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

### **FORM 10-Q**

(Mark One)

Z QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 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 (State or other jurisdiction of incorporation or organization)

25 Hartwell Avenue Lexington, MA

(Address of Principal Executive Offices)

20-8121647 (I.R.S. Employer Identification Number)

> 02421 (Zip Code)

(978) 349-3200

(Registrant's telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

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

Title o	Title of Each Class			Name of Exchange on which registered					
Class A common stock	k, \$0.01 par value	per share RPID		The Nasdaq Capital Ma	The Nasdaq Capital Market				
5	0 ()	ed all reports required to be filed by Section 1 e such reports), and (2) has been subject to suc		ecurities Exchange Act of 1934 during the precent for the past 90 days. Yes $\square$ No $\square$	eding 12 months (or for				
2	0	tted electronically every Interactive Data File od that the registrant was required to submit s	•	nitted pursuant to Rule 405 of Regulation S-T ( No $\Box$	§232.405 of this chapter)				
5	0 0	accelerated filer, an accelerated filer, a non-ac ""smaller reporting company," and "emergin	,	naller reporting company, or an emerging growth in Rule 12b-2 of the Exchange Act.	h company. See the				
Large accelerated filer		Accelerated filer							
Non-accelerated filer	X	Smaller reporting company	X	Emerging growth company	$\boxtimes$				
If an emerging growth company, ir standards provided pursuant to Sec	2	5	ended transition per	riod for complying with any new or revised fina	uncial accounting				
<b>T P</b> ( <b>1 1 1 1 1 1 1 1 1 1</b>				N					

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  $\Box$  No  $\boxtimes$  As of November 5, 2024, there were 37,724,692 shares of the registrant's Class A common stock, par value \$0.01, outstanding. As of November 5, 2024, there were 5,309,529 shares of the registrant's Class B common stock, par value \$0.01, outstanding.

# TABLE OF CONTENTS

		Page
<u>Part I</u>	Financial Information	
<u>Item 1.</u>	Financial Statements	<u>6</u>
	Condensed Consolidated Balance Sheets as of September 30, 2024 and December 31, 2023 (Unaudited)	<u>6</u>
	Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2024 and 2023 (Unaudited)	2
	Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2024 and 2023 (Unaudited)	<u>8</u>
	Condensed Consolidated Statements of Stockholders' Equity for the three and nine months ended September 30, 2024 and 2023 (Unaudited)	<u>9</u>
	Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2024 and 2023 (Unaudited)	<u>11</u>
	Notes to Condensed Consolidated Financial Statements (Unaudited)	<u>13</u>
<u>Item 2.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>31</u>
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	<u>46</u>
<u>Item 4.</u>	Controls and Procedures	<u>46</u>
<u>Part II</u>	Other Information	
Item 1.	Legal Proceedings	<u>47</u>
Item 1A.	Risk Factors	<u>47</u>
Item 2.	Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities	<u>78</u>
Item 3.	Defaults Upon Senior Securities	<u>78</u>
Item 4.	Mine Safety Disclosures	<u>78</u>
<u>Item 5.</u>	Other Information	<u>78</u>
Item 6.	Exhibits	<u>79</u>
Exhibit Index		<u>79</u>
<u>Signatures</u>		<u>80</u>

### FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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, our efforts to reduce our use of cash for operating and investing activities and the assumptions underlying our expectation for achieving positive cash flow by the end of 2027;
- 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 enhancements to 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 regain and 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 Quarterly Report on Form 10-Q. 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 under Part II, Item 1A, "Risk Factors" of this Quarterly Report on Form 10-Q. The forward-looking statements in this Quarterly Report on Form 10-Q are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this Quarterly Report on Form 10-Q 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.

### SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q. 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 service contracts to existing customers declines, our future operating results would be adversely affected;
- We may need to raise additional capital to fund our existing operations, improve our platform or develop and commercialize new products or expand our operations;
- 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 U.S. Food and Drug Administration ("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 improve the effectiveness of our marketing and sales organization to adequately expand our business with new and existing customers and address our customers' needs or to expand our customer base, our business may be adversely affected;
- Our 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;
- If our primary manufacturing and development facility becomes damaged or inoperable or we are required to vacate our existing facility, our ability to conduct and pursue our manufacturing and development efforts will be jeopardized;
- Our manufacturing operations are dependent upon third-party suppliers, including single-source suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business;
- If we are unable to obtain and maintain sufficient intellectual property protection for our technology, including the Growth Direct platform, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired;
- Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time;
- The market price of our Class A common stock has been and may continue to be volatile and fluctuate substantially, which could result in substantial losses for our stockholders;
- 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.

#### TRADEMARKS

Solely for convenience, our trademarks and trade names in this Quarterly Report on Form 10-Q are referred to without the ® and <sup>TM</sup> 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 Quarterly Report on Form 10-Q and shall not be deemed "filed" under the Exchange Act.

# PART I -FINANCIAL INFORMATION

### **Item 1. Financial Statements**

### **RAPID MICRO BIOSYSTEMS, INC.** Condensed consolidated balance sheets (Unaudited)

(In thousands, except share and per share amounts)

	s	eptember 30, 2024	December 31, 2023
Assets			
Current assets:			
Cash and cash equivalents	\$	22,044	\$ 24,285
Short-term investments		38,788	67,768
Accounts receivable		3,740	5,532
Inventory		21,253	19,961
Prepaid expenses and other current assets		2,109	 2,869
Total current assets		87,934	120,415
Property and equipment, net		11,563	12,832
Right-of-use assets, net		5,420	6,240
Long-term investments		—	2,911
Other long-term assets		642	770
Restricted cash		284	 284
Total assets	\$	105,843	\$ 143,452
Liabilities and Stockholders' Equity	-		
Current liabilities:			
Accounts payable	\$	2,329	\$ 1,973
Accrued expenses and other current liabilities		7,038	9,907
Deferred revenue		5,360	5,974
Lease liabilities, short-term		1,193	1,132
Total current liabilities		15,920	18,986
Lease liabilities, long-term		5,261	6,214
Other long-term liabilities		289	263
Total liabilities		21,470	 25,463
Commitments and contingencies (Note 14)			
Stockholders' equity:			
Class A common stock, \$0.01 par value; 210,000,000 shares authorized at September 30, 2024 and December 31, 2023; 37,715,205 shares and 37,099,909 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively		277	271
		377	371
Class B common stock, \$0.01 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; 5,309,529 shares issued and outstanding at September 30, 2024 and December 31, 2023		53	53
Preferred stock, \$0.01 par value: 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; zero shares issued and outstanding at September 30, 2024 and December 31, 2023		_	
Additional paid-in capital		549,468	546,051
Accumulated deficit		(465,608)	(428,385)
Accumulated other comprehensive loss		83	(101)
Total stockholders' equity		84,373	117,989
Total liabilities and stockholders' equity	\$	105,843	\$ 143,452

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

Condensed consolidated statements of operations (Unaudited)

(In thousands, except share and per share amounts)

		Three Months En	ded S	September 30,	Nine Months Ended September 30,		
		2024		2023	 2024		2023
Revenue:	-						
Product revenue	\$	5,255	\$	4,200	\$ 13,505	\$	10,693
Service revenue		2,349		1,945	6,328		5,489
Total revenue		7,604		6,145	 19,833		16,182
Costs and operating expenses:							
Cost of product revenue		5,314		5,691	15,404		15,361
Cost of service revenue		1,668		2,085	5,519		6,134
Research and development		3,609		3,116	11,195		9,502
Sales and marketing		3,376		3,498	10,284		10,161
General and administrative		5,676		6,204	17,121		19,399
Total costs and operating expenses		19,643		20,594	 59,523		60,557
Loss from operations		(12,039)		(14,449)	(39,690)		(44,375)
Other income (expense):							
Interest income, net		768		1,093	2,589		3,169
Other expense, net		(39)		(26)	(91)		(66)
Total other income, net		729		1,067	2,498		3,103
Loss before income taxes	-	(11,310)		(13,382)	(37,192)		(41,272)
Income tax expense		13		10	31		23
Net loss	\$	(11,323)	\$	(13,392)	 (37,223)		(41,295)
Net loss per share — basic and diluted	\$	(0.26)	\$	(0.31)	\$ (0.86)	\$	(0.96)
Weighted average common shares outstanding — basic and diluted		43,668,656		43,080,095	43,510,911		42,985,184

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

### Condensed consolidated statements of comprehensive loss (Unaudited) (In thousands)

	Т	Three Months Ended September 30,				Nine Months Ended September 30,			
		2024	2023	3		2024		2023	
Net loss	\$	(11,323)	\$	(13,392)	\$	(37,223)	\$	(41,295)	
Other comprehensive income (loss):									
Unrealized gain on investments, net of tax		108		242		184		656	
Comprehensive loss	\$	(11,215)	\$	(13,150)	\$	(37,039)	\$	(40,639)	

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

# Condensed consolidated statements of stockholders' equity

(Unaudited) (In thousands, except share amounts)

	Cla Comm	iss A on sto	ck	Cla Commo		ock	1	Additional paid-in	$\begin{array}{c c c c c c c c c c c c c c c c c c c $			
	Shares	A	mount	Shares	1	Amount		capital	1			Total
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 under ESPP	198,299		2	—		—		166		—	—	168
Vesting of restricted stock units	185,331		2	—		—		(2)		—	—	
Issuance of Class A common stock upon exercise of common stock options	20			_		_		_		_	_	_
Stock-based compensation expense			—	—		—		1,085		—	—	1,085
Net loss			—	—		—				(13,322)	—	(13,322)
Other comprehensive income	—		—	—		—				—	23	23
Balances at March 31, 2024	37,483,559	\$	375	5,309,529	\$	53	\$	547,300	\$	(441,707)	\$ (78)	\$ 105,943
Vesting of restricted stock units	113,074		1	_		—		(1)				
Issuance of Class A common stock upon exercise of common stock options	294		_	_		_		_		_	_	_
Stock-based compensation expense	—		—	—		—		1,171		—	—	1,171
Net loss	—		—	—		—				(12,578)	—	(12,578)
Other comprehensive income	—		—	—		—				—	53	53
Balances at June 30, 2024	37,596,927	\$	376	5,309,529	\$	53	\$	548,470	\$	(454,285)	\$ (25)	\$ 94,589
Issuance of Class A common stock under ESPP	88,918		1	_		—		62			_	63
Vesting of restricted stock units	20,104		_	_		_		_		—	—	_
Issuance of Class A common stock upon exercise of common stock options	9,256		_	_		_		7		_	_	7
Stock-based compensation expense			_	_		_		929		—	—	929
Net loss	—		—	_		—				(11,323)	—	(11,323)
Other comprehensive income				_				_		_	108	108
Balances at September 30, 2024	37,715,205	\$	377	5,309,529	\$	53	\$	549,468	\$	(465,608)	\$ 83	\$ 84,373

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

# Condensed consolidated statements of stockholders' equity

(Unaudited), continued

(In thousands, except share amounts)

	Class Common		Clas Commo		Additional paid-in	Accumulated	Accumulated other comprehensive	
	Shares	Amount	Shares	Amount	capital	deficit	loss	Total
Balances at December 31, 2022	36,538,805	\$ 366	5,553,379	\$ 55	\$ 540,775	\$ (375,918)	\$ (1,109)	\$164,169
Issuance of Class A common stock under ESPP	125,536	1	_	_	123	_	_	124
Vesting of restricted stock units	96,303	1	—	—	(1)	—	—	—
Restricted stock award liability accretion	_	_	_		341	_	_	341
Issuance of Class A common stock upon exercise of common stock options	7,896		_		6	_	_	6
Stock-based compensation expense		—	—	—	1,243	—	—	1,243
Net loss	_	_	_	_	_	(13,887)	—	(13,887)
Other comprehensive income	_	—	—	—	_	—	447	447
Balances at March 31, 2023	36,768,540	\$ 368	5,553,379	\$ 55	\$ 542,487	\$ (389,805)	\$ (662)	\$ 152,443
Vesting of restricted stock units	4,954	_		_				
Conversion of Class B common stock to Class A common stock	243,850	2	(243,850)	(2)	_	_	_	_
Stock-based compensation expense	—	—	—	—	1,234	—	—	1,234
Net loss	—	—	—	—	—	(14,016)	—	(14,016)
Other comprehensive loss	—	_		—	—	—	(33)	(33)
Balances at June 30, 2023	37,017,344	\$ 370	5,309,529	\$ 53	\$ 543,721	\$ (403,821)	\$ (695)	\$ 139,628
Issuance of Class A common stock under ESPP	60,501	1			57			58
Vesting of restricted stock units	9,253	—	—	—	—	—	—	—
Issuance of Class A common stock upon exercise of common stock options	934	_	_	_	_	_	_	_
Stock-based compensation expense	_	_	—	_	1,251	—	—	1,251
Net loss		_	_	_	—	(13,392)	_	(13,392)
Other comprehensive loss			—	—		_	242	242
Balances at September 30, 2023	37,088,032	\$ 371	5,309,529	\$ 53	\$ 545,029	\$ (417,213)	\$ (453)	\$ 127,787

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

### Condensed consolidated statements of cash flows (Unaudited) (In thousands)

	Nine Months Ended September 30,		
	 2024	2023	
Cash flows from operating activities:			
Net loss	\$ (37,223) \$	(41,295	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	2,493	2,311	
Stock-based compensation expense	3,185	3,728	
Provision for excess and obsolete inventory	95	34	
Noncash lease expense	862	899	
Accretion on investments	(985)	(1,766	
Other	25	26	
Changes in operating assets and liabilities:			
Accounts receivable	1,792	1,462	
Inventory	(1,388)	960	
Prepaid expenses and other current assets	759	1,817	
Other long-term assets	(150)	5	
Accounts payable	357	(2,157	
Accrued expenses and other current liabilities	(3,451)	(1,462	
Deferred revenue	(615)	(146	
Net cash used in operating activities	 (34,244)	(35,584	
Cash flows from investing activities:			
Purchases of property and equipment	(1,267)	(1,427	
Purchases of investments	(29,496)	(50,928	
Sale of investments	3,957		
Maturity of investments	58,600	84,500	
Net cash provided by investing activities	31,794	32,145	
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	182	
Payments on finance lease obligations	(29)	(27	
Net cash provided by financing activities	 209	161	
Net decrease in cash, cash equivalents and restricted cash	 (2,241)	(3,278	
Cash, cash equivalents and restricted cash at beginning of period	24,569	27,348	
Cash, cash equivalents and restricted cash at end of period	\$ 22,328 \$	24,070	

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

Condensed consolidated statements of cash flows, continued (Unaudited) (In thousands)

	Nine M	Ionths Ended Se	ptember 30,
	2024		2023
Supplemental disclosure of cash flow information			
Cash paid for interest	\$	27 \$	29
Supplemental disclosure of non-cash investing activities			
Obtaining a right of operating assets in exchange for lease liability	\$	— \$	151
Purchases of property and equipment in accounts payable and accrued expenses	\$	28 \$	204

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

### Notes to condensed consolidated financial statements (Amounts in thousands, except share and per share amounts) (Unaudited)

### 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**

These condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles 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. Certain information and note disclosures normally included in the consolidated financial statements prepared in accordance with GAAP have been condensed or omitted. Therefore, these condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in the Company's audited consolidated financial statements for the year ended December 31, 2023. 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").

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2024 and the results of its operations and its cash flows for the three and nine months ended September 30, 2024 and 2023. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2024 and 2023 are also unaudited. The results for the three and nine months ended September 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period.

### 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. The Company expects that its existing cash and 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 unaudited interim condensed consolidated financial statements were issued.

### 2. Summary of significant accounting policies

### Use of estimates

The preparation of the Company's condensed 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 condensed consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, calculating the standalone selling price 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.

There have been no significant changes to the Company's significant accounting policies during both the three and nine months ended September 30, 2024, as compared to those disclosed in Note 2 of the audited consolidated financial statements as of December 31, 2023 filed with the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

### 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, shortterm and long-term investments and accounts receivable. The Company maintains its cash and cash equivalents and investments with financial institutions that management believes to be of high credit quality, and does not believe that it is subject to unusual credit risk beyond the 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 represented 10% or more of the Company's total revenue:

	Three Months End	ded September 30,	Nine Months End	Nine Months Ended September 30,			
	2024	2023	2024	2023			
Customer A	21.0 %	*	11.6 %	*			
Customer B	*	14.7 %	14.1 %	18.2 %			
Customer C	*	11.4 %	*	*			
Customer D	*	10.2 %	*	*			
	21.0 %	36.3 %	25.7 %	18.2 %			

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

	September 30,	December 31,
	2024	2023
Customer E	12.8 %	21.4 %
Customer F	12.5 %	*
Customer G	12.3 %	*
Customer H	*	16.4 %
Customer I	*	12.4 %
Customer B	*	10.7 %
	37.6 %	60.9 %

### \* less than 10%

The Company relies on third parties for the supply and manufacture of certain components of its products as well as third-party logistics providers. There were no significant concentrations around a single third-party supplier, manufacturer, or logistics provider for the three and nine months ended September 30, 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 both September 30, 2024 and December 31, 2023, the Company held cash of \$0.1 million in banks located outside of the United States.

#### **Restricted** cash

As of both September 30, 2024 and December 31, 2023, the Company was required to maintain guaranteed investment certificates of \$0.3 million with maturities of three months to one year that are subject to an insignificant risk of changes in value. The guaranteed investment certificates are held for the benefit of the landlord 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 condensed consolidated balance sheets.

### 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 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 September 30, 2024 and December 31, 2023, the allowance for doubtful accounts for expected credit losses was zero.

#### 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 related to the Company's enterprise resource planning ("ERP") system capitalized in other long-term assets at September 30, 2024 and December 31, 2023, respectively, net of accumulated amortization of \$1.0 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. For the three and nine months ended September 30, 2024 and 2023, there was \$0.1 million and \$0.3 million, respectively, of amortization expense related to capitalized software development costs recorded in the condensed consolidated statements of operations.

### 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, short-term and long-term 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. The accrual for these warranty obligations is included in accrued expenses and other current liabilities in the condensed consolidated balance sheets. The following table presents a summary of changes in the amount reserved for warranty cost (in thousands):

	Thr	Three Months Ended September 30,					Nine Months Ended September 30,			
	2	2024		2023		2024		2023		
Balance, beginning of period	\$	520	\$	526	\$	689	\$	872		
Warranty provisions				171		_		171		
Warranty repairs		—		_		(169)		(346)		
Balance, end of period	\$	520	\$	697	\$	520	\$	697		

### Segment information

The Company determined its operating segment after considering the Company's organizational structure and the information regularly reviewed and evaluated by the Company's chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company has determined that its CODM is its Chief Executive Officer. The CODM reviews the financial information on a consolidated basis for purposes of evaluating financial performance and allocating resources. On the basis of these factors, the Company determined that it operates and manages its business as one operating segment, that develops, manufactures, markets and sells Systems and related LIMS connection software, consumables and services; and accordingly has one reportable segment for financial reporting purposes. Substantially all of the Company's long-lived assets are held in the United States.

### **Revenue** recognition

### 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 \$0.2 million and \$0.1 million in contract assets as of September 30, 2024 and December 31, 2023, respectively, included in prepaid expenses and other current assets.

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 September 30, 2024 or December 31, 2023. Deferred revenue was \$5.4 million and \$6.0 million at September 30, 2024 and December 31, 2023, respectively. Revenue recognized during each of the three months ended September 30, 2024 and 2023 that was included in deferred revenue at the prior period-end was \$1.2 million. Revenue recognized during the nine months ended September 30, 2024 and 2023 that was included in deferred revenue at the prior period-end was \$3.9 million and \$3.3 million, respectively.



### 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(s) 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 services, 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):

	Th	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024			2023		2024		2023	
Product and service revenue — recurring	\$	3,675	\$	3,410	\$	11,262	\$	10,255	
Product and service revenue — non-recurring		3,929		2,735		8,571		5,927	
Total revenue	\$	7,604	\$	6,145	\$	19,833	\$	16,182	

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

	T	Three Months Ended September 30,				Nine Months Ended September 30,			
		2024		2023		2024		2023	
United States	\$	3,423	\$	2,665	\$	8,232	\$	6,987	
Switzerland		1,357		1,058		3,932		2,991	
Germany		923		478		2,358		1,392	
Japan		227		167		1,399		1,621	
All other countries		1,674		1,777		3,912		3,191	
Total revenue	\$	7,604	\$	6,145	\$	19,833	\$	16,182	

#### Advertising costs

Advertising costs are expensed as incurred and are included in sales and marketing expenses in the condensed consolidated statements of operations. Advertising costs were less than \$0.1 million during each of the three months ended September 30, 2024 and 2023, and were \$0.2 million during each of the nine months ended September 30, 2024 and 2023.

#### 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) stock-based awards with both service-based and Company performance 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 stock units granted to employees based on the common stock value on the date of grant. The purchase price of the restricted stock is the common stock value on the date of grant.

### Recently issued accounting pronouncements

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups ("JOBS") 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 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 amendments in this update are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. 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. ASU 2023-09 provides more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The amendments in this update are effective for annual periods beginning after December 15, 2024. Early adoption 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 September 30, 2024								
	 Level 1 Level 2		Level 3			Total			
Assets									
Cash equivalents	\$ 14,293	\$		\$		\$	14,293		
Short-term investments	38,788						38,788		
	\$ 53,081	\$	_	\$		\$	53,081		

		Fair value measurements as of 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 three and nine months ended September 30, 2024 and 2023, there were no transfers in or out of Level 3.

#### Valuation of short-term and long-term investments

U.S. Treasury bills and notes included in short-term and long-term investments were valued by the Company using quoted prices in active markets for identical securities, which represents a Level 1 measurement within the fair value hierarchy. The Company's certificates of deposit included in short-term and long-term investments were valued using quoted prices for similar assets in active markets (or identical assets in inactive markets), which represent a Level 2 measurement within the fair value hierarchy.

### 4. Investments

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

		September 30, 2024						
	Gross Amortized unrealized cost gains			mortized unrealized unrealized			Fair value	
Short-term investments	_							
U.S. Government Treasury Notes	\$	38,705	\$	83	\$	_	\$	38,788
	\$	38,705	\$	83	\$	—	\$	38,788

	December 31, 2023							
	 Amortized cost		Gross unrealized gains		Gross unrealized losses		Fair value	
Short-term investments								
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	
		_		_		_		

### 5. Inventory

Inventory consisted of the following (in thousands):

	September 30.		December 31,		
	2024		2023		
Raw materials	\$ 11,	44 5	\$ 12,873		
Work in process		277	150		
Finished goods	9,4	32	6,938		
Total	\$ 21,	53 8	\$ 19,961		

Raw materials, work in process and finished goods were net of adjustments to net realizable value of \$0.6 million as of both September 30, 2024 and December 31, 2023.



# 6. Prepaid expenses and other current assets

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

	Septe	mber 30,	De	ecember 31,	
		2024		2023	
Prepaid insurance	\$	28	\$	1,282	
Contract asset		228		51	
Deposits		638		667	
Other receivables		174		137	
Prepaid financing fees		290		292	
Other		751		440	
	\$	2,109	\$	2,869	

### 7. Property and equipment, net

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

2024Manufacturing and laboratory equipment\$ 14,431Computer hardware and software2,139Office furniture and fixtures623	December 31,		
Computer hardware and software 2,139	2023		
•	13,750		
Office furniture and fixtures 623	1,960		
	589		
Leasehold improvements 8,998	8,551		
Construction-in-process 1,804	2,292		
27,995	27,142		
Less: Accumulated depreciation (16,432)	(14,310)		
\$ 11,563 \$	5 12,832		

Depreciation and amortization expense related to property and equipment was \$0.7 million for each of the three months ended September 30, 2024 and 2023, and was \$2.1 million and \$2.0 million for the nine months ended September 30, 2024 and 2023, respectively.

### 8. Accrued expenses and other current liabilities

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

Sep	tember 30,	De	cember 31,
<u> </u>	2024	2023	
\$	4,634	\$	4,808
	1,641		4,017
	520		689
	239		252
	4		141
\$	7,038	\$	9,907
		\$ 4,634 1,641 520 239 4	2024           \$         4,634         \$           1,641         520         239           4         4         4

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 in the three months ended September 30, 2024, 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 in the third quarter of 2024. The Company made \$0.2 million in payments during the three and nine months ended September 30, 2024 related to the

Operational Efficiency Program. The company had \$0.4 million in remaining payments under the Operational Efficiency Program as of September 30, 2024.

### 9. Common stock and common stock warrants

As of both September 30, 2024 and December 31, 2023, the Company's restated certificate of incorporation authorized the issuance of Class A and Class B common stock. 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 September 30, 2024, no cash dividends had been declared or paid.

As of September 30, 2024, the Company had reserved 23,915,460 shares of Class A common stock for the exercise of outstanding stock options and warrants, 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) and the conversion of Class B common stock.

Outstanding warrants to purchase common stock consisted of the following:

		September 30, 2024									
Issuance date	Contractual term	Balance sheet classification	Shares of common stock issuable upon exercise of warrant		hted average ercise price						
	(in years)										
July 24, 2017	10	Equity	16,954	\$	293.42						
April 12, 2018	10	Equity	30,000	\$	1.00						
July 14, 2021 *	10	Equity	975,109	\$	1.46						
			1,022,063								

		December 31, 2023							
Issuance date	Contractual term	Balance sheet classification		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						

<sup>\*</sup> In connection with the Company's initial public offering ("IPO"), preferred stock warrants were automatically converted to Class A common stock warrants. The contractual term of the converted Class A common stock warrants remained consistent with the original term of the preferred stock warrants, with original issue dates between 2017-2020.



#### 10. Stock-based compensation

### 2010 Stock Option and Grant Plan

The Company's 2010 Stock Option and Grant Plan (the "2010 Plan") provided 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 Company's IPO in July 2021, no additional awards are being granted under the 2010 Plan and shares of existing outstanding options that were issued under the 2010 Plan and are forfeited or canceled 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"). 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; 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 September 30, 2024, there were 4,551,792 shares available for issuance under the 2021 Plan.

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

	Three Months Endeo	l September 30,	Nine Months Ended September 30,			
	2024	2023	2024	2023		
Risk-free interest rate	*	4.2 %	4.3 %	3.9 %		
Expected term (in years)	*	6.1	5.9	6.0		
Expected volatility	*	47.1 %	50.0 %	47.1 %		
Expected dividend yield	*	0 %	0 %	0 %		

\*- No options granted in the respective period.



#### 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	(255,166)		4.96		
Forfeited	(357,740)		1.67		
Outstanding as of September 30, 2024	6,860,505	\$	2.32	6.51	\$ 155
Options vested and expected to vest as of September 30, 2024	6,860,505	\$	2.32	6.51	\$ 155
Options exercisable as of September 30, 2024	4,694,428	\$	2.59	5.54	\$ 132

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 Class A common stock for those options that had exercise prices lower than such fair value.

The intrinsic value of stock options exercised the nine months ended September 30, 2024 was less than \$0.1 million.

The weighted average grant-date fair value per share of stock options granted during the three months ended September 30, 2023 was \$0.49, and during the nine months ended September 30, 2024 and 2023 was \$0.48 and \$0.59, respectively. No options were granted in the three months ended September 30, 2024.

### **Restricted stock units**

Restricted stock unit grants to employees typically have a three-year service-based vesting term in which vesting occurs annually on the anniversary of the grant date. During the nine months ended September 30, 2024, the Company granted restricted stock units with service-based vesting conditions only. The Company expenses the fair value of the restricted stock units over the expected vesting period and accounts for forfeitures prospectively as they occur.

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

	Number of shares	Weigi aver: fair v	age
Unvested as of December 31, 2023	1,681,760	\$	2.28
Granted	1,157,765	\$	0.93
Vested	(459,024)	\$	3.11
Forfeited	(273,253)	\$	1.61
Unvested as of September 30, 2024	2,107,248	\$	1.44

W-:-L4-J

The weighted average grant-date fair value per share of restricted stock units granted during the three months ended September 30, 2024 and 2023 was \$0.78 and \$0.97, respectively, and during the nine months ended September 30, 2024 and 2023 was \$0.93 and \$1.22, 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 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 nine months ended September 30, 2024, there were 287,217 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 each of the three and nine months ended September 30, 2024 and 2023. As of September 30, 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. The following weighted average assumptions were used in the calculation of fair value of shares under the 2021 ESPP at the grant date for both the nine months ended September 30, 2024 and 2023:

	Three Months End	led September 30,	Nine Months Ende	ed September 30,
	2024	2023	2024	2023
Risk-free interest rate	4.6 %	5.5 %	5.0 %	5.3 %
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	42.6 %	47.7 %	46.0 %	47.8 %
Expected dividend yield	0 %	0 %	0 %	0 %

### 2023 Inducement Plan

In May 2023, the 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 May 2023, pursuant to the Inducement Plan, the Company granted inducement awards to the Company's Senior Vice President, Sales & Marketing, in the form of an option to purchase 220,000 shares of the Company's Class A common stock, with an exercise price per share of \$0.83, and 110,000 restricted stock units. The option and restricted stock unit awards were granted as inducements material to the commencement of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

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.

In March 2024, pursuant to the Inducement Plan as amended, the Company granted inducement awards to the Company's Vice President, Legal, in the form of an option to purchase 150,000 shares of the Company's Class A common

stock, with an exercise price per share of 0.99, and 75,000 restricted stock units. The option and restricted stock unit awards were granted as inducements material to the commencement of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

As of September 30, 2024, no shares were available for future issuance under the Inducement Plan.

#### Stock-based compensation

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

	Т	Three Months Ended September 30,				Nine Months Ended September 30			
		2024		2023		2024		2023	
Cost of revenue	\$	142	\$	159	\$	437	\$	502	
Research and development		123		135		395		398	
Sales and marketing		98		119		325		385	
General and administrative		566		838		2,028		2,443	
Total stock-based compensation expense	\$	929	\$	1,251	\$	3,185	\$	3,728	

As of September 30, 2024, total unrecognized compensation expense related to unvested stock options held by employees and directors was \$2.3 million, which is expected to be recognized over a weighted average period of 1.5 years. Additionally, unrecognized compensation expense related to unvested restricted stock units held by employees and directors was \$1.9 million, which is expected to be recognized over a weighted average period of 1.8 years.

### 11. Income taxes

During both the three and nine months ended September 30, 2024 and 2023, the pretax losses incurred by the Company, as well as the research and development tax credits generated, received no corresponding tax benefit because the Company concluded that it is more likely than not that the Company will be unable to realize the value of any resulting deferred tax assets. The Company will continue to assess its position in future periods to determine if it is appropriate to reduce a portion of its valuation allowance.

The Company's tax provision and the resulting effective tax rate for interim periods is determined based upon its estimated annual effective tax rate, adjusted for the effect of discrete items arising in that quarter. The income tax provision was generated from operations in Germany and Switzerland.

The impact of such discrete items could result in a higher or lower effective tax rate during a particular quarter, based upon the mix and timing of actual earnings or losses versus annual projections. In each quarter, the Company updates its estimate of the annual effective tax rate, and if the estimated annual tax rate changes, a cumulative adjustment is made in that quarter.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of both September 30, 2024 and December 31, 2023 the Company recorded a full valuation allowance against its net deferred tax assets.

The Company files 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 U.S. federal, state and international jurisdictions, where applicable. There are currently no pending tax examinations in the U.S., and the Company has not received notice of examination from any jurisdictions in the U.S.

### 12. Net loss per share

As of September 30, 2024, the Company had Class A common stock and Class B common stock. Both share classes have the same rights to the Company's earnings and neither of the classes have any prior or senior rights to dividends to the other share class.

Basic and diluted net loss per share was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,				Nine Months Ended September 30		
	 2024		2023		2024		2023
Numerator:							
Net loss	\$ (11,323)	\$	(13,392)	\$	(37,223)	\$	(41,295)
Denominator:							
Weighted average Class A common shares outstanding-basic and							
diluted	38,359,127		37,770,566		38,201,382		37,539,885
Weighted average Class B common shares outstanding-basic and							
diluted	5,309,529		5,309,529		5,309,529		5,445,299
Total shares for EPS—basic and diluted	43,668,656		43,080,095		43,510,911		42,985,184
Net loss per share attributable to Class A common stockholders							
—basic and diluted	\$ (0.26)	\$	(0.31)	\$	(0.86)	\$	(0.96)
Net loss per share attributable to Class B common stockholders							
basic and diluted	\$ (0.26)	\$	(0.31)	\$	(0.86)	\$	(0.96)

The Company's potentially dilutive securities, which include stock options, restricted 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 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 for the periods indicated because including them would have had an anti-dilutive effect:

	Septeml	ber 30,
	2024	2023
Options to purchase common stock	6,860,505	6,795,549
Unvested restricted common stock	2,107,248	1,782,401
Warrants to purchase common stock	286,084	286,324
Options to purchase common stock under ESPP	29,699	22,051
	9,283,536	8,886,325

### 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.

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

The Company has made an accounting policy election to account for lease and non-lease components in its contracts as single lease components for all asset classes. The non-lease components typically represent additional services transferred to the Company, such as common area maintenance for real estate, which are variable in nature and recorded in variable lease expense in the period incurred.

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

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. The furniture financing lease agreement is immaterial to the Company's condensed consolidated financial statements. 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):

	Nine Months Ended September 30,			
		2024		2023
Cash paid for amounts included in measurement of lease liabilities:				
Operating cash outflows - payments on operating leases	\$	997	\$	956
Operating cash outflows - payments on financing leases	\$	27	\$	29
Financing cash outflows - payments on financing leases	\$	29	\$	27
Right-of-use assets obtained in exchange for new lease obligations:				
Investing non-cash activities - establishment of right of use operating assets	\$	—	\$	151

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

	Septen	September 30, 2024		ember 31, 2023
Operating Leases:				
Operating lease assets	\$	5,245	\$	5,972
Operating lease liabilities, short-term	\$	1,148	\$	1,090
Operating lease liabilities, long-term		5,083		5,952
Total operating lease liabilities	\$	6,231	\$	7,042
Financing Leases:				
Office furniture and fixtures	\$	386	\$	386
Accumulated depreciation		(211)		(118)
Net property, plant and equipment	\$	175	\$	268
Lease liabilities, short-term	\$	46	\$	42
Lease liabilities, long-term		177		262
Total financing lease liabilities	\$	223	\$	304
Weighted-average remaining lease term - operating leases (in years):		4.79		5.54
Weighted-average remaining lease term - financing leases (in years):		4.75		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):

	Thre	e Months Er	ided S	eptember 30,	Nine Months Ended September 30,			
		2024		2024		2023	2024	2023
Operating lease cost	\$	305	\$	314	914	899		
Financing lease cost - amortization of right-of-use asset		11		12	36	37		
Financing lease cost - interest on lease liability		10		9	27	29		
Variable lease cost		234		172	675	522		
Total lease cost	\$	560	\$	507	1,652	1,487		

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 \$0.5 million for each of the three months ended September 30, 2024 and 2023, and was \$1.6 million and \$1.4 million for the nine months ended September 30, 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 each of the three and nine months ended September 30, 2024 and 2023.

Maturities of the Company's operating lease liabilities as of September 30, 2024 were as follows (in thousands):

	rating Lease Aaturities
2024 (excluding the nine months ended September 30)	\$ 337
2025	1,368
2026	1,401
2027	1,435
2028	1,469
Thereafter	804
Total lease payments	\$ 6,814
Less imputed interest	(583)
Total present value of lease liabilities	\$ 6,231

Maturities of the Company's financing lease liability as of September 30, 2024 were as follows (in thousands):

	Financing Lease Maturities
2024 (excluding the nine months ended September 30)	\$ 18
2025	75
2026	75
2027	75
2028	75
Thereafter	 38
Total lease payments	\$ 356
Less imputed interest	(133)
Total present value of lease liabilities	\$ 223

#### 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 condensed consolidated financial statements as of September 30, 2024 and December 31, 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 Code. This plan covers all U.S. 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 \$0.2 million to the plan during each of the three months ended September 30, 2024 and 2023, and made contributions of \$0.7 million and \$0.6 million to the plan during the nine months ended September 30, 2024 and 2023, respectively.

### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated condensed financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited Consolidated Financial Statements and related notes thereto for the year ended December 31, 2023, included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 1, 2024 (the "2023 Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, 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 Form 10-Q, 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 ("MQC") detection platform. We develop, manufacture, market and sell the Growth Direct system and related proprietary consumables, and value-added services to enable rapid MQC testing in the manufacture of biologics, cell and gene therapies, vaccines, sterile injectables, and other healthcare products. Our system delivers the power of industrial automation to bioprocessing and pharmaceutical manufacturing firms by modernizing and digitizing their MQC operations. Our Growth Direct platform, developed with over 15 years of active feedback from our customers, was purpose-built to meet the growing demands posed by the increasing scale, complexity, and regulatory scrutiny confronting global pharmaceutical manufacturing. Our Growth Direct platform comprises the Growth Direct system, optional laboratory information management system ("LIMS") connection software (which the majority of our customers purchase) and other software, 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, advancing our technological capabilities, 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. To date, we have funded our operations primarily with proceeds from sales of redeemable convertible preferred stock, borrowings under loan agreements, revenue from products, services and contracts, and proceeds from our IPO, as well as our cost-reimbursement/cost sharing contracts with the U.S. Department of Health and Human Services Biomedical Advanced Research & Development Authority ("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 cost 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"). These actions are expected to result in approximately \$7 million in annual cash savings and enable us to achieve 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.

Since our inception, we have incurred net losses in each year. We generated revenue of \$7.6 million and \$6.1 million for the three months ended September 30, 2024 and 2023, respectively, and incurred net losses of \$11.3 million and



\$13.4 million for those same periods, respectively. As of September 30, 2024, we had an accumulated deficit of \$465.6 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 a combination of equity offerings and debt financings. If we are unable to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue our expansion plans including the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations.

We believe that our cash and cash equivalents and investments as of September 30, 2024 enable us to fund our operating expenses and capital expenditure requirements for at least twelve months following the issuance date of the unaudited interim condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2024. 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 and interest rate environment 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 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 for our business. Our ability to successfully address these challenges is subject to various risks and uncertainties, including those described under the section titled "Risk Factors" to this Quarterly Report on Form 10-Q.

### 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 improving the efficiency and effectiveness of our sales team. We are making targeted investments in these organizations and expect to continue to do so



in the future. Examples of these investments include new tools and training for the sales organization, targeted marketing initiatives, expanding lead generation capabilities and hosting Growth Direct demonstrations and other customer-focused events.

### Expansion within our existing customer base

There is an opportunity to broaden adoption and increase utilization of our Growth Direct platform throughout our existing customers' organizations as these customers purchase 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 September 30, 2024, approximately 42% of our customers have purchased Growth Direct systems for multiple sites, and approximately 58% 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 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 through the end of 2024.

### **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 contract development and manufacturing organizations, or 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.

In order to improve our gross margins, we 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 on our automated consumables manufacturing 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 related costs to provide and support 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. We have recently experienced positive trends in our gross margins, improving from (27)% for the three months ended September 30, 2023 to 8% for the three months ended September 30, 2024, and from (33)% for the nine months ended September 30, 2023 to (5)% for the nine months ended September 30, 2024. 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.

	Three	e Months Ended S	September 30,	Change			
	20	)24	2023	Amount	%		
		(dollars in thousands)					
Systems placed:							
Systems placed in period		7	5	2	40.0 %		
Cumulative systems placed		156	135	21	15.6 %		
Systems validated:							
Systems validated in period		4	4	0	— %		
Cumulative systems validated		133	112	21	18.8 %		
Product and service revenue — total	\$	7,604 \$	6,145	\$ 1,459	23.7 %		
Product and service revenue — recurring	\$	3,675 \$	3,410	\$ 265	7.8 %		

	1	Nine Months Ended Sej	otember 30,	Change			
		2024	2023	Amount	%		
		(dollars in thousands)					
Systems placed:							
Systems placed in period		15	10	5	50.0 %		
Cumulative systems placed		156	135	21	15.6 %		
Systems validated:							
Systems validated in period		12	9	3	33.3 %		
Cumulative systems validated		133	112	21	18.8 %		
Product and service revenue — total	\$	19,833 \$	16,182 \$	3,651	22.6 %		
Product and service revenue — recurring	\$	11,262 \$	10,255 \$	1,007	9.8 %		

### 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 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 in 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 install and 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 has taken 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 the validation is completed. However, the timeline for such transition may be longer depending on the specific circumstances of each individual customer. 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 placement volume and timing, whether customers have previously validated Growth Direct systems within their site or network, access to customer sites, customer site readiness, availability of required customer personnel 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 our 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 48.3% and 55.5% of our total revenue for the three months ended September 30, 2024 and 2023, respectively. Recurring revenue was 56.8% and 63.4% of our total revenue for the nine months ended September 30, 2024 and 2023, respectively. 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 validated systems in the period, as well as other variables such as the volume of tests being conducted and the test application(s) being used on customers' 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.

	Sept	e Months Ended ember 30, 2024 n thousands)	Percentage of Total Revenue	Three Months Ended September 30, 2023 (in thousands)		Percentage of Total Revenue
Product revenue	\$	5,255	69.1 %	\$	4,200	68.3 %
Service revenue		2,349	30.9 %		1,945	31.7 %
Total revenue	\$	7,604	100.0 %	\$	6,145	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 September 30, 2024, we had placed 156 Growth Direct systems with over 40 customers globally, including 70% of the top twenty pharmaceutical companies as measured by revenue, and the manufacturers of approximately 19% of globally approved cell and gene therapies, including manufacturers of 100% 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. Although we do not require our customers to use our installation and validation services, our customers typically elect to purchase those services from us. 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 into our existing customers and markets and expand into new customers and markets.

#### Consumables

Our consumable revenue is a recurring product revenue stream comprised of two proprietary consumables to capture test samples for analysis on the Growth Direct system, an Environmental Monitoring consumable, and a Water/Bioburden consumable. Both proprietary consumables support the growth-based compendial method for MQC testing mandated by global regulators and provide results that are comparable to traditional consumables. Our consumables are designed with features that enable automation on the Growth Direct system, with bar coding for tracking and data integrity, and physical characteristics for robotic handling, to support vision detection and 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. Other than revenue from service contracts, which is recurring service revenue, revenue from all other field services as well as validation services are non-recurring service revenue streams.

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 preventative maintenance visits. 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, perform one-time paid field service, and provide preventative maintenance service during the one-year assurance warranty period. We recognize revenue from installation services, one-time paid field service, and preventative maintenance service during the assurance warranty period 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, royalties, depreciation and amortization expense, allocated information technology and facility-related costs, overhead and other costs related to those sales recognized as product revenue in the period.

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

As part of our Operational Efficiency Program, we have implemented actions to reduce employee-related expenses and certain other nonemployee related costs. For future periods, we expect our costs of revenue to increase or decrease commensurate with product and service volumes. 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

37

expenses associated with reduced headcount and certain other non-employee-related costs. For future periods, we expect sales and marketing expenses to increase or decrease as and when we make investments into our sales and marketing organization, including in the number of sales and marketing personnel and our continued efforts 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 nonemployee-related costs. For future periods, we expect these expenses to increase or decrease, as applicable, commensurate with the size, scope and complexity of our general and administrative functions.

#### Other income (expense)

#### Interest income, net

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

#### Other expense, net

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

#### Income tax expense

We generated significant taxable losses during each of the three and nine months ended September 30, 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.

#### **Results of operations**

#### Comparison of the three months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,				Change		
		2024		2023		Amount	%
				(in thousands)			
Revenue:							
Product revenue	\$	5,255	\$	4,200	\$	1,055	25.1 %
Service revenue		2,349		1,945	_	404	20.8 %
Total revenue		7,604		6,145		1,459	23.7 %
Costs and operating expenses:	_						
Cost of product revenue		5,314		5,691		(377)	(6.6)%
Cost of service revenue		1,668		2,085		(417)	(20.0)%
Research and development		3,609		3,116		493	15.8 %
Sales and marketing		3,376		3,498		(122)	(3.5)%
General and administrative		5,676		6,204		(528)	(8.5)%
Total costs and operating expenses		19,643		20,594		(951)	(4.6)%
Loss from operations		(12,039)		(14,449)		2,410	(16.7)%
Other income (expense):							
Interest income, net		768		1,093		(325)	(29.7)%
Other expense, net		(39)		(26)		(13)	50.0 %
Total other income (expense), net		729		1,067		(338)	(31.7)%
Loss before income taxes		(11,310)		(13,382)		2,072	(15.5)%
Income tax expense		13		10		3	30.0 %
Net loss	\$	(11,323)	\$	(13,392)	\$	2,069	(15.4)%

#### Revenue

Product revenue increased by \$1.1 million, or 25.1%, with the increase largely attributable to higher system placements, improvements in average selling prices during the period, as well as higher system-related revenue, primarily from LIMS connection software and other software sales.

Service revenue increased by \$0.4 million, or 20.8%. The increase in service revenue was primarily due to increases in revenue related to validations and installations as well as higher service contract revenue due to an increase in the cumulative number of Growth Direct systems validated and under such contracts.

#### Costs and operating expenses

#### Costs of revenue

Cost of product revenue decreased by \$0.4 million, or 6.6%. The decrease was driven by lower material, labor and overhead costs as a result of the impact of cost reduction activities, improvements in production efficiencies and increased production volumes for both systems and consumables, partially offset by the higher volume of Growth Direct systems sold.

Cost of service revenue decreased by \$0.4 million, or 20.0%. This decrease was primarily attributable to lower service headcount and headcountrelated costs.



#### Research and development

	Three Months Ended September 30,			Change		
	 2024		2023		Amount	%
		(do	llars in thousands)			
Research and development	\$ 3,609	\$	3,116	\$	493	15.8 %
Percentage of total revenue	47.5 %	)	50.7 %			

Research and development expenses increased by \$0.5 million, or 15.8%. This increase was primarily due to higher spending on new product development activities, including our rapid sterility application, as well as increased headcount-related costs and facilities costs related to our innovation center and lab in our existing Lexington, Massachusetts facility.

#### Sales and marketing

	Three Months Ended September 30,			Change		
	 2024		2023	 Amount	%	
		(dolla	rs in thousands)			
Sales and marketing	\$ 3,376	\$	3,498	\$ (122)	(3.5)%	
Percentage of total revenue	44.4 %	, D	56.9 %			

Sales and marketing expenses remained relatively consistent, decreasing \$0.1 million, or 3.5%.

#### General and administrative

	Three Months Ended September 30,			Change		
	 2024		2023		Amount	%
		(dolla	ars in thousands)			
General and administrative	\$ 5,676	\$	6,204	\$	(528)	(8.5)%
Percentage of total revenue	74.6 %	)	101.0 %			

General and administrative expenses decreased by \$0.5 million, or 8.5%. The decrease was largely attributable to lower headcount-related costs and one-time bonus expense related to the 2022 retention bonus program which ended in the third quarter of 2023.

#### Other income (expense)

#### Interest income

Interest income, which is related to interest earned on our investments, decreased \$0.3 million primarily as a result of lower investment balances during the three months ended September 30, 2024.

#### Other expense

Other expense, which is comprised of miscellaneous expenses unrelated to our core business, was flat for each of the three months ended September 30, 2024 and 2023.

#### Income tax expense

Income tax expense was less than \$0.1 million for each of the three months ended September 30, 2024 and 2023. The expense in each period was attributable to an income tax provision related to our German subsidiary.



#### Comparison of the nine months ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,				Change		
		2024		2023	 Amount	%	
			(d	ollars in thousands)			
Revenue:							
Product revenue	\$	13,505	\$	10,693	\$ 2,812	26.3 %	
Service revenue		6,328		5,489	839	15.3 %	
Total revenue		19,833		16,182	 3,651	22.6 %	
Costs and operating expenses:							
Cost of product revenue		15,404		15,361	43	0.3 %	
Cost of service revenue		5,519		6,134	(615)	(10.0)%	
Research and development		11,195		9,502	1,693	17.8 %	
Sales and marketing		10,284		10,161	123	1.2 %	
General and administrative	_	17,121		19,399	(2,278)	(11.7)%	
Total costs and operating expenses		59,523		60,557	(1,034)	(1.7)%	
Loss from operations		(39,690)		(44,375)	 4,685	(10.6)%	
Other income (expense):							
Interest income, net		2,589		3,169	(580)	(18.3)%	
Other (expense) income, net		(91)		(66)	(25)	37.9 %	
Total other income (expense), net		2,498		3,103	 (605)	(19.5)%	
Loss before income taxes		(37,192)		(41,272)	 4,080	(9.9)%	
Income tax expense		31		23	8	34.8 %	
Net loss	\$	(37,223)	\$	(41,295)	\$ 4,072	(9.9)%	

#### Revenue

Product revenue increased by \$2.8 million, or 26.3%. The increase was driven primarily by a higher volume of system placements as well as higher average selling prices in consumables. Higher system-related revenue, particularly from our LIMS connection software and other software sales, also contributed to the increase.

Service revenue increased by \$0.8 million, or 15.3%. The increase in service revenue was primarily driven by increases in revenue related to validations and installations as well as higher service contract revenue as a result of an increase in the cumulative number of Growth Direct systems validated and under such contracts.

#### Costs and operating expenses

#### Costs of revenue

Cost of product revenue remained relatively consistent, increasing 0.3%. Increased costs due to higher volumes of systems and consumables sold was almost entirely offset by lower material, labor and overhead costs. The cost reductions were primarily the result of material cost reduction activities, improvements in production efficiencies and increased production volumes for both consumables and systems.

Cost of service revenue decreased by \$0.6 million, or 10.0%. This decrease was primarily attributable to lower headcount and headcount-related costs and one-time bonus expense related to the 2022 retention bonus program which ended in the third quarter of 2023.

#### Research and development

	Nine Months Endo September 30,		Change		
	 2024	2023	Amount	%	
	 (dollar	rs in thousands)			
Research and development	\$ 11,195 \$	9,502 \$	1,693	17.8 %	
Percentage of total revenue	56.4 %	58.7 %			

Research and development expenses increased by \$1.7 million, or 17.8%. This increase was primarily due to higher spending on new product development activities, including our rapid sterility application, as well as increased headcount-related costs, engineering costs, and facilities costs related to our innovation center and lab in our Lexington, Massachusetts facility.

#### Sales and marketing

	Nine Months Ended September 30,				Change		
	 2024		2023		Amount	%	
	 (dollars in thousands)						
Sales and marketing	\$ 10,284	\$	10,161	\$	123	1.2 %	
Percentage of total revenue	51.9 %	ó	62.8 %				

Sales and marketing expenses increased by \$0.1 million, or 1.2%. This increase was primarily due to higher headcount-related costs.

#### General and administrative

	Nine Mo Septe	onths En mber 30		Change	
	 2024		2023	 Amount	%
		(dolla	ars in thousands)		
General and administrative	\$ 17,121	\$	19,399	\$ (2,278)	(11.7)%
Percentage of total revenue	86.3 %	0	119.9 %		

General and administrative expenses decreased by \$2.3 million, or 11.7%. This decrease was primarily attributable to lower headcount and headcount-related costs as well as lower bonus expense related to the 2022 retention bonus program which ended in the third quarter of 2023. Lower public company operating costs, including third-party legal fees and business insurance premiums, also contributed to the decrease.

#### Other income (expense)

#### Interest income

Interest income decreased \$0.6 million, or 18.3% due to lower investment balances during the nine months ended September 30, 2024.

#### Other expense

Other expense, which is comprised of miscellaneous expenses unrelated to our core business, were flat for each of the nine months ended September 30, 2024 and 2023.

#### Income tax expense (benefit)

Income tax expense was less than \$0.1 million for each of the nine months ended September 30, 2024 and 2023. The expense in each period was attributable to an income tax provision related to our German subsidiary.



#### 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 the proceeds from our IPO.

In July 2024, we completed an enterprise-wide review of opportunities to realize operational efficiencies. Based on the results of this review, we implemented our Operational Efficiency Program for certain cost 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. These actions are expected to result in approximately \$7 million in annual cash savings and enable us to achieve 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.

We believe that our cash, cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months following the date the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 were issued.

As of September 30, 2024, we had the following cash and investment-related assets on our condensed consolidated balance sheet (in thousands):

	Se	ptember 30, 2024
Cash and cash equivalents	\$	22,044
Short-term investments		38,788
Restricted cash		284
Total	\$	61,116

#### 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 \$3.2 million as of September 30, 2024, including \$0.6 million in short-term obligations.

In June 2021, we entered into a sublease agreement for our Lexington, Massachusetts headquarters, which expires in June 2029. The sublease 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 \$3.6 million as of September 30, 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 our Lexington, Massachusetts facility for an additional five years following expiration of the sublease.

#### **Cash flows**

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

		Nine Months Ended September 30,				
		2024		2023		
	¢	(24.244)	¢	(25.50.4)		
Net cash used in operating activities	\$	(34,244)	\$	(35,584)		
Net cash provided by investing activities		31,794		32,145		
Net cash provided by financing activities		209		161		
Net decrease in cash and cash equivalents and restricted cash	\$	(2,241)	\$	(3,278)		

#### **Operating** activities

During the nine months ended September 30, 2024, net cash used in operating activities was \$34.2 million, a decrease of \$1.3 million compared to the prior-year period. The lower use of net cash was primarily a result of the timing of payments to vendors and increased customer cash receipts. This decrease was offset by increased inventory purchases, and higher usage of cash to settle accrued expenses and other current liabilities mainly as a result of higher annual bonus payments made during the nine months ended September 30, 2024. During the nine months ended September 30, 2023, these payments were limited due to annual bonuses being temporarily replaced by a retention bonus program for non-executive employees in that period. The temporary retention bonus program was established in connection with our August 2022 restructuring action and concluded in the third quarter of 2023.

#### Investing activities

Net cash provided by investing activities was \$32.1 million during each of the nine months ended September 30, 2024 and 2023. Lower investment maturities and sales were offset by lower investment purchases and a reduction in cash used to purchase property and equipment in the current-year period.

#### Financing activities

During the nine months ended September 30, 2024, net cash provided by financing activities was flat compared to the nine months ended September 30, 2023, at \$0.2 million.

#### 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"). To regain compliance, the closing bid price of our common stock must be at least \$1.00 or higher for a minimum of ten consecutive business days, though Nasdaq has the discretion to extend the ten business day period to up to 20 consecutive business days.

The initial period during which we were required to regain compliance with the Bid Price Requirement expired on July 31, 2024. Because we did not regain compliance with the requirement during the initial period, we transferred the listing of our Class A common stock to the Nasdaq Capital Market, in order to secure an additional 180 calendar day compliance period ending on January 27, 2025. As a condition of securing such additional compliance period, we informed Nasdaq that we intend to regain compliance with the Bid Price Requirement during the second compliance period, which may include the implementation of a reverse stock split if necessary. We intend to monitor the closing bid price of our Class A common stock and take such reasonable measures to regain compliance with the Bid Price Requirement. However, there can be no assurance that we will be able to regain compliance with the Bid Price Requirement even during the second compliance period, nor can there be any assurance that we will receive the necessary approvals from our stockholders to effect a reverse stock split. If we do not cure the deficiency during the additional compliance period and regain compliance with the Bid Price Requirement, Nasdaq will provide written notice that our common stock will be subject to delisting. In the event of such notification, we may appeal Nasdaq's delisting determination. However, there can be no assurance that, if



we receive a delisting notice and appeal the delisting determination by Nasdaq, such appeal would be successful. As a result, there can be no assurance that we will be able to continue the listing of our Class A common stock on Nasdaq.

#### 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 variability to continue for the foreseeable future, which may cause fluctuations in our operating results and financial metrics.

#### **Critical accounting estimates**

Our condensed 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.

Our significant accounting policies are described in more detail in Note 2 — Summary of Significant Accounting Policies to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the 2023 Form 10-K, other than as disclosed in Note 2 — Summary of Significant Accounting Policies — to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

#### 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 condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

#### **Emerging growth company status**

The Jumpstart Our Business Startups Act of 2012 (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. We cannot predict if investors will find our common shares less attractive because we may rely on these



exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates and inflationary pressure. There has been no material change in our exposure to market risks from that discussed in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of the 2023 Form 10-K.

#### **Item 4. 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. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

#### 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 Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Our disclosure controls and procedures are designed to ensure (a) that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer to allow timely decisions regarding required disclosures. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **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 September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### PART II - OTHER INFORMATION

#### **Item 1. Legal Proceedings**

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any material 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 1A. Risk Factors.

Our business involves significant risks. Stockholders should carefully consider the risks and uncertainties described below and the other information in this Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements" on page <u>3</u>. 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.

The risk factors denoted with a "\*", if any, are newly added or have been materially updated from our 2023 Form 10-K.

#### 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 three months ended September 30, 2024, we incurred a net loss of \$11.3 million. As of September 30, 2024, we had an accumulated deficit of \$465.6 million. In July 2024, based on our enterprise-wide review of opportunities to realize operational efficiencies, we implemented certain cost-savings 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 for any substantial period of time. While our goal to achieve positive cash flow is underpinned by our rec

#### 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 recently experienced positive trends in our gross margins, improving from (27)% for the three months ended September 30, 2023 to 8% for the three months ended September 30, 2024, and from (33)% for the nine months ended September 30, 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 Quarterly Report on Form 10-Q could result in the actual operating results being different from our guidance, and the differences may be adverse and material.

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

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 system, or if our existing customers decide to purchase fewer of our consumables and service contracts or terminate their relationships with us, our revenue could significantly decrease, which would have an adverse effect on our financial condition and results of operations and could adversely impact our ability to execute on our growth strategy.

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

We expect 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 September 30, 2024 of \$60.8 million, and anticipated cash flow from operations, will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months following the date these consolidated financial statements were issued. This estimate and our expectation regarding the sufficiency of our existing cash, cash equivalents, and investments are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Until such time, if ever, as we can generate sufficient 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 present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- the costs of manufacturing and shipping our products or of providing services to our customers, which may impact our operating gross margins in any given period;
- the cost of maintaining our operations, manufacturing, our product offerings, and our sales and marketing efforts;
- our rate of progress in and costs of launching and commercializing new products, and the cost of the sales and marketing activities associated with, establishing and expanding adoption of our Growth Direct system;
- our rate of progress in, and cost of research and development activities associated with, products in research and development;
- the effect of competing technological and market developments;
- any expenses we may incur in connection with undertaking efforts to improve our environment, social and governance metrics as requested by our customers, investors and other stakeholders;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- costs related to domestic and international expansion.

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

#### **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, 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 Rapid Sterility system with an existing customer in the second quarter of 2024. We plan to continue to scale our manufacturing capabilities for the Rapid Sterility application through the end of 2024. 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, 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.

53

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. 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 improve the effectiveness of our marketing and sales organization with new and existing customers and address our customers' needs or to expand our customer base, our business may be adversely affected.

We have limited experience in marketing and selling our products and we currently rely on a small team to make direct sales in countries around the world. There are significant risks involved with relying on our own marketing and sales capabilities, including our ability to design and execute effective sales processes, generate and convert sufficient sales opportunities into new customers and place additional systems with existing customers. We 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 includes 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 resumed growth in our business operations. The volatility in our growth has required significant time and attention from our management, and placed strains on our operational and manufacturing systems and processes, financial systems and internal controls and other aspects of our business. 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 defined engineers, 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. 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 and may not meet the expectations of our customers, which means our business, financial condition, results of operations and prospects could suffer.

Our Growth Direct platform includes the Growth Direct system, proprietary consumables and our LIMS connection software. While we rigorously test our platform and its components, there could be undetected errors or defects. Disruptions or other performance problems with our platform or with the components that comprise our platform may adversely impact our customers' manufacturing process, compliance workflow or business, harm our reputation and result in reduced revenue or increased costs, 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 includes 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 related actions or announcements, may make it increasingly difficult for us to hire and retain our executive officers, key employees,



consultants and advisors. If we are unable to attract qualified personnel and retain our current employees, our ability to develop and sell our products could be limited and our business and customer relationships could be materially harmed.

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

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

Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious software, bugs or viruses, human acts and natural disasters. 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.

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

In the ordinary course of our business, we collect and store sensitive data, including personal information, intellectual property and proprietary business information owned or controlled by ourselves or our employees, customers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. These applications and data encompass a wide variety of business-critical information, including research and development information, customer information, commercial information and business and financial information. We, like all companies storing business-critical information, face a number of risks relative to protecting this critical information, including loss of access, inappropriate use or disclosure, unauthorized access or exfiltration, inappropriate modification, inappropriate destruction, and the risk of our being unable to adequately monitor and audit and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may still be vulnerable to, and we have in the past experienced, attacks by hackers or viruses or breaches due to employee error, malfeasance or other malicious or inadvertent disruptions. Further, attacks upon information technology systems, including those involving system disrupting ransomware and digital extortion, fraudulent messages purporting to be from legitimate individuals or organizations in order to induce actions directed by bad actors, sometimes known as "phishing", and transmission of fraudulent invoices or other requests for payments by malicious organizations purporting to be legitimate vendors and suppliers, are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives, capabilities, and expertise. We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. While we have measures in place to identify, detect and mitigate security threats and incidents, they are not failproof, so we may also experience security incidents that may remain undetected for an extended period. Any such incident could result in the compromise of our information systems, and the data stored there could be accessed, encrypted, corrupted, modified, publicly disclosed, lost or stolen. Any such incident could result in legal claims or proceedings, including for breaches of confidential information obligations with contractual counterparties, and liability under federal or state laws that protect the privacy of personal information, and regulatory penalties. Notice of breaches may be required to affected individuals,



customers, or other state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. Although we have implemented security measures to prevent, detect and respond to security incidents, our data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access to our information systems, and the loss, destruction or, dissemination of data stored within them could also disrupt or halt our operations and damage our reputation, any of which could adversely affect our business.

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

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

In the United States, various federal and state regulators, including governmental agencies like the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. Such laws may have potentially conflicting requirements that would make compliance challenging.

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

In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personally identifiable information has been disclosed as a result of a data breach. Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, the EU General Data Protection Regulation, or EU GDPR, has extraterritorial reach and adds a broad array of requirements for handling personal data. In particular, the EU GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the European Economic Area, security breach notifications and the security and confidentiality of personal data. Further, from January 1, 2021, following Brexit, companies handling personal data of individuals in the UK have to comply with the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the EU GDPR in UK national law. The 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.

## 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.

### 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 September 30, 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 could result in tariffs and other protective measures;
- natural disasters, the severity and frequency of which may be amplified by global climate change, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks, including severe penalties such as criminal and civil penalties, disgorgement and other remedial measures, that relate to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010 and similar anti-bribery and anticorruption laws in other jurisdictions.

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

Certain legal and political risks are also inherent in foreign operations. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. 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 conflicts 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, geopolitical conflicts and the U.S. presidential election. The global credit and financial markets have 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

63

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

We currently conduct our primary development and manufacturing at our facility located in Lowell, Massachusetts. Our facility and equipment could be harmed or rendered inoperable or inaccessible by natural or man-made disasters, the severity and frequency of which may be amplified by global climate change, or other circumstances beyond our control, including fire, power loss, communications failure, war or terrorism, or another catastrophic event, such as a pandemic or similar outbreak or public health crisis, which may render it difficult or impossible for us to support our customers and develop products. The inability to manufacture our systems and consumables could develop if our facility is inoperable or suffers a loss of utilization for even a short period of time and may result in the loss of customers or harm to our reputation. Disruptions in our manufacturing operations could also adversely affect our efforts to improve the gross margins of our products. Furthermore, our facility and the equipment we use to perform our manufacturing and development could be unavailable or costly and time consuming to repair or replace. It would be difficult, time consuming and expensive to rebuild our facility, to locate and qualify a new facility or license or transfer our proprietary technology to a third party. Even in the event we are able to find a third party to assist in manufacturing and development efforts, we may be unable to negotiate commercially reasonable terms to engage with the third party. To mitigate certain of these risks associated with the manufacture of our consumables, we have constructed a back-up consumable manufacturing facility in Lexington, Massachusetts. While we believe that we could, if necessary, transfer our manufacturing capabilities to our back-up 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 manufacture 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 2043, certain of our earliest unexpired U.S. patents covering the Growth Direct system and its use are scheduled to expire in 2024. Although we own other patents with later expiration dates that cover various improvements and consumables for the Growth Direct platform, these other patents may not provide the same protection as the earliest-filed patents. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing 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. governmentcan 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 in the future in-license intellectual property related to our product offerings. If we lose these rights, our business may be materially adversely affected, our ability to develop improvements to our Growth Direct platform and to develop new technologies may be negatively and substantially impacted, and if disputes arise, we may be subjected to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technology covered by these license agreements.

In the future, we may need to obtain licenses from third parties to advance our research, development and commercialization activities. These intellectual property license agreements may impose various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations on us. Our rights to use the technology we may license may be subject to the continuation of and compliance with the terms of these agreements. Licenses can be terminated and their terms may be materially modified in ways that are significantly adverse to our business interest for any number of reasons. For example, we may fail to comply with our obligations under these agreements, we may use the licensed intellectual property in an unauthorized manner or we may become subject to bankruptcy-related proceedings. Similarly, disputes may arise with respect to our licensing agreements and/or our licensors might conclude that we have materially breached our obligations under our license agreements. If any such in-license agreement is terminated, or if licensed intellectual property fail to provide the intended exclusivity, competitors or other third parties might have the freedom to market or develop products similar to ours. In addition, absent the rights granted to us under such license agreements, we may infringe the intellectual property rights that are the subject of those agreements, we may be required to cease our development and commercialization activities that are deemed infringing, and in such event we may ultimately need to modify our activities or products to design around such infringement, which will consume time and resources and may not be ultimately successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

#### 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, misappropriate 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 Quarterly Report on Form 10-Q.

### \*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 (the "Bid Price Requirement"). We have previously received notifications from Nasdaq that we were not in compliance with the Bid Price Requirement. 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. To regain compliance, the closing bid price of our common stock must be at least \$1.00 or higher for a minimum of ten consecutive business days, though Nasdaq has the discretion to extend the ten business day period to up to 20 consecutive business days.

The initial period during which we were required to regain compliance with the Bid Price Requirement expired on July 31, 2024. Because we did not regain compliance with the requirement during the initial period, we transferred the listing of our Class A common stock to the Nasdaq Capital Market, in order to secure an additional 180 calendar day compliance period ending on January 27, 2025. As a condition of securing such additional compliance period, we informed Nasdaq that we intend to regain compliance with the Bid Price Requirement during the second compliance period, which may include the implementation of a reverse stock split if necessary. We intend to monitor the closing bid price of our Class A common stock and take such reasonable measures to regain compliance with the Bid Price Requirement. However, there can be no assurance that we will be able to regain compliance with the Bid Price Requirement even during the second compliance period, nor can there be any assurance that we will receive the necessary approvals from our stockholders to effect a reverse stock split. If implemented, a reverse stock split may have undesirable consequences. For example, a reverse stock split would have the effect of combining the outstanding shares of our Class A common stock into a smaller number of outstanding shares, which may adversely affect the liquidity and trading volume in our Class A common stock. In addition, a reverse stock split may be viewed negatively by some investors, analysts and other stock market participants, and some companies that have implemented reverse stock splits have experienced subsequent declines in their share price and corresponding market capitalization. If we do not cure the deficiency during the additional compliance period and regain compliance with the Bid Price Requirement, Nasdag will provide written notice that our common stock will be subject to delisting. In the event of such notification, we may appeal Nasdaq's delisting determination. However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by Nasdaq, such appeal would be successful. As a result, there can be no assurance that we will be able to continue the listing of our Class A common stock on Nasdaq.

Even if we regain compliance with the Bid Price Requirement, there can be no assurance that we will continue to comply with the other continued listing standards of Nasdaq. 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.

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 September 30, 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, and correspondingly decreasing the relative voting power of the current holders of our 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 the last day of the fiscal year following the fifth anniversary of the closing of the IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed \$1.235 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 the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

We 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 financing 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, 2023, we had U.S. federal and state net operating loss, or NOL, carryforwards of \$229.3 million and \$100.4 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 \$216.5 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 \$2.2 million and \$3.2 million, respectively. These tax credits may be available to offset future tax liabilities and begin to expire in 2038 and 2024, respectively.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change by value in its equity ownership by one or more stockholders or groups of stockholders owning at least 5% of the corporation's stock over a rolling three-year period, is subject to limitations on its ability to utilize its pre-ownership change NOLs and



tax credits to offset future taxable income or income tax liabilities for U.S. federal income tax purposes. Similar rules may apply under state tax laws. The Company has completed a Section 382 study through July 31, 2020 to assess the limitations on use of NOLs and research and development credits due to changes in control. The study determined that ownership changes materially limited the NOL carryforwards and research and development tax credits available to offset future tax liabilities and the limitations have been reflected in the amounts of NOL carryforwards, research and development tax credits, and deferred tax assets disclosed above. The Company has not completed a Section 382 study for post July 31, 2020 transactions which could create an additional limitation although materially all of the current federal NOL carryforwards can be carried forward indefinitely. We have in the past experienced, and we may in the future experience ownership changes, some of which are outside our control. For these reasons, we are not able to utilize a material portion of the NOLs and tax credits even if we attain profitability.

#### General risk factors

### There is increasing 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 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

#### 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.

#### Item 3. Defaults Upon Senior Securities

None.

#### Item 4. Mine Safety Disclosures

Not applicable.

#### **Item 5. Other Information**

#### (c) Director and Officer Trading Plans and Arrangements

None of our directors or officers adopted, modified or terminated a Rule 10b5-1 trading arrangement, or adopted, modified or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarter ended September 30, 2024.

### Item 6. Exhibits

Exhibit Number	Description of Exhibit
<u>3.1</u>	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40952) filed on July 21, 2021)
<u>3.2</u>	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)
<u>3.3</u>	Certificate of Amendment to Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40952) filed on May 24, 2024)
<u>31.1*</u>	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
<u>31.2*</u>	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
<u>32.1**</u>	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
<u>32.2**</u>	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
<u>104*</u>	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

\* Filed herewith.

\*\* Furnished herewith.

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, duly authorized.

Date: November 7, 2024

### **RAPID MICRO BIOSYSTEMS, INC.**

By:	/s/ Robert Spignesi
	Robert Spignesi
	President and Chief Executive Officer
	(Principal Executive Officer)

/s/ Sean Wirtjes

Sean Wirtjes Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

80

By:

### 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 quarterly report on Form 10-Q 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: November 7, 2024

By: /s/ Robert Spignesi

 
 Name:
 Robert Spignesi

 Title:
 Chief Executive Officer (principal executive officer)

### 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 quarterly report on Form 10-Q 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: November 7, 2024

By: /s/ Sean Wirtjes

 
 Name:
 Sean Wirtjes

 Title:
 Chief Financial Officer (principal financial officer and principal accounting officer)

### 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 quarterly report of Rapid Micro Biosystems, Inc. (the "Company") on Form 10-Q for the period ended September 30, 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: November 7, 2024

By: /s/ Robert Spignesi

 
 Name:
 Robert Spignesi

 Title:
 Chief Executive Officer (principal executive officer)

### 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 quarterly report of Rapid Micro Biosystems, Inc. (the "Company") on Form 10-Q for the period ended September 30, 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: November 7, 2024

By: /s/ Sean Wirtjes

 
 Name:
 Sean Wirtjes

 Title:
 Chief Financial Officer (principal financial officer and principal accounting officer)