The increase was also due to a $0.6 million increase in allocated facility and information technology costs and a net increase of $0.3 million in other general research and development expenses.

Sales and marketing

	Year Ended December 31,		Change	
	2022	2021	Amount	%
	(dollars in thousands)			
Sales and marketing	$ 14,994	$ 11,815	$ 3,179	26.9 %
Percentage of total revenue	87.5 %	50.9 %		

Sales and marketing expenses increased by $3.2 million, or 26.9%. This increase was due to an increase in employee-related costs (including commissions earned) of $4.3 million primarily as a result of the expansion of our direct sales and marketing organizations to drive sales growth, an increase in allocated facility and information technology costs of $0.6 million, and an increase of $0.2 million in other general sales and marketing costs. These increases were partially offset by

lower consulting fees, which decreased by $1.9 million due to lower spending on strategy and market analysis projects as well as a reduction in marketing consulting due to the expansion of our in-house marketing team.

General and administrative

	Year Ended December 31,		Change	
	2022	2021	Amount	%
	(dollars in thousands)			
General and administrative	$ 26,819	$ 17,895	$ 8,924	49.9 %
Percentage of total revenue	156.5 %	77.0 %		

General and administrative expenses increased by $8.9 million, or 49.9%. This increase was driven by a $3.5 million increase in employee-related costs due to higher headcount, a $1.5 million increase in legal, audit, tax and business insurance costs associated with operating as a public company for the full year in 2022, an increase in facilities, depreciation, and information technology costs of $1.3 million, and a net increase of $0.4 million other costs. In addition to the above expenses, one-time costs related to an unsolicited, non-binding proposal we received from a shareholder to acquire all of our outstanding common stock and our strategic alternatives review process contributed the remaining $2.2 million to the increase.

Other income (expense)

Interest income (expense), net

Interest income (expense) for the years ended December 31, 2022 and 2021 was income of $1.8 million compared to expense of $2.6 million, respectively. The increase of $4.4 million, or 168.2%, was the result of lower interest expense due to the repayment of our $25.0 million 2020 Term Loan in September 2021 and higher interest income due to higher interest rates on our investments.

Change in fair value of preferred stock warrant liability

The change in fair value of preferred stock warrant liability was zero for the year ended December 31, 2022, compared to a loss of $19.6 million for the year ended December 31, 2021. The loss in the prior year was due to an increase in the fair value of the underlying preferred stock immediately prior to conversion of common stock as a result of our IPO.

Loss on extinguishment of debt

Loss on extinguishment of debt was zero for the year ended December 31, 2022, compared to a $3.1 million loss for the year ended December 31, 2021. The loss in the prior year was due to the repayment of our 2020 Term Loan in September 2021. We determined the loss on extinguishment of debt to be the difference between the reacquisition price of the debt and net carrying value of the extinguished debt.

Other income (expense), net

Other income (expense) was less than $0.1 million of income for the year ended December 31, 2022 compared to $0.8 million of expense for the year ended December 31, 2021. The expense in the prior year was related to an exit fee we were obligated to pay a former lender in the event of a qualifying exit event prior to December 31, 2026, or the Exit Fee. As defined in the agreement, a “qualifying exit event” included a public offering of its common stock. The IPO was deemed to be a “qualifying event” and we expensed and paid the Exit Fee in July 2021.

Income tax (benefit) expense

Income tax (benefit) expense was a benefit of $0.6 million and expense of $0.1 million for the years ended December 31, 2022 and 2021, respectively. Both the benefit and the expense recorded related to our German subsidiary, Rapid Micro Biosystems Europe GmbH. During the year ended December 31, 2022, we adjusted an uncertain tax liability we had recorded for that subsidiary as a result of the favorable outcome of an examination for the tax years 2016 through 2018, resulting in the favorable income tax benefit in the period.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. To date, we have funded our operations primarily through proceeds from sales of redeemable convertible preferred stock, borrowings under loan agreements, revenue from sales of our products, services and contracts and proceeds from our IPO.

On August 11, 2022, our board of directors approved the Restructuring Plan to right-size our cost structure based on our lowered 2022 outlook. We will continue to invest in key growth initiatives including enhanced commercial capabilities and key product development programs that are expected to drive future revenue growth. We recorded a restructuring charge of $1.1 million in the third quarter of 2022 primarily related to severance, employee benefits, outplacement and related costs under the Restructuring Plan. We made payments of $0.6 million during the year-ended December 31, 2022 related to the Restructuring Plan and have $0.5 million recorded within accrued expenses as of December 31, 2022.

We believe that our cash, cash equivalents and short and long-term investments will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months following the date the consolidated financial statements contained in this Annual Report on Form 10-K for the year ended December 31, 2022 were issued. Further, we do not have any banking relationship, cash or investment accounts with Silicon Valley Bank.

As of December 31, 2022, we had the following cash and investment-related assets on our consolidated balance sheet (in thousands):

	December 31, 2022
Cash and cash equivalents	$ 27,064
Short-term investments	81,584
Long-term investments	29,790
Restricted cash	284
Total	$ 138,722

Contractual obligations and commitments

In October 2013, we entered into an operating lease for office and manufacturing space in Lowell, Massachusetts, which expires in July 2026. The terms of the lease include options for a one-time, five-year extension of the lease and early termination of the lease in July 2024 as well as a $0.7 million tenant improvement allowance which has been drawn down in full. In March 2022, we amended the lease for our office and manufacturing space in Lowell, Massachusetts. The amendment increased the amount of facility space subject to the lease and extended the expiration of the lease from July 2026 to July 2029. The terms of the amendment include options for a one-time, five-year extension of the lease and early termination of the lease in July 2026 (subject to an early termination fee), as well as a $0.3 million tenant improvement allowance. Monthly rent payments are fixed and future minimum lease payments under the lease (as amended) are $4.1 million as of December 31, 2022, including $0.6 million in short-term obligations.

In December 2020, we entered into a non-cancelable agreement with a service provider for software as a service and cloud hosting services. As of December 31, 2022, we had committed to minimum payments under these arrangements

totaling $0.8 million through January 31, 2026, including short-term obligations of $0.2 million. We had $0.1 million and zero accrued for the software subscription as of December 31, 2022 and December 31, 2021, respectively.

In June 2021, we entered into a sublease agreement for office and back-up manufacturing space in Lexington, Massachusetts, which expires in June 2029. The sublease agreement includes an option to terminate the sublease in July 2026, subject to an early termination fee. Monthly rent payments are fixed and future minimum lease payments over the term of the sublease are $5.6 million, including $0.7 million in short-term obligations. We also have the right to use furniture and equipment specified in the sublease agreement for an additional $0.6 million in future payments over the term of the sublease with the option to purchase the furniture and equipment at the end of the sublease term. Short-term obligations related to the furniture and equipment were less than $0.1 million as of December 31, 2022. Concurrent with entering into the sublease agreement, we executed an option agreement with the property owner which provides us the option to enter into a new direct lease for the Lexington facility for an additional five years following expiration of the sublease.

For additional information on our contractual obligation and commitments please see Note 16 — *Commitments and Contingencies* to our consolidated financial statements.

Cash flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,	
	2022	2021
Net cash used in operating activities	$ (58,547)	$ (54,964)
Net cash used in investing activities	(93,469)	(13,289)
Net cash provided by financing activities	693	216,745
Net (decrease) increase in cash and cash equivalents and restricted cash	$ (151,323)	$ 148,492

Operating activities

During the year ended December 31, 2022, operating activities used $58.5 million of cash, primarily resulting from our net loss of $60.8 million and net cash used by changes in our operating assets and liabilities of $5.3 million, partially offset by non-cash charges of $7.6 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2022 consisted primarily of an increase of $5.8 million mostly attributed to higher inventory to build safety stock and support a projected increase in demand, a decrease in accrued expenses and other current liabilities of $2.8 million primarily due to the timing of vendor expenses and the amount and timing of bonus payments, and a $0.4 million increase in accounts receivable primarily due to an increase in billings correlating with an increase in systems placed and recurring annual service contracts. These net operating cash uses were partially offset by an increase in accounts payable of $1.5 million due to timing of vendor invoices and payments, an increase in deferred revenue of $1.4 million primarily due to advanced billings for service contracts and pending validation services, a decrease in prepaid expenses and other current liabilities of $0.6 million primarily due to timing of payments and a decrease of other long-term assets of $0.2 million.

During the year ended December 31, 2021, operating activities used $55.0 million of cash, primarily resulting from our net loss of $73.5 million and net cash used by changes in our operating assets and liabilities of $8.0 million, partially offset by non-cash charges of $26.6 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2021 consisted primarily of an increase of $6.8 million in raw material inventory to build safety stock and support a projected increase in demand, an increase of $1.1 million in prepaid expenses and other current assets primarily due to insurance costs premium increases associated with operating as a public company, an increase of $0.9 million in other long-term assets primarily related to costs capitalized as a result of the implementation of a new Enterprise Resource Planning software during 2021, and a decrease in deferred revenue of $1.1 million due to timing of advanced billings for validation services and performance of the related services partially offset by an increase in advance billings

related to a higher number of systems under service contracts. These net operating cash uses were partially offset by an increase of $1.8 million in accrued expenses, accounts payable and other current liabilities primarily due to timing of invoicing and cash disbursements, as well as an increase of $0.1 million in deferred rent.

Investing activities

During the year ended December 31, 2022, net cash used in investing activities was $93.5 million, consisting of $179.2 million in purchases of investments and $6.7 million of capital expenditures, partially offset by investment maturities of $92.5 million.

During the year ended December 31, 2021, net cash used in investing activities was $13.3 million, consisting of capital expenditures of $3.2 million and $10.1 million in net purchases of investments.

Financing activities

During the year ended December 31, 2022, net cash provided by financing activities was $0.7 million, consisting of $0.6 million and $0.2 million from the issuance of common stock upon exercise of stock options and purchase of common stock under the employee stock purchase plan, respectively.

During the year ended December 31, 2021, net cash provided by financing activities was $216.7 million, consisting of net proceeds of $164.1 million from the initial public offering of Class A common stock, net of issuance costs, $79.7 million of net proceeds from the sale of the Series D1 and Series D2 Preferred Stock, net of issuance costs, and $0.9 million from the issuance of common stock upon exercise of stock options and purchase of restricted stock awards. Partially offsetting cash provided by financing activities in 2021 was the repayment of term loans of $26.2 million and payment of debt extinguishment fees of $1.9 million.

Long-term debt

In May 2020, we entered into the 2020 Term Loan which provided for borrowings of an initial $25.0 million tranche upon closing and options to borrow up to an aggregate of $35.0 million in two additional tranches of $20.0 million under the second tranche, or the Term B Loan, and $15.0 million under the third tranche, or the Term C Loan, subject to certain Growth Direct system sales milestones.

At closing, we issued warrants to purchase 1,195,652 shares of Series C1 Preferred Stock to the lender with an exercise price of $1.15 per share. We paid a $0.8 million facility fee in connection with the 2020 Term Loan.

In September 2021, we agreed to pay in full all of our outstanding obligations under the 2020 Term Loan in the amount of $28.7 million, comprised of the principal amount of the 2020 Term Loan, interest previously paid-in-kind, accrued cash interest, a prepayment premium, and other fees and expenses. As a result, with the exception of the warrants issued to the lender, all obligations under the 2020 Term Loan were satisfied, released, discharged and/or terminated in full.

Seasonality

Our revenues can vary from quarter to quarter as a result of factors such as our customers' budgetary cycles and extended summer vacation periods that can impact our ability to deliver products and provide onsite services to our customers during those periods. We expect this volatility to continue for the foreseeable future, which may cause fluctuations in our operating results and financial metrics. In addition, trends may vary in the future as our revenue mix shifts from non-recurring to recurring revenues.

Critical accounting policies and significant judgments and estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. Our estimates are based on our historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 — *Summary of Significant Accounting Policies* — to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following critical accounting policies are those most important to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

Product revenue

We derive product revenue primarily from the sale of Growth Direct systems and related consumables. Product revenue is recognized when control of the promised systems and consumables is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those products or consumables (the transaction price). For Growth Direct systems and consumables sold by us, control transfers to the customer at a point in time.

Service revenue

We derive service revenue primarily from the sale of validation services, service contracts and field service (including installation). Revenue is recognized when services are provided to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those services (the transaction price). Service revenue is recognized over time using an input method based on time lapsed for service contracts and using an output method based on milestones achieved for validation services and field service.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct product or service to a customer that are both capable of being distinct, whereby the customer can benefit from the product or service either on its own or together with other resources that are readily available, and are distinct in the context of the contract, whereby the transfer of the product or service is separately identifiable from other promises in the contract. Our main performance obligations in customer arrangements are Growth Direct systems, LIMS connection software, proprietary consumables, validation services, field service and services due under service contracts.

Multiple performance obligations

Our contracts may include multiple performance obligations when customers purchase a combination of products and services such as Growth Direct system sold together with the LIMS connection software, proprietary consumables or services. For these arrangements, we allocate the contract's transaction price to each performance obligation on a relative standalone selling price basis using our best estimate of the standalone selling price of each distinct product or service in the contract. The primary methods used to estimate standalone selling prices are based on the prices observed in standalone sales to customers or cost-plus margin depending on the nature of the obligation and available evidence of fair value. Allocation of the transaction price is determined at contract's inception.

Non-commercial revenue

We have generated non-commercial revenue from long-term contracts with BARDA, which is part of the U.S. government. The contract is a cost-reimbursable, cost-sharing contract, whereby BARDA reimburses us for a percentage of the total costs that have been incurred including indirect allowable rates. We include the unconstrained amount of consideration in the transaction price. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur.

Stock-based compensation

We measure stock-based option awards granted to employees, officers and directors based on their fair value on the date of grant using the Black-Scholes option-pricing model. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. We account for forfeitures as they occur. The straight-line method of expense recognition is applied to all awards with service-only conditions.

The fair value of each stock option is estimated on the grant date using the Black-Scholes option-pricing model, which uses inputs such as the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield.

We measure all restricted common stock and restricted stock units granted to employees based on the common stock value on the date of grant. The purchase price of the restricted common stock was the common stock value on the date of grant.

Valuation of inventory

We value inventory at the lower of cost or net realizable value. Cost is computed using the first-in, first-out method. We regularly review inventory quantities on-hand for excess and obsolescence and, when circumstances indicate, we record charges to write down inventories to their estimated net realizable value after evaluating future demand, expected product life cycles and current inventory levels. Such charges are classified as cost of product revenue in the statements of operations. Any write-down of inventory to net realizable value creates a new cost basis.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 — *Summary of Significant Accounting Policies* to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Emerging growth company status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies, and our financial statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the closing of the IPO, (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

Further, even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

As of December 31, 2022, we had cash, cash equivalents and short- and long-term investments of $138.4 million, which consisted of cash, money market funds, U.S. treasury bills, certificates of deposit, and U.S. treasury notes. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

Foreign currency exchange risk

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation risk

While we have experienced some impact from inflation related mainly to our materials, labor and freight costs, we have been able to mitigate further impacts through the maintenance of increased inventory levels and long-term contracts and commitments with key suppliers, some of which was implemented under our coronavirus risk mitigation strategy. As a result, we do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant incremental inflationary pressures, we may not be able to meaningfully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition or results of operations.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on effectiveness of controls and procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource

constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of disclosure controls and procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company's principal executive and principal financial officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under that framework, our management concluded that our internal controls over financial reporting were effective as of December 31, 2022.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the year ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

2022 Annual Bonuses

On March 9, 2023, the board of directors of the Company approved the following additional bonus amounts granted at the discretion of the Board in excess of the amounts earned pursuant to predetermined performance objectives for the 2022 fiscal year in consideration for each such individual's efforts related to the Company's strategic alternatives review process and the Restructuring Plan: $90,106 for Robert Spignesi, President and Chief Executive Officer, and $12,480 for Sean Wirtjes, Chief Financial Officer. Each bonus will be payable in cash on March 9, 2023.

Retention Bonuses

On March 9, 2023, the board of directors of the Company, approved a retention bonus arrangement with Mr. Wirtjes (the "Recipient") in the amount of $62,400 (the "Retention Bonuses") pursuant to the terms of a Retention Bonus Agreement (the "Retention Agreement"). The Retention Bonus is payable in cash on or within 10 days following September 1, 2023 (the "Retention Date") so long as the Recipient remains actively employed with the Company or its subsidiaries on the Retention Date. In the event that the Recipient's employment is terminated by us without "cause" (as defined in the employment agreement between such Recipient and the Company) or by the Recipient for "good reason" (as defined in the employment agreement between such Recipient and the Company), in each case on or prior to the Retention Date, the Recipient will be entitled to receive the full amount of such Retention Bonus in cash within 30 days of such termination date, subject to the execution and non-revocation of a release of claims in favor of the Company.

The foregoing is a summary of certain material terms of the Retention Agreement, does not purport to be complete, and is qualified in its entirety by reference to the full text of the form of the Retention Agreement attached hereto as Exhibit 10.20 and incorporated herein by reference.

Performance RSU Award Agreement

On March 9, 2023, the board of directors of the Company approved a form of performance restricted stock unit award (the "Award Agreement") to be used as a template for awards of restricted stock units under the Company's 2021 Incentive Award Plan that will be earned based on achievement of specified performance goals. The Award Agreement provides that restricted stock units vest upon the later of the anniversary of the grant date or the date that such performance goals are achieved, provided that the grantee continues to be a service provider on such vesting date.

The foregoing is a summary only of certain material terms of the Award Agreement, does not purport to be complete, and is qualified in its entirety by reference to the full text of the Award Agreement attached hereto as Exhibit 10.21 and incorporated herein by reference.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be set forth in our Proxy Statement for the 2023 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be set forth in our Proxy Statement for the 2023 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be set forth in our Proxy Statement for the 2023 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be set forth in our Proxy Statement for the 2023 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services.

Our independent public accounting firm is PricewaterhouseCoopers LLP, Boston, Massachusetts (PCAOB Auditor ID: 238).

The information required by this Item 14 will be set forth in our Proxy Statement for our 2023 Annual Meeting of Stockholders and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The following documents are filed as part of this Annual Report on Form 10-K:

(a)(1) Financial Statements.

For a list of consolidated financial statements included herein, see Index to Consolidated Financial Statements on page F-1 attached to this Annual Report on Form 10-K, incorporated into this item by reference.

(a)(2) Financial Statement Schedules.

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(a)(3) Exhibits.

The exhibits filed as part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page, which Exhibit Index is incorporated herein by reference.

Item 16. Form 10-K Summary.

We may voluntarily include a summary of information required by Form 10-K under this Item 16. We have elected not to include such summary information.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40952) filed on July 21, 2021)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40952) filed on July 21, 2021)
3.3	Certificate of Designations of Series A Junior Participating Cumulative Preferred Stock of the Registrant classifying and designating the Series A Junior Participating Cumulative Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form 8-A (File No. 001-40592) filed on August 12, 2022)
3.4	Certificate of Designations of Series B Junior Participating Cumulative Preferred Stock of the Registrant classifying and designating the Series B Junior Participating Cumulative Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form 8-A (File No. 001-40592) filed on August 12, 2022)
4.1	Specimen Stock Certificate evidencing the shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
4.2	Forms of Common Stock Warrant Agreements (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
4.3	Form of Series A1 Warrant Agreement (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
4.4	Form of Series B1 Warrant Agreement (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
4.5	Form of Series C1 Warrant Agreement (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
4.6	Stockholder Rights Agreement, dated as of August 11, 2022, between the Registrant and Computershare Trust Company, N.A., as Rights Agent (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form 8-A (File No. 001-40592) filed on August 12, 2022)
4.7*	Description of Capital Stock
10.1**	License Agreement, dated May 13, 2013 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
10.2	Lease Agreement, dated October 21, 2013, by and between the Registrant and Farley White Pawtucket, LLC, as amended (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
10.3	Seventh Amended and Restated Investors' Rights Agreement (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
10.4	Sublease, dated June 8, 2021, by and between the Registrant and National Medical Care, Inc. (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
10.5†	Rapid Micro Biosystems, Inc. 2010 Stock Option and Grant Plan, as amended, and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
10.6†	Rapid Micro Biosystems, Inc. 2021 Incentive Award Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)
10.7†	Rapid Micro Biosystems, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)
10.8	Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)
10.9†	Form of Indemnification Agreement for Directors and Executive Officers (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)
10.10†	Employment Agreement, dated July 8, 2021, by and between the Registrant and Robert Spignesi (incorporated by reference to Exhibit 10.9 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)

Exhibit Number	Description of Exhibit
10.11†	Employment Agreement, dated July 8, 2021, by and between the Registrant and Sean Wirtjes (incorporated by reference to Exhibit 10.10 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)
10.12†	Employment Agreement, dated July 8, 2021, by and between the Registrant and John Wilson (incorporated by reference to Exhibit 10.11 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)
10.13†	Employment Agreement, dated July 8, 2021, by and between the Registrant and Victoria Vezina (incorporated by reference to Exhibit 10.12 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)
10.14†	Employment Agreement, dated July 8, 2021, by and between the Registrant and Jonathan Paris (incorporated by reference to Exhibit 10.13 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on July 12, 2021)
10.15†	Employment Agreement, dated October 1, 2021, by and between the Registrant and Richard A. Keys (incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 24, 2022)
10.16†	Separation Agreement, dated as of August 24, 2022, between the Registrant and Richard Keys (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-40592) filed on November 10, 2022)
10.17†	2021 Incentive Award Plan UK Sub-Plan (incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 24, 2022)
10.18†	Form of Global Restricted Stock Unit Agreement under the Rapid Micro Biosystems, Inc. 2021 Incentive Award Plan (incorporated by reference to Exhibit 10.17 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 24, 2022)
10.19†	Form of Global Stock Option Grant Agreement under the Rapid Micro Biosystems, Inc. 2021 Incentive Award Plan (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 24, 2022)
10.20*†	Form of Retention Agreement
10.21*†	Form of Performance Restricted Stock Unit Agreement under the Rapid Micro Biosystems, Inc. 2021 Incentive Award Plan
10.22	Seventh Amendment to Lease Agreement as amended, dated March 18, 2022, by and between the Registrant and Farley White Pawtucket, LLC (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 24, 2022)
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (Reg. No. 333-257431) filed on June 25, 2021)
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm
24.1*	Power of Attorney (included in signature page)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of 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 Rule 13a-14(a) or Rule 15d-14(a) of 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 its 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 (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

Furnished herewith.

† Indicates management contract or compensatory plan.

** Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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 Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

RAPID MICRO BIOSYSTEMS, INC.

Date: March 10, 2023

By: /s/ Robert Spignesi

Robert Spignesi
President and Chief Executive Officer

POWER OF ATTORNEY AND SIGNATURES

Each person whose individual signature appears below hereby authorizes and appoints Robert Spignesi and Sean Wirtjes, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K 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/ Robert Spignesi **Robert Spignesi**	President, Chief Executive Officer and Director *(principal executive officer)*	March 10, 2023
/s/ Sean Wirtjes **Sean Wirtjes**	Chief Financial Officer *(principal financial officer and principal accounting officer)*	March 10, 2023
/s/ Jeffrey Schwartz **Jeffrey Schwartz**	Director	March 10, 2023
/s/ David Hirsch, M.D., Ph.D. **David Hirsch, M.D., Ph.D.**	Director	March 10, 2023
/s/ Richard Kollender **Richard Kollender**	Director	March 10, 2023
/s/ Melinda Litherland **Melinda Litherland**	Director	March 10, 2023
/s/ Inese Lowenstein **Inese Lowenstein**	Director	March 10, 2023
/s/ Natale Ricciardi **Natale Ricciardi**	Director	March 10, 2023

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Rapid Micro Biosystems, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Rapid Micro Biosystems, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, of comprehensive loss, of stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2022.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 10, 2023

We have served as the Company's auditor since 2010.

RAPID MICRO BIOSYSTEMS, INC.
Consolidated balance sheets
(In thousands, except share and per share amounts)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 27,064	$ 178,387
Short-term investments	81,584	15,110
Accounts receivable	5,369	5,005
Inventory	21,187	15,671
Prepaid expenses and other current assets	3,372	3,951
Total current assets	138,576	218,124
Property and equipment, net	13,818	11,304
Right-of-use assets	7,063	—
Long-term investments	29,790	9,966
Other long-term assets	1,119	1,491
Restricted cash	284	284
Total assets	$ 190,650	$ 241,169
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,428	$ 3,944
Accrued expenses and other current liabilities	8,150	10,917
Deferred revenue	4,706	3,305
Lease liabilities, short-term	766	—
Total current liabilities	19,050	18,166
Deferred rent, long-term	—	813
Lease liabilities, long-term	7,202	—
Other long-term liabilities	229	1,210
Total liabilities	26,481	20,189
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Class A common stock, $0.01 par value; 210,000,000 shares authorized at December 31, 2022 and 2021; 36,538,805 shares and 34,564,040 shares issued and outstanding at December 31, 2022 and 2021, respectively	366	346
Class B common stock, $0.01 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; 5,553,379 shares and 6,903,379 shares issued and outstanding at December 31, 2022 and 2021, respectively	55	69
Preferred stock, $0.01 par value: 10,000,000 shares authorized at December 31, 2022 and 2021; zero shares issued and outstanding at December 31, 2022 and 2021	—	—
Additional paid-in capital	540,775	535,693
Accumulated deficit	(375,918)	(315,112)
Accumulated other comprehensive loss	(1,109)	(16)
Total stockholders' equity	164,169	220,980
Total liabilities and stockholders' equity	$ 190,650	$ 241,169

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

RAPID MICRO BIOSYSTEMS, INC.
Consolidated statements of operations
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	2021
Revenue:		
Product revenue	$ 11,056	$ 15,512
Service revenue	6,077	6,125
Non-commercial revenue	—	1,595
Total revenue	17,133	23,232
Costs and operating expenses:		
Cost of product revenue	18,477	23,434
Cost of service revenue	7,196	5,922
Cost of non-commercial revenue	—	1,617
Research and development	12,866	9,781
Sales and marketing	14,994	11,815
General and administrative	26,819	17,895
Total costs and operating expenses	80,352	70,464
Loss from operations	(63,219)	(47,232)
Other income (expense):		
Interest income (expense), net	1,778	(2,608)
Change in fair value of preferred stock warrant liability	—	(19,643)
Loss on extinguishment of debt	—	(3,100)
Other income (expense), net	59	(850)
Total other income (expense), net	1,837	(26,201)
Loss before income taxes	(61,382)	(73,433)
Income tax (benefit) expense	(576)	91
Net loss	(60,806)	(73,524)
Accretion of redeemable convertible preferred stock to redemption value	—	(1,761)
Cumulative redeemable convertible preferred stock dividends	—	(2,747)
Net loss attributable to common stockholders — basic and diluted	$ (60,806)	$ (78,032)
Net loss per share attributable to Class A and Class B common stockholders — basic and diluted	$ (1.43)	$ (3.94)
Weighted average common shares outstanding — basic and diluted	42,454,403	19,783,539

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

RAPID MICRO BIOSYSTEMS, INC.
Consolidated statements of comprehensive loss (In thousands)

	Year Ended December 31,	
	2022	2021
Net loss	$ (60,806)	$ (73,524)
Other comprehensive loss:		
Unrealized loss on investments, net of tax	(1,093)	(17)
Comprehensive loss	$ (61,899)	$ (73,541)

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

RAPID MICRO BIOSYSTEMS, INC.
Consolidated statements of stockholders' equity
(In thousands, except share amounts)

	Class A Common stock		Class B Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive	Total
	Shares	Amount	Shares	Amount				
Balances at December 31, 2021	34,564,040	$ 346	6,903,379	$ 69	$ 535,693	$ (315,112)	$ (16)	$ 220,980
Conversion of Class B common stock to Class A common stock	1,350,000	14	(1,350,000)	(14)	—	—	—	—
Issuance of Class A common stock upon exercise of common stock	572,932	6	—	—	562	—	—	568
Issuance of Class A common stock under ESPP	51,833	—	—	—	159	—	—	159
Restricted stock award liability accretion	—	—	—	—	342	—	—	342
Stock-based compensation expense	—	—	—	—	4,019	—	—	4,019
Net loss	—	—	—	—	—	(60,806)	—	(60,806)
Other comprehensive loss	—	—	—	—	—	—	(1,093)	(1,093)
Balances at December 31, 2022	36,538,805	$ 366	5,553,379	$ 55	$ 540,775	$ (375,918)	$ (1,109)	$ 164,169

	Redeemable convertible preferred stock		Class A Common stock		Class B Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2020	133,021,640	$ 151,826	612,850	$ 6	—	$ —	$ 114,575	$ (241,588)	$ 1	$ (127,006)
Issuance of Series D1 redeemable convertible preferred stock, net of issuance costs of $1,278	22,086,725	78,274	—	—	—	—	—	—	—	—
Issuance of Series D2 redeemable convertible preferred stock, net of issuance costs of $19	413,268	1,469	—	—	—	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	1,761	—	—	—	—	(1,761)	—	—	(1,761)
Cumulative redeemable convertible preferred stock dividends	—	2,747	—	—	—	—	(2,747)	—	—	(2,747)
Conversion of preferred stock to common stock	(155,521,633)	(236,077)	24,200,920	242	6,903,379	69	235,766	—	—	236,077
Conversion of preferred warrants to Class A common stock warrants	—	—	—	—	—	—	23,760	—	—	23,760
Issuance of Class A common stock in initial public offering, net of issuance costs of $16,032	—	—	9,006,604	90	—	—	164,010	—	—	164,100
Restricted stock award liability accretion	—	—	—	—	—	—	19	—	—	19
Issuance of Class A common stock upon exercise of common stock	—	—	268,718	2	—	—	11	—	—	13
Issuance of Class A common stock upon exercise of common stock	—	—	226,043	4	—	—	219	—	—	223
Issuance of Restricted Class A common stock awards	—		248,905	2	—	—	(2)	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,843	—	—	1,843
Net loss	—	—	—	—	—	—	—	(73,524)	—	(73,524)
Other comprehensive loss	—	—	—	—	—	—	—	—	(17)	(17)
Balances at December 31, 2021	—	$ —	34,564,040	$ 346	6,903,379	$ 69	$ 535,693	$ (315,112)	$ (16)	$ 220,980

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

RAPID MICRO BIOSYSTEMS, INC.
Consolidated statements of cash flows (In thousands)

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (60,806)	$ (73,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,837	1,529
Stock-based compensation expense	4,019	1,843
Non-cash lease expense	1,143	—
Change in fair value of preferred stock warrant liability	—	19,643
Provision recorded for inventory	326	60
Noncash interest expense	—	390
Loss (gain) on disposal of property and equipment	28	(18)
Accretion on investments	(662)	(3)
Loss on extinguishment of debt	—	3,100
Other, net	(107)	14
Changes in operating assets and liabilities		
Accounts receivable	(364)	(17)
Inventory	(5,843)	(6,766)
Prepaid expenses and other current assets	578	(1,105)
Other long-term assets	179	(851)
Accounts payable	1,484	(524)
Accrued expenses and other current liabilities	(2,760)	2,305
Deferred revenue	1,401	(1,117)
Deferred rent, long term	—	107
Other long-term liabilities	—	(30)
Net cash used in operating activities	(58,547)	(54,964)
Cash flows from investing activities:		
Purchases of property and equipment	(6,740)	(3,217)
Proceeds from sale of property and equipment	—	20
Purchases of investments	(179,229)	(25,092)
Maturity of investments	92,500	15,000
Net cash used in investing activities	(93,469)	(13,289)
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	79,743
Proceeds from issuance of Class A common stock - stock option exercise	566	403
Proceeds from issuance of Class A common stock - employee stock purchase plan	160	—
Proceeds from issuance of restricted Class A stock award	—	523
Proceeds from initial public offering of Class A and Class B common stock, net of issuance costs	—	164,100
Proceeds from exercise of Class A common stock warrants	—	13
Payments on finance lease obligations	(33)	(12)
Repayment of term loans	—	(26,159)
Payment of debt extinguishment fees	—	(1,866)
Net cash provided by financing activities	693	216,745
Net (decrease) increase in cash, cash equivalents and restricted cash	(151,323)	148,492
Cash, cash equivalents and restricted cash at beginning of period	178,671	30,179
Cash, cash equivalents and restricted cash at end of period	$ 27,348	$ 178,671

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

RAPID MICRO BIOSYSTEMS, INC.
Consolidated statements of cash flows (In thousands)

	Year Ended December 31,	
	2022	2021
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 42	$ 2,590
Supplemental disclosure of non-cash investing activities		
Establishment of property and equipment retirement cost asset	$ —	$ 188
Establishment of right of use operating assets	$ 7,605	$ —
Purchases of property and equipment in accounts payable	$ 561	$ 1,957
Supplemental disclosure of non-cash financing activities		
Establishment of right of use finance assets	$ 366	$ —
Assets acquired under capital lease	$ —	$ 372
Conversion of preferred stock to Class A and Class B common stock	$ —	$ 236,077
Conversion of preferred stock warrants to Class A common stock warrants	$ —	$ 23,760
Accretion of redeemable convertible preferred stock to redemption value	$ —	$ 1,761
Cumulative redeemable convertible preferred stock dividends	$ —	$ 2,747

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

1. Nature of the business and basis of presentation

Rapid Micro Biosystems, Inc. (the "Company") was incorporated under the laws of the State of Delaware on December 29, 2006. The Company develops, manufactures, markets and sells Growth Direct systems ("Systems"), proprietary consumables, laboratory information management system ("LIMS") connection software, and services to address rapid microbial analysis used for quality control in the manufacture of pharmaceuticals, medical devices and personal care products. The Company's technology uses a highly sensitive camera and the natural auto fluorescence of living cells to identify and quantify microbial growth faster and more accurately than the traditional method, which relies on the human eye. The Company currently sells to customers in North America, Europe and Asia. The Company is headquartered in Lowell, Massachusetts.

Basis of presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries in Germany and Switzerland. All intercompany accounts and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Reclassification

Certain amounts in the prior period financial statements have been reclassified to conform to the presentation of the current period financial statements.

Reverse stock split

On July 9, 2021, the Company effected a one-for-five reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's Preferred Stock (see Note 10). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the Preferred Stock conversion ratios.

Initial public offering

On July 19, 2021, the Company closed an initial public offering ("IPO") of its Class A common stock, which resulted in the sale of 7,920,000 shares of its Class A common stock at a public offering price of $20.00 per share, before underwriting discounts. The offering resulted in gross proceeds of $158.4 million and net proceeds to the Company of $143.8 million from the initial public offering after deducting underwriting discounts, commissions and offering expenses payable by the Company.

On August 4, 2021, the underwriters exercised their overallotment option in part and purchased 1,086,604 shares of Class A common stock at the initial public offering price of $20.00 per share less underwriting discounts and commissions. The overallotment option exercise resulted in net proceeds of $20.2 million.

Liquidity

The Company has incurred recurring losses and net cash outflows from operations since its inception. The Company expects to continue to generate significant operating losses for the foreseeable future. The Company expects that its existing cash, cash equivalents and investments will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months following the date these consolidated financial statements were issued.

2. Summary of significant accounting policies

Use of estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the 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 periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, calculating the standalone selling price of products and services for revenue recognition, the valuation of inventory, and the valuation of stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific and relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Risk of concentrations of credit, significant customers and significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term and long-term investments and accounts receivable. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company maintains its cash and cash equivalents with financial institutions that management believes to be of high credit quality. The Company has not experienced any losses on such accounts or any other-than-temporary losses with respect to its cash equivalents and investments and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Significant customers are those which represent more than 10% of the Company's total revenue or accounts receivable balance at each respective balance sheet date. The following table presents customers that represent 10% or more of the Company's total revenue:

	Year Ended December 31,	
	2022	2021
Customer A	22.8 %	16.7 %
	22.8 %	16.7 %

The following table presents customers that represent 10% or more of the Company's accounts receivable:

	Year Ended December 31,	
	2022	2021
Customer A	21.4 %	19.5 %
Customer B	16.7 %	*
Customer C	11.8 %	*
Customer D	*	12.6 %
Customer E	*	10.6 %
Customer F	*	10.0 %
	49.9 %	52.7 %

* – less than 10%

The Company relies on third parties for the supply and manufacture of certain of its products as well as logistics. In instances where these parties fail to perform their obligations, the Company may be unable to find alternative suppliers to satisfactorily deliver its products to its customers on time, if at all, which could have a material adverse effect on the Company's operating results, financial condition and cash flows and damage its customer relationships. There are no significant concentrations around a single third-party supplier or manufacturer for the year ended December 31, 2022 or 2021.

Debt issuance costs

The Company capitalizes certain legal and other third-party fees that are directly associated with the issuance of debt as debt issuance costs. Debt issuance costs are recorded as a direct reduction of the carrying amount of the associated debt on the consolidated balance sheets and amortized as interest expense on the consolidated statement of operations using the effective interest method, which approximates the straight-line method. As of December 31, 2022 and 2021, the Company had no debt issuance costs on its consolidated balance sheets. During the year ended December 31, 2022 and 2021, the Company recorded zero and $0.4 million, respectively, in amortization of debt issuance costs within interest income (expense) in the consolidated statement of operations.

Cash equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents that are readily convertible to cash are stated at cost, which approximates fair value. At December 31, 2022 and 2021, the Company held cash of $0.2 million and $0.3 million in banks located outside of the U.S., respectively.

Restricted cash

As of December 31, 2022 and 2021, the Company was required to maintain guaranteed investment certificates of $0.3 million, with maturities of three months to one year that are subject to an insignificant risk of changes in value. The guaranteed investment certificates are held for the benefit of landlords in connection with operating leases which have remaining terms of greater than one year and are classified as restricted cash (non-current) on the Company's consolidated balance sheet.

Investments

The Company's short-term and long-term investments are classified as available-for-sale and recorded at fair value based upon market prices at period end. Unrealized gains and losses are recorded in accumulated other comprehensive income as a separate component of stockholders' equity. Realized gains and losses and declines in value of investments

determined to be other than temporary are included as a component of interest income (expense), net in the consolidated statement of operations. The costs of investments for purposes of computing realized and unrealized gains and losses is based on the specific identification method.

The Company evaluates its short-term and long-term investments with unrealized losses for other-than-temporary impairment. When assessing investments for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be other-than-temporary, the Company reduces the investment to fair value through a charge to the consolidated statement of operations. No such adjustments were necessary during the periods presented.

The Company's short-term investments as of December 31, 2022 and 2021 had maturities of less than one year, and long-term investments as of December 31, 2022 and 2021 had maturities greater than one year.

Accounts receivable

Accounts receivable are customer obligations that are unconditional. Accounts receivable are presented net of an allowance for doubtful accounts, which represents an estimate of amounts that may not be collectible. The Company performs ongoing credit evaluations of its customers and, if necessary, provides an allowance for doubtful accounts and expected losses. The Company writes off accounts receivable against the allowance when it determines a balance is uncollectible and no longer actively pursues collection of the receivable. The Company does not have any off-balance-sheet credit exposure related to customers. As of December 31, 2022 and 2021, the Company recorded zero allowance for doubtful accounts. Additionally, for the years ended December 31, 2022 and 2021, the Company recorded zero provision for bad debts or recoveries.

Inventory

Inventory is valued at the lower of cost or net realizable value. Cost is computed using the first-in, first-out method. The Company regularly reviews inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, records charges to write down inventories to their estimated net realizable value, after evaluating historical sales, future demand, market conditions and expected product life cycles. Such charges are classified as cost of product revenue in the consolidated statements of operations. Any write-down of inventory to net realizable value creates a new cost basis.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Manufacturing and laboratory equipment	5-10 years
Computer hardware and software	3 years
Office furniture and fixtures	5-7 years
Leasehold improvements	Shorter of remaining life of lease or useful life

Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related

accumulated depreciation or amortization are eliminated from the consolidated balance sheet and any resulting gains or losses are included in the consolidated statement of operations in the period of disposal. Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service.

Software development costs

The Company accounts for software development costs for internal-use software under the provisions of ASC 350-40, "Internal-Use Software" ("ASC 350"). Accordingly, certain costs to develop internal-use computer software are capitalized, provided these costs are expected to be recoverable. There was $1.4 million and $1.3 million of software development costs capitalized in other long-term assets at December 31, 2022 and 2021, respectively, net of accumulated amortization of $0.4 million and $0.1 million, respectively. The capitalized costs are being amortized on a straight-line basis over the initial subscription term of five years. There was $0.3 million and $0.1 million of amortization expense recorded in the consolidated statement of operations for the years ended December 31, 2022 and 2021.

Impairment of long-lived assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss is based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2022 or 2021.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents, investments, and its redeemable convertible preferred stock warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

Product warranties

The Company offers a one-year limited assurance warranty on system sales, which is included in the selling price. Product warranties provide assurance that the Company's product functions in accordance with standard specifications. Warranties cover for repairs and replacements when the product does not function in accordance with agreed specifications. The standard assurance warranty does not cover, and no warranty is provided for, parts which by their nature are normally required to be replaced periodically. The accrued warranty cost is based on estimated material, labor and other costs that the Company expects to incur to fulfill the warranty obligation. Estimates are primarily based on historical information, current cost data and future forecasts. The Company periodically assesses the adequacy of the warranty accrual and adjusts the amount as necessary. If the historical data used to calculate the adequacy of the warranty accrual are not indicative of future requirements, additional or reduced warranty accrual may be required. The warranty accrual is included in accrued expenses and other current liabilities in the consolidated balance sheets. The following table presents a summary of changes in the amount reserved for warranty cost (in thousands):

	Year Ended December 31,	
	2022	2021
Balance, beginning of the period	$ 598	$ 637
Warranty provisions	646	—
Warranty repairs	(372)	(39)
Balance, end of the year	$ 872	$ 598

Classification and accretion of redeemable convertible preferred stock

Prior to the IPO and the conversion of redeemable convertible preferred stock to Class A and Class B common stock, the Company had classified redeemable convertible preferred stock outside of stockholders' equity because the shares contained certain redemption features that were not solely within the control of the Company. Costs incurred in connection with the issuance of each series of redeemable convertible preferred stock was recorded as a reduction of gross proceeds from issuance. The Company recorded periodic accretion to the carrying values of its outstanding redeemable convertible preferred stock such that the carrying value of the redeemable convertible preferred stock would have been equal to the redemption value at the earliest date of redemption. Adjustments to the carrying values of the redeemable convertible preferred stock to record this accretion at each reporting date were considered deemed dividends, which adjusted retained earnings (or in the absence of retained earnings, additional paid-in capital) and increased or decreased net loss attributable to common stockholders in computing basic and diluted earnings per share.

Preferred stock warrant liability

Prior to the IPO and the conversion of redeemable convertible preferred stock warrant liabilities to Class A common stock warrants, the Company classified warrants for the purchase of shares of its redeemable convertible preferred stock (see Notes 3 and 10) as a liability on its consolidated balance sheets as these warrants were freestanding financial instruments that may have required the Company to transfer assets upon exercise. The warrant liability was initially recorded at fair value on the issuance date of each warrant and was subsequently remeasured to fair value at each reporting date using the Black-Scholes pricing model. Changes in the fair value of the warrant liability were recognized as a component of other income (expense) in the consolidated statements of operations. Changes in the fair value of the preferred stock warrant liability were recognized up until the warrants qualified for equity classification upon IPO.

Segment information

The Company determined its operating segment after considering the Company's organizational structure and the information regularly reviewed and evaluated by the Company's chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company has determined that its CODM is its Chief Executive Officer. The CODM reviews the financial information on a consolidated basis for purposes of evaluating financial

performance and allocating resources. On the basis of these factors, the Company determined that it operates and manages its business as one operating segment, that develops, manufactures, markets and sells systems and related LIMS connection software, consumables and services; and, accordingly, has one reportable segment for financial reporting purposes. Substantially all of the Company's long-lived assets are held in the United States.

Revenue recognition

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In order to achieve this core principle, the Company applies the following five steps when recording revenue:

(1) identify the contract, or contracts, with the customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when, or as, performance obligations are satisfied.

The Company derives revenue from the sale of its products and services through direct sales representatives and distributors. The Company's arrangements are generally noncancelable and nonrefundable after ownership passes to the customer or distributor.

Product revenue

The Company derives product revenue primarily from the sale of its systems, optional LIMS connection software, which facilitates the transfer of data captured by the system to the customer's existing LIMS software, and proprietary consumables. Revenue is recognized when control of the products is transferred to the customer.

Transfer of control is generally at shipment or delivery, depending on contractual terms, and occurs when title and risk of loss transfers to the customer, which represents the point in time when the customer obtains the use of and substantially all of the benefits of the product. Upon delivery, the System is fully functional for use by the customer. As such, the Company's performance obligation related to product sales is satisfied at a point in time. The Company's principal terms of sale are free carrier shipping point.

Service revenue

The Company derives service revenue primarily from validation services, service contracts and field service (including installation). The Company's validation services include validation and documentation services performed utilizing systems purchased by the customer. Service contracts are around-the-clock maintenance support which can be purchased by the customer after the expiration of the one-year assurance warranty included with each system purchase. Field service revenue primarily consists of services provided by field service engineers to install the system at the customer site and perform two preventative maintenance services during the warranty period. Service revenue is recognized over time using an input method based on time lapsed for service contracts and output method based on milestone achieved for validation services and field service.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct product or service to a customer that are both capable of being distinct, whereby the customer can benefit from the product or service either on its own or together with other resources that are readily available, and are distinct in the context of the contract, whereby the transfer of the product or service is separately identifiable from other promises in the contract. The Company's main performance obligations in customer arrangements are systems, LIMS connection software, consumables, validation services, service contracts, and field service.

Payment terms

Payment terms for customer orders are typically between 30 to 90 days after the shipment or delivery of the product. For certain products, services and customer types, the Company requires payment before the products or services are delivered to, or performed for, the customer. None of the Company's contracts contain a significant financing component.

Multiple performance obligations with an arrangement

The Company's contracts may include multiple performance obligations when customers purchase a combination of products and services such as system sold together with the LIMS connection software, consumables or services. For these arrangements, the Company allocates the contract's transaction price to each performance obligation on a relative standalone selling price basis using the Company's best estimate of the standalone selling price of each distinct product or service in the contract. The primary methods used to estimate standalone selling prices are based on the prices observed in standalone sales to customers or cost-plus margin depending on the nature of the obligation and available evidence of fair value. Allocation of the transaction price is determined at contract's inception.

Remaining performance obligations

The Company does not disclose the value of remaining performance obligations for (i) contracts with an original contract term of one year or less, (ii) contracts for which the Company recognizes revenue at the amount to which it has the right to invoice when that amount corresponds directly with the value of services performed, and (iii) variable consideration allocated entirely to a wholly unsatisfied performance obligation or to a wholly unsatisfied distinct service that forms part of a single performance obligation. The Company does not have material remaining performance obligations associated with contracts with terms greater than one year.

Contract balances from contracts with customers

Contract assets arise from unbilled amounts in customer arrangements when revenue recognized exceeds the amount billed to the customer and the Company's right to payment is conditional and not only subject to the passage of time. The Company had $0.1 million and $0.3 million in contract assets as of December 31, 2022 and 2021, respectively, included in prepaid expenses and other current assets. These balances relate to unbilled amounts with commercial customers as well as an amount in the prior year related to the BARDA agreement.

Contract liabilities represent the Company's obligation to transfer goods or services to a customer for which it has received consideration (or the amount is due) from the customer. The Company has a contract liability related to service revenue, which consists of amounts that have been invoiced but that have not been recognized as revenue. Amounts expected to be recognized as revenue within 12 months of the balance sheet date are classified as current deferred revenue and amounts expected to be recognized as revenue beyond 12 months of the balance sheet date are classified as noncurrent deferred revenue. The Company did not record any non-current deferred revenue as of December 31, 2022 or 2021. Deferred revenue was $4.7 million and $3.3 million at December 31, 2022 and 2021, respectively. Revenue recognized during the year ended December 31, 2022 that was included in deferred revenue at the prior year-end was $2.7 million. Revenue recognized during the year ended December 31, 2021 that was included in deferred revenue at the prior year-end was $3.8 million.

Non-commercial revenue

The Company has historically generated revenue from a long-term contract with the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority ("BARDA") a part of the U.S. government. The Company's contracts with the U.S. government are typically subject to the Federal Acquisition Regulation ("FAR") and are priced based on estimated or actual costs of producing goods or providing services. The FAR provides guidance on the types of costs that are allowable in establishing prices for goods or services provided under U.S. government contracts. In September 2017, the Company signed a contract with BARDA, which was subsequently modified on multiple occasions

to increase the contract value and adjust the cost share reimbursement rate. Modifications were accounted for in accordance with the contract modification framework. The contract is a cost-reimbursable, cost-sharing arrangement, whereby BARDA reimburses the Company for a percentage of the total costs that have been incurred including indirect allowable costs. All funding under this contract was fully earned by the fourth quarter of 2021. However, the Company is now in the process of closing out its BARDA contract, which includes a true-up of actual reimbursable costs to those previously billed at provisional rates for each year of performance. Any true-up will be recognized as non-commercial revenue once finalized.

Disaggregated revenue

The Company disaggregates revenue based on the recurring and non-recurring, and commercial and non-commercial, nature of the underlying sale. Recurring revenue includes sales of consumables and service contracts. Non-recurring revenue includes sales of systems, LIMS connection software, validation services, field service, and revenue under the Company's contract with BARDA. The following table presents the Company's revenue by the recurring or non-recurring and commercial or non-commercial nature of the revenue stream (in thousands):

	Year Ended December 31,	
	2022	2021
Product and service revenue — recurring	$ 10,983	$ 7,819
Product and service revenue — non-recurring	6,150	13,818
Non-commercial revenue — non-recurring	—	1,595
Total revenue	$ 17,133	$ 23,232

The following table presents the Company's revenue by customer geography (in thousands):

	Year Ended December 31,	
	2022	2021
United States	$ 8,767	$ 12,892
Germany	2,649	1,695
Switzerland	2,756	4,314
All other countries	2,961	4,331
Total revenue	$ 17,133	$ 23,232

Contract acquisition costs

The Company incurs and pays commissions on systems, LIMS connection software, validation services, consumables, and service contracts. The period of the related revenue stream is typically less than one year in duration, and as such, the Company applies the practical expedient to expense the costs in the period in which they were incurred. The Company does not pay commissions on non-commercial revenue with BARDA.

Cost of revenue

Cost of product revenue primarily consists of costs for raw material parts and associated freight, shipping and handling costs, royalties, contract manufacturer costs, salaries and other personnel costs including stock-based compensation expense, depreciation and amortization expense, scrap, warranty cost, inventory reserves, allocated information technology and facility-related costs, overhead and other costs related to those sales recognized as product revenue in the period. Cost of service revenue primarily consists of salaries and other personnel costs including stock-based compensation expense, travel costs, materials consumed when performing installations, validations and other services, allocated information technology and facility-related costs, costs associated with training and other expenses related to service revenue recognized in the period. Cost of non-commercial revenue primarily consists of salaries and other personnel costs including

stock-based compensation expense, consulting expense, materials, travel and other costs related to revenue recognized as non-commercial revenue during the period.

Shipping and handling fees

Shipping and handling fees billed to customers for product shipments are recorded in product revenue in the consolidated statements of operations. Shipping and handling costs incurred for inventory purchases and product shipments are recorded in cost of product revenue in the consolidated statements of operations.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities including, employee-related expenses, such as salaries, bonuses and other personnel costs including stock-based compensation expense, the cost of developing maintaining and improving new and existing products designs, the cost of hardware and software engineering, the cost of research materials and supplies, external costs of outside consultants engaged to conduct research and development services associated with the Company's technology and products, and information technology and facilities expenses, which include direct and allocated expenses for rent, maintenance of facilities and insurance, as well as related depreciation and amortization. The costs incurred for the development of system software that will be sold are capitalized when technological feasibility has been established. The Company has continued to develop the software associated with its platform and products, and the associated costs have been expensed as incurred, when the nature of improvements did not significantly improve the performance or functionality of the software.

Advertising costs

Advertising costs are expensed as incurred and are included in sales and marketing expenses in the consolidated statements of operations. Advertising costs were $0.1 million during both of the years ended December 31, 2022 and 2021.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditures. Amounts incurred are classified within general and administrative expense in the consolidated statement of operations.

Stock-based compensation

The Company measures all stock-based awards granted to employees, officers and directors based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company issues stock-based awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. Forfeitures are accounted for as they occur. The Company has not issued any stock-based awards with performance-based vesting conditions.

The Company measures all restricted common stock and restricted stock units granted to employees based on the common stock value on the date of grant. The purchase price of the restricted common stock is the common stock value on the date of grant.

The Company classifies stock-based compensation expense in its consolidated statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which uses the following inputs: (i) the fair value per share of the common stock issuable upon exercise of the

option, (ii) the expected term of the option, (iii) expected volatility of the price of the common stock, (iv) the risk-free interest rate, and (v) the expected dividend yield. The exercise price of the option cannot be less than the fair market value of a share of common stock on the date of grant. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla". The Company historically has been a private company and lacks company-specific historical and implied volatility information for its stock. Therefore, the Company estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on its common stock and does not expect to pay any cash dividends in the foreseeable future.

Income taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Foreign currency translation and transactions

The Company has determined that the functional and reporting currency for its operations in Germany and Switzerland is the U.S. Dollar. Gains and losses arising from currency exchange rate fluctuations on transactions denominated in a currency other than the local functional currency are included in other income (expense), net.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2022 and 2021, comprehensive loss included $1.1 million and less than $0.1 million, respectively, of unrealized gains and losses on investments, net of tax.

Net loss per share attributable to common stockholders

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be

allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding stock options, shares expected to be purchased under the employee stock purchase plan, unvested restricted stock units, and warrants to purchase common stock are considered potential dilutive common shares.

In periods in which the Company reports a net loss attributable to common stockholders diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2022 and 2021, as such basic net loss per share attributable to common stockholders was the same as diluted net loss per share attributable to common stockholders.

Recently adopted accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) to increase transparency and comparability among organizations related to their leasing arrangements. The update requires lessees to recognize most leases, with the exception of short-term leases if a policy election is made, on their balance sheets as a right-of-use ("ROU") asset representing the right to use an underlying asset and a lease liability representing the obligation to make lease payments over the lease term, measured on a discounted basis, while recognizing lease expense on their income statements in a manner similar to current GAAP. The guidance also requires entities to disclose key quantitative and qualitative information about its leasing arrangements.

The Company leases office and manufacturing space under operating lease agreements. The Company leases furniture under a financing agreement. The Company adopted Topic 842 on January 1, 2022 using the optional transition method to the modified retrospective approach. Under this transition provision, results for reporting periods beginning on January 1, 2022 are presented under Topic 842 while prior period amounts continue to be reported and disclosed in accordance with the Company’s historical accounting treatment under ASC Topic 840, Leases.

The Company elected the “package of practical expedients” permitted under the transition guidance, which among other things, does not require reassessment of whether contracts entered into prior to adoption are or contain leases, and allows carryforward of the historical lease classification for existing leases. The Company did not elect the “hindsight” practical expedient, and therefore measured the ROU assets and lease liabilities using the remaining portion of the lease term at adoption on January 1, 2022.

The Company made an accounting policy election not to recognize ROU assets and lease liabilities for leases with a term of twelve months or less. For all other leases, the Company recognizes ROU assets and lease liabilities based on the present value of lease payments over the lease term at the commencement date of the lease (or January 1, 2022 for existing leases upon the adoption of ASC 842). Lease payments may include fixed rent escalation clauses or payments that depend on an index (such as the consumer price index). Subsequent changes to an index and any other periodic market-rate adjustments to base rent are recorded in variable lease expense in the period incurred. The ROU assets also include any initial direct costs incurred and lease payments made at or before the commencement date and are reduced by any lease incentives.

The Company has made an accounting policy election to account for lease and non-lease components in its contracts as single lease components for all asset classes. The non-lease components typically represent additional services

transferred to the Company, such as common area maintenance for real estate, which are variable in nature and recorded in variable lease expense in the period incurred.

The Company uses its incremental borrowing rate which is the rate of interest the Company would have to pay to borrow on a collateralized basis over a similar term and amount in a similar economic environment to determine the present value of lease payments as the Company's leases do not have a readily determinable implicit discount rate. Judgment is applied in assessing factors such as Company specific credit risk, lease term, nature, and quality of the underlying collateral, currency, and economic environment in determining the incremental borrowing rate to apply to each lease.

Upon adoption, the Company recorded operating lease ROU assets and lease liabilities of $6.0 million and $7.0 million, respectively, the difference relating to deferred rent. The Company recorded financing lease ROU assets and lease liabilities of approximately $0.4 million. The adoption of the new lease standard on January 1, 2022 did not materially impact our consolidated statements of operations, comprehensive loss or cash flows.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (ASC 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various areas related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application. The Company adopted this guidance effective January 1, 2022, and the adoption had no material impact on its consolidated financial statements and related disclosures.

Recently issued accounting pronouncements

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the newer revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326)* ("ASU 2016-13"). The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available for sale, and trade receivables. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. The new standard will be effective for the Company beginning January 1, 2023. The FASB subsequently issued other related ASUs that amend ASU No. 2016-13 to provide clarification and additional guidance. The Company evaluated the impact of the new standard concluding that it will not have a material impact on its consolidated financial statements.

3. Fair value of financial assets and liabilities

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values (in thousands):

	Fair value measurements as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 22,072	$ —	$ —	$ 22,072
Short-term investments	81,093	491	—	81,584
Long-term investments	26,431	3,359	—	29,790
	$ 129,596	$ 3,850	$ —	$ 133,446

	Fair value measurements at December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 173,755	$ —	$ —	$ 173,755
Short-term investments	15,110	—	—	15,110
Long term investments	9,966	—	—	9,966
	$ 198,831	$ —	$ —	$ 198,831

During the years ended December 31, 2022 and 2021, respectively, there were no transfers between Level 1, Level 2 and Level 3.

Valuation of short-term and long-term investments

U.S. Treasury bills and notes included in short-term and long-term investments were valued by the Company using quoted prices in active markets for identical securities, which represents a Level 1 measurement within the fair value hierarchy. The Company's certificates of deposit included in short-term and long-term investments were valued using quoted prices for similar assets in active markets (or identical assets in inactive markets), which represent a Level 2 measurement within the fair value hierarchy. There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the years ended December 31, 2022 and 2021.

Valuation of preferred stock warrant liability

The warrant liability at December 31, 2021 was related to warrants (the "Warrants") to purchase shares of the Company's Series A1, B1, and C1 redeemable convertible preferred stock (see Note 11). The fair value of the warrant liability was determined based on inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The Company used the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the warrant liability. Key estimates and assumptions impacting the fair value measurement include (i) the fair value per share of the underlying shares of applicable series of redeemable convertible preferred stock issuable upon exercise of the Warrants, (ii) the remaining contractual term of the Warrants, (iii) the risk-free interest rate, (iv) the expected dividend yield and (v) expected volatility of the price of the underlying applicable series of redeemable convertible preferred stock. The Company estimated the fair value per share of the underlying applicable series of redeemable convertible preferred stock based, in part, on the results of third-party valuations and additional factors deemed relevant. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the Warrant. The Company estimated a zero expected dividend yield based on the fact that the Company has never

paid or declared dividends and does not intend to do so in the foreseeable future. As the Company has historically been a private company and lacks company-specific historical and implied volatility information of its stock, the expected stock volatility was based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the Warrant.

In connection with the IPO, all of the Company's outstanding preferred stock warrants were automatically converted to Class A common stock warrants. The Company performed a final fair value assessment of these warrants as of the date of its IPO which resulted in a charge of $8.2 million that was recorded within other income (expense) in the Company's consolidated statement of operations. The Company determined the conversion to Class A common stock warrants resulted in equity classification of the Class A common stock warrants and reclassified the fair value of the preferred stock warrant liability as of the IPO date into stockholders' equity (see Note 12).

The table below quantifies the weighted average of the unobservable inputs used to fair value the preferred stock warrant liability prior to their conversion into common stock warrants in connection with the Company's IPO in July 2021:

	Year Ended December 31, 2021
Fair value of Series A1 preferred stock	$ 3.01
Fair value of Series B1 preferred stock	$ 3.26
Fair value of Series C1 preferred stock	$ 3.30
Remaining contractual term (in years)	6.8
Risk-free interest rate	1.2%
Expected dividend yield	— %
Expected volatility	42.0%

The following table provides a rollforward of the aggregate fair values of the Company's preferred stock warrant liability, for which fair values are determined using Level 3 inputs (in thousands):

	Year Ended December 31, 2021
Balance, beginning of period	$ 4,117
Initial fair value of Series C1 preferred stock warrants	—
Change in fair value of preferred stock warrants	19,643
Conversion of preferred stock warrants to common stock warrants	(23,760)
Balance, end of period	$ —

4. Investments

Short-term and long-term investments by investment type consisted of the following (in thousands):

	December 31, 2022			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Short-term investments				
Certificates of Deposit	$ 491	$ —	$ —	$ 491
U.S. Government Treasury Bills	$ 32,115	$ 1	$ (40)	$ 32,076
U.S. Government Treasury Notes	49,625		(608)	49,017
	$ 82,231	$ 1	$ (648)	$ 81,584
Long-term Investments				
Certificates of Deposit	3,391	4	(36)	3,359
U.S. Government Treasury Notes - Maturity Up To Two Years	26,861	1	(431)	26,431
	$ 30,252	$ 5	$ (467)	$ 29,790

	December 31, 2021			
Short-term investments	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. Government Treasury Bills	$ 4,983	$ —	$ (2)	$ 4,981
U.S. Government Treasury Notes	$ 10,142	$ —	$ (13)	$ 10,129
	$ 15,125	$ —	$ (15)	$ 15,110
Long-term Investments				
U.S. Government Treasury Notes - Maturity Up To Two Years	$ 9,966	$ —	$ —	$ 9,966
	$ 9,966	$ —	$ —	$ 9,966

5. Inventory

Inventory consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Raw materials	$ 15,014	$ 10,135
Work in process	1,599	1,235
Finished goods	4,574	4,301
Total	$ 21,187	$ 15,671

Raw materials, work in process and finished goods were net of adjustments to realizable value of $1.1 million and $1.2 million, as of December 31, 2022 and 2021, respectively.

6. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Prepaid insurance	$ 1,500	$ 1,622
Contract asset	112	396
Deposits	1,055	1,262
Lease receivables, current portion	—	231
Other	705	440
	$ 3,372	$ 3,951

7. Property and equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Manufacturing and laboratory equipment	$ 13,408	$ 13,277
Computer hardware and software	1,651	1,742
Office furniture and fixtures	589	745
Leasehold improvements	8,260	3,012
Construction-in-process	1,712	4,313
	25,620	23,089
Less: Accumulated depreciation	(11,802)	(11,785)
	$ 13,818	$ 11,304

Depreciation and amortization expense related to property and equipment was $2.5 million and $1.5 million for the years ended December 31, 2022 and 2021, respectively. The Company had $2.3 million and less than $0.1 million of fully depreciated assets disposed of during the years ended December 31, 2022 and 2021, respectively.

8. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Accrued employee compensation and benefits expense	$ 3,217	$ 3,569
Accrued vendor expenses	3,212	5,500
Accrued warranty expense	872	598
Deferred rent, current portion	—	131
Accrued taxes	329	781
Other	520	338
	$ 8,150	$ 10,917

On August 11, 2022, the board of directors of the Company approved an organizational restructuring plan (the "Restructuring Plan") to right-size its cost structure based on its lowered 2022 outlook. The Company recorded a restructuring charge of $1.1 million in the third quarter of 2022 primarily related to severance, employee benefits,

outplacement and related costs under the Restructuring Plan. The Company made payments of $0.6 million during the year ended December 31, 2022 related to the Restructuring Plan and had $0.5 recorded within accrued expenses as of December 31, 2022.

9. Long-term debt

There was no long-term debt outstanding as of December 31, 2022 or December 31, 2021.

Term loan agreements

2020 Term Loan

In May 2020, the Company entered into a $60.0 million term loan facility with a new lender (the "2020 Term Loan"), which provided for borrowings of an initial $25.0 million tranche upon closing and options to borrow up to an aggregate of $35.0 million in two additional tranches of $20.0 million under the second tranche (the "Term B Loan") and $15.0 million under the third tranche (the "Term C Loan").

At closing, the Company issued warrants to purchase 1,195,652 shares of Series C1 Preferred Stock to the lender with an exercise price of $1.15 per share which were accounted for as debt discount. The Company paid a $0.8 million facility fee in connection with the term loan facility. The Company allocated the $0.8 million term loan facility fee to the three loan tranches on a pro-rata basis based on the amount available to be drawn down under each tranche. The Company allocated $0.3 million to the initial draw which was recorded within debt issuance cost as an offset to the carrying value of the 2020 Term Loan and amortized over the term of the loan within interest expense on the consolidated statement of operations. Additionally, the Company allocated $0.3 million to the Term B Loan and $0.2 million to the Term C Loan, all of which was recorded within prepaid expenses and other current assets on the consolidated balance sheet and is being amortized on a straight-line basis over the debt access period within interest expense on the consolidated statement of operations.

The Company incurred debt issuance costs of $1.5 million in connection with the 2020 Term Loan including $0.9 million of professional fees and $0.6 million for the fair value of the warrants issued with the debt. Interest expense on the 2020 Term Loan totaled $2.5 million for year ended December 31, 2021, which included amortization of the debt discount of $0.3 million.

In September 2021, the Company repaid the 2020 Term Loan and incurred a debt extinguishment loss of $3.1 million, which was comprised of a $1.8 million prepayment penalty, $1.1 million expense related to unamortized discounts, and $0.2 million in unamortized prepaid facility fees and other charges.

10. Redeemable convertible preferred stock

The Company has historically issued Series A1 redeemable convertible preferred stock (the "Series A1 Preferred Stock"), Series B1 redeemable convertible preferred stock (the "Series B1 Preferred Stock"), Series C1 redeemable convertible preferred stock (the "Series C1 Preferred Stock"), Series C2 redeemable convertible preferred stock (the "Series C2 Preferred Stock"), Series D1 redeemable convertible preferred stock (the "Series D1 Preferred Stock") and Series D2 redeemable convertible preferred stock (the "Series D2 Preferred Stock"). The Series A1 Preferred Stock, Series B1 Preferred Stock, Series C1 Preferred Stock, Series C2 Preferred Stock, Series D1 Preferred Stock, and Series D2 Preferred Stock are collectively referred to as the "Preferred Stock".

In March 2021, the Company issued and sold 22,086,725 shares of Series D1 Preferred Stock and 413,268 shares of Series D2 Preferred Stock to new and existing investors at a price of $3.60 per share for gross proceeds of $79.5 million

and $1.5 million, respectively. The Company incurred issuance costs in connection with this transaction of $2.7 million and recorded them as a reduction to the carrying value of the Series D1 Preferred Stock and Series D2 Preferred Stock.

On June 25, 2021, investors exchanged a total of 11,437,301 shares and 2,364,509 shares of Series C1 and D1 Preferred Stock to an equal number of shares of Series C2 and D2 Preferred Stock, respectively.

On July 14, 2021, the IPO resulted in the automatic conversion of all Series A1, Series B1, Series C1 and Series D1 preferred stock into 24,200,920 shares of Class A common stock and of all Series C2 and Series D2 preferred stock into 6,903,379 shares of Class B common stock. On July 19, 2021, the Company restated its certificate of incorporation and authorized 10,000,000 shares of $0.01 par value Preferred Stock.

11. Preferred stock warrants

In connection with the 2020 Term Loan, the Company issued 1,195,652 warrants to purchase shares of Series C1 Preferred Stock at an exercise price of $1.15 per share. The Company's warrants were immediately exercisable and expire 10 years after issuance. The fair value of the warrants on the issuance date was $0.7 million. Prior to the IPO, the Company also had outstanding warrants to purchase shares of Preferred Stock issued in connection with previous financing agreements.

In connection with the IPO, all of the Company's outstanding preferred stock warrants were automatically converted to Class A common stock warrants. The Company determined the conversion to Class A common stock warrants resulted in equity classification of the Class A common stock warrants and reclassified the fair value of the preferred stock warrant liability as of the IPO date into stockholders' equity (see Note 12).

12. Common stock and common stock warrants

As of December 31, 2022 and 2021, the Company's restated certificate of incorporation authorized the issuance of 210,000,000 shares of $0.01 par value Class A common stock.

On June 25, 2021, the Company filed an amended and restated certificate of incorporation, which effected a recapitalization of the Company's then outstanding common stock to Class A common stock and authorized an additional new class of common stock (Class B common stock). Rights of the holders of Class A common stock and Class B common stock are identical, except with respect to voting and conversion. On July 19, 2021, the Company filed an amended and restated certificate of incorporation which authorized Class A common stock and Class B common stock to 210,000,000 shares and 10,000,000 shares, respectively. As of December 31, 2022, there were 36,538,805 shares of Class A common stock issued and outstanding, and 5,553,379 shares of Class B common stock issued and outstanding.

Each share of Class A common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. The Company's Class B common stock is non-voting. Class A and Class B common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of Preferred Stock. As of December 31, 2022, no cash dividends had been declared or paid.

As of December 31, 2022, the Company had reserved 20,118,778 shares of Class A common stock for the exercise of outstanding stock options, vesting of restricted stock units, the number of shares remaining available for grant under the Company's 2021 Incentive Award Plan (see Note 13), the number of shares available for purchase under the Company's Employee Stock Purchase Plan (see Note 13), for the exercise of outstanding common stock warrants and for the conversion of Class B common stock.

Prior to its IPO, the Company issued warrants to purchase preferred stock in conjunction with previous financing arrangements. In connection with the IPO, all outstanding preferred stock warrants were automatically converted to Class A common stock warrants. The contractual terms of the converted Class A common stock warrants remained consistent with the original terms of the preferred stock warrants. The Company determined the event resulted in equity classification of the Class A common stock warrants and reclassified the fair value of the preferred stock warrant liability as of the IPO date into equity.

As of December 31, 2022 and 2021, warrants to purchase the Class A common stock outstanding consisted of the following:

	December 31, 2022			
Issuance date	Contractual term	Balance sheet classification	Shares of common stock issuable upon exercise of warrant	Weighted average exercise price
	(in years)			
July 24, 2017	10	Equity	17,194	$ 292.81
April 12, 2018	10	Equity	30,000	$ 1.00
July 14, 2021	10	Equity	975,109	$ 1.46
			1,022,303	

	December 31, 2021			
Issuance date	Contractual term	Balance sheet classification	Shares of common stock issuable upon exercise of warrant	Weighted average exercise price
	(in years)			
July 24, 2017	10	Equity	25,835	$ 295.15
April 12, 2018	10	Equity	30,000	$ 1.00
July 14, 2021	10	Equity	975,109	$ 1.46
			1,030,944	

13. Stock-based compensation

2010 Stock Option and Grant Plan

The Company's 2010 Stock Option and Grant Plan (the "2010 Plan") provides for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards and other stock-based awards to employees, officers, directors and consultants of the Company.

In March 2021, the Board of Directors approved an increase to the 2010 Plan shares by 382,889 shares. Following the effectiveness of the IPO, no additional awards are being granted under the 2010 Plan and shares of existing outstanding options that are forfeited or cancelled will be available for grant under the 2021 Incentive Award Plan.

2021 Incentive Award Plan

In July 2021, the Board of Directors adopted, and the Company's stockholders approved, the 2021 Incentive Award Plan (the "2021 Plan"), which became effective in connection with the IPO of Class A common stock. The 2021 Plan provides for the grant of stock options, including incentive stock options and non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based and cash-based awards. The 2021 Plan has a term of ten years. The aggregate number of shares of Class A common stock available for issuance under the 2021 Plan is equal to (i) 4,200,000 shares; (ii) any shares which are subject to the 2010 Plan awards that become available for issuance

under the 2021 Plan; and (iii) an annual increase for ten years on the first day of each calendar year beginning on January 1, 2022, equal to the lesser of (A) 5% of the aggregate number of shares of Class A common stock outstanding on the last day of the immediately preceding calendar year and (B) such smaller amount of shares as determined by the Board of Directors. No more than 33,900,000 shares of Class A common stock may be issued under the 2021 Plan upon the exercise of incentive stock options. As of December 31, 2022, there were 4,179,239 shares available for issuance under the 2021 Plan.

The 2021 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee or management if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of a share of common stock on the date of grant and the term of the stock option may not be greater than ten years. Stock options granted to employees, officers, and consultants typically vest over a four-year period, and stock options granted to members of the board of directors typically vest over a three-year period.

During the years ended December 31, 2022 and 2021, the Company granted to employees, officers and directors options to purchase 1,708,293 shares and 2,011,479 shares, respectively, of common stock. The Company recorded stock-based compensation expense for options granted to employees, officers, and directors of $2.8 million and $1.8 million during the years ended December 31, 2022 and 2021, respectively.

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option- pricing model to determine the grant-date fair value of stock options granted to employees and directors:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	2.14 %	1.02 %
Expected term (in years)	6.0	6.0
Expected volatility	43.3 %	44.4 %
Expected dividend yield	0 %	0 %

Stock options

The following table summarizes the Company's stock option activity since December 31, 2021:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding as of December 31, 2021	4,823,100	$ 5.06	7.62	$ 31,041
Granted	1,708,293	7.11		
Exercised	(572,932)	0.99		
Expired	(71,521)	11.04		
Forfeited	(845,632)	11.40		
Outstanding as of December 31, 2022	5,041,308	$ 5.05	7.55	$ 532
Options vested and expected to vest as of December 31, 2022	5,041,308	$ 5.05	7.55	$ 532
Options exercisable as of December 31, 2022	2,745,821	$ 3.38	6.58	$ 393

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock.

The intrinsic value of stock options exercised during the years ended December 31, 2022 and 2021 was $2.9 million and $1.6 million, respectively.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2022 and 2021 was $3.13 and $4.89, respectively.

Restricted stock

In February 2021, the Company granted 248,903 shares of restricted stock to an employee under the 2010 Plan with a four-year vesting term. In connection with the grant, the employee paid $0.5 million, which represents the $2.10 per share fair value of the common stock on the date of the restricted stock grant. The restricted common stock is no longer vesting due to the employees termination, and the Company expect to settle the restricted common stock in accordance with contractual provisions. At December 31, 2022 and December 31, 2021, the Company has $0.3 million and $0.5 million, respectively, in unvested restricted common stock liability included in accrued expenses and other long-term liabilities, respectively.

The following table summarizes the Company's restricted stock activity since December 31, 2021:

	Number of shares	Weighted average fair value (in years)
Unvested as of December 31, 2021	248,903	$ 2.10
Granted	—	
Vested	(93,338)	$ 2.10
Forfeited	—	
Unvested as of December 31, 2022	155,565	$ 2.10

Restricted stock units

Restricted stock unit grants to employees have a three-year vesting term in which vesting occurs annually on the anniversary of the grant date. The Company expenses the fair value of the restricted stock units over the vesting period and accounts for forfeitures prospectively as they occur. The Company recorded stock-based compensation expense for restricted stock units granted to employees and officers of $1.0 million and zero during the years ended December 31, 2022 and 2021, respectively.

The following table summarizes restricted stock units granted to Company employees during the year ended December 31, 2022:

	Number of shares	Weighted average fair value
Unvested as of December 31, 2021	—	
Granted	668,246	$ 7.12
Vested	—	
Forfeited	(136,125)	7.35
Unvested as of December 31, 2022	532,121	$ 7.06

The weighted average grant-date fair value per share of restricted stock units granted during the year ended December 31, 2022 was $7.12. There were no restricted stock units granted during the year ended December 31, 2021.

Stock-based compensation

Stock-based compensation expense was classified in the consolidated statements of operations as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Cost of revenue	$ 530	$ 329
General and administrative	2,630	1,025
Sales and marketing	475	346
Research and development	384	143
Total stock-based compensation expense	$ 4,019	$ 1,843

As of December 31, 2022, total unrecognized compensation expense related to unvested stock options held by employees and directors was $6.8 million, which is expected to be recognized over weighted average period of 2.4 years. Additionally, unrecognized compensation expense related to unvested restricted stock units held by employees and directors was $2.7 million, which is expected to be recognized over a weighted average period of 2.2 years.

2021 Employee Stock Purchase Plan

In July 2021, the board of directors adopted, and the Company's stockholders approved, the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective in connection with the IPO of Class A common stock. The aggregate number of shares of Class A common stock available for issuance under the 2021 ESPP is equal to (i) 400,000 shares and (ii) an annual increase for ten years on the first day of each calendar year beginning on January 1, 2022, equal to the lesser of (A) 1% of the aggregate number of shares of Class A common stock outstanding on the last day of the immediately preceding calendar year and (B) such smaller amount of shares as determined by the board of directors. No more than 6,300,000 shares of Class A common stock may be issued under the 2021 ESPP.

Under the 2021 ESPP, eligible employees may purchase shares of the Company's common stock through payroll deductions of up to 15% of eligible compensation during an offering period. Generally, each offering period will be for 6 months as determined by the Company's board of directors. In no event may an employee purchase more than 100,000 shares per offering period based on the closing price on the first trading date of an offering period or the last trading date of an offering period, or more than $25,000 worth of stock during any calendar year. The purchase price for shares to be purchased under the 2021 ESPP is 85% of the lesser of the market price of the Company's common stock on the first trading date of an offering period or on any purchase date during an offering period (March 14 or September 14).

During the year ended December 31, 2022, there were 51,833 shares of Class A common stock purchased under the 2021 ESPP. The Company recognized $0.1 million of expense related to the 2021 ESPP for the year ended December 31, 2022. As of December 31, 2022, 693,807 shares were available for future issuance under the 2021 ESPP.

The Company estimates the fair value of shares issued to employees under the 2021 ESPP using the Black-Scholes option-pricing model. The following weighted average assumptions were used in the calculation of fair value of shares under the 2021 ESPP at the grant date for the year ended December 31, 2022 (there were no offering periods for the year ended December 31, 2021):

	Year Ended December 31, 2022
Risk-free interest rate	2.60 %
Expected term (in years)	0.5
Expected volatility	49.1 %
Expected dividend yield	0 %

14. Income taxes

The components of the Company's loss before income tax (benefit) expense are as follows (in thousands):

	Year Ended December 31,	
	2022	2021
United States	$ (61,396)	$ (73,643)
Foreign	14	$ 210
Loss before income tax provision	$ (61,382)	$ (73,433)

The components of income tax (benefit) expense are as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Current income tax provision:		
Federal	$ —	$ —
State	—	—
Foreign	(576)	91
Total current income tax (benefit) expense	(576)	91
Deferred income tax provision:		
Federal	(13,347)	17,099
State	(2,824)	2,923
Foreign	—	—
Total deferred income tax provision	(16,171)	20,022
Change in deferred tax asset valuation allowance	16,171	(20,022)
Total (benefit) expense for income taxes	$ (576)	$ 91

During the years ended December 31, 2022 and 2021, the Company did not record income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from those items. The only income tax provision was generated from operations in Germany and

Switzerland. A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory income tax rate	21.0 %	21.0 %
State income taxes, net of federal benefit	3.6	(3.1)
Federal and state research and development tax credits	0.6	0.5
Unrecognized tax benefits reserve and interest change	1.0	(0.1)
Change in valuation allowance	(25.3)	26.4
Permanent differences	0.1	(0.5)
Section 382/383 limitation	—	(38.7)
Unrealized gain (loss) on value of warrants	—	(5.6)
Effective income tax rate	1.0 %	(0.1)%

Net deferred tax assets consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Net operating loss carryforwards	$ 46,387	$ 33,663
Research and development credit carryforwards	4,403	3,605
Research and development capitalized costs	6,119	4,041
Inventories	390	196
Lease liability	1,858	—
Accrued expenses	778	1,076
Unrealized loss	270	—
Other	712	139
Total deferred tax assets	60,917	42,720
Deferred tax liabilities:		
Right-of-use assets	(1,644)	—
Depreciation	(340)	(229)
Total deferred tax liabilities	(1,984)	(229)
Valuation allowance	(58,933)	(42,491)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had U.S. federal and state net operating loss ("NOL") carryforwards of $189.3 million and 87.1 million respectively, which may be available to offset future taxable income and begin to expire at various dates beginning in 2038 and 2032, respectively. Additionally, the Company had federal NOLs of $176.6 million generated since 2018 that will not expire. The Tax Cuts and Jobs Act (TCJA) enacted on December 22, 2017 limits a taxpayer's ability to utilize NOL deduction in a year to 80% taxable income for federal NOL arising in tax years beginning after 2017. The Coronavirus Aid, Relief, and Economic Security (CARES) Act enacted on March 27, 2020 removes the 80% taxable income limitation for federal NOL deductions in taxable years beginning prior to January 1, 2021.

As of December 31, 2022, the Company also had U.S. federal and state research and development tax credit carryforwards of $1.5 million and $2.9 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2038 and 2024, respectively.

Utilization of the U.S. federal and state NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has completed a Section 382 study through July 31, 2020 to assess whether one or multiple ownership changes(s) occurred. According to the results from the study, the Company has four ownership changes which occurred on July 1, 2009, April 3, 2014, July 25, 2017, and April 12, 2018, as defined by Section 382. These ownership changes materially limit the NOL carryforwards and research and development tax credits available to offset future tax liabilities. The Section 382 study concluded that $121.5 million of federal NOL carryforwards, $58.4 million of state NOL carryforwards, and $2.4 million of federal research and development tax credits will expire unutilized from these ownership changes. These expirations and unutilized NOL carryforwards and research and development tax credits have been reflected in the amounts of NOL carryforwards, research and development tax credits, and deferred tax assets disclosed above. The Company has not completed a Section 382 study for post July 31, 2020 transactions which could create an additional limitation although materially all of the current federal NOL carryforwards can be carried forward indefinitely.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. The Company considered its history of cumulative net operating losses incurred since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of as of December 31, 2022 and 2021. The Company reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets relates primarily to the decrease in NOL carryforwards and research and development tax credit carryforwards and were as follows (in thousands):

	December 31, 2022	December 31, 2021
Valuation allowance as of beginning of year	$ 42,491	$ 62,513
Increases recorded to income tax provision	17,726	13,067
Decreases recorded as a benefit to income tax provision	(1,284)	(33,089)
Valuation allowance as of end of year	$ 58,933	$ 42,491

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	December 31, 2022	December 31, 2021
Unrecognized tax benefits as of beginning of year	$ 623	$ 569
Additions for tax positions of prior years	—	54
Reductions for tax positions of prior years	(623)	—
Unrecognized tax benefits as of end of year	$ —	$ 623

The Company recognizes interest and penalties related to unrecognized tax benefits in U.S. Federal, state, and foreign income tax expense. For the each of years ended December 31, 2022, and 2021, the Company recognized less than $0.1 million in interest and penalties. The Company had approximately $0.1 million and zero of interest and penalties accrued as of both December 31, 2022 and 2021.

The Company files U.S. income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations in the U.S. The Company has not received notice of examination by any jurisdictions in the U.S.

The Company has a branch in Germany that has concluded its examination in its local country for the years ended December 31, 2016 through the year ended December 31, 2018. The tax resulting from the examination was less than the uncertain tax position recorded generating a tax provision benefit in the year of $0.6 million.

15. Net loss per share

Net loss per share attributable to the common stockholders

As of December 31, 2022, the Company had Class A common stock and Class B common stock. According to the Company's restated certificate of incorporation, both classes have the same rights to the Company's earnings and neither of the shares have any prior or senior rights to dividends to other shares.

The Company reported net loss attributable to common stockholders for the years ended December 31, 2022 and 2021, as such basic net loss per share attributable to common stockholders was the same as diluted net loss per share attributable to common stockholders. Basic and diluted net loss per share attributable to common stockholders was calculated as follow (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss	$ (60,806)	$ (73,524)
Accretion of redeemable convertible preferred stock to redemption value	—	(1,761)
Cumulative redeemable convertible preferred stock dividends	—	(2,747)
Net loss attributable to common stockholders—basic and diluted	$ (60,806)	$ (78,032)
Denominator:		
Weighted average Class A common shares outstanding—basic and diluted	36,727,742	16,568,267
Weighted average Class B common shares outstanding—basic and diluted	5,726,661	3,215,272
Total shares for EPS—basic and diluted	42,454,403	19,783,539
Net loss per share attributable to Class A common stockholders—basic and diluted	$ (1.43)	$ (3.94)
Net loss per share attributable to Class B common stockholders—basic and diluted	$ (1.43)	$ (3.94)

The Company's potentially dilutive securities, which include stock options, restricted stock, redeemable convertible preferred stock, common stock warrants and preferred stock warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2022	2021
Options to purchase common stock	5,076,650	4,823,100
Warrants to purchase common stock	286,324	294,964
Unvested restricted common stock	697,361	—
Options to purchase common stock under ESPP	181,558	—
	6,241,893	5,118,064

16. Leases

The Company adopted Topic 842 on January 1, 2022 using the optional transition method to the modified retrospective approach. The impact of the adoption of Topic 842 to the Company's applicable balance sheet items as of January 1, 2022 is presented in the table below (in thousands). The standard did not have a material impact to the Company's consolidated statements of operations, comprehensive loss or cash flows.

	As Reported December 31, 2021	Adjustments ASC 842 Adoption	Adjusted January 1, 2022
Assets			
Right-of-use assets, net, operating	$ —	$ 6,039	$ 6,039
Right-of-use assets, net, financing	—	366	366
Property and equipment, net	11,304	(351)	10,953
Total	$ 11,304	$ 6,054	$ 17,358
Total assets	$ 241,169	$ 6,054	$ 247,223
Liabilities and Stockholders' Equity			
Current liabilities:			
Lease liabilities, short-term, operating	$ —	$ 1,023	$ 1,023
Lease liabilities, short-term, financing	—	33	33
Accrued expenses	10,917	(160)	10,757
Total	$ 10,917	$ 896	$ 11,813
Total current liabilities	$ 18,166	$ 896	$ 19,062
Lease liabilities, long-term, operating	—	5,960	5,960
Lease liabilities, long-term, financing	—	341	341
Deferred rent, long-term	813	(813)	—
Other long-term liabilities	1,210	(330)	880
Total	$ 2,023	$ 5,158	$ 7,181
Total liabilities	$ 20,189	$ 6,054	$ 26,243
Total stockholders' equity	$ 220,980	$ —	$ 220,980
Total liabilities and stockholders' equity	$ 241,169	$ 6,054	$ 247,223

The Company determines if an arrangement is or contains a lease at inception, which is the date on which the terms of the contract are agreed to, and the agreement creates enforceable rights and obligations. Under ASC 842, a contract is or contains a lease when (i) explicitly or implicitly identified assets have been deployed in the contract and (ii) the customer obtains substantially all of the economic benefits from the use of that underlying asset and directs how and for what purpose the asset is used during the term of the contract. The Company also considers whether its service arrangements include the right to control the use of an asset. See Note 2 for more information on the Company’s accounting policies for leases.

The Company leases office and manufacturing space under operating lease agreements that have initial terms ranging from approximately 8 to 10 years. The Company leases furniture under a financing lease agreement that has an initial term of approximately 8 years. Some leases include one or more options to renew, generally at the Company's sole discretion, with renewal terms that can extend the lease term by up to 5 years. In addition, certain leases contain termination options, where the rights to terminate are held by either the Company, the lessor, or both parties. Options to extend a lease are included in the lease term when it is reasonably certain that the Company will exercise the option. Options to terminate a lease are excluded from the lease term when it is reasonably certain that the Company will not

exercise the option. The Company's leases generally do not contain any material restrictive covenants or residual value guarantees.

Supplemental cash flow information related to leases is as follows (in thousands):

	Year Ended December 31, 2022
Cash paid for amounts included in measurement of lease liabilities:	
Operating cash outflows - payments on operating leases	$ 1,207
Operating cash outflows - payments on financing leases	$ 42
Financing cash outflows - payments on financing leases	$ 33
Right-of-use assets obtained in exchange for new lease obligations:	
Operating leases	$ 7,605
Financing leases	$ 366

Supplemental balance sheet information related to the Company's operating and financing leases is as follows (in thousands):

	December 31, 2022
Operating Leases:	
Operating lease assets	$ 6,746
Operating lease liabilities, short-term	$ 729
Operating lease liabilities, long-term	6,898
Total operating lease liabilities	$ 7,627
Financing Leases:	
Office furniture and fixtures	$ 386
Accumulated depreciation	(69)
Net property, plant and equipment	$ 317
Current portion of long-term debt	$ 37
Long-term debt	304
Total financing lease liabilities	$ 341
Weighted-average remaining lease term - operating leases (in years):	6.54
Weighted-average remaining lease term - financing leases (in years):	6.50
Weighted-average discount rate - operating leases:	3.7 %
Weighted-average discount rate - financing leases:	12.0 %

The components of lease expense were as follows (in thousands):

	Year Ended December 31, 2022
Operating lease cost	$ 1,144
Financing lease cost - amortization of right-of-use asset	49
Financing lease cost - interest on lease liability	42
Short-term lease cost	59
Variable lease cost	617
Total lease cost	$ 1,911

Operating lease cost is recognized on a straight-line basis over the lease term. Total rent expense, including the Company's share of the lessors' operating expenses, was $1.8 million for the year ended December 31, 2022. Financing lease cost includes asset amortization on a straight-line basis over the lease term and interest accretion calculated using the effective interest method. Total financing lease asset depreciation and interest expense was $0.1 million for the year ended December 31, 2022.

In March 2022, the Company amended the lease for its office and manufacturing space in Lowell, Massachusetts (the "Amendment"). The Amendment increased the amount of facility space subject to the lease and extended the expiration of the lease from July 2026 to July 2029. The terms of the Amendment include options for a one-time, five-year extension of the lease and early termination of the lease in July 2026 (subject to an early termination fee), as well as a $0.3 million tenant improvement allowance. Monthly rent payments are fixed and future minimum lease payments under the lease (as amended) are $4.6 million. Included in the $4.6 million are leases with commencement dates expected later in 2023 and therefore are not recorded on the consolidated balance sheets as of December 31, 2022. The future minimum lease payments related to these leases are approximately $0.9 million. The Amendment qualified as a lease modification and resulted in a right of use asset and lease liability in the amount of $1.2 million and $1.3 million, respectively, recognized in March 2022, and an additional right of use asset and lease liability of $0.7 million recognized in May 2022.

Maturities of the Company's operating lease liabilities as of December 31, 2022 were as follows (in thousands):

	Operating Lease Maturities
2023	$ 1,273
2024	1,306
2025	1,339
2026	1,372
2027	1,404
Thereafter	2,223
Total lease payments	$ 8,917
Less imputed interest	(1,019)
Total present value of lease liabilities	$ 7,898

Maturities of the Company's financing lease liability as of December 31, 2022 were as follows (in thousands):

	Financing Lease Maturities
2023	$ 75
2024	75
2025	75
2026	75
2027	75
Thereafter	113
Total lease payments	$ 488
Less imputed interest	(147)
Total present value of lease liabilities	$ 341

Maturities of the Company's operating lease liabilities as of December 31, 2021 were as follows (in thousands):

	Year Ended December 31, 2021
2022	$ 1,139
2023	1,169
2024	1,199
2025	1,229
2026	1,044
Thereafter	1,953
Total minimum lease commitments	$ 7,733

17. Commitments and contingencies

Software subscription

During the year ended December 31, 2020, the Company entered into a non-cancelable agreement with a service provider for software as a service and cloud hosting services. As of December 31, 2022, the Company had committed to minimum payments under this arrangement totaling $0.8 million through January 31, 2026. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company had $0.1 million accrued for the software subscription as of December 31, 2022 and December 31, 2021.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to customers, vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and certain of its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2022 and December 31, 2021.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to legal proceedings.

18. Benefit plans

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the plan may be made at the discretion of the Company's board of directors. The Company made contributions of $0.8 million and $0.3 million to the plan during the years ended December 31, 2022 and 2021, respectively.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Spignesi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rapid Micro Biosystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2023

By: /s/ Robert Spignesi
Name: Robert Spignesi
Title: Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean Wirtjes, certify that:

1. I have reviewed this Annual Report on Form 10-K of Rapid Micro Biosystems, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2023

By: /s/ Sean Wirtjes
Name: Sean Wirtjes
Title: Chief Financial Officer
(principal financial officer and principal accounting officer)

Exhibit 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

In connection with the Annual Report of Rapid Micro Biosystems, Inc. (the "Company") on Form 10-K for the period ended December 31, 2022 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2023

By: /s/ Robert Spignesi
Name: Robert Spignesi
Title: Chief Executive Officer
(principal executive officer)

Exhibit 32.2

CERTIFICATION OF PRINCIPAL ACCOUNTING OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Rapid Micro Biosystems, Inc. (the "Company") on Form 10-K for the period ended December 31, 2022 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2023

By: /s/ Sean Wirtjes

Name: Sean Wirtjes

Title: Chief Financial Officer

(principal financial officer and principal accounting officer)

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