Rapid Micro Biosystems, Inc.

2024 ANNUAL REPORT

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, 2024
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.)**
25 Hartwell Avenue Lexington, MA	**02421**
(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 Capital 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 $28,178,899.

The number of shares of the registrant's Class A common stock, par value $0.01, outstanding as of February 24, 2025 was 38,737,161.
The number of shares of the registrant's Class B common stock, par value $0.01, outstanding as of February 24, 2025 was 4,499,529.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024 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, (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, (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 our ability to achieve positive cash flow;
- the anticipated impact of our operational efficiency program and our goal to achieve positive cash flow by the end of 2027, our efforts to reduce our use of cash for operating and investing activities and the assumptions underlying such goal;
- 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 platform and systems, our management of inventory and supply chain, our capital expenditures, our research and development activities and our sales, marketing, manufacturing and distribution activities;
- our ability to maintain and expand our customer base for our Growth Direct platform and systems, including expectations for customer adoption of new applications for our Growth Direct system;
- the effectiveness of our sales force and our sales processes;
- 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 and launch 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 inflation and fluctuations in interest rates on our business and operating costs;
- our ability to remain in compliance with the listing requirements of Nasdaq;
- our expectations regarding the potential impact of ongoing conditions in the financial markets and banking system on our operations and financial results; 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, 2024.

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.

INTERNET POSTING OF INFORMATION

We routinely post information that may be important to investors in the "Investors" section of our website at www.rapidmicrobio.com. We encourage investors and potential investors to consult our website regularly for important information about us. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K and shall not be deemed "filed" under the Exchange Act.

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 achieve and maintain positive cash flow and profitability;
- Our limited operating history makes it difficult to evaluate our future prospects and the risks and challenges we may encounter;
- Our business depends on the commercial 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 have in the past and may in the future 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 services to existing customers declines, our future operating results would be adversely affected;
- We may need or otherwise decide to raise additional capital to fund our existing operations, improve our platform or develop and commercialize new products or expand our operations;
- Our business relies heavily on establishing and maintaining our position in the market as a leading provider of automated microbial quality control ("MQC") testing;
- We may not be successful in expanding our business with existing customers and driving adoption of our solutions with new customers;
- 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 existing and future products on the Growth Direct platform, our business could suffer;
- We have limited experience in marketing and sales, and if we are unable to successfully market our products to new and existing customers, address our customers' needs or to expand our customer base, our business may be adversely affected;
- Our operational efficiency program, including a reduction in workforce, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business;
- 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;

- We may not realize the intended benefits of our strategic partnerships and other collaborations, and such relationships may introduce additional risks to our business.

- If our primary manufacturing facility or development facility become damaged or inoperable or we are required to vacate one or both facilities, our ability to conduct and pursue our manufacturing and/or development efforts would 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;

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

- We have been, and may continue to be, subject to the actions of activist shareholders or unsolicited acquisition proposals, 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 and cell and gene therapies, vaccines, 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, consistent and timely 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 and cell and gene therapies, vaccines, 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.

Our Growth Direct platform improves the traditional MQC process, maintaining the fundamental trusted method of MQC testing involving growth-based detection of viable organisms, 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 are on a mission to transform the MQC test market by standardizing 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 using 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 results in half the time or less compared to the traditional method, 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, Europe, and the Asia-Pacific region as well as distributors supporting certain territories. 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 98 sites in 18 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 162 systems and sold over 6 million consumables globally. Our customer base includes 70% of the top twenty largest pharmaceutical companies as measured by revenue and the manufacturers of approximately 17% of U.S. Food and Drug Administration ("FDA") approved cell and gene therapies, including 86% 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, 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 practices, or cGMP, and by other international regulatory agencies. Current MQC testing methods are manual, laborious, and have lacked innovation over the past several decades.

To guarantee the quality of the end products and the safety of patients who receive them, pharmaceutical 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, drug inputs 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.

The traditional method poses several operational problems:

- **Delayed results** — Colonies must grow to a certain size, typically around 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 typically 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.

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, and complete response letters, or CRLs, resulting in 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 and cell and gene therapies require complex multi-step manufacturing processes which demand rapid, 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.

We believe the total addressable market for MQC testing is large and growing. Based on a total global sales opportunity of an estimated 10,000 Growth Direct systems and our current pricing for our products, we estimate the market for system sales to be approximately $5.0 billion. In addition, based on an estimate of approximately 350 million tests conducted annually that could be addressed by our MQC testing solutions, we estimate the market for annual recurring sales of our consumables and services to be approximately $5.0 billion.

We are especially focused on serving the high-growth biologics and cell and gene therapy markets, which have the highest MQC testing intensity per batch of manufactured product, and are expected to grow at a faster rate than the broader market. 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 and other 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.

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 50% or more compared to 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.

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 traditional visual plate counting assays, allowing for operator familiarity of use, ease of integration into existing MQC protocols, and a streamlined regulatory validation process.

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. Studies of the Growth Direct comparing its vision-based detection and enumeration of colonies against the MQC gold-standard United States Pharmacopeia, or USP, <61> benchmark reference set of microorganisms demonstrate that the Growth Direct delivers the same results or better as traditional, manual verification of colonies.

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 less compared to the traditional method.

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.

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 proprietary consumables plates to capture test samples for analysis on the Growth Direct system. These applications include Environmental Monitoring ("EM"), Water ("W"), Bioburden ("BB"), and Sterility ("ST"). All 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 sample tracking and data integrity. Two bar code options can be used—one generated during our manufacturing process to define the test application, media type and expiration dates, and a second generated by the Growth Direct system at time of testing to define the sample ID and LIMS reference number.

We made the Growth Direct rapid sterility application available for commercial sale and placed the first rapid sterility system at one of our existing customers in the second quarter of 2024. We are continuing our efforts to scale our manufacturing capabilities for the rapid sterility application. This new test leverages our existing Growth Direct platform technology, providing customers with all the benefits they are accustomed to with the Growth Direct system. These benefits include full automation, enhanced data integrity, reduced human error and lower hands-on labor costs.

Sterility testing is 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.

Our new rapid sterility test is designed to deliver time to organism detection, or TTD, in as little as 12 hours and final time-to-result, or TTR, in as little as one to three days, enabling faster release of final pharmaceutical product, allowing manufacturers to benefit from faster time to market, less potential waste and reduced inventory and holding costs. This represents a significant improvement over widely used traditional test methods and provides compelling differentiation when compared to current rapid sterility products.

The program to develop our new rapid sterility test was historically 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. The contract funding with BARDA ended in December 2021.

Growth Direct LIMS connection software

Our Growth Direct software allows for two-way integration to a customer's 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. Through this offering, we help our customers validate their Growth Direct system for full routine use faster, typically in just three to nine months after the Growth Direct system is placed and installed, and develop confidence in the operation of our platform.

Support begins prior to system purchase when our sales representative brings in one of our validation experts for consultation about specific application requirements. Our validation team offers 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 annual service contracts. 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.

Integration with MODA® Platform

In the fourth quarter of 2024, Lonza, a Swiss multinational manufacturing company for the pharmaceutical, biotechnology and nutrition sectors, published a white paper discussing a recent collaboration involving our Growth Direct technology. Lonza sought to achieve paperless quality control laboratories using automated digital systems. As part of this ambition, Lonza sought an end-to-end automated solution to optimize EM at four of its cell and gene therapy manufacturing sites across North America, Europe, and Asia. Our Growth Direct system was successfully integrated with Lonza's MODA-EM Module to combine paperless processes with automated microbial enumeration for pharmaceutical quality control. The MODA-EM is a software module used by many pharmaceutical companies that enables paperless data collection and management for quality control microbiology. We believe this integration showcased the compatibility of our Growth Direct platform with commonly-used technologies at our customers and potential customers and may further promote its adoption. According to Lonza, the project provided a valuable blueprint for the industry to emulate.

Distribution and Collaboration Agreement

On February 21, 2025, we entered into a Distribution and Collaboration Agreement (the “Distribution Agreement”) with Millipore S.A.S., a subsidiary of the Life Science business of Merck KGaA, Darmstadt, Germany, which operates in the U.S. as MilliporeSigma ("MilliporeSigma”). Pursuant to the Distribution Agreement, we granted MilliporeSigma a global, co-exclusive right to sell our products, initially consisting of our Growth Direct systems and related consumables, into all fields related to industrial quality control applications in the pharmaceutical, medical device, personal care, cosmetics and food and beverage spaces in all regions of the world. During the term of the Distribution Agreement, MilliporeSigma will receive tier-based transfer pricing on such products. We will continue to directly market, sell, manufacture and distribute our products and provide all services to customers, including in respect of system installation, validation, maintenance and support.

Over the first two years of the Distribution Agreement, MilliporeSigma has committed to purchase a minimum number of Growth Direct systems. Thereafter, we and MilliporeSigma will evaluate and mutually agree on additional purchase commitments, if any. Pursuant to the Distribution Agreement, we are permitted to continue to sell our products independently and through our existing distributors, but we may not grant the right to sell the products covered by the Distribution Agreement to other third parties so long as a purchase commitment by MilliporeSigma is in place. The initial term of the Distribution Agreement is five years, unless earlier terminated by us or MilliporeSigma in accordance with its terms.

The Distribution Agreement also contemplates future collaboration by the parties, including with respect to sourcing materials and service delivery. In that regard, within six months, the parties intend to negotiate in good faith towards a supply agreement, pursuant to which the parties will explore cost-saving measures within our supply chain focused on accelerating gross margin improvement, particularly with respect to consumables. The focus of such supply agreement may include raw materials and components as well as manufacturing and supply chain services. The parties intend to share in any cost savings achieved in the supply of the products through this supply agreement. Additionally, within one year, the parties intend to negotiate in good faith towards a services agreement to permit us and MilliporeSigma to provide certain services to each other's customers. The parties also intend to explore additional opportunities for collaboration, such as joint development efforts for the enhancement of our products or introducing new products to be covered by the distribution arrangement.

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 accurate results in half the time or less 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, thereby 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 sets 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 50% or more, 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, 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, with at least 80 granted and pending patents globally, including 10 granted unexpired patents and 17 pending patent applications in the U.S. as of December 31, 2024.

- **Top-tier customers 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' workflows and the majority of our customers have purchased multiple systems and over 40% have deployed Growth Direct systems 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 costs to switch away from our systems that are 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** — Our Growth Direct provides for recurring revenues through ongoing consumables and service contracts. When our customers invest in our technology, they commit to 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 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, which is described in a case study written by us and several of our customers and published in the PDA Journal of Pharmaceutical Science and Technology in November 2022; and 3) and by helping our customers obtain regulatory acceptance from the FDA and EMA for the use of our technology and validation strategy for new drug applications with the bioburden application (environmental monitoring and water do not need regulatory license changes). Our technology has also been audited regularly by regulatory inspectors as part of routine audits of customer sites, with no citations received to date. Historically, we also secured substantial long-term government contracts from BARDA to support development of our rapid sterility kit as part of a 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.

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 and cell and gene therapy manufacturing — Our MQC process automation platform is particularly well-suited to the manufacturing of biologics and cell and gene therapies. Some of 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 contract development and manufacturing organizations, or 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 top 50 pharmaceutical companies and leading CDMOs — With the launch of our latest generation Growth Direct in 2017, 46 global customers have adopted the Growth Direct platform to automate MQC testing in 98 manufacturing facilities. We intend to drive global adoption by broadly seeking new customers in our core pharmaceutical manufacturing end markets. Our primary 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 target geographies include North America, Europe, and the Asia-Pacific region.

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 70% 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 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 and over 40% have deployed Growth Direct systems across multiple facility locations. We accomplish this expansion via direct peer-to-peer selling facilitated by our commercial team, and seek to partner 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 much faster 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 uniquely 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 that we made available for commercial sale in 2024; 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 customers 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 have a global commercial team that includes direct sales, commercial operations, validation, field services, strategic marketing, marketing communications and product management. This staff is located in North America, Europe and the Asia-Pacific region, and we also maintain direct customer support teams providing validation and/or field service capabilities in these territories. We intend to regularly evaluate and, as appropriate, adjust or expand our sales, support, and marketing efforts, including in the context of our distribution and collaboration arrangements.

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, our customer advisory board, 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 online phone and help desk, remote support and on-site field service.

Gross margin improvement

The majority of our customers are large global pharmaceutical manufacturers and CDMOs. In order to meet the expectations of our customers, we have made significant investments to build infrastructure and develop capabilities in areas such as procurement, manufacturing, distribution, quality and after sales service. In the third and fourth quarters of 2024, we achieved positive gross margins for the first time in our company's history. Maintaining these positive gross margins in future periods will depend on our ability to execute on our business objectives, including generating sufficient

revenues to cover the costs of producing and delivering our products and services. In addition, in order to further improve our gross margins, we seek to reduce such costs and are actively targeting numerous areas including:

- Reducing instrument and consumable product costs (materials and labor) through activities including strategic sourcing and product redesign;
- Increasing product manufacturing efficiency through activities including increased throughput of products currently manufactured and reduced variability of uptime on our automated consumables manufacturing line, moving manufacturing of other consumable products on to this automated line and manufacturing process optimization; and
- Increasing productivity and efficiency in our service organization.

At the same time, we also expect future revenues from both products and services to grow at rates significantly higher than the costs related to providing and supporting those products and services. As a result, we also expect increasing revenues from both products and services to contribute significantly to future gross margin expansion.

Manufacturing and supply

Our primary manufacturing facility is located in Lowell, Massachusetts. The facility has over 67,000 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 International Organization for Standardization (ISO)-8 cleanroom with ISO-5 laminar flow hoods for consumable manufacturing, and dedicated areas for media preparation. The facility has robust quality control from materials receiving to product distribution. In addition to our primary manufacturing facility, we have a back-up manufacturing facility for consumables in Lexington, Massachusetts.

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 facility, 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 most of our parts. We believe that having dual sources for our components helps reduce the risk of a production delay caused by a disruption in the supply of those components. 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 currently contract with third party vendors to sterilize our consumables before shipping to customers.

We continue to invest in our manufacturing capabilities to enhance our current 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.

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. 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.

As of December 31, 2024, we own 10 granted unexpired patents in the United States, 53 issued patents in foreign jurisdictions, including Australia, Canada, China, countries in Europe, India, Japan and Mexico, and 17 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. 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 2032 and 2045, 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.

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 offers a partially-automated system for MQC testing, and Clever Culture Systems, which offers an environmental monitoring product focused on the pharmaceutical microbiology market. 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. Smaller or early-stage companies may also prove to be significant competitors, particularly if they establish collaborative arrangements with large companies. 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.

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.

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 (ISO). 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.

Employees

As of December 31, 2024, we had 163 full-time employees across the globe, of which 34 were engaged in sales and marketing, 31 in research and development, 72 in manufacturing and service, and 26 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. 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, employee stock purchase plan (ESPP), pet insurance and paid time off.

We proudly support 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, our 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, of which membership grew by approximately 48% in 2024. 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 the 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. Our Code of Business Conduct and Ethics is also posted on our website located at https://investors.rapidmicrobio.com/corporate-governance/documents-and-charters. 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 achieve and maintain positive cash flow and profitability.

We have incurred significant losses since our inception. For the years ended December 31, 2024 and 2023, we incurred net losses of $46.9 million and $52.5 million, respectively. As of December 31, 2024, we had an accumulated deficit of $475.3 million. In July 2024, based on our enterprise-wide review of opportunities to realize operational efficiencies, we implemented certain cost-saving actions including a reduction in our workforce, the closure of open and planned positions and reductions in other non-headcount-related expenses across the business (the "Operational Efficiency Program"). However, in future periods, our operating expenses may continue to increase as we grow our business. Since our inception, we have financed our operations primarily from private placements of equity, 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. While we implemented our Operational Efficiency Program with the goal of achieving positive cash flow without additional financing, there can be no assurance that we will attain this goal. Our Operational Efficiency Program and intention to reach positive cash flow are based on our expectations of business performance that are generally consistent with our historical performance, including with respect to revenue and gross margins, which may not be replicated in future periods. Our goal also depends on our ability to realize additional cost savings that we believe are reasonably achievable, but are not guaranteed. We will need to generate significant additional revenue, significantly improve our gross margin and/or further reduce costs to achieve positive cash flow and profitability, and even if achieved, we cannot be sure that we will sustain positive cash flow and profitability for any substantial period of time. While our goal to achieve positive cash flow is underpinned by our recent and historical performance, such performance is not necessarily indicative of our future results.

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

We 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 our products had a longer commercial history. While our product and services revenue has continued to increase in recent periods, if our strategy to grow and scale our business is not successful, we may not be able to achieve continued revenue growth. 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 we seek to innovate in and disrupt the current microbial quality control market, 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 in the United States and abroad. We may not be successful in such a transition and, as a result, our business may be adversely affected.

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

Our business is dependent on sales of our Growth Direct systems and related consumables and services. 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 and 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. For example, we have experienced positive trends in our gross margins, improving from (3)% to 12% for the three months ended December 31, 2023 and December 31, 2024, and improving from (24)% for the twelve months ended December 31, 2023 to (0.4)% for the twelve months ended December 31, 2024. Expansion in gross margins in future periods may not be linear and may be subject to variability from period to period. 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 summer vacation and end-of-year periods;
- 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, completion, and output of manufacturing runs;
- the costs of manufacturing and shipping our products or of providing services to our customers, which may impact our operating gross margin in any given period;
- 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;
- our implementation of cost reduction efforts, and the resulting costs and savings related to these actions; 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 any single factor, or the cumulative effects of a combination of factors, 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 have in the past and may in the future 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 announce earnings guidance and other expectations regarding the future performance of our business in our quarterly and annual earnings conference calls, quarterly and annual earnings releases, or otherwise, that represents our management's estimates as of the date of such disclosure. 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. 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, the costs of manufacturing and shipping our products or of providing services to our customers, as well as the impact of global economic uncertainty and financial market conditions, geopolitical events, such as conflicts in Ukraine and the Middle East, rising inflation, rising interest rates, and public health crises, all of which have in the past and may in the future adversely affect our business and operating results. 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.

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 such disclosure. 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 services to existing customers declines, our future operating results would be adversely affected.

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. Our current commercial strategy includes targeting sales to customers that are receptive to entering into multi-system deals with us. As a result, in the near term, we have observed and we continue to expect that 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. For example, in the past, we have experienced occasions in which customers' facilities in which our Growth Direct systems were used have been closed or sold, which resulted in the reduction, suspension, or cessation of purchases of consumables at such sites. If we are unable to sell our Growth Direct system to new customers, if our existing customers do not expand their use of our systems, 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 or otherwise decide to raise additional capital to fund our existing operations, improve our platform or develop and commercialize new products or expand our operations.

We expect that our efforts to maintain our position in the MQC industry, including improving our Growth Direct platform and developing new products, will continue to require significant resources. Based upon our current operating plan, we believe our existing cash, cash equivalents, and short-term investments as of December 31, 2024 of $50.7 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 of this Annual Report on Form 10-K. 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 cash flow, 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. While we implemented our Operational Efficiency Program with the goal of achieving positive cash flow without additional financing, there can be no assurance that we will attain this goal. Our Operational Efficiency Program and intention to reach positive cash flow are based on our expectations of business performance that are generally consistent with our historical performance, including with respect to revenue and gross margins, which may not be replicated in future periods. Our goal also depends on our ability to realize additional cost savings that we believe are reasonably achievable, but are not guaranteed. In addition, we may selectively and opportunistically 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 funding requirements may increase significantly if one or more of the other risks, events or circumstances described elsewhere in these risk factors are realized. 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.

Risks Related to Our Business and Strategy

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 our position as a leader in automated MQC testing and the competitive advantages that such 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 and are able to obtain traction with customers, we may not be able to maintain our lead position and execute our business strategy. If we are unable to expand or continue to expand our customers in growing areas of drug manufacturing, such as biologics and 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.

We may not be successful in expanding our business with existing customers and driving adoption of our solutions with new customers.

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 expand our Growth Direct platform to customers who manufacture cell and gene therapies.

Our ability 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, and cell and gene therapies in particular, 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. For example, we recently made generally available for commercial sale our rapid sterility application for use on the Growth Direct system, for which we have expended significant time and resources to develop. We placed our first Growth Direct rapid sterility system with an existing customer in the second quarter of 2024. We are continuing to scale our manufacturing capabilities for the rapid sterility application. However, there can be no assurance that we will successfully commercialize this new sterility test, scale our manufacturing capabilities to support customer demand or that this product will achieve broad acceptance by customers. Furthermore, because this is a new application, we may encounter technical or other product challenges as customers adopt and implement Growth Direct rapid sterility into their workflows. 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 existing and future products on the Growth Direct platform, 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. Products in our inventory that have shelf lives may also expire before we are able to sell them to customers. We may be unable to sell such excess inventory, which could adversely impact our working capital and result in our expenditure of resources to accumulate inventory that we are unable to sell. 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.

In addition, if we commercialize additional products in the future, 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 successfully market our products to new and existing customers, 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 have recently expanded our sales organization and implemented measures designed to improve the effectiveness of our salesforce, but there can be no assurance that those efforts will translate into improved commercial outcomes.

Competition for employees capable of selling expensive instruments into the pharmaceutical 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. 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.

We may engage distributors or other strategic partners for the sale of our products, including in jurisdictions outside of the U.S. There can be no assurance that we can identify and enter into arrangements with distributors or other strategic partners on terms that are favorable to us or at all. In some cases, 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 industry experience and knowledge, including that of jurisdictions outside of the U.S. Even if we are successful in identifying distributors, such distributors may engage in sales practices that violate federal, state, local or foreign laws or our internal policies. Furthermore, with respect to distributors in non-U.S. jurisdictions, 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.

Our Operational Efficiency Program, including a reduction in workforce, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In July 2024, we implemented our Operational Efficiency Program, which included a reduction in our workforce, the closure of open and planned positions and reductions in other non-headcount-related expenses across the business. While the goal of our Operational Efficiency Program is to achieve positive cash flow by the end of 2027 without additional financing, there can be no assurance that we will attain this goal. Our Operational Efficiency Program and intention to reach positive cash flow are based on our expectations of business performance that are generally consistent with our historical performance, including with respect to revenue and gross margins, which may not be replicated in future periods. Our goal also depends on our ability to realize additional cost savings that we believe are reasonably achievable, but are not guaranteed.

As a result, we may not realize, in full or in part, the anticipated benefits and cost savings from our Operational Efficiency Program due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from our Operational Efficiency Program, while maintaining our business performance, our operating results and financial condition could be adversely affected. For example, changes in our commercial salesforce may adversely impact our ability to sell our products to customers in any or across geographies. Reduced headcount in our research and development teams may impair our ability and efforts to develop and commercialize new or improved products. Decreased resources within our operations teams may negatively affect our ability to build our products in an efficient manner or at all, and may contribute to unfavorable movement in gross margins. Within our general and administrative teams, reductions may result in degraded support to our other business functions, including in respect of finance, legal and human resources.

If future results of operations lag our expectations, we may undertake additional workforce reductions or restructuring activities. Our Operational Efficiency Program 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 development plans, each of which could have an adverse impact on our business, operating results and financial condition. Our Operational Efficiency Program 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 devoted significant efforts to streamline our business operations and refocus our personnel strategy, with the goal of achieving sustained 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. As needed, we expect to selectively 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, sales and marketing staff, software, manufacturing, distribution and quality assurance personnel in order to develop and launch new products, innovate and

improve our existing products and successfully commercialize our platform and solutions. 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 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.

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, robustness and features;
- 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, is growing and may continue to 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. Although 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 migrates away from using our solutions to that of a competitor. Without the timely introduction of new products, services and enhancements, our offerings will likely become less competitive over time, thus harming our competitive position. In some instances, specific circumstances of particular customer(s) may require us to innovate on our products to meet those needs, and failure to do so may hinder our ability to sell our solutions to or maintain our relationships with those customer(s). 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 achieve 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 or may not otherwise 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. There could be undetected errors or defects despite our rigorous testing of our platform and its components, and the Growth Direct platform may otherwise not meet the expectations of our customers. 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, such as those associated with repairs, replacements or reacquisitions of our systems. If such challenges occur, 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 or reacquired Growth

Direct systems under warranty. Our failure to prevent or adequately address any of foregoing risks 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 or that of competitive products, and will enable more efficient or improved drug manufacturing. Pharmaceutical companies and contract development and manufacturing organizations, or CDMOs, 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, or new methods of automated MQC testing being developed and sold by emerging competitors. There can be no guarantee that our platform will meet the expectations or needs of these companies or CDMOs.

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 and competitive products 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, contract organizations 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. 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 successful sales and the 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.

Our Operational Efficiency Program that we implemented in July 2024 included a reduction in our workforce and the closure of open and planned positions, and is intended to reduce our use of cash for operating activities with the goal of enabling us to achieve positive cash flow without additional financing. This action, and any future similar 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. For example, in July 2024, many industries and businesses were disrupted globally by a software glitch associated with Crowdstrike's cybersecurity software. While we did not experience material downtime in our information technology systems, similar events in the future may disrupt our operations. Moreover, despite network security and back-up measures, our servers remain 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.

Cybersecurity incidents and data breaches, data loss 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, 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 and may continue to experience in the future, attacks by hackers or viruses or data breaches due to employee error, malfeasance or other malicious or inadvertent disruptions. Further, attacks upon information technology systems, including ransomware attacks and digital extortion, business email compromises, social engineering, including phishing attacks, denial of service attacks, computer malware, malicious codes, viruses, wrongful intrusions, wrongful conduct by insider employees or vendors, data breaches, and other malicious internet-based activity 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 victim entity, 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 notifications and/or disclosures, as well as 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 cybersecurity incidents and data 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.

Further, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach.

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, safeguard and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Our efforts to comply with such laws could require significant resources and expenses and 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 of personal information we collect and process. The regulatory environment in the U.S. and abroad 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 laws relating to the privacy and security of personal information impose obligations on how we collect, store, use, transmit, secure, and otherwise process such data. These laws, such as Section 5 of the Federal Trade Commission Act, the California Consumer Privacy Act (CCPA) and numerous other U.S. state consumer privacy laws, generally provide consumers right to restrict our use of their personal information and limit our disclosure to third parties. The CCPA, for example, establishes data privacy rights for California residents and obligates covered businesses to comply with specific requirements related to data use, transparency, deletion, and opt-out of the selling or sharing of personal information. 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. Such laws may have potentially conflicting requirements that would make compliance challenging.

More than a dozen other U.S. states have passed their own comprehensive privacy laws with more expected to pass in the coming years. Such laws 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 adverse changes in business data collection and use practices and policies. Some states have also either passed or proposed privacy and data protection legislation specifically protecting health-related information. For example, Washington state's My Health My Data Act, which entered into force on March 31, 2024, expands the definition of consumer health data, affords consumers with privacy rights and creates a private right of action, which could increase the risk of litigation. The existence of varying and potentially conflicting comprehensive privacy laws in different U.S. states could make our compliance obligations more complex, may require us to expend significant resources in connection with our compliance efforts and subject us to enforcement actions or otherwise incur liability for any actual or perceived noncompliance, including litigation, enforcement actions and reputational harm leading to a loss of existing and future business.

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, with respect to the collection and processing of personal data relating to our personnel, customers and establishments in Europe, we are subject to the EU General Data Protection Regulation, or EU GDPR, the UK General Data Protection Regulation (UK GDPR), as well as applicable data protection laws in effect in the Member States of the EEA and in the UK (including the UK Data Protection Act 2018) which govern the processing of personal data in connection with (a) our offering of goods or services to/the monitoring of the behavior of individuals in the UK and EEA; or (b) the activities of any of our establishments in the UK or any EEA Member State, such as our German subsidiary. In this Annual Report on Form 10-K, references to "GDPR" encompass both the EU GDPR and UK GDPR, unless specific otherwise. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requiring disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, limiting retention periods for personal data, creating mandatory data breach notification requirements in certain circumstances, and requiring that certain measures (including contractual requirements) are put in place when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA or the U.K., including transfers of personal data from Europe to the United States in certain circumstances. Any inability to transfer personal data from Europe to the United States in compliance with data protection laws may impede our operations and may adversely affect our business and financial position. Switzerland has also implemented data protection laws with similar obligations and triggers to the GDPR which we may be subject to in connection with our Swedish subsidiary, personnel and customers.

The complex and evolving nature of data protection laws and regulations may lead to additional compliance costs, including as a result of diverging international data privacy laws and regulations and related uncertainties. There can be no assurances that we will be successful in our efforts to comply with the multitude of U.S., state, federal, and foreign privacy and data security laws, and violations of such laws could result in regulatory investigations and significant fines, as well as civil claims including class actions, and reputational damage.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, Executive Order 14117 on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern, as implemented by Department of Justice regulations issued in December 2024, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

Like many companies, we use artificial intelligence and machine learning (AI) technologies, including generative AI, to efficiently grow and manage our business. These technologies have increasingly been the focus of attention for lawmakers and regulators around the globe.

The use of AI tools by our employees or third parties on which we relay may increase over time and may lead to unauthorized or unintended disclosures of confidential information (including personal information or proprietary data). In addition, we may use AI outputs to inform certain decisions we make, and the outputs we rely on may be incomplete, inaccurate, or otherwise flawed, despite appearing to be accurate and reliable. Potential flaws in the AI tools that we use, or our incorrect application of them, could cause us to make decisions that unfairly bias certain individuals or classes of individuals and adversely impact their rights. As a result, we could face adverse consequences, including exposure to reputational and competitive harm, loss of business, and legal and contractual liabilities. A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with safety requirements, intellectual property and privacy laws, ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and

lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict.

We may evaluate strategic opportunities 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.

As part of our business strategy, we may opportunistically pursue acquisitions of businesses and assets that we believe may be complementary or synergistic with our own, or 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 businesses or assets 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 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 fund any such acquisitions or joint ventures, we may choose from a number of financing alternatives that may be accompanied by drawbacks. For example, if we incur debt, we may be required to abide by restrictive covenants or grant security interests in our assets to secure such debt. If we issue equity as consideration, such issuances would dilute the ownership of our stockholders or, in the case of preferred equity, may impose preferential terms that are senior to those of our common 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.

We may not realize the intended benefits of our strategic partnerships and other collaborations, and such relationships may introduce additional risks to our business.

We have entered and continue to seek to enter into strategic partnerships and other kinds of collaborations as part of our business strategy. While we believe that these and similar relationships are critical to our ability to innovate, expand our market reach and deliver comprehensive solutions to our customers, they involve numerous risks and uncertainties. We may not achieve the expected benefits from these types of strategic collaborations and these relationships may introduce complexities and risks into our business.

For example, in January 2025, we announced that Lonza successfully integrated our Growth Direct system with its MODA-EM module to combine paperless processes with automated microbial enumeration for pharmaceutical quality control, as discussed further under Item 1. Business—Integration with MODA® Platform. There can be no assurance that the benefits observed by Lonza will be replicated in the experiences of other customers, or that such benefits, even if achieved by other customers, will drive further market adoption of our platform. In addition, as a large, multinational manufacturing company, Lonza may seek similar collaboration opportunities to integrate other technologies and platforms, including those of our competitors. As a result, despite the current integration of our Growth Direct system with Lonza's MODA-EM module, we may not experience increased sales of our products.

In addition, in February 2025, we entered into a Distribution and Collaboration Agreement with Millipore S.A.S., a subsidiary of the Life Science business of Merck KGaA, Darmstadt, Germany, which operates in the U.S. as MilliporeSigma, pursuant to which we granted our collaborator the co-exclusive right to distribute certain of our products, as described further under Item 1. Business—Distribution and Collaboration Agreement with Millipore S.A.S. Our ability to generate sales and product revenue under this agreement is dependent on the performance and cooperation of our distributor. Our distributor may not meet its obligations, including with respect to its initial purchase commitments, experience financial difficulties, undergo adverse changes in its business or shift its focus away from selling our products. Furthermore, during the term of the agreement, we are prohibited from engaging other third parties to sell our products so

long as a purchase commitment by the distributor is in place. There can be no assurance that our distributor will make additional commitments to purchase our products. The interests of our distributor may diverge from ours, and disagreements over key decisions or strategies could lead to conflict, impaired collaboration or the dissolution of the collaboration. We may not successfully manage channel conflicts with our distributor and our selling efforts to certain customers may overlap with those of our distributor, which may lead to disputes over which party should receive credit for a given sale or which party should manage the customer relationships that are created or deepened during the course of the collaboration. Our distributor is headquartered in France and, as a subsidiary of a large, multinational science and technology company, may have different corporate cultures, operational procedures and business practices, all of which can be challenging to manage. In engaging in its selling and marketing efforts, our distributor may place substantial and time-sensitive demands on the attention and resources of our employees and management, including those related to answering questions and fielding requests from its salesforce and otherwise assisting our distributor with its commercial activities in respect of our products, all of which may divert the focus of our personnel.

Our distribution arrangement includes tier-based transfer pricing on the covered products, which may adversely impact the margins that we achieve on sales of our products. If our distributor achieves commercial traction with our products, we may become reliant on our distributor through increased sales to customers. In addition, if we enter into a supply agreement or a services agreement as contemplated by our distribution and collaboration agreement, we may become dependent on the distributor in our efforts to service our customers and lower the costs of our products. In that event, we may suffer significant and adverse consequences to our business operations, sales, revenue, product margins and customer experience in the event our collaboration is terminated.

Additionally, while our distribution arrangement is global and covers all fields related to industrial quality control applications in the pharmaceutical, medical device, personal care, cosmetics and food and beverage spaces, we have historically focused our selling efforts to pharmaceuticals manufacturers and specifically in North America, Europe and, to a lesser extent, Asia-Pacific. There can be no assurance that our distributor will be successful in achieving market penetration of our products in additional fields or geographies. Expanding the application of our products into such additional fields and geographies may introduce additional risks, including in respect of regulatory and compliance, as we seek to navigate and comply with laws and regulations applicable to such fields and territories. Any non-compliance by us or our distributor with applicable laws and regulations could lead to legal liabilities, financial penalties and reputational damage for us.

If we are unable to effectively manage these risks and uncertainties, our relationships with current and prospective collaborators may not deliver the expected benefits, and may also introduce risks that could adversely affect our business operations, financial condition, and results of operations.

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

Our standard terms and conditions for customers generally provide for 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, 2024, we had an amount reserved for warranty costs of $0.5 million. Substantial amounts of warranty claims could have a material adverse effect on our business, financial condition and results of operations.

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, cybersecurity, 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.

Our business strategy includes achieving significant and increasing sales to customers and sites outside of the U.S. As a result, we have established relationships with customers outside of the U.S. and in the future intend to expand our international customer base. To that end, our staff is located in North America, Europe and the Asia-Pacific region, and we intend to further expand our international presence. 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 have resulted or could in the future result in tariffs and other protective measures taken by the U.S. or other countries;
- 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. 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. In addition, in certain geographies, we may need to rely on distributors, partners and other collaborators to penetrate those markets, and there can be no assurance that we will be able to secure relationships with such parties or that such parties will comply with legal and regulatory standards that are applicable to our business. 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.

High inflation rates could negatively impact our revenues and profitability if increases in the prices of our Growth Direct systems or a decrease in customer 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.

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 spending by our customers or they have 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 geopolitical events 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, including as a result of an economic downturn and geopolitical events, such as changes in U.S. federal policy that affect the geopolitical landscape. Changes to policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. For example, during the prior Trump administration, increased tariffs were implemented on goods imported into the U.S., particularly from China, Canada, and Mexico. On February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10% additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them. The global credit and financial markets have also generally experienced severe volatility and disruptions in the past several years. A severe or prolonged economic downturn,

such as the global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur.

A weak or declining economy could also result in supply chain disruptions, volatile demand for our products, abrupt changes in our customers' buying patterns, limitations on our customers' access to financial resources and ability to satisfy obligations to us, or other adverse impacts to our ability to place our Growth Direct systems. Furthermore, although we do not have any customer or direct supplier relationships in Ukraine, Russia or the Middle East at this time, the ongoing military conflicts in those regions and related sanctions, as well as export controls or actions that may be initiated by nations including the United States, the European Union, Russia or other jurisdictions, and other potential uncertainties could adversely affect our business and/or our supply chain, business partners or customers. 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.

Risks Related to Manufacturing and Supply

If our primary manufacturing facility or development facility becomes damaged or inoperable or we are required to vacate one or both facilities, our ability to conduct and pursue our manufacturing and/or development efforts would be jeopardized.

We currently conduct our primary development and manufacturing efforts at our facility located in Lowell, Massachusetts, and our primary development efforts at our facility located in Lexington, Massachusetts. Our facilities 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 Lowell 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. Disruptions in our manufacturing operations could also adversely affect our efforts to improve the gross margins of our products. Furthermore, our facilities 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 facilities, 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. To mitigate certain of these risks associated with the manufacture of our consumables at our Lowell facility, our Lexington, Massachusetts facility has been designed to serve as a back-up consumable manufacturing facility if needed. While we believe that we could, if necessary, transfer our manufacturing capabilities to the Lexington facility, there can be no assurance that we would achieve such transfer in a timely manner or at all and mitigate disruption to our overall business.

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 discontinued production of the camera, and we have obtained a supply we believe is sufficient to allow us to meet customer demand while qualifying 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.

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property related to our products and technologies, particularly patents, in the United States and other countries. Obtaining, maintaining and enforcing patents in our industry is costly, time consuming and complex, and we may fail to do so with respect to patents on important products, services and technologies in a timely fashion, at a reasonable cost or at all, in the U.S. or in other potentially relevant jurisdictions. 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. Even if we can patent the technology, the patent may be limited in scope, and such limitation may be inadequate to protect our products, or to block competitor products that are similar or adjacent to ours. In addition, 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. 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. 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 issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications may be challenged in opposition, derivation, reexamination, inter partes review, post-grant review, interference, or in court proceedings. See "*—We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful*." Any successful challenge to our patents 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. 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.

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, subject to applicable extensions. Once 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 2045, certain of our earlier U.S. patents are scheduled to expire in 2032. 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 similar or identical products 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 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 earliest patents expire. Any disclosure, either intentional or unintentional, by our employees, consultants or vendors, 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. From time to time, we may share trade secrets with customers, collaborators, suppliers, vendors and other third parties, 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 and expensive to protect. We take steps to protect our intellectual property and proprietary technology by maintaining physical and electronic security measures and by entering into agreements, including confidentiality, non-disclosure 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, if any of these parties breach the agreements and disclose our proprietary information, including our trade secrets, we may expend significant time and resources to assert our rights against such parties and we ultimately may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection 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.

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

We intend to continue to expand our commercial operations in territories outside the United States, including in Europe and the Asia-Pacific region. 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 objections that we may be unable to overcome. In addition, third parties may be given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. 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 may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or by contract. 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 our development activities 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 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 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, important intellectual property. 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.

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 third-party patent and other proprietary rights. 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, fees 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.

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 may 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 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.

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. 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.

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 Stock Market, the liquidity of our Class A common stock would be adversely affected and the market price of our common stock could decrease.

The Nasdaq Stock Market LLC ("Nasdaq"), on which our Class A common stock is currently listed has minimum requirements that a company must meet in order to remain listed, including that we maintain a minimum closing bid price of $1.00 per share for our Class A common stock. We have previously received notifications from Nasdaq that we were not in compliance with its minimum bid price requirements. Most recently, on February 2, 2024, we received a letter from Nasdaq notifying us that the closing bid price of our Class A common stock was below $1.00 per share for the preceding 30 consecutive trading days and that, as a result, the company was not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Global Select Market under Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). In order to extend the time period during which we were required to seek to regain compliance with the Bid Price Requirement, we transferred the listing of our Class A common stock to the Nasdaq Capital Market effective as of August 5, 2024. On November 11, 2024, we received a letter from the Staff indicating that we had regained compliance with the Bid Price Requirement, following ten (10) consecutive business days during which the closing bid price of our Class A common stock was equal to or greater than $1.00 per share.

Even though we have regained compliance with the Bid Price Requirement, there can be no assurance that we will in the future continue to comply with the Bid Price Requirement and other continued listing standards of Nasdaq in the future. If we fail to comply with one or more other Nasdaq listing rules, our Class A common stock may also become subject to delisting as a result of such deficiencies, 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.

A delisting of our Class A common stock from Nasdaq could materially reduce the liquidity of our Class A common stock and result in a corresponding material reduction in the price of our Class A common stock. In addition, delisting could harm our ability to raise capital on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors and employees and fewer business development opportunities. Further, any potential delisting of our Class A common stock from Nasdaq would also make it more difficult for our stockholders to sell their shares in the public market.

Sales of a substantial number of shares of our Class A common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could depress the market price of our Class A common stock.

Except for shares of our Class A common stock that are held by our directors, officers and affiliates, which are subject to certain restrictions on resale under the Securities Act of 1933, as amended, or the Securities Act, and the rules and regulations promulgated thereunder, all other shares of our Class A common stock listed on Nasdaq are generally freely tradable. These include shares held by stockholders, including those that hold large positions in our securities, that are not our affiliates as such term is defined under Rule 144 of the Securities Act. Sales of a substantial number of shares of our common stock by such stockholders, particularly at a time when daily trading volumes in our stock are low, has had and may continue to have the effect of depressing the trading price of our common stock. Such downward pressure in the trading price of our common stock may also be exerted by investors' expectations or perceptions that such sales could occur.

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. Furthermore, 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, have the ability to control all matters submitted to stockholders for approval.

Based on the number of shares of Class A common stock outstanding as of December 31, 2024, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock 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 that require a majority vote, 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 a "smaller reporting company," and the reduced disclosure requirements applicable to us 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 December 31, 2026. However, if certain events occur prior to such date, including if we become a "large accelerated filer," our annual gross revenues exceed $1.235 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 December 31, 2026. 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 are also 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 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 timeline as other public companies.

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 control over financial reporting is effective for a given period, we may in the future identify one or more material weaknesses, 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 and do not qualify as a non-accelerated filer. 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.

We have been, and may continue to be, subject to the actions of activist stockholders or unsolicited acquisition proposals, 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 stockholders urging us to take certain corporate actions, such as changing the composition of our board of directors, our management team, selling our company or similar strategic initiatives. If activist stockholder 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, in connection with the unsolicited proposal from a stockholder to acquire all of our outstanding common stock in June 2022, we retained the services of various advisors, including legal, financial, and communications professionals, to advise us in considering the stockholder'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 activist stockholder 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 ability to use our net operating losses and research and development tax credits to offset future taxable income or income tax liabilities is subject to certain limitations.

As of December 31, 2024, we had U.S. federal and state net operating loss, or NOL, carryforwards of $268.4 million and $114.8 million, respectively. These NOLs 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 $255.6 million generated since 2018, which do 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 $2.8 million and $3.2 million, respectively. These tax credits may be available to offset future tax liabilities and begin to expire in 2038 and 2025, 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 11—*Income taxes* to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

General risk factors

There is increased attention to environmental, social and governance matters that may impact our business.

There is an increasing focus by U.S. and international regulators, customers, and other stakeholders on environmental, social and governance ("ESG") matters in our industry. Complying with new laws or regulations concerning climate related matters or other ESG matters will result in increased compliance costs and create additional non-compliance risks. Failure to adequately meet our customer's expectations or comply with any such laws or regulations may result in loss of business and an adverse impact on our business, financial condition, and results of operations.

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.

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. 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 could 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, a diversion of management's attention and resources, and negative publicity, all of which could harm our business.

Conditions in the banking system and financial markets, including the failure of banks and financial institutions, could have an adverse effect on our operations and financial results.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial

services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10 and March 12, 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of Silicon Valley Bank, Signature Bank and Silvergate Capital Corp, respectively, after each bank was unable to continue their operations. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future.

Although we do not maintain any deposit accounts, credit agreements or letters of credit with any financial institution currently in receivership, we are unable to predict the extent or nature of the impacts of these evolving circumstances at this time. If, for example, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened. While it is not possible at this time to predict the extent of the impact that the failure of these financial institutions or the high market volatility and instability of the banking sector could have on economic activity and our business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

In an effort to protect our business against cybersecurity threats, we have implemented a cybersecurity risk management program that is integrated with our internal risk management processes and designed to identify and protect against cyber threats as well as to respond to and recover from cyber incidents, as applicable. Our cybersecurity risk management program is informed by industry standards, such as the National Institute of Standards and Technology (NIST) Cybersecurity Framework, and is supported by periodic internal and external information security assessments and testing.

We have also established incident response policies and procedures, overseen by our Information Technology, or IT, Director, to review and classify cybersecurity incidents and to define roles and responsibilities for response and remediation in the event of a cyber incident. We also have implemented a process to provide cybersecurity awareness training to employees during onboarding and on an annual basis thereafter.

In addition, we collaborate with third-party advisory firms to periodically review and evaluate our security measures, which informs our ongoing strategy and execution of our cybersecurity program. We also leverage third-party providers to augment our internal security resources, including to support our ongoing monitoring and threat detection capabilities. We have a process to evaluate certain critical third-party providers before engagement as well as periodically thereafter, which may include a review of available audit reports, security documentation, operating controls, and industry reputation, as well as contractual requirements, as appropriate.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition; however, like other companies in our industry, we and our third-party vendors have from time to time experienced threats and security incidents that could affect our information or systems. For more information, please see our Risk Factors.

Governance Related to Cybersecurity Risks

Our board of directors considers cybersecurity risk as part of its risk oversight and has delegated the Audit Committee of the board of directors oversight of cybersecurity risks. The Audit Committee oversees management’s implementation of the cybersecurity program. We have also established a process for escalation of major cyber incidents, if applicable, to be reported to the Executive Leadership Team and the Audit Committee. Additionally, we conduct periodic meetings to keep the Executive Leadership Team and Audit Committee apprised of our risk management and overall cyber strategy, as appropriate.

Our IT Director leads day-to-day IT operations across all areas of the business and is responsible for advising on the strategic and operational processes related to our cyber risk management program. Our current IT Director has over 25 years of IT management experience, including over 15 years of experience in cybersecurity management in both public and private companies. In addition, we have assembled an IT Steering Committee, or ITSC, which is comprised of the

Executive Leadership Team as well as IT management, to support management and to maintain visibility of the status and ongoing strategy of our cybersecurity program.

Item 2. Properties.

Our principal office is located in Lexington, Massachusetts, where we sublease 33,339 square feet of office, back-up manufacturing, sales demonstration lab and research and development innovation space, which expires in June 2029. We also lease 67,663 square feet of office, laboratory, manufacturing and inventory-storage space in Lowell, Massachusetts. We lease this space under a lease agreement, as amended, which expires in July 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. On August 5, 2024, our Class A common stock was transferred to the Nasdaq Capital Market. There is no established public trading market for our Class B common stock.

Holders

As of February 24, 2025, there were 35 holders of record of our Class A common stock and 1 holder 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

None.

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 and 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 50% or more compared to 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.

In July 2024, we completed an enterprise-wide review of opportunities to realize operational efficiencies. Based on the results of this review, we are implementing certain actions to reduce costs including a reduction in our workforce, the closure of open and planned positions and reductions in other non-headcount-related expenses across the business (the "Operational Efficiency Program"). These actions are expected to result in approximately $6 million to $7 million in annual cash savings and enable us to achieve our goal of positive cash flow by the end of 2027 without additional financing. We plan to continue to invest in key initiatives that are expected to drive future revenue growth and gross margin improvement, including product development and cost reduction programs. We recorded a charge of $0.6 million in the third quarter of 2024 related to the Operational Efficiency Program.

On February 21, 2025, we entered into a Distribution and Collaboration Agreement (the "Distribution Agreement") with Millipore S.A.S., a subsidiary of the Life Science business of Merck KGaA, Darmstadt, Germany, which operates in the U.S. as MilliporeSigma ("MilliporeSigma"). Pursuant to the Distribution Agreement, we granted MilliporeSigma a global, co-exclusive right to sell our products, initially consisting of our Growth Direct systems and related consumables, into all fields related to industrial quality control applications in the pharmaceutical, medical device, personal care, cosmetics and food and beverage spaces in all regions of the world. During the term of the Distribution Agreement, MilliporeSigma will receive tier-based transfer pricing on such products. We will continue to directly market, sell,

manufacture and distribute our products and provide all services to customers, including in respect of system installation, validation, maintenance and support.

Over the first two years of the Distribution Agreement, MilliporeSigma has committed to purchase a minimum number of Growth Direct systems. Thereafter, we and MilliporeSigma will evaluate and mutually agree on additional purchase commitments, if any. Pursuant to the Distribution Agreement, we are permitted to continue to sell our products independently and through our existing distributors, but we may not grant the right to sell the products covered by the Distribution Agreement to other third parties so long as a purchase commitment by MilliporeSigma is in place. The initial term of the Distribution Agreement is five years, unless earlier terminated by us or MilliporeSigma in accordance with its terms.

The Distribution Agreement also contemplates future collaboration by the parties, including with respect to sourcing materials and service delivery. In that regard, within six months, the parties intend to negotiate in good faith towards a supply agreement, pursuant to which the parties will explore cost-saving measures within our supply chain focused on accelerating gross margin improvement, particularly with respect to consumables. The focus of such supply agreement may include raw materials and components as well as manufacturing and supply chain services. The parties intend to share in any cost savings achieved in the supply of the products through this supply agreement. Additionally, within one year, the parties intend to negotiate in good faith towards a services agreement to permit us and MilliporeSigma to provide certain services to each other's customers. The parties also intend to explore additional opportunities for collaboration, such as joint development efforts for the enhancement of our products or introducing new products to be covered by the distribution arrangement.

Since our inception, we have incurred net losses in each year. We generated revenue of $28.1 million and $22.5 million for the years ended December 31, 2024 and 2023, respectively, and incurred net losses of $46.9 million and $52.5 million for those same years. As of December 31, 2024, we had an accumulated deficit of $475.3 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.

While we implemented our Operational Efficiency Program with the goal of achieving positive cash flow without additional financing, there can be no assurance that we will attain this goal. Our Operational Efficiency Program and intention to attain positive cash flow are based on our expectations and underlying assumptions of business performance that are generally consistent with our historical performance, including with respect to revenue growth and gross margin improvement, which may not be replicated in future periods. Our goal also depends on our ability to realize additional cost savings that we believe are reasonably achievable, but are not guaranteed. While we seek to achieve and sustain positive cash flow, if we are unable to generate revenue, improve our gross margins, and/or control our operating costs sufficiently, we may need to raise additional funding, which we would expect to secure through equity offerings, debt financings or a combination thereof. If we are unable to raise capital or enter into such agreements as, if 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.

We believe that our cash, cash equivalents and investments as of December 31, 2024 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."

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, and the Asia-Pacific region.

We are focused on enhancing customer engagement and experience and continuing to improve 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 our sales organization, targeted marketing, expanding lead generation capabilities and hosting customer-related Growth Direct demonstrations and other customer-focused events.

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, 2024, approximately 41% of our customers have purchased Growth Direct systems for multiple sites, and approximately 57% 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 new product approvals or increases in their manufacturing volumes for existing products.

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, such as our rapid sterility application, 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.

We made the Growth Direct Rapid Sterility application available for commercial sale and placed the first Rapid Sterility system at one of our existing customers in the second quarter of 2024. We plan to continue efforts to scale our manufacturing capabilities for the Rapid Sterility application.

Revenue mix

Our revenue is derived from sales of our Growth Direct systems, our LIMS connection and other software, proprietary consumables, and services. Growth Direct system revenue involves a capital selling process and tends to be somewhat concentrated within a relatively small (but varied) group of customers each year, so it is subject to variability from quarter to quarter.

Gross margin improvement

The majority of our customers are large global pharmaceutical manufacturers and CDMOs. In order to meet the expectations of our customers, we have made significant investments to build infrastructure and develop capabilities in areas such as procurement, manufacturing, distribution, quality and after-sales service. Given our current business scale, our revenues are not yet sufficient to fully cover these costs, impacting our current gross margin profile. For additional information, see *Item 1. Business - Gross margin improvement* included in this Annual Report on Form 10-K.

We have experienced positive trends in gross margin, improving from (49.8)% to (24.4)% to (0.4)% for the years ended December 31, 2022, 2023 and 2024, respectively. While we expect gross margins to continue to trend positively, expansion in gross margins in future periods may not be linear and may be subject to variability from period to period.

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	%
	2024	2023		
	(dollars in thousands)			
Systems placed:				
Systems placed in period	21	16	5	31.3%
Cumulative systems placed	162	141	21	14.9%
Systems validated:				
Systems validated in period	16	18	(2)	(11.1%)
Cumulative systems validated	137	121	16	13.2%
Product and service revenue — total	$ 28,051	$ 22,519	$ 5,532	24.6%
Product and service revenue — recurring	$ 15,451	$ 13,546	$ 1,905	14.1%

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 in 2022 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.

In July 2024, we placed our 150th Growth Direct system with an existing global biopharma customer, which we believe represents a significant milestone demonstrating the strong continued interest in and adoption of our technology by customers.

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. In addition, in exceptional cases, we have reacquired Growth Direct systems from customers that were previously placed and, in some cases, previously validated. Our metrics showing cumulative systems placed and cumulative systems validated are not reduced to reflect these reacquired systems.

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, 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.

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 55.1% and 60.2% of our total revenue for the years ended December 31, 2024 and 2023, 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 and in routine use 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.

Components of results of operations

Revenue

We generate revenue from sales of our Growth Direct system (including our LIMS connection and other software), consumables, validation services, service contracts and field service. 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, 2024	Percentage of total revenue	Year Ended December 31, 2023	Percentage of total revenue
	(in thousands)		(in thousands)	
Product revenue	$ 18,728	66.8 %	$ 14,805	65.7 %
Service revenue	9,323	33.2 %	7,714	34.3 %
Total revenue	$ 28,051	100.0 %	$ 22,519	100.0 %

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, 2024, we had placed 162 Growth Direct systems to forty-six customers globally, including 70% of the top twenty largest pharmaceutical companies as measured by revenue and the manufacturers of approximately 17% of U.S. Food and Drug Administration

("FDA") approved cell and gene therapies, including manufacturers of 86% of approved gene-modified autologous CAR-T cell 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 three proprietary consumables to capture test samples for analysis on the Growth Direct system, an Environmental Monitoring ("EM") consumable, a Water/ Bioburden ("W/BB") consumable, and a Sterility ("ST") consumable. Our 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 enter routine use and 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.

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, 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.

As part of our Operational Efficiency Program, we have implemented actions to reduce employee-related expenses and certain other non-employee related costs. For future periods, we expect our costs of revenue to increase or decrease commensurate with product and service volumes, albeit at a lesser rate. Such costs may be further impacted by our ongoing efforts to reduce product costs and increase manufacturing productivity and efficiencies as well as service productivity.

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 headcount-related costs for those functions as well as expenses for information technology systems and services, software, rent, facilities maintenance, and insurance as well as related depreciation and amortization.

Our research and development costs are expensed as incurred. As part of our Operational Efficiency Program, we have implemented actions to reduce research and development employee-related expenses associated with reduced headcount and certain other non-employee-related costs. We believe that our continued investment in research and development is essential to our long-term competitive position. For future periods, we expect our research and development expenses to increase or decrease commensurate with the size, scope and complexity of our research and development activities.

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. As part of the Operational Efficiency Program, we have implemented actions to reduce sales and marketing employee-related expenses associated with reduced headcount and certain other non-employee-related costs. For future periods, 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 executive, finance, legal, human resources and general management employees, as well as director and officer insurance costs and professional fees for legal, patent, accounting, audit, investor relations, recruiting, consulting, regulatory, compliance, board of directors' fees and other services. General and administrative expenses also include direct and allocated information technology and facility-related costs. As part of our Operational Efficiency Program, we have implemented actions to reduce general and administrative employee-related expenses associated with reduced headcount and certain other non-employee-related costs. For future periods, we expect these expenses to increase or decrease, as applicable, as the size, scope and complexity of our general and administrative functions increase or decrease.

Other income (expense)

Interest income, net

Interest income, net is comprised primarily of interest income from investments.

Other (expense) income, net

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

Income tax expense

We generated significant taxable losses during the years ended December 31, 2024 and 2023, 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.

We have not recorded any U.S. federal or state income tax benefits for the net operating losses, or NOLs, we have incurred in each year or for the research and development tax credits we have generated in the United States. As of December 31, 2024, we had U.S. federal and state NOL carryforwards of $268.4 million and $114.8 million, respectively. These NOLs may be available to offset future taxable income and begin to expire in 2038 and 2032, respectively. Additionally, we had a U.S. federal NOL carryforward of $255.6 million generated since 2018, which do not expire. As of December 31, 2024, we also had U.S. federal and state research and development tax credit carryforwards of $2.8 million and $3.2 million, respectively. These tax credits may be available to offset future tax liabilities and begin to expire in 2038 and 2025, 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 through that date. We have not completed a Section 382 study of transactions subsequent to July 31, 2020 which may have created additional limitations although materially all of the current U.S. 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 11—*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, 2024 and 2023

	Year Ended		Change	
	December 31, 2024	December 31, 2023	Amount	%
	(dollars in thousands)			
Revenue:				
Product revenue	$ 18,728	$ 14,805	$ 3,923	26.5 %
Service revenue	9,323	7,714	1,609	20.9 %
Total revenue	$ 28,051	$ 22,519	$ 5,532	24.6 %

Revenue

Product revenue increased by $3.9 million, or 26.5%, with the increase primarily attributable to an increase in Growth Direct system placements in 2024 as well as higher consumable shipment volumes due to an increase in cumulative validated Growth Direct systems. Additionally, higher selling prices for both consumables and systems as well as increased sales of other product were realized during the year.

Service revenue increased by $1.6 million, or 20.9%. The increase was largely due to increased recurring revenue from service contracts due to our growing number of validated Growth Direct systems at customer sites as well as increases in validation service revenue.

Costs of revenue

	Year Ended		Change	
	December 31, 2024	December 31, 2023	Amount	%
	(dollars in thousands)			
Cost of product revenue	$ 21,041	$ 20,060	$ 981	4.9 %
Cost of service revenue	$ 7,119	$ 7,944	$ (825)	(10.4)%

Cost of product revenue increased by $1.0 million, or 4.9%. The increase was driven by costs related to higher volume of both Growth Direct system placements and consumable shipments. This increase was partially offset by a favorable mix impact of product sold as well as a reduction in our costs to manufacture our products.

Cost of service revenue decreased by $0.8 million, or 10.4%. This decrease was primarily due to lower employee-related costs due to lower headcount.

Research and development

	Year Ended December 31,		Change	
	2024	2023	Amount	%
	(dollars in thousands)			
Research and development	$ 14,597	$ 12,820	$ 1,777	13.9 %
Percentage of total revenue	52.0 %	56.9 %		

Research and development expenses increased by $1.8 million, or 13.9%. The increase in expense was attributable to higher spending on new product development activities, including our rapid sterility application, as well as increased headcount-related costs and higher facilities costs related to our new innovation center and lab in our Lexington, Massachusetts facility.

	Year Ended December 31,		Change	
	2024	2023	Amount	%
	(dollars in thousands)			
Sales and marketing	$ 13,266	$ 13,322	$ (56)	(0.4)%
Percentage of total revenue	47.3 %	59.2 %		

Sales and marketing expenses remained relatively flat year over year. The slight decrease was primarily attributable to a reduction in consulting fees partially offset by an increase in headcount-related costs.

General and administrative

	Year Ended December 31,		Change	
	2024	2023	Amount	%
	(dollars in thousands)			
General and administrative	$ 21,947	$ 24,936	$ (2,989)	(12.0)%
Percentage of total revenue	78.2 %	110.7 %		

General and administrative expenses decreased by $3.0 million, or 12.0%. This decrease was primarily driven by a reduction in headcount. Lower public company operating costs, including business insurance premiums and legal fees as well as facility-related expenses, also contributed to the decrease.

Other income (expense)

Interest income, net

Interest income for the years ended December 31, 2024 and 2023 was $3.2 million and $4.2 million, respectively. The decrease of $1.0 million, or 24.8%, was due to lower investment balances during the year.

Other expense, net

Other (expense) income, which is comprised of miscellaneous expenses and income unrelated to our core business, remained relatively flat between the years ended December 31, 2024 and 2023.

Income tax expense

Income tax expense was less than $0.1 million for each of the years ended December 31, 2024 and 2023. The expense recorded related to our German and Swiss subsidiaries.

Liquidity and capital resources

Since our inception, we have incurred 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 and services, and proceeds from our IPO.

If our expectations and underlying assumptions of business performance, including revenue growth, gross margin improvements, and/or control of operating costs, are not realized, we may need to raise additional funding, which could be through equity offerings, debt financings or a combination thereof. For example, on December 15, 2023, we entered into a sales agreement, or the ATM Agreement, to establish an "at-the-market" facility with Cowen and Company, LLC, or Cowen, pursuant to which we may issue and sell shares of their Class A common stock. During the year ended December 31, 2024 through the filing date of this Annual Report on Form 10-K, we did not issue or sell any shares of our Class A common stock under this facility. If we are unable to raise capital as, if and when, needed, we may have to significantly delay, scale back or discontinue our expansion plans including further development and commercialization efforts of one or more of our products.

We believe that our cash, cash equivalents and short-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, 2024 were issued.

As of December 31, 2024, we had the following cash and investment-related assets on our consolidated balance sheet (in thousands):

	December 31, 2024
Cash and cash equivalents	$ 16,911
Short-term investments	33,821
Restricted cash	365
Total	$ 51,097

Contractual obligations and commitments

In October 2013, we entered into an operating lease for office and manufacturing space in Lowell, Massachusetts. In March 2022, we amended the lease to increase the amount of facility space subject to the lease and extend 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). Monthly rent payments are fixed and future minimum lease payments under the lease (as amended) are $3.0 million as of December 31, 2024, including $0.6 million in short-term obligations.

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 $3.4 million as of December 31, 2024, including $0.7 million in short-term obligations. 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 14 — *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,	
	2024	2023
Net cash used in operating activities	$ (44,153)	$ (45,081)
Net cash provided by investing activities	36,657	42,153
Net cash provided by financing activities	203	149
Net decrease in cash and cash equivalents and restricted cash	$ (7,293)	$ (2,779)

Operating activities

During the year ended December 31, 2024, net cash used in operating activities was $44.2 million, a decrease of $0.9 million compared to the prior year. The decreased use of net cash was primarily a result of working capital and reduced headcount resulting in less employee related costs, such as travel, business insurance, etc. The timing of payments to vendors and cash collections from customers contributed to the reduction in net cash used in operating activities.

Investing activities

During the year ended December 31, 2024, net cash provided by investing activities was $36.7 million, a decrease of $5.5 million compared to the year ended December 31, 2023. The change was largely attributable to lower cash inflows

from maturities and sales of short-term investments (net of outflow for purchases), marginally offset by lower purchases of property and equipment.

Financing activities

During the year ended December 31, 2024, net cash provided by financing activities was $0.2 million, an increase of $0.1 million compared to the year ended December 31, 2023. In both periods, substantially all of the net cash provided by financing activities related to proceeds from stock option exercises and purchases from our ESPP.

Nasdaq notice of failure to satisfy a continued listing rule

On February 2, 2024, we received a notification letter from the Nasdaq Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq") notifying us that the bid price for our Class A common stock, par value $0.01 per share, had closed below $1.00 per share for the preceding thirty consecutive business days and that, as a result, we were not in compliance with the minimum bid price requirement for continued inclusion on the Nasdaq Global Select Market under Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). In order to extend the time period during which we were required to regain compliance with the Bid Price Requirement, we transferred the listing of our Class A common stock to the Nasdaq Capital Market effective as of August 5, 2024. On November 11, 2024, we received a letter from the staff of Nasdaq indicating that we had regained compliance with the Bid Price Requirement, following ten (10) consecutive business days during which the closing bid price of our Class A common stock was equal to or greater than $1.00 per share.

Even though we have regained compliance with the Bid Price Requirement, there can be no assurance that we will in the future continue to comply with the Bid Price Requirement and other continued listing standards of Nasdaq in the future. If we fail to comply with one or more other Nasdaq listing rules, our Class A common stock may also become subject to delisting as a result of such deficiencies, 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.

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.

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 (including installation services) 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.

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 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 $1.235 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, 2024, we had cash, cash equivalents and short-term investments of $50.7 million, which consisted of cash, money market funds, U.S. treasury bills, 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, including through long-term contracts and commitments with key suppliers. 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, 2024, 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 control over financial reporting was effective as of December 31, 2024.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. As a non-accelerated filer and emerging growth company, we are exempt from the auditor attestation requirement under Section 404(b) of the Sarbanes-Oxley Act.

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 quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) **Compensatory Arrangements of Certain Officers**

On February 24, 2025, our board of directors 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 2024 fiscal year: $100,534 for Robert Spignesi, President and Chief Executive Officer, $33,068 for Sean Wirtjes, Chief Financial Officer, and $33,068 for John Wilson, Chief Operating Officer. Each individual's bonus was paid in cash on or about February 27, 2025.

(b) **Director and Officer Trading Arrangements**

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement, or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the fourth quarter ended December 31, 2024.

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 2025 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 2025 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 2025 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 2025 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 2025 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, as amended on May 23, 2024
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 (File 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 (File 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 (File 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 (File 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 (File 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 (incorporated by reference to Exhibit 4.7 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 1, 2024)
10.1	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 (File No. 333-257431) filed on June 25, 2021)
10.2	Seventh Amended and Restated Investors' Rights Agreement (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-257431) filed on June 25, 2021)
10.3	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 (File No. 333-257431) filed on June 25, 2021)
10.4†	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 (File No. 333-257431) filed on June 25, 2021)
10.5†	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 (File No. 333-257431) filed on July 12, 2021)
10.6†	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 (File No. 333-257431) filed on July 12, 2021)
10.7†	Rapid Micro Biosystems, Inc. 2023 Inducement Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-271659) filed on May 4, 2023)
10.8†	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 (File No. 333-257431) filed on July 12, 2021)
10.9†	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 (File No. 333-257431) filed on July 12, 2021)

Exhibit Number	Description of Exhibit
10.10†	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 (File No. 333-257431) filed on July 12, 2021)
10.11†	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 (File No. 333-257431) filed on July 12, 2021)
10.12†	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 (File No. 333-257431) filed on July 12, 2021)
10.13†	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)
10.14†	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)
10.15†	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)
10.16†	Form of Retention Agreement (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 10, 2023)
10.17†	Form of Performance Restricted Stock Unit Agreement under the Rapid Micro Biosystems, Inc. 2021 Incentive Award Plan (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 10, 2023)
10.18	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)
10.19†	Second Amended and Restated Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 1, 2024)
10.20†	First Amendment to Rapid Micro Biosystems, Inc. 2023 Inducement Plan (incorporated by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 1, 2024)
10.21*†	Second Amendment to Rapid Micro Biosystems, Inc. 2023 Inducement Plan
10.22+*	Distribution and Collaboration Agreement, dated February 21, 2025, by and between the Registrant and Millipore S.A.S.
19.1	Second Amended and Restated Insider Trading Compliance Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 1, 2024)
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File 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
97.1	Compensation Recovery Policy for Executive Officers (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K (File No. 001-40592) filed on March 1, 2024)
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.

Exhibit Number	Description of Exhibit
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)

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* 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: February 28, 2025

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)*	February 28, 2025
/s/ Sean Wirtjes **Sean Wirtjes**	Chief Financial Officer *(principal financial officer and principal accounting officer)*	February 28, 2025
/s/ Kirk D. Malloy, Ph.D. **Kirk D. Malloy, Ph.D.**	Chair of the Board of Directors	February 28, 2025
/s/ Richard Kollender **Richard Kollender**	Director	February 28, 2025
/s/ Melinda Litherland **Melinda Litherland**	Director	February 28, 2025
/s/ Inese Lowenstein **Inese Lowenstein**	Director	February 28, 2025
/s/ Natale Ricciardi **Natale Ricciardi**	Director	February 28, 2025
/s/ Jeffrey Schwartz **Jeffrey Schwartz**	Director	February 28, 2025

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, 2024 and 2023, 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, 2024 and 2023, 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.

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
February 28, 2025

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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 16,911	$ 24,285
Short-term investments	33,821	67,768
Accounts receivable	7,519	5,532
Inventory	20,200	19,961
Prepaid expenses and other current assets	2,466	2,869
Total current assets	80,917	120,415
Property and equipment, net	11,193	12,832
Right-of-use assets	5,163	6,240
Long-term investments	—	2,911
Other long-term assets	531	770
Restricted cash	365	284
Total assets	$ 98,169	$ 143,452
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,535	$ 1,973
Accrued expenses and other current liabilities	7,217	9,907
Deferred revenue	6,599	5,974
Lease liabilities, short-term	1,214	1,132
Total current liabilities	17,565	18,986
Lease liabilities, long-term	4,954	6,214
Other long-term liabilities	298	263
Total liabilities	22,817	25,463
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Class A common stock, $0.01 par value; 210,000,000 shares authorized at December 31, 2024 and 2023; 37,729,242 shares and 37,099,909 shares issued and outstanding at December 31, 2024 and 2023, respectively	377	371
Class B common stock, $0.01 par value; 10,000,000 shares authorized at December 31, 2024 and 2023; 5,309,529 shares issued and outstanding at December 31, 2024 and 2023	53	53
Preferred stock, $0.01 par value: 10,000,000 shares authorized at December 31, 2024 and 2023; zero shares issued and outstanding at December 31, 2024 and 2023	—	—
Additional paid-in capital	550,157	546,051
Accumulated deficit	(475,274)	(428,385)
Accumulated other comprehensive income (loss)	39	(101)
Total stockholders' equity	75,352	117,989
Total liabilities and stockholders' equity	$ 98,169	$ 143,452

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,	
	2024	2023
Revenue:		
Product revenue	$ 18,728	$ 14,805
Service revenue	9,323	7,714
Total revenue	28,051	22,519
Costs and operating expenses:		
Cost of product revenue	21,041	20,060
Cost of service revenue	7,119	7,944
Research and development	14,597	12,820
Sales and marketing	13,266	13,322
General and administrative	21,947	24,936
Total costs and operating expenses	77,970	79,082
Loss from operations	(49,919)	(56,563)
Other income (expense):		
Interest income, net	3,164	4,210
Other expense, net	(112)	(83)
Total other income, net	3,052	4,127
Loss before income taxes	(46,867)	(52,436)
Income tax expense	22	31
Net loss	$ (46,889)	$ (52,467)
Net loss per share — basic and diluted	$ (1.08)	$ (1.22)
Weighted average common shares outstanding — basic and diluted	43,575,705	43,024,039

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,	
	2024	2023
Net loss	$ (46,889)	$ (52,467)
Other comprehensive income:		
Unrealized gain on investments, net of tax	140	1,008
Comprehensive loss	$ (46,749)	$ (51,459)

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

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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 loss	Total
	Shares	Amount	Shares	Amount				
Balances at December 31, 2023	37,099,909	$ 371	5,309,529	$ 53	$ 546,051	$ (428,385)	$ (101)	$ 117,989
Issuance of Class A common stock upon exercise of common stock options	9,570	—	—	—	7	—	—	7
Issuance of Class A common stock under ESPP	287,217	3	—	—	228	—	—	231
Vesting of restricted stock units	332,546	3	—	—	(3)	—	—	—
Stock-based compensation expense	—	—	—	—	3,874	—	—	3,874
Net loss	—	—	—	—	—	(46,889)	—	(46,889)
Other comprehensive income	—	—	—	—	—	—	140	140
Balances at December 31, 2024	37,729,242	$ 377	5,309,529	$ 53	$ 550,157	$ (475,274)	$ 39	$ 75,352

	Class A Common stock		Class B Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	36,538,805	$ 366	5,553,379	$ 55	$ 540,775	$ (375,918)	$ (1,109)	$ 164,169
Conversion of Class B common stock to Class A common stock	243,850	2	(243,850)	(2)	—	—	—	—
Issuance of Class A common stock upon exercise of common stock options	8,830	—	—	—	6	—	—	6
Issuance of Class A common stock under ESPP	186,037	2	—	—	180	—	—	182
Vesting of restricted stock units	122,387	1	—	—	(1)	—	—	—
Restricted stock award liability accretion	—	—	—	—	341	—	—	341
Stock-based compensation expense	—	—	—	—	4,750	—	—	4,750
Net loss	—	—	—	—	—	(52,467)	—	(52,467)
Other comprehensive income	—	—	—	—	—	—	1,008	1,008
Balances at December 31, 2023	37,099,909	$ 371	5,309,529	$ 53	$ 546,051	$ (428,385)	$ (101)	$ 117,989

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, 2024	Year Ended December 31, 2023
Cash flows from operating activities:		
Net loss	$ (46,889)	$ (52,467)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	3,362	3,105
Stock-based compensation expense	3,874	4,750
Noncash lease expense	1,166	1,203
Provision recorded for inventory	95	34
Accretion on investments	(1,024)	(2,295)
Other, net	34	34
Changes in operating assets and liabilities		
Accounts receivable	(1,987)	(163)
Inventory	(335)	1,193
Prepaid expenses and other current assets	403	272
Other long-term assets	(150)	5
Accounts payable	562	(3,455)
Accrued expenses and other current liabilities	(3,890)	1,434
Deferred revenue	626	1,269
Net cash used in operating activities	(44,153)	(45,081)
Cash flows from investing activities:		
Purchases of property and equipment	(1,365)	(1,845)
Purchases of investments	(35,035)	(62,492)
Sales of investments	3,957	—
Maturity of investments	69,100	106,490
Net cash provided by investing activities	36,657	42,153
Cash flows from financing activities:		
Proceeds from issuance of Class A common stock - stock option exercise	7	6
Proceeds from issuance of Class A common stock - employee stock purchase plan	231	180
Payments on finance lease obligations	(35)	(37)
Net cash provided by financing activities	203	149
Net decrease in cash, cash equivalents and restricted cash	(7,293)	(2,779)
Cash, cash equivalents and restricted cash at beginning of period	24,569	27,348
Cash, cash equivalents and restricted cash at end of period	$ 17,276	$ 24,569

	Year Ended December 31, 2024	Year Ended December 31, 2023
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 40	$ 38
Supplemental disclosure of non-cash investing activities		
Obtaining a right-of-use asset in exchange for a lease liability	$ —	$ 151
Purchases of property and equipment in accounts payable/accrued expenses	$ 309	$ 443

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

RAPID MICRO BIOSYSTEMS, INC.
Notes to consolidated financial statements
(Amounts in thousands, except share and per share amounts)

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 the Asia-Pacific region. The Company is headquartered in Lexington, 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").

Liquidity

The Company has incurred recurring losses and net cash outflows from operations since its inception. The Company expects to continue to generate operating losses for the foreseeable future. To date, the Company has funded operations primarily through proceeds from sales of redeemable convertible preferred stock, borrowings under loan agreements, revenue from sales of our products and services, and proceeds from the IPO.

If the Company's expectations and underlying assumptions of business performance, including revenue growth, gross margin improvements, and control of operating costs, are not realized, the Company may need to reduce spending or raise additional funding which could be through equity offerings, debt financings or a combination thereof. For example, on December 15, 2023, the Company entered into a sales agreement, or the ATM Agreement, to establish an "at-the-market" facility with Cowen and Company, LLC, or Cowen, pursuant to which the Company may issue and sell shares of their Class A common stock. During the year ended December 31, 2024 through the filing date of this Annual Report, we did not issue or sell any shares of our Class A common stock under this facility. If the Company is unable to raise capital as, if and when, needed, the Company may have to significantly delay, scale back or discontinue its expansion plans including further development and commercialization efforts of one or more of its products.

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,	
	2024	2023
Customer A	15.3 %	16.5 %
Customer B	14.4 %	— %
	29.7 %	16.5 %

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

	Year Ended December 31,	
	2024	2023
Customer A	*	10.7 %
Customer B	27.5 %	*
Customer C	*	16.4 %
Customer D	*	12.4 %
Customer E	11.5 %	*
Customer F	10.3 %	21.4 %
	49.3 %	60.9 %

* – 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, 2024 or 2023.

Cash and 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, 2024 and 2023, the Company held cash of $0.2 million and $0.1 million in banks located outside of the U.S., respectively.

Restricted cash

As of December 31, 2024 and 2023, the Company was required to maintain guaranteed investment certificates with a value of $0.4 million and $0.3 million, respectively, 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, 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, 2024 and 2023 had maturities of less than one year, and long-term investments as of December 31, 2023 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 for expected credit losses, 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 credit losses. A provision to the allowance for doubtful accounts for expected credit losses is recorded based on factors including the length of time the receivables are past due, the current business environment, the geographic market, and the Company's historical experience. Provisions to the allowance for doubtful accounts for expected credit losses are recorded to general and administrative expenses in the consolidated statements of operations. 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, 2024 and 2023, the allowance for doubtful accounts for expected credit losses was zero.

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 $1.6 million and $1.4 million of software development costs primarily related to the Company's enterprise resource planning ("ERP") system capitalized in other long-term assets at both December 31, 2024 and 2023, respectively, net of accumulated amortization of $1.1 million and $0.7 million, respectively. These capitalized costs are being amortized on a straight-line basis over the initial subscription term of five years. There was $0.4 million and $0.3 million of amortization expense recorded in the consolidated statement of operations for the year ended December 31, 2024 and 2023, respectively.

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, 2024 or 2023.

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 and investments 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,	
	2024	2023
Balance, beginning of the period	$ 689	$ 872
Warranty provisions	—	171
Warranty repairs	(169)	(354)
Balance, end of the year	$ 520	$ 689

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, specifically net loss on the consolidated statement of operations, for purposes of evaluating financial performance and allocating resources. The CODM reviews all functional expenses (cost of revenues, sales and marketing, research and development, and general and administrative) at the consolidated level to manage the Company's operations. Other segment items included in consolidated net loss are interest income, other expense, and provision for income taxes. These line items are reflected in the consolidated statement of operations. The chief operating decision maker considers budget-to-actual variances on a monthly basis for the profit measure when making decisions about allocating capital and personnel to the segment. 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. The measure of the segment's assets is reported on the balance sheet as total consolidated assets. Substantially all of the Company's long-lived assets are held in the United States.

Revenue recognition

Revenue is recognized when or as a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled 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.

Revenue is measured as the amount of consideration the Company expects to be entitled in exchange for transferring products to a customer (transaction price). To the extent that the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. However, most arrangements have a fixed transaction price with no variable consideration apart from discounts.

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 primarily consists of services provided by field service engineers to install the system at the customer site and perform 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 and apply to all performance obligations within an arrangement. 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. The standalone selling prices used in the allocation 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 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 less than $0.1 million in contract assets included in prepaid expenses and other current assets in the consolidated balance sheets as of both December 31, 2024 and 2023. These balances relate to unbilled amounts with customers.

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 non-current deferred revenue. The Company did not record any non-current deferred revenue as of December 31, 2024 or 2023. Deferred revenue was $6.6 million and $6.0 million at December 31, 2024 and 2023, respectively. Revenue recognized during the year ended December 31, 2024 that was included in deferred revenue at the prior year-end was $4.6 million. Revenue recognized during the year ended December 31, 2023 that was included in deferred revenue at the prior year-end was $3.5 million.

Disaggregated revenue

The Company disaggregates revenue based on the recurring and non-recurring nature of the underlying sale. Recurring revenue includes sales of consumables and service contracts. The Company considers these to be recurring revenues because customers typically place purchase orders on a periodic basis as they use their Growth Direct system over time. These arrangements typically contain a single performance obligation and thus the entire consideration to which the Company is entitled is allocated entirely to that performance obligation. Non-recurring revenue includes sales of systems, LIMS connection software, validation services, and field service, and typically contains multiple performance obligations. The Company considers these to be non-recurring revenues because customers typically place single purchase orders for a bundle of products and services on a one-time or infrequent basis. For these arrangements, significant judgment is applied

in identifying the distinct performance obligations, determination of the transaction price, transaction price allocation, and determination of standalone selling price for each of the distinct performance obligations.

The following table presents the Company's revenue by the recurring or non-recurring nature of the revenue stream (in thousands):

	Year Ended December 31,	
	2024	2023
Product and service revenue — recurring	$ 15,451	$ 13,546
Product and service revenue — non-recurring	12,600	8,973
Total revenue	$ 28,051	$ 22,519

The following table presents the Company's revenue, classified by the major geographic areas in which our customers were located (in thousands):

	Year Ended December 31,	
	2024	2023
United States	$ 10,639	$ 9,879
Switzerland	5,668	3,995
Germany	3,049	2,116
Japan	2,053	2,562
All other countries	6,642	3,967
Total revenue	$ 28,051	$ 22,519

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.

Cost of revenue

Cost of product revenue primarily consists of costs for raw material parts and associated freight, shipping and handling costs, 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.

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 $0.2 million and $0.3 million during the years ended December 31, 2024 and 2023, respectively.

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 (i) service-based vesting conditions only and (ii) both service-based and Company performance-based vesting conditions, and records the expense for these awards using the straight-line method. Forfeitures are accounted for prospectively as they occur.

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 (expense) income, net.

Comprehensive Income (loss)

Comprehensive income (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, 2024 and 2023, comprehensive income (loss) included gains of $0.1 million and $1.0 million, respectively, of unrealized gains 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, 2024 and 2023, 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 November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures. The new standard requires enhanced disclosures about a public entity's reportable segments including more detailed information about a reportable segment's expenses. The amendments in this update apply to all public entities that are required to report segment information, and include those entities that have a single reportable segment.

The new standard was adopted at December 31, 2024, had no material impact, and will be applied retrospectively for interim and annual periods.

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 was effective for the Company beginning January 1, 2023 and primarily impacted trade accounts receivable. The amendments in this update were adopted using a modified retrospective transition method as of January 1, 2023, which had no cumulative impact to retained earnings. The adoption of this new standard had no material impact on the Company's consolidated financial statements. The Company's concentrations of credit risks are limited due to the large number of customers and their dispersion across a number of geographic areas. Substantially all of the Company's trade receivables are concentrated in the pharmaceuticals industry in the U.S. and internationally or with distributors who operate in international markets. The Company's historical credit losses have not been significant due to this dispersion and the financial stability of the Company's customers. The Company considers its historical credit losses to be immaterial to its business and, therefore, has not provided all the disclosures otherwise required by the standard.

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 November 2024, the FASB issued ASU 2024-03, titled "Disaggregation of Income Statement Expenses." This update requires that public businesses provide more detailed disclosures about specific natural expense categories within their footnotes. The primary objective is to enhance transparency and provide investors with a clearer understanding of an entity's cost structure. The amendments in this update are effective for both annual and interim periods beginning after December 15, 2026. Early adoption is permitted. The Company is currently evaluating the impact on its consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The standard requires the Company to provide further disaggregated income tax disclosures for specific categories on the effective tax rate reconciliation, as well as additional information about federal, state/local and foreign income taxes. The standard also requires the Company to annually disclose its income taxes paid (net of refunds received), disaggregated by jurisdiction. The standard is effective on January 1, 2025 for fiscal year reporting. The standard is to be applied on a prospective basis, although optional retrospective application is permitted. The company is currently evaluating the impact on its consolidated financial statements and related disclosures.

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, 2024			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 13,721	$ —	$ —	$ 13,721
Short-term investments	33,821	—	—	33,821
	$ 47,542	$ —	$ —	$ 47,542

	Fair value measurements at December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 20,306	$ —	$ —	$ 20,306
Short-term investments	62,625	5,143	—	67,768
Long term investments	2,911	—	—	2,911
	$ 85,842	$ 5,143	$ —	$ 90,985

During the years ended December 31, 2024 and 2023, respectively, there were no transfers between Level 1, Level 2 and Level 3.

Cash equivalents

Cash equivalents consist of money market funds and treasury bills, and are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets. The Company considers all highly liquid interest-earning investments with a maturity of 90 days or less at the date of purchase to be cash equivalents. The fair values of these investments approximate their carrying values.

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 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, 2024 and 2023.

4. Investments

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

	December 31, 2024			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Short-term investments				
U.S. Government Treasury Notes	33,783	38	—	33,821
	$ 33,783	$ 38	$ —	$ 33,821

	December 31, 2023			
Short-term investments	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Certificates of Deposit	$ 5,164	$ —	$ (21)	$ 5,143
U.S. Government Treasury Bills	16,184	9	—	16,193
U.S. Government Treasury Notes	46,536	42	(146)	46,432
	$ 67,884	$ 51	$ (167)	$ 67,768
Long-term Investments				
U.S. Government Treasury Notes - Maturity Up To Two Years	2,896	15	—	2,911
	$ 2,896	$ 15	$ —	$ 2,911

During the year ended December 31, 2024, the Company sold available-for-sale securities with a carrying value of $4.0 million and received proceeds of $4.0 million. As of December 31, 2024, the remaining available-for-sale investments had a fair value of $33.8 million.

5. Inventory

Inventory consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Raw materials	$ 10,560	$ 12,873
Work in process	372	150
Finished goods	9,268	6,938
Total	$ 20,200	$ 19,961

Raw materials, work in process and finished goods were net of adjustments to realizable value of $0.6 million as of December 31, 2024 and 2023.

6. Prepaid expenses and other current assets

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

	December 31, 2024	December 31, 2023
Prepaid insurance	$ 838	$ 1,282
Contract asset	6	51
Deposits	489	667
Prepaid financing fees	290	292
Other	843	577
	$ 2,466	$ 2,869

7. Property and equipment, net

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

	December 31, 2024	December 31, 2023
Manufacturing and laboratory equipment	$ 14,457	$ 13,750
Computer hardware and software	1,847	1,960
Office furniture and fixtures	638	589
Leasehold improvements	9,178	8,551
Construction-in-process	1,594	2,292
	27,714	27,142
Less: Accumulated depreciation	(16,521)	(14,310)
	$ 11,193	$ 12,832

Depreciation and amortization expense related to property and equipment was $2.9 million and $2.7 million for the years ended December 31, 2024 and 2023, respectively. The Company had $0.7 million and $0.2 million of fully depreciated assets disposed of during the years ended December 31, 2024 and 2023, respectively.

8. Accrued expenses and other current liabilities

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

	December 31, 2024	December 31, 2023
Accrued employee compensation and benefits expense	$ 4,464	$ 4,808
Accrued vendor expenses	1,846	4,017
Accrued warranty expense	520	689
Accrued taxes	235	252
Other	152	141
	$ 7,217	$ 9,907

In July 2024, the Company completed an enterprise-wide review of opportunities to realize operational efficiencies. Based on the results of this review, the Company implemented certain cost actions, including a reduction in the Company's workforce, the closure of open and planned positions, and reductions in other non-headcount-related expenses across the business (the "Operational Efficiency Program"). The Company recorded a related charge of $0.6 million in costs and operating expenses third quarter of 2024. The Company made $0.3 million in payments during the year ended December 31, 2024 related to the Operational Efficiency Program.

9. Common stock and common stock warrants

As of December 31, 2024 and 2023, the Company's restated certificate of incorporation authorized the issuance of 210,000,000 shares and 10,000,000 shares of $0.01 par value Class A and Class B common stock, respectively. 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, 2024, no cash dividends had been declared or paid.

As of December 31, 2024, there were 37,729,242 shares of Class A common stock issued and outstanding, and 5,309,529 shares of Class B common stock issued and outstanding.

On December 15, 2023, the Company entered into an ATM Agreement with Cowen, pursuant to which the Company may issue and sell shares of its Class A common stock having aggregate sales proceeds of up to $50,000,000 from time to time through Cowen, acting as sales agent and/or principal. The prospectus filed by the Company related to the ATM Agreement permits the issuance and sale of up to $10,000,000 of shares of Class A common stock from time to time The Company agreed to pay Cowen a commission of up to 3.0% of the gross proceeds from any sales of shares of its Class A common stock under this facility. During the years ended December 31, 2024 and 2023, the Company did not issue or sell any shares of its Class A common stock under the ATM Agreement.

As of December 31, 2024, the Company had reserved 23,899,504 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 10), the number of shares available for purchase under the Company's Employee Stock Purchase Plan (see Note 10), for the exercise of outstanding common stock warrants and for the conversion of Class B common stock.

During the year-ended December 31, 2024, 2,159 warrants to purchase Class A common stock expired during the year.

As of December 31, 2024 and 2023, warrants to purchase the Class A common stock outstanding consisted of the following:

	December 31, 2024				
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	15,035	$	298.96
April 12, 2018	10	Equity	30,000	$	1.00
July 14, 2021 *	10	Equity	975,109	$	1.46
			1,020,144		

	December 31, 2023				
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		

* – The contractual terms of Class A common stock warrants remained consistent with the original terms of the preferred stock warrants which converted to Class A common stock warrants in connection with the IPO.

10. 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.

Following the effectiveness of the IPO in July 2021, no additional awards are being granted under the 2010 Plan and shares of existing outstanding options that are forfeited or cancelled under the 2010 Plan 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, 2024, there were 5,073,051 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.

2023 Inducement Plan

In May 2023, the Company's board of directors adopted the 2023 Inducement Plan (the "Inducement Plan") pursuant to which the Company reserved 330,000 shares of Class A common stock to be used exclusively for grants of equity-based awards to individuals who were not previously employees or directors of the Company as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Inducement Plan provides for the grant of equity-based awards in the form of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and dividend equivalent rights. The Inducement Plan was adopted by the board of directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. In February 2024, the Company amended its Inducement Plan to reserve an additional 225,000 shares of its Class A common stock. The amendment was adopted by the compensation committee of the board of directors, without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. As of December 31, 2024, 217,013 shares were available for future issuance under the Inducement Plan. In February 2025, the Company amended its Inducement Plan to reserve an additional 476,000 shares of its Class A common stock. The amendment was adopted by the board of directors, without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules.

Stock options

The following table summarizes the Company's stock option activity since December 31, 2023:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
			(in years)	(in thousands)
Outstanding as of December 31, 2023	6,530,511	$ 2.59	7.12	$ —
Granted	952,470	0.93		
Exercised	(9,570)	0.75		
Expired	(587,552)	3.26		
Forfeited	(589,354)	1.38		
Outstanding as of December 31, 2024	6,296,505	$ 2.39	6.18	$ 135
Options vested and expected to vest as of December 31, 2024	6,296,505	$ 2.39	6.18	$ 135
Options exercisable as of December 31, 2024	4,597,682	$ 2.64	5.36	$ 121

During the years ended December 31, 2024 and 2023, the Company granted to employees, officers and directors options to purchase 952,470 shares and 2,039,155 shares, respectively, of common stock. The Company recorded stock-based compensation expense for options granted to employees, officers, and directors of $2.3 million and $3.1 million during the years ended December 31, 2024 and 2023, 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,	
	2024	2023
Risk-free interest rate	4.31 %	3.90 %
Expected term (in years)	5.9	6.0
Expected volatility	49.8 %	47.1 %
Expected dividend yield	0 %	0 %

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 both of the years ended December 31, 2024 and 2023 was less than $0.1 million.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2024 and 2023 was $0.48 and $0.59, respectively.

In March 2023, the board of directors approved a one-time repricing of certain outstanding stock options held by non-executive employees. As a result of the repricing, the exercise prices of eligible vested and unvested stock options were adjusted to reflect the fair market value of Class A common stock on the date of the repricing. The effect of the repricing is included within the table above in the weighted average exercise price of the options outstanding as of December 31, 2023. The repricing was immaterial to the Company's consolidated statements of operations.

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. During the year ended December 31, 2024, the Company granted restricted stock units with service-based vesting conditions as well as restricted stock units with a combination of service-based and Company

performance-based vesting conditions. 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 $1.6 million and $1.5 million during the years ended December 31, 2024 and 2023, respectively.

The following table summarizes restricted stock units granted to Company employees during the year ended December 31, 2024:

	Number of shares	Weighted average grant date fair value
Unvested as of December 31, 2023	1,681,760	$ 2.28
Granted	1,194,965	$ 0.94
Vested	(477,386)	$ 3.05
Forfeited	(457,651)	$ 1.45
Unvested as of December 31, 2024	1,941,688	$ 1.46

The weighted average grant-date fair value per share of restricted stock units granted during the years ended December 31, 2024 and 2023 was $0.94 and $1.22, respectively. The total fair value of shares vested during the years ended December 31, 2024 and 2023 was $0.4 million and $0.2 million, respectively.

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 years ended December 31, 2024 and 2023, there were 287,217 and 186,037, respectively, shares of Class A common stock purchased under the 2021 ESPP. The Company recognized less than $0.1 million of expense related to the 2021 ESPP for both of the years ended December 31, 2024 and 2023. As of December 31, 2024, 956,940 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. At the grant date, the following weighted average assumptions were used in the calculation of fair value of shares under the 2021 ESPP:

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	4.98 %	5.32 %
Expected term (in years)	0.5	0.5
Expected volatility	45.9 %	47.8 %
Expected dividend yield	0 %	0 %

Stock-based compensation

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

	Year Ended December 31,	
	2024	2023
Cost of revenue	$ 517	$ 642
General and administrative	2,429	3,085
Sales and marketing	417	494
Research and development	511	529
Total stock-based compensation expense	$ 3,874	$ 4,750

As of December 31, 2024, total unrecognized compensation expense related to unvested stock options held by employees and directors was $1.7 million, which is expected to be recognized over weighted-average period of 1.4 years. Additionally, unrecognized compensation expense related to unvested restricted stock units held by employees and directors was $1.4 million, which is expected to be recognized over a weighted-average period of 1.8 years.

11. Income taxes

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

	Year Ended December 31,	
	2024	2023
United States	$ (46,872)	$ (52,455)
Foreign	5	19
Loss before income tax provision	$ (46,867)	$ (52,436)

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

	Year Ended December 31,	
	2024	2023
Current income tax provision:		
Federal	$ —	$ —
State	—	—
Foreign	22	31
Total current income tax expense	22	31
Deferred income tax provision:		
Federal	(9,846)	(11,177)
State	(1,648)	(1,241)
Foreign	—	—
Total deferred income tax provision	(11,494)	(12,418)
Change in deferred tax asset valuation allowance	11,494	12,418
Total expense for income taxes	$ 22	$ 31

During the years ended December 31, 2024 and 2023, 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,	
	2024	2023
Federal statutory income tax rate	21.0 %	21.0 %
State income taxes, net of federal benefit	2.8	1.9
Foreign tax differential	(0.1)	—
Federal and state research and development tax credits	1.3	1.3
Change in valuation allowance	(23.8)	(23.2)
Permanent differences	(1.0)	(1.1)
Other differences	(0.3)	—
Effective income tax rate	(0.1)%	(0.1)%

Net deferred tax assets consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Net operating loss carryforwards	$ 65,302	$ 55,761
Research and development credit carryforwards	6,042	5,361
Research and development capitalized costs	8,297	7,100
Inventories	326	343
Lease liability	1,413	1,656
Accrued expenses	1,244	1,352
Unrealized loss	—	24
Other	1,500	1,281
Total deferred tax assets	84,124	72,878
Deferred tax liabilities:		
Right-of-use assets	(1,188)	(1,405)
Unrealized gain	(9)	—
Depreciation	(353)	(359)
Total deferred tax liabilities	(1,550)	(1,764)
Valuation allowance	(82,574)	(71,114)
Net deferred tax assets	$ —	$ —

As of December 31, 2024, the Company had U.S. federal and state net operating loss ("NOL") carryforwards of $268.4 million and $114.8 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 U.S. federal NOLs of $255.6 million generated since 2018 that will not expire.

As of December 31, 2024, the Company also had U.S. federal and state research and development tax credit carryforwards of $2.8 million and $3.2 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2038 and 2025, 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 prior to July 31, 2020 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 generated prior to July 31, 2020. The Section 382 study concluded that $121.5 million of U.S. federal NOL carryforwards, $58.4 million of state NOL carryforwards, and $2.4 million of federal research and development tax credits will expire unutilized due to 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 any transactions subsequent to July 31, 2020 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 of $82.6 million and $71.1 million has been established against the net deferred tax assets as of December 31, 2024 and 2023, respectively. The Company reevaluates the positive and negative evidence at each reporting

period. The valuation allowance increased $11.5 million during the year ended December 31, 2024 primarily due to net operating losses generated, capitalized research and development expenses, and research and development tax credits.

The Company recognizes interest and penalties related to unrecognized tax benefits in U.S. federal, state, and foreign income tax expense. For the years ended December 31, 2024, and 2023, the Company recognized zero in interest and penalties. The Company had zero of interest and penalties accrued as of December 31, 2024 and 2023, respectively.

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.

In recent years, the Organization for Economic Co-operation and Development (“OECD”) and member countries have been focused on taxation issues relating to multi-national companies. In October 2021, more than 130 countries agreed to implement Pillar 2, a plan introduced by the OECD providing for a global minimum tax rate of 15% (calculated on a country-by-country basis) for those companies having consolidated revenue of at least €750 million; with any shortfall of the 15% minimum tax resulting in a related tax assessment ("Top-Up Tax"). The implementation of the Pillar 2 global minimum tax rules is intended to apply for tax years beginning in 2024. The main purpose of such rules is to minimize tax base erosion and profit shifting from higher tax jurisdictions to lower tax jurisdictions by multi-national companies. On February 2, 2023, the OECD issued various administrative guidance including transitional safe harbor rules available in conjunction with the implementation of the Pillar 2 global minimum tax. Based upon the current OECD rules and administrative guidance, the Company does not anticipate being subject to material Top-Up Taxes as various tax jurisdictions begin enacting such legislation. The Company is continuing to monitor the potential impact of the Pillar 2 proposals and developments on our consolidated financial statements and related disclosures, including eligibility for any transitional safe harbor rules.

12. Net loss per share

Net loss per share attributable to the common stockholders

As of December 31, 2024, the Company had Class A common stock and Class B common stock. Both classes have the same rights to the Company’s earnings and neither of the shares have any preference rights to dividends to other shares.

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,	
	2024	2023
Numerator:		
Net loss	$ (46,889)	$ (52,467)
Denominator:		
Weighted average Class A common shares outstanding—basic and diluted	38,266,176	37,612,962
Weighted average Class B common shares outstanding—basic and diluted	5,309,529	5,411,077
Total shares for EPS—basic and diluted	43,575,705	43,024,039
Net loss per share attributable to Class A common stockholders—basic and diluted	$ (1.08)	$ (1.22)
Net loss per share attributable to Class B common stockholders—basic and diluted	$ (1.08)	$ (1.22)

The Company’s potentially dilutive securities, which include common stock options, restricted common stock units, and common 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,	
	2024	2023
Options to purchase common stock	6,296,505	6,530,511
Warrants to purchase common stock	284,165	286,324
Unvested restricted common stock units	1,941,688	1,681,760
Options to purchase common stock under ESPP	102,509	224,510
	8,624,867	8,723,105

13. Leases

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,	
	2024	2023
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash outflows - payments on operating leases	$ 1,334	$ 1,285
Operating cash outflows - payments on financing leases	$ 40	$ 38
Financing cash outflows - payments on financing leases	$ 35	$ 37
Right-of-use assets obtained in exchange for new lease obligations:		
Operating leases	$ —	$ 151

Supplemental balance sheet information related to the Company's operating and financing leases is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Operating Leases:		
Operating lease assets	$ 4,998	$ 5,972
Operating lease liabilities, short-term	$ 1,167	$ 1,090
Operating lease liabilities, long-term	4,784	5,952
Total operating lease liabilities	$ 5,951	$ 7,042
Financing Leases:		
Office furniture and fixtures	$ 386	$ 386
Accumulated depreciation	(221)	(118)
Net property, plant and equipment	$ 165	$ 268
Lease liabilities, short-term	$ 47	$ 42
Lease liabilities, long-term	170	262
Total financing lease liabilities	$ 217	$ 304
Weighted-average remaining lease term - operating leases (in years):	4.54	5.54
Weighted-average remaining lease term - financing leases (in years):	4.50	5.50
Weighted-average discount rate - operating leases:	3.8 %	3.8 %
Weighted-average discount rate - financing leases:	12.0 %	12.0 %

The components of lease expense were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Operating lease cost	$ 1,218	$ 1,203
Financing lease cost - amortization of right-of-use asset	45	49
Financing lease cost - interest on lease liability	40	38
Variable lease cost	885	694
Total lease cost	$ 2,188	$ 1,984

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 $2.1 million and $1.9 million for the years ended December 31, 2024 and 2023, respectively. 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 less than $0.1 million for both of the years ended December 31, 2024 and 2023.

Maturities of the Company's operating lease liabilities as of December 31, 2024 were as follows (in thousands):

	Operating Lease Maturities
2025	$ 1,368
2026	1,401
2027	1,435
2028	1,468
Thereafter	805
Total lease payments	$ 6,477
Less imputed interest	(526)
Total present value of lease liabilities	$ 5,951

Maturities of the Company's financing lease liability as of December 31, 2024 were as follows (in thousands):

	Financing Lease Maturities
2025	$ 75
2026	75
2027	75
2028	75
Thereafter	38
Total lease payments	$ 338
Less imputed interest	(121)
Total present value of lease liabilities	$ 217

14. Commitments and contingencies

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, 2024 and 2023.

Legal proceedings

The Company is not a party to any material 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.

15. Benefit plans

The Company maintains 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 to the plan during both the years ended December 31, 2024 and 2023.

16. Subsequent Events

On February 21, 2025, the Company entered into a Distribution and Collaboration Agreement (the "Distribution Agreement") with Millipore S.A.S., a subsidiary of the Life Science business of Merck KGaA, Darmstadt, Germany, which operates in the U.S. as MilliporeSigma ("MilliporeSigma"). Pursuant to the Distribution Agreement, the Company granted MilliporeSigma a global, co-exclusive right to sell our products, initially consisting of our Growth Direct systems and related consumables, into all fields related to industrial quality control applications in the pharmaceutical, medical device, personal care, cosmetics and food and beverage spaces in all regions of the world. During the term of the Distribution Agreement, MilliporeSigma will receive tier-based transfer pricing on such products. The Company will continue to directly market, sell, manufacture and distribute our products and provide all services to customers, including in respect of system installation, validation, maintenance and support.

Over the first two years of the Distribution Agreement, MilliporeSigma has committed to purchase a minimum number of Growth Direct systems. Thereafter, the Company and MilliporeSigma will evaluate and mutually agree on additional purchase commitments, if any. Pursuant to the Distribution Agreement, the Company is permitted to continue to sell its products independently and through its existing distributors, but the Company may not grant the right to sell the products covered by the Distribution Agreement to other third parties so long as a purchase commitment by MilliporeSigma is in place. The initial term of the Distribution Agreement is five years, unless earlier terminated by the Company or MilliporeSigma in accordance with its terms.

The Distribution Agreement also contemplates future collaboration by the parties, including with respect to sourcing materials and service delivery. In that regard, within six months, the parties intend to negotiate in good faith towards a supply agreement, pursuant to which the parties will explore cost-saving measures within the Company's supply chain focused on accelerating gross margin improvement, particularly with respect to consumables. The focus of such supply agreement may include raw materials and components as well as manufacturing and supply chain services. The parties intend to share in any cost savings achieved in the supply of the products through this supply agreement. Additionally, within one year, the parties intend to negotiate in good faith towards a services agreement to permit the Company and MilliporeSigma to provide certain services to each other's customers. The parties also intend to explore additional opportunities for collaboration, such as joint development efforts for the enhancement of our products or introducing new products to be covered by the distribution arrangement. At this time, an estimate of the impact of the Distribution Agreement on our financial statements cannot be made.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-257981, 333-270531, 333-271659, and 333-277599) and Form S-3 (No. 333-276081) of Rapid Micro Biosystems, Inc. of our report dated February 28, 2025 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
February 28, 2025

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (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: February 28, 2025

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

   (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: February 28, 2025

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, 2024 (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: February 28, 2025

By: /s/ Robert Spignesi

Name: Robert Spignesi

Title: Chief Executive Officer

(principal executive officer)

Exhibit 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

In connection with the Annual Report of Rapid Micro Biosystems, Inc. (the "Company") on Form 10-K for the period ended December 31, 2024 (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: February 28, 2025

By: /s/ Sean Wirtjes

Name: Sean Wirtjes

Title: Chief Financial Officer

(principal financial officer and principal accounting officer)

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RAPID MICRO BIOSYSTEMS, INC.

CORPORATE AND OTHER INFORMATION

Executive Officers

Robert Spignesi
President and Chief Executive Officer

Sean Wirtjes
Chief Financial Officer

John Wilson
Chief Operating Officer

Board of Directors

Kirk D. Malloy, Ph.D., Board Chair
Founder and Principal, BioAdvisors, LLC

Robert Spignesi
President and Chief Executive Officer
of Rapid Micro Biosystems, Inc.

Richard Kollender
Chief Executive Officer and Director
of Reaction Biology Corporation

Melinda Litherland
Former Partner, Deloitte & Touche LLP

Inese Lowenstein
Former Senior Talent Advisor
to Danaher Corporation

Natale Ricciardi
Former President, Global Manufacturing, and Senior
Vice President at Pfizer Inc.

Jeffrey Schwartz
Chief Operating Officer
of Bain Capital Private Equity, LP

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Boston, Massachusetts