

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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)
1001 Pawtucket Boulevard West, Suite 280
Lowell, MA
(Address of Principal Executive Offices)

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

01854
(Zip Code)

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

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

Title of Each Class	Trading symbol(s)	Name of Exchange on which registered
Class A common stock, \$0.01 par value per share	RPID	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>	Emerging growth company	<input checked="" type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of October 31, 2023, there were 37,089,376 shares of the registrant's Class A common stock, par value \$0.01, outstanding.

As of October 31, 2023, there were 5,309,529 shares of the registrant's Class B common stock, par value \$0.01, outstanding.

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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 ability to generate cash flow;
- our expectations and assumptions related to our future funding requirements and available capital resources, which may be impacted by market uptake of our Growth Direct system, our management of inventory and supply chain, our research and development activities and the expansion of our sales, marketing, service, manufacturing and distribution capabilities;
- our ability to maintain and expand our customer base for our Growth Direct platform and systems;
- our exploration of strategic alternatives for the Company;
- the effectiveness of enhancements of our sales processes;
- the impact of our restructuring on the Company;
- anticipated trends and growth rates in our business and in the markets in which we operate;
- our research and development activities and prospective new features, products and product approvals;
- our ability to anticipate market needs and successfully develop new and enhanced solutions to meet those needs, including prospective products;
- our ability to hire and retain necessary qualified employees to grow our business and expand our operations;
- our expectations regarding the potential impact of inflation and fluctuations in interest rates on our business and operating costs;
- our ability to remain in compliance with the listing requirements of the Nasdaq Global Select Market;
- our expectations regarding the potential impact of ongoing conditions in the banking system and financial markets 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 in Part I, Item 1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 under the heading “Risk Factors.” 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.

TRADEMARKS

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

INTERNET POSTING OF INFORMATION

We routinely post information that may be important to investors in the “Investors” section of our website at www.rapidmicrobio.com. We encourage investors and potential investors to consult our website regularly for important information about us. The contents of our website are not incorporated by reference in this 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)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,786	\$ 27,064
Short-term investments	65,603	81,584
Accounts receivable	3,907	5,369
Inventory	20,193	21,187
Prepaid expenses and other current assets	1,556	3,372
Total current assets	115,045	138,576
Property and equipment, net	12,870	13,818
Right-of-use assets, net	6,489	7,063
Long-term investments	14,620	29,790
Other long-term assets	856	1,119
Restricted cash	284	284
Total assets	\$ 150,164	\$ 190,650
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,271	\$ 5,428
Accrued expenses and other current liabilities	6,946	8,150
Deferred revenue	4,560	4,706
Lease liabilities, short-term	841	766
Total current liabilities	15,618	19,050
Lease liabilities, long-term	6,504	7,202
Other long-term liabilities	255	229
Total liabilities	22,377	26,481
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Class A common stock, \$0.01 par value; 210,000,000 shares authorized at September 30, 2023 and December 31, 2022; 37,088,032 shares and 36,538,805 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	371	366
Class B common stock, \$0.01 par value; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; 5,309,529 shares and 5,553,379 issued and outstanding at September 30, 2023 and December 31, 2022, respectively	53	55
Preferred stock, \$0.01 par value; 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; zero shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Additional paid-in capital	545,029	540,775
Accumulated deficit	(417,213)	(375,918)
Accumulated other comprehensive loss	(453)	(1,109)
Total stockholders' equity	127,787	164,169
Total liabilities and stockholders' equity	\$ 150,164	\$ 190,650

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	\$ 4,200	\$ 3,209	\$ 10,693	\$ 8,212
Service revenue	1,945	1,530	5,489	4,547
Total revenue	6,145	4,739	16,182	12,759
Costs and operating expenses:				
Cost of product revenue	5,691	5,627	15,361	13,220
Cost of service revenue	2,085	1,906	6,134	5,478
Research and development	3,116	2,973	9,502	9,463
Sales and marketing	3,498	3,930	10,161	10,870
General and administrative	6,204	7,189	19,399	19,687
Total costs and operating expenses	20,594	21,625	60,557	58,718
Loss from operations	(14,449)	(16,886)	(44,375)	(45,959)
Other income (expense):				
Interest income, net	1,093	575	3,169	947
Other (expense) income, net	(26)	(21)	(66)	70
Total other income (expense), net	1,067	554	3,103	1,017
Loss before income taxes	(13,382)	(16,332)	(41,272)	(44,942)
Income tax expense (benefit)	10	7	23	(583)
Net loss	\$ (13,392)	\$ (16,339)	\$ (41,295)	\$ (44,359)
Net loss per share — basic and diluted	\$ (0.31)	\$ (0.38)	\$ (0.96)	\$ (1.05)
Weighted average common shares outstanding — basic and diluted	43,080,095	42,517,992	42,985,184	42,404,243

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

RAPID MICRO BIOSYSTEMS, INC.**Condensed consolidated statements of comprehensive loss****(Unaudited)****(In thousands)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	\$ (13,392)	\$ (16,339)	\$ (41,295)	\$ (44,359)
Other comprehensive income:				
Unrealized gain (loss) on investments, net of tax	242	(473)	656	(1,376)
Comprehensive loss	<u>\$ (13,150)</u>	<u>\$ (16,812)</u>	<u>\$ (40,639)</u>	<u>\$ (45,735)</u>

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

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

	Class A Common stock		Class B Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
	Shares	Amount	Shares	Amount				
Balances at December 31, 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 income	—	—	—	—	—	—	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.

RAPID MICRO BIOSYSTEMS, INC.
Condensed consolidated statements of stockholders' equity
(Unaudited), continued
(In thousands, except share amounts)

	Class A Common stock		Class B Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total
	Shares	Amount	Shares	Amount				
Balances at December 31, 2021	34,564,040	\$ 346	6,903,379	\$ 69	\$ 535,693	\$ (315,112)	\$ (16)	\$ 220,980
Conversion of Class B common stock to Class A common stock	1,350,000	14	(1,350,000)	(14)	—	—	—	—
Restricted stock award liability accretion	—	—	—	—	154	—	—	154
Issuance of Class A common stock upon exercise of common stock options	475,033	5	—	—	466	—	—	471
Stock-based compensation expense	—	—	—	—	983	—	—	983
Net loss	—	—	—	—	—	(14,930)	—	(14,930)
Other comprehensive loss	—	—	—	—	—	—	(588)	(588)
Balances at March 31, 2022	36,389,073	\$ 365	5,553,379	\$ 55	\$ 537,296	\$ (330,042)	\$ (604)	\$ 207,070
Restricted stock award liability accretion	—	—	—	—	44	—	—	44
Stock-based compensation expense	—	—	—	—	1,258	—	—	1,258
Net loss	—	—	—	—	—	(13,090)	—	(13,090)
Other comprehensive loss	—	—	—	—	—	—	(315)	(315)
Balances at June 30, 2022	36,389,073	\$ 365	5,553,379	\$ 55	\$ 538,598	\$ (343,132)	\$ (919)	\$ 194,967
Issuance of Class A common stock under ESPP	51,833	—	—	—	159	—	—	159
Restricted stock award liability accretion	—	—	—	—	29	—	—	29
Stock-based compensation expense	—	—	—	—	673	—	—	673
Net loss	—	—	—	—	—	(16,339)	—	(16,339)
Other comprehensive loss	—	—	—	—	—	—	(473)	(473)
Balances at September 30, 2022	36,440,906	\$ 365	5,553,379	\$ 55	\$ 539,459	\$ (359,471)	\$ (1,392)	\$ 179,016

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

RAPID MICRO BIOSYSTEMS, INC.
Condensed consolidated statements of cash flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (41,295)	\$ (44,359)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,311	1,977
Stock-based compensation expense	3,728	2,914
Provision for excess and obsolete inventory	34	219
Noncash lease expense	899	846
Loss (gain) on disposal of property and equipment	—	19
Accretion on investments	(1,766)	(237)
Other	26	(116)
Changes in operating assets and liabilities:		
Accounts receivable	1,462	346
Inventory	960	(5,472)
Prepaid expenses and other current assets	1,817	(152)
Other long-term assets	5	69
Accounts payable	(2,157)	(275)
Accrued expenses and other current liabilities	(1,462)	(2,770)
Deferred revenue	(146)	99
Net cash used in operating activities	<u>(35,584)</u>	<u>(46,892)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(1,427)	(5,929)
Purchases of investments	(50,928)	(155,340)
Maturity of investments	84,500	55,000
Net cash provided by (used in) investing activities	<u>32,145</u>	<u>(106,269)</u>
Cash flows from financing activities:		
Proceeds from issuance of Class A common stock - stock option exercise	6	471
Proceeds from issuance of Class A common stock - employee stock purchase plan	182	159
Payments on finance lease obligations	(27)	(24)
Net cash provided by financing activities	<u>161</u>	<u>606</u>
Net decrease in cash, cash equivalents and restricted cash	(3,278)	(152,555)
Cash, cash equivalents and restricted cash at beginning of period	27,348	178,671
Cash, cash equivalents and restricted cash at end of period	<u>\$ 24,070</u>	<u>\$ 26,116</u>

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

RAPID MICRO BIOSYSTEMS, INC.
Condensed consolidated statements of cash flows, continued
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2023	2022
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ 29	\$ 32
Supplemental disclosure of non-cash investing activities		
Establishment of right of use operating assets	\$ 151	\$ 7,605
Purchases of property and equipment in accounts payable and accrued expenses	\$ 204	\$ 11
Supplemental disclosure of non-cash financing activities		
Establishment of right of use finance assets	\$ —	\$ 366

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

RAPID MICRO BIOSYSTEMS, INC.

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 Lowell, 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, 2022. 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, 2023 and the results of its operations and its cash flows for the three and nine months ended September 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2023 and 2022 are also unaudited. The results for the three and nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, 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 significant 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 significant accounting policies during the three and nine months ended September 30, 2023, as compared to the significant accounting policies disclosed in Note 2 of the audited consolidated financial statements as of December 31, 2022 filed with the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Risk of concentrations of credit, significant customers and significant suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term and long-term investments and accounts receivable. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company maintains its cash and cash equivalents and investments with financial institutions that management believes to be of high credit quality. The Company has not experienced any other-than-temporary losses with respect to its cash equivalents and investments 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 represent 10% or more of the Company's total revenue:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Customer A	14.7 %	23.1 %	18.2 %	22.2 %
Customer B	11.4 %	*	*	*
Customer C	10.2 %	*	*	*
Customer D	*	19.5 %	*	*
	<u>36.3 %</u>	<u>42.6 %</u>	<u>18.2 %</u>	<u>22.2 %</u>

* – less than 10%

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

	September 30,	December 31,
	2023	2022
Customer A	11.0 %	21.4 %
Customer E	19.7 %	*
Customer F	17.6 %	*
Customer G	*	11.8 %
Customer H	*	16.7 %
	<u>48.3 %</u>	<u>49.9 %</u>

* – 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 are no significant concentrations around a single third-party supplier or manufacturer for the three and nine months ended September 30, 2023 or 2022.

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 September 30, 2023 and December 31, 2022, the Company held cash of \$0.3 million and \$0.2 million, respectively, in banks located outside of the United States.

Restricted cash

As of September 30, 2023 and December 31, 2022, 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 consolidated balance sheets.

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. The Company had \$0.8 million of software development costs, net of amortization, capitalized in other long-term assets at September 30, 2023. These capitalized costs are being amortized on a straight-line basis over the initial subscription term of five years. For each of the three months ended September 30, 2023 and 2022, there was \$0.1 million, and for each of the nine months ended September 30, 2023 and 2022, there was \$0.3 million 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Balance, beginning of period	\$ 526	\$ 936	\$ 872	\$ 598
Warranty provisions	171	295	171	646
Warranty repairs	—	(320)	(346)	(333)
Balance, end of period	\$ 697	\$ 911	\$ 697	\$ 911

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 \$0.1 million in contract assets as of both September 30, 2023 and December 31, 2022, 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, 2023 or December 31, 2022. Deferred revenue was \$4.6 million and \$4.7 million at September 30, 2023 and December 31, 2022, respectively. Revenue recognized during the three months ended September 30, 2023 and 2022 that was included in deferred revenue at the prior period-end was \$1.2 million and \$0.5 million, respectively. Revenue recognized during the nine months ended September 30, 2023 and 2022 that was included in deferred revenue at the prior period-end was \$3.3 million and \$2.3 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 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Product and service revenue — recurring	\$ 3,410	\$ 2,908	\$ 10,255	\$ 8,066
Product and service revenue — non-recurring	2,735	1,831	5,927	4,693
Total revenue	\$ 6,145	\$ 4,739	\$ 16,182	\$ 12,759

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
United States	\$ 2,665	\$ 2,091	\$ 6,987	\$ 6,452
Switzerland	1,058	608	2,991	2,096
Germany	478	1,413	1,392	2,238
Japan	167	—	1,621	—
All other countries	1,777	627	3,191	1,973
Total revenue	\$ 6,145	\$ 4,739	\$ 16,182	\$ 12,759

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 the three months ended September 30, 2023 and 2022, and were \$0.2 million and less than \$0.1 million during the nine months ended September 30, 2023 and 2022, respectively.

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 service-based vesting conditions only and 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 and 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 adopted accounting pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments — Credit Losses (Topic 326) (“ASU 2016-13”). The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available for sale, and trade receivables. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. The new standard was effective for the Company beginning January 1, 2023 and primarily impacted trade accounts receivable. The amendments in this update were adopted using a modified retrospective transition method as of January 1, 2023, which had no cumulative impact to retained earnings. The adoption of this new standard had no material impact on the Company's unaudited consolidated financial statements. The Company's concentrations of credit risks are limited due to the large number of customers and their dispersion across a number of geographic areas. Substantially all of the Company's trade receivables are concentrated in the pharmaceuticals industry in the U.S. and internationally or with distributors who operate in international markets. The Company's historical credit losses have not been significant due to this dispersion and the financial stability of the Company's customers. The Company considers its historical credit losses to be immaterial to its business and, therefore, has not provided all the disclosures otherwise required by the standard. The Company updated its accounting policy disclosure for accounts receivable as follows:

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 allowances 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 allowances for doubtful accounts for expected credit losses are recorded to general and administrative expenses. 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, 2023 and December 31, 2022, the allowance for doubtful accounts for expected credit losses was zero.

Recently issued accounting pronouncements

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

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, 2023			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	\$ 18,473	\$ —	\$ —	\$ 18,473
Short-term investments	59,978	5,625	—	65,603
Long-term investments	14,620	—	—	14,620
	<u>\$ 93,071</u>	<u>\$ 5,625</u>	<u>\$ —</u>	<u>\$ 98,696</u>

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

During the three and nine months ended September 30, 2023 and 2022, there were no transfers between Level 1, Level 2 and Level 3.

Valuation of short-term and long-term investments

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

4. Investments

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

	September 30, 2023			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Short-term investments				
Certificates of Deposit	\$ 5,670	\$ —	\$ (45)	\$ 5,625
U.S. Government Treasury Bills	16,206	—	(10)	16,196
U.S. Government Treasury Notes	44,137	—	(355)	43,782
	<u>\$ 66,013</u>	<u>\$ —</u>	<u>\$ (410)</u>	<u>\$ 65,603</u>
Long-term Investments				
U.S. Government Treasury Notes - Maturity Between One and Two Years	14,663	—	(43)	14,620
	<u>\$ 14,663</u>	<u>\$ —</u>	<u>\$ (43)</u>	<u>\$ 14,620</u>
	December 31, 2022			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
Short-term investments				
Certificates of Deposit	\$ 491	\$ —	\$ —	\$ 491
U.S. Government Treasury Bills	32,115	1	(40)	32,076
U.S. Government Treasury Notes	49,625	—	(608)	49,017
	<u>\$ 82,231</u>	<u>\$ 1</u>	<u>\$ (648)</u>	<u>\$ 81,584</u>
Long-term Investments				
Certificates of Deposit	\$ 3,391	\$ 4	\$ (36)	\$ 3,359
U.S. Government Treasury Notes - Maturity Between One and Two Years	26,861	1	(431)	26,431
	<u>\$ 30,252</u>	<u>\$ 5</u>	<u>\$ (467)</u>	<u>\$ 29,790</u>

5. Inventory

Inventory consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	\$ 14,225	\$ 15,014
Work in process	579	1,599
Finished goods	5,389	4,574
Total	<u>\$ 20,193</u>	<u>\$ 21,187</u>

Raw materials, work in process and finished goods were net of adjustments to net realizable value of \$0.7 million and \$1.1 million as of September 30, 2023 and December 31, 2022, respectively.

6. Prepaid expenses and other current assets

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

	September 30, 2023	December 31, 2022
Prepaid insurance	\$ 38	\$ 1,500
Contract asset	69	112
Deposits	647	1,055
Other	802	705
	<u>\$ 1,556</u>	<u>\$ 3,372</u>

7. Property and equipment, net

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

	September 30, 2023	December 31, 2022
Manufacturing and laboratory equipment	\$ 13,687	\$ 13,408
Computer hardware and software	1,870	1,651
Office furniture and fixtures	588	589
Leasehold improvements	8,551	8,260
Construction-in-process	1,789	1,712
	26,485	25,620
Less: Accumulated depreciation	(13,615)	(11,802)
	<u>\$ 12,870</u>	<u>\$ 13,818</u>

Depreciation and amortization expense related to property and equipment was \$0.7 million and \$0.6 million for the three months ended September 30, 2023 and 2022, respectively. Depreciation and amortization expense related to property and equipment was \$2.0 million and \$1.7 million for the nine months ended September 30, 2023 and 2022, respectively. The Company had zero fully depreciated assets disposed of during the three months ended September 30, 2023 and 2022, and had zero and \$2.3 million in fully depreciated assets disposed of during the nine months ended September 30, 2023 and 2022, respectively.

8. Accrued expenses and other current liabilities

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

	September 30, 2023	December 31, 2022
Accrued employee compensation and benefits expense	\$ 4,547	\$ 3,217
Accrued vendor expenses	1,279	3,212
Accrued warranty expense	697	872
Accrued taxes	287	329
Other	136	520
	<u>\$ 6,946</u>	<u>\$ 8,150</u>

On August 11, 2022, the board of directors of the Company approved an organizational restructuring plan (the “Restructuring Plan”) to right-size its cost structure based on its lowered 2022 outlook. The Company will continue to invest in key growth initiatives including enhancing commercial execution and key product development programs that are expected to drive future revenue growth. The Restructuring Plan involved an approximately 20% reduction in the Company’s workforce, including employees, contractors and temporary employees, which is largely focused on non-commercial functions. The Company recorded a restructuring charge of \$1.1 million in the third quarter of 2022 primarily related to severance, employee benefits, outplacement and related costs under the Restructuring Plan. The Company made no payments during the three months ended September 30, 2023 and made payments of \$0.5 million during the nine months ended September 30, 2023 related to the Restructuring Plan. The Company had no remaining payments as of September 30, 2023.

9. Common stock and common stock warrants

As of September 30, 2023 and December 31, 2022, 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, 2023, no cash dividends had been declared or paid.

As of September 30, 2023, the Company had reserved 22,091,879 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.

As of September 30, 2023 and December 31, 2022, outstanding warrants to purchase common stock consisted of the following:

Issuance date	Contractual term (in years)	Balance sheet classification	Shares of common stock issuable upon exercise of warrant	Weighted average exercise price
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
			<u>1,022,303</u>	

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 initial public offering ("IPO"), 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 is equal to the sum of (i) 4,200,000 shares; (ii) any shares which are subject to the 2010 Plan awards that become available for issuance under the 2021 Plan; and (iii) an annual increase for ten years on the first day of each calendar year beginning on January 1, 2022, equal to the lesser of (A) 5% of the aggregate number of shares of Class A common stock outstanding on the last day of the immediately preceding calendar year and (B) such smaller amount of shares as determined by the board of directors. No more than 33,900,000 shares of Class A common stock may be issued under the 2021 Plan upon the exercise of incentive stock options. As of September 30, 2023, there are 3,212,318 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 grant-date fair value of stock options granted to employees and directors:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Risk-free interest rate	4.2 %	3.2 %	3.9 %	2.1 %
Expected term (in years)	6.1	6.1	6.0	6.0
Expected volatility	47.1 %	44.4 %	47.1 %	43.2 %
Expected dividend yield	0 %	0 %	0 %	0 %

Stock options

The following table summarizes the Company's stock option activity since December 31, 2022:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding as of December 31, 2022	5,041,308	\$ 5.05	7.55	\$ 532
Granted	1,994,222	1.17		
Exercised	(8,830)	0.82		
Expired	(80,348)	5.92		
Forfeited	(150,803)	2.60		
Outstanding as of September 30, 2023	6,795,549	\$ 2.66	7.57	\$ 513
Options vested and expected to vest as of September 30, 2023	6,795,549	\$ 2.66	7.57	\$ 513
Options exercisable as of September 30, 2023	3,583,257	\$ 2.71	6.44	\$ 349

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 during the nine months ended September 30, 2023 and 2022 was less than \$0.1 million and \$2.8 million, respectively.

The weighted average grant-date fair value per share of stock options granted during the three months ended September 30, 2023 and 2022 was \$0.49 and \$1.72, respectively, and during the nine months ended September 30, 2023 and 2022 was \$0.59 and \$3.20, respectively.

In March 2023, the board of directors approved a one-time repricing of certain outstanding stock options held by non-executive employees. As a result of the repricing, the exercise prices of eligible vested and unvested stock options were adjusted to reflect the fair market value of Class A common stock on the date of the repricing. The repricing was immaterial to the Company's financial results.

Restricted stock

In February 2021, the Company granted 248,903 shares of restricted stock to an employee under the 2010 Plan with a four-year vesting term. In connection with the grant, the employee paid \$0.5 million, which represents the \$2.10 per share fair value of the common stock on the date of the restricted stock grant. At September 30, 2023 and December 31, 2022, the Company had zero and \$0.3 million, respectively, in unvested restricted common stock liability included in other current liabilities and other long-term liabilities, respectively, related to these shares. The restricted common stock is no longer vesting due to the employee's termination and the Company waived its repurchase right during the first quarter of 2023, which resulted in all then-outstanding and unvested shares becoming fully vested.

The following table summarizes the Company's restricted stock activity since December 31, 2022:

	Number of shares	Weighted average fair value
Unvested as of December 31, 2022	155,565	\$ 2.10
Granted	—	
Vested	(155,565)	\$ 2.10
Forfeited	—	
Unvested as of September 30, 2023	—	\$ —

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, 2023, the Company granted restricted stock units with service-based vesting conditions as well as restricted stock units with a combination of

service-based and Company performance-based vesting conditions. The Company expenses the fair value of the restricted stock units over the 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, 2022:

	Number of shares	Weighted average fair value
Unvested as of December 31, 2022	532,121	\$ 7.06
Granted	1,461,458	\$ 1.22
Vested	(161,989)	\$ 7.42
Forfeited	(49,189)	\$ 3.08
Unvested as of September 30, 2023	<u>1,782,401</u>	<u>\$ 2.35</u>

The weighted average grant-date fair value per share of restricted stock units granted during the three months ended September 30, 2023 and 2022 was \$0.97 and \$3.64, respectively, and during the nine months ended September 30, 2023 and 2022 was \$1.22 and \$7.36, respectively.

2021 Employee Stock Purchase Plan

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

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

During the nine months ended September 30, 2023, there were 186,037 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, 2023 and 2022. As of September 30, 2023, 873,158 shares were available for future issuance under the 2021 ESPP.

The Company estimates the fair value of shares issued to employees under the 2021 ESPP using the Black-Scholes option-pricing model. The following weighted average assumptions were used in the calculation of fair value of shares under the 2021 ESPP at the grant date for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Risk-free interest rate	5.5 %	3.8 %	5.3 %	2.6 %
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	47.7 %	53.3 %	47.8 %	49.1 %
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).

As of September 30, 2023, 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of revenue	\$ 159	\$ 118	\$ 502	\$ 387
Research and development	135	93	398	266
Sales and marketing	119	93	385	370
General and administrative	838	369	2,443	1,891
Total stock-based compensation expense	\$ 1,251	\$ 673	\$ 3,728	\$ 2,914

As of September 30, 2023, total unrecognized compensation expense related to unvested stock options held by employees and directors was \$5.3 million, which is expected to be recognized over a weighted average period of 2.0 years. Additionally, unrecognized compensation expense related to unvested restricted stock units held by employees and directors was \$3.1 million, which is expected to be recognized over a weighted average period of 2.1 years.

11. Income taxes

During the three and nine months ended September 30, 2023 and 2022, 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 in the future.

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 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 September 30, 2023 and December 31, 2022 the Company has 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. As a result of a favorable outcome related to the tax examination for our German subsidiary, we recorded an income tax benefit of \$0.6 million for the nine months ended September 30, 2022.

12. Net loss per share

As of September 30, 2023, the Company had Class A common stock and Class B common stock. Both classes have the same rights to the Company's earnings and neither of the shares have any prior or senior rights to dividends to other shares.

The Company reported a net loss for the three and nine months ended September 30, 2023 and 2022, as such basic net loss per share was the same as diluted net loss per share. 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,	
	2023	2022	2023	2022
Numerator:				
Net loss	\$ (13,392)	\$ (16,339)	\$ (41,295)	\$ (44,359)
Denominator:				
Weighted average Class A common shares outstanding—basic and diluted	37,770,566	36,964,613	37,539,885	36,619,187
Weighted average Class B common shares outstanding—basic and diluted	5,309,529	5,553,379	5,445,299	5,785,056
Total shares for EPS—basic and diluted	43,080,095	42,517,992	42,985,184	42,404,243
Net loss per share attributable to Class A common stockholders—basic and diluted	\$ (0.31)	\$ (0.38)	\$ (0.96)	\$ (1.05)
Net loss per share attributable to Class B common stockholders—basic and diluted	\$ (0.31)	\$ (0.38)	\$ (0.96)	\$ (1.05)

The Company's potentially dilutive securities, which include stock options, restricted stock, 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:

	Three and Nine Months Ended September 30,	
	2023	2022
Options to purchase common stock	6,795,549	5,242,448
Unvested restricted common stock	1,782,401	677,112
Warrants to purchase common stock	286,324	286,324
Options to purchase common stock under ESPP	22,051	8,107
	8,886,325	6,213,991

13. Leases

The Company determines if an arrangement is or contains a lease at inception, which is the date on which the terms of the contract are agreed to, and the agreement creates enforceable rights and obligations. Under ASC 842, a contract is or contains a lease when (i) explicitly or implicitly identified assets have been deployed in the contract and (ii) the customer obtains substantially all of the economic benefits from the use of that underlying asset and directs how and for what purpose the asset is used during the term of the contract. The Company also considers whether its service arrangements include the right to control the use of an asset. See Note 2 for more information on the Company's accounting policies for leases.

The Company leases office and manufacturing space under operating lease agreements that have initial terms ranging from approximately 8 to 10 years. The Company leases furniture under a financing lease agreement that has an initial term of approximately 8 years. Some leases include one or more options to renew, generally at the Company's sole discretion, with renewal terms that can extend the lease term by up to 5 years. In addition, certain leases contain termination options, where the rights to terminate are held by either the Company, the lessor, or both parties. Options to extend a lease are included in the lease term when it is reasonably certain that the Company will exercise the option. Options to terminate a lease are excluded from the lease term when it is reasonably certain that the Company will not exercise the option. The Company's leases generally do not contain any material restrictive covenants or residual value guarantees.

Supplemental cash flow information related to leases is as follows (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash outflows - payments on operating leases	\$ 956	\$ 893
Operating cash outflows - payments on financing leases	\$ 29	\$ 32
Financing cash outflows - payments on financing leases	\$ 27	\$ 24
Right-of-use assets obtained in exchange for new lease obligations:		
Operating leases	\$ 151	\$ 7,605
Financing leases	\$ —	\$ 366

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

	September 30, 2023	December 31, 2022
Operating Leases:		
Operating lease assets	\$ 6,209	\$ 6,746
Accrued expenses and other current liabilities	\$ 801	\$ 729
Operating lease liabilities	6,231	6,898
Total operating lease liabilities	<u>\$ 7,032</u>	<u>\$ 7,627</u>
Financing Leases:		
Office furniture and fixtures	\$ 386	\$ 386
Accumulated depreciation	(106)	(69)
Net property, plant and equipment	<u>\$ 280</u>	<u>\$ 317</u>
Current portion of long-term debt	\$ 40	\$ 37
Long-term debt	273	304
Total financing lease liabilities	<u>\$ 313</u>	<u>\$ 341</u>
Weighted-average remaining lease term - operating leases (in years):	5.79	6.54
Weighted-average remaining lease term - financing leases (in years):	5.75	6.50
Weighted-average discount rate - operating leases:	3.8 %	3.7 %
Weighted-average discount rate - financing leases:	12.0 %	12.0 %

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease cost	\$ 314	\$ 297	\$ 899	\$ 847
Financing lease cost - amortization of right-of-use asset	12	12	37	37
Financing lease cost - interest on lease liability	9	11	29	32
Short-term lease cost	—	14	—	45
Variable lease cost	172	138	522	454
Total lease cost	<u>\$ 507</u>	<u>\$ 472</u>	<u>\$ 1,487</u>	<u>\$ 1,415</u>

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 and \$0.4 million for the three months ended September 30, 2023 and 2022, respectively, and was \$1.4 million and \$1.3 million for the nine months ended September 30, 2023 and 2022, 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 the three and nine months ended September 30, 2023 and 2022.

Maturities of the Company's operating lease liabilities as of September 30, 2023 were as follows (in thousands):

	Operating Lease Maturities
2023 (excluding the nine months ended September 30)	\$ 329
2024	1,334
2025	1,368
2026	1,401
2027	1,435
Thereafter	2,273
Total lease payments	<u>\$ 8,140</u>
Less imputed interest	<u>(837)</u>
Total present value of lease liabilities	<u>\$ 7,303</u>

Maturities of the Company's financing lease liability as of September 30, 2023 were as follows (in thousands):

	Financing Lease Maturities
2023 (excluding the nine months ended September 30)	\$ 19
2024	75
2025	75
2026	75
2027	75
Thereafter	113
Total lease payments	<u>\$ 432</u>
Less imputed interest	<u>(119)</u>
Total present value of lease liabilities	<u>\$ 313</u>

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, 2023 and December 31, 2022.

Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to legal proceedings.

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 and \$0.6 million to the plan during the three and nine months ended September 30, 2023 and 2022, 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, 2022, included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 10, 2023, as amended (the “2022 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 the 2022 Form 10-K and 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), 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 system accelerates time to results by several days, up to a 50% improvement over the traditional method, and reduces MQC testing to a simple two-step workflow, eliminating up to 85% of the manual steps of traditional MQC, generating significant time, operational, and cost savings for our customers. We seek to establish the Growth Direct platform as the trusted global standard in automated MQC by delivering the speed, accuracy, security, and data integrity 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”).

Since our inception, we have incurred net losses in each year. We generated revenue of \$6.1 million and \$4.7 million for the three months ended September 30, 2023 and 2022, respectively, and incurred net losses of \$13.4 million and \$16.3 million for those same periods, respectively. As of September 30, 2023, we had an accumulated deficit of \$417.2 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 as well as our service capabilities to meet growing demand for our products and services;
- investing in research and development to develop new products and further enhance our existing products;

- protecting and building on our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

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

We believe that our cash and cash equivalents and investments as of September 30, 2023 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, 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “Liquidity and Capital Resources.”

Effects of inflation and interest rates

The current inflationary environment and rising interest rates could have a negative impact on our results of operations, cash flows and overall financial condition. We may experience inflationary pressures on significant cost categories including labor, materials and freight. We continue to monitor the impact of inflation on these costs in order to minimize its effects through productivity improvements and cost reductions. There can be no assurance, however, that our operating results will not be affected by inflation in the future. In addition, inflation and increased interest rates may decrease demand for our Growth Direct systems, as our customers may face economic uncertainty 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 and other factors as set forth in Part I, Item 1A of our 2022 Form 10-K.

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, 2023, approximately 40% of our customers have purchased Growth Direct systems for multiple sites, and approximately 55% of our customers have purchased multiple Growth Direct systems. Increased utilization amongst existing customers can also occur as customers advance through the Growth Direct platform adoption cycle from early validation of initial applications to validation and conversion of multiple applications on the Growth Direct platform or as the result of 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.

Revenue mix

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

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 Months Ended September 30,		Change	
	2023	2022	Amount	%
(dollars in thousands)				
Systems placed:				
Systems placed in period	5	3	2	66.7 %
Cumulative systems placed	135	123	12	9.8 %
Systems validated:				
Systems validated in period	4	4	—	— %
Cumulative systems validated	112	100	12	12.0 %
Product and service revenue — total	\$ 6,145	\$ 4,739	\$ 1,406	29.7 %
Product and service revenue — recurring	\$ 3,410	\$ 2,908	\$ 502	17.3 %

	Nine Months Ended September 30,		Change	
	2023	2022	Amount	%
(dollars in thousands)				
Systems placed:				
Systems placed in period	10	7	3	42.9 %
Cumulative systems placed	135	123	12	9.8 %
Systems validated:				
Systems validated in period	9	16	(7)	(43.8)%
Cumulative systems validated	112	100	12	12.0 %
Product and service revenue — total	\$ 16,182	\$ 12,759	\$ 3,423	26.8 %
Product and service revenue — recurring	\$ 10,255	\$ 8,066	\$ 2,189	27.1 %

Growth Direct system placements

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

The number of Growth Direct system placements and rate of growth varies from period-to-period due to factors including, but not limited to, Growth Direct system order volume and timing, and access to customer sites (including coronavirus related restrictions in 2022 and the timing of customer site construction activities). As a result, we expect to experience continued variability in our period-to-period number of Growth Direct system placements due to the aforementioned factors.

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 takes anywhere from three to nine months. Once a validation has been completed, we generally expect our customers to transition from their legacy manual method to our automated method and begin regular utilization of consumables over a period of up to three months after 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 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 55.5% and 61.4% of our total revenue for the three months ended September 30, 2023 and 2022, respectively. Recurring revenue was 63.4% and 63.2% of our total revenue for the nine months ended September 30, 2023 and 2022, respectively. Our recurring revenue as a percentage of the total product and service revenue will generally vary based upon the number of Growth Direct systems placed and the cumulative number of 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 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.

	Three Months Ended September 30, 2023	Percentage of total revenue	Three Months Ended September 30, 2022	Percentage of total revenue
	(in thousands)		(in thousands)	
Product revenue	\$ 4,200	68.3 %	\$ 3,209	67.7 %
Service revenue	1,945	31.7 %	1,530	32.3 %
Total revenue	<u>\$ 6,145</u>	100.0 %	<u>\$ 4,739</u>	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, 2023, we had placed 135 Growth Direct systems to over 40 customers globally, including two-thirds of the top twenty pharmaceutical companies as measured by revenue and approximately 20% of globally approved cell and gene therapies, including approximately 80% of commercially available CAR-T 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 composed of two proprietary consumables to capture test samples for analysis on the Growth Direct system, an Environmental Monitoring ("EM") consumable, and a Water/Bioburden ("W/BB") consumable. Both proprietary consumables support the growth-based compendial method for MQC testing mandated by global regulators and provide results that are comparable to traditional consumables. Our consumables are designed with features that enable automation on the Growth Direct system, with bar coding for tracking and data integrity, and physical characteristics for robotic handling, to support vision detection, and to prevent counterfeiting.

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

LIMS Connection Software

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

Service revenue

We derive service revenue from validation services, field service including installations, and service contracts sold to our customers. 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.

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, maintenance of facilities and insurance as well as related depreciation and amortization.

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

Sales and marketing

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

General and administrative

General and administrative expenses consist primarily of salaries, bonuses and other personnel costs including stock-based compensation expense for our 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. General and administrative expenses are expected to increase in future years as the number of administrative personnel grows to support increasing business size and complexity.

Other income (expense)

Interest income, net

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

Other income (expense), net

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

Income tax expense (benefit)

We generated significant taxable losses during the three and nine months ended September 30, 2023 and 2022 and, therefore, have not recorded any U.S. federal or state income tax expense during those periods. However, we did record an immaterial amount of foreign income tax expense during each of those periods. Additionally, as a result of a favorable outcome related to the tax examination for our German subsidiary, we recorded an income tax benefit of \$0.6 million for the nine months ended September 30, 2022.

Results of operations

Comparison of the three months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Change	
	2023	2022	Amount	%
	(in thousands)			
Revenue:				
Product revenue	\$ 4,200	\$ 3,209	\$ 991	30.9 %
Service revenue	1,945	1,530	415	27.1 %
Total revenue	6,145	4,739	1,406	29.7 %
Costs and operating expenses:				
Cost of product revenue	5,691	5,627	64	1.1 %
Cost of service revenue	2,085	1,906	179	9.4 %
Research and development	3,116	2,973	143	4.8 %
Sales and marketing	3,498	3,930	(432)	(11.0)%
General and administrative	6,204	7,189	(985)	(13.7)%
Total costs and operating expenses	20,594	21,625	(1,031)	(4.8)%
Loss from operations	(14,449)	(16,886)	2,437	(14.4)%
Other income (expense):				
Interest income, net	1,093	575	518	90.1 %
Other expense, net	(26)	(21)	(5)	23.8 %
Total other income (expense), net	1,067	554	513	92.6 %
Loss before income taxes	(13,382)	(16,332)	2,950	(18.1)%
Income tax expense	10	7	3	42.9 %
Net loss	\$ (13,392)	\$ (16,339)	\$ 2,947	(18.0)%

Revenue

Product revenue increased by \$1.0 million, or 30.9%, with \$0.6 million of this increase attributable to a higher volume of system placements in the quarter and the remainder attributable to favorable increases in price and mix related to our consumables.

Service revenue increased by \$0.4 million, or 27.1%. The increase in service revenue was primarily due to an increase in revenue from service contracts as a result of an increase in the cumulative number of Growth Direct systems validated and under such contracts. Increases in both installation and validation revenues also contributed to the increase in service revenue.

During 2022, including the third quarter, COVID-19 related restrictions had a negative effect on our product and service revenue. These restrictions have since eased and our increased access to customers has positively impacted our product and service revenue for the three months ended September 30, 2023 as compared to prior periods.

Costs and operating expenses

Costs of revenue

Cost of product revenue increased by \$0.1 million, or 1.1%. The increase was driven primarily by costs associated with a higher volume of system placements of \$0.4 million, \$0.2 million related to consumables mix, and \$0.4 million related to a temporary reduction in manufacturing efficiency due to downtime to implement enhancements to our

automated consumables manufacturing line. The increase due to these factors was offset by a net reduction in other production costs recognized in the period of \$0.9 million due in part to the benefit of higher production volumes.

Cost of service revenue increased by \$0.2 million, or 9.4%. This increase was primarily attributable to greater headcount-related costs due to hiring of staff as well as incremental travel costs to support the higher number of validated systems at customer sites.

Research and development

	Three Months Ended September 30,		Change	
	2023	2022	Amount	%
	(dollars in thousands)			
Research and development	\$ 3,116	\$ 2,973	\$ 143	4.8 %
Percentage of total revenue	50.7 %	62.7 %		

Research and development expenses increased by \$0.1 million, or 4.8%. This increase was primarily due to higher spending on new product development activities, including headcount-related costs, largely offset by lower third party spend.

Sales and marketing

	Three Months Ended September 30,		Change	
	2023	2022	Amount	%
	(dollars in thousands)			
Sales and marketing	\$ 3,498	\$ 3,930	\$ (432)	(11.0)%
Percentage of total revenue	56.9 %	82.9 %		

Sales and marketing expenses decreased by \$0.4 million, or 11.0%. This decrease was primarily the result of a reduction in nonrecurring severance-related costs related to our organizational restructuring announced in August 2022 (the "2022 Restructuring"). Excluding the impact of these nonrecurring costs, sales and marketing expenses decreased by \$0.1 million in the three months ended September 30, 2023.

General and administrative

	Three Months Ended September 30,		Change	
	2023	2022	Amount	%
	(dollars in thousands)			
General and administrative	\$ 6,204	\$ 7,189	\$ (985)	(13.7)%
Percentage of total revenue	101.0 %	151.7 %		

General and administrative expenses decreased by \$1.0 million, or 13.7%. The decrease was attributable to a \$1.4 million reduction in legal and investor relations-related costs as compared to the prior-year period when we received an unsolicited non-binding proposal from a stockholder to acquire the Company. Additionally, there was an overall net decrease of \$0.1 million related to actions taken in connection with our 2022 Restructuring, including employee severance and retention. Higher stock compensation expenses of \$0.5 million due mainly to annual equity grants partially offset the decreases described above.

Other income (expense)

Interest income

Interest income increased by \$0.5 million, or 90.1%. The increase was due to higher interest rates earned on our investments.

Other (expense) income

Other (expense) income, which is comprised of miscellaneous expenses unrelated to our core business, remained flat for the three months ended September 30, 2023 and 2022.

Income tax expense

Income tax expense was less than \$0.1 million for the three months ended September 30, 2023 and 2022. The expense is attributable to an income tax provision related to our German subsidiary.

Comparison of the nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		Change	
	2023	2022	Amount	%
	(dollars in thousands)			
Revenue:				
Product revenue	\$ 10,693	\$ 8,212	\$ 2,481	30.2 %
Service revenue	5,489	4,547	942	20.7 %
Total revenue	16,182	12,759	3,423	26.8 %
Costs and operating expenses:				
Cost of product revenue	15,361	13,220	2,141	16.2 %
Cost of service revenue	6,134	5,478	656	12.0 %
Research and development	9,502	9,463	39	0.4 %
Sales and marketing	10,161	10,870	(709)	(6.5)%
General and administrative	19,399	19,687	(288)	(1.5)%
Total costs and operating expenses	60,557	58,718	1,839	3.1 %
Loss from operations	(44,375)	(45,959)	1,584	(3.4)%
Other income (expense):				
Interest income, net	3,169	947	2,222	234.6 %
Other (expense) income, net	(66)	70	(136)	(194.3)%
Total other income (expense), net	3,103	1,017	2,086	205.1 %
Loss before income taxes	(41,272)	(44,942)	3,670	(8.2)%
Income tax expense (benefit)	23	(583)	606	(103.9)%
Net loss	\$ (41,295)	\$ (44,359)	\$ 3,064	(6.9)%

Revenue

Product revenue increased by \$2.5 million, or 30.2%. The increase was primarily due to higher volumes of both system placements and consumable shipments. Service revenue increased by \$0.9 million, or 20.7%.

The increase in service revenue was primarily driven by an increase in revenue from service contracts 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 increased by \$2.1 million or 16.2%. The increase in cost of product revenue was driven by higher volumes of both Growth Direct systems and consumables, which contributed \$1.8 million. In addition, a temporary reduction in manufacturing efficiency due in part to downtime to implement enhancements to our automated

consumables manufacturing line resulted in \$1.2 million of additional cost. Partially offsetting these increased costs were reductions in labor and overhead spending coupled with a benefit from production activities totaling \$0.7 million, and a \$0.2 million reduction in other costs of product revenue.

Cost of service revenue increased by \$0.7 million, or 12.0%. This increase was primarily attributable to headcount-related costs due to hiring of staff as well as incremental travel costs to support the growing number of validated systems at customer sites.

Research and development

	Nine Months Ended September 30,		Change	
	2023	2022	Amount	%
	(dollars in thousands)			
Research and development	\$ 9,502	\$ 9,463	\$ 39	0.4 %
Percentage of total revenue	58.7 %	74.2 %		

Research and development expenses remained relatively flat, increasing less than \$0.1 million, or 0.4%. This increase was primarily due to higher spending on new product development activities, including headcount-related costs, largely offset by lower third party spend.

Sales and marketing

	Nine Months Ended September 30,		Change	
	2023	2022	Amount	%
	(dollars in thousands)			
Sales and marketing	\$ 10,161	\$ 10,870	\$ (709)	(6.5)%
Percentage of total revenue	62.8 %	85.2 %		

Sales and marketing expenses decreased by \$0.7 million, or 6.5%. This decrease was primarily due to a reduction in nonrecurring severance-related costs as well as lower compensation and benefit related costs as a result of headcount reductions made as part of our 2022 Restructuring, the latter of which impacted our non-quota carrying portion of our sales organization. Excluding the impact of the nonrecurring severance-related costs, sales and marketing expenses decreased by \$0.1 million in the nine months ended September 30, 2023.

General and administrative

	Nine Months Ended September 30,		Change	
	2023	2022	Amount	%
	(dollars in thousands)			
General and administrative	\$ 19,399	\$ 19,687	\$ (288)	(1.5)%
Percentage of total revenue	119.9 %	154.3 %		

General and administrative expenses decreased by \$0.3 million, or 1.5%. This decrease was attributable to a \$0.8 million decrease in third-party spend due to cost savings initiatives implemented as part of our 2022 Restructuring, a \$0.7 million reduction in legal and investor relations-related costs following an unsolicited non-binding proposal from a stockholder to acquire the Company in June 2022, a \$0.4 million reduction in business insurance premiums and a \$0.1 million decrease in other expenses. These decreases were largely offset by several increases including the \$0.6 million impact of the retention bonus program we put into place in connection with our 2022 Restructuring, which replaced the annual bonus for eligible employees in 2022 and thereby decreased net bonus expense in the prior-year period. Additionally, higher stock compensation expenses of \$0.6 million due mainly to annual equity grants made in the first quarter of 2023 and higher depreciation expense of \$0.5 million related to capital improvements we made to our Lexington, Massachusetts back-up manufacturing facility in 2022 partially offset the decreases described above.

Other income (expense)*Interest income*

Interest income increased \$2.2 million, or 234.6% due to higher interest rates earned on our investments.

Other (expense) income

Other (expense) income, which is comprised of miscellaneous expenses unrelated to our core business, remained relatively flat for the nine months ended September 30, 2023 and 2022.

Income tax expense (benefit)

Income tax expense (benefit) was expense of less than \$0.1 million for the nine months ended September 30, 2023 compared to a benefit of \$0.6 million for the nine months ended September 30, 2022. Both the expense and the benefit recorded related to our German subsidiary. During the nine months ended September 30, 2022, we adjusted an uncertain tax liability we had recorded for that subsidiary as a result of the favorable outcome of an examination for the tax years 2016 through 2018, resulting in an income tax benefit in that period.

Liquidity and capital resources

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

We believe that our cash, cash equivalents and short- and long-term investments will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months following the date the condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, were issued.

As of September 30, 2023, we had the following cash and investment-related assets on our condensed consolidated balance sheet (in thousands):

	<u>September 30, 2023</u>
Cash and cash equivalents	\$ 23,786
Short-term investments	65,603
Long-term investments	14,620
Restricted cash	284
Total	<u>\$ 104,293</u>

Contractual obligations and commitments

In October 2013, we entered into an operating lease for office and manufacturing space in Lowell, Massachusetts, which expires in July 2026. The terms of the lease include options for a one-time, five-year extension of the lease and early termination of the lease in July 2024 as well as a \$0.7 million tenant improvement allowance which has been drawn down in full. In March 2022, we amended this 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) as well as a \$0.3 million tenant improvement allowance. Monthly rent payments are fixed and future minimum lease payments under the lease (as amended) are \$3.8 million as of September 30, 2023, including \$0.6 million in short-term obligations.

In June 2021, we entered into a sublease agreement for office and back-up manufacturing space in Lexington, Massachusetts, which expires in June 2029. The sublease 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 \$4.3 million as of September 30, 2023, 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,	
	2023	2022
Net cash used in operating activities	\$ (35,584)	\$ (46,892)
Net cash provided by (used in) investing activities	32,145	(106,269)
Net cash provided by financing activities	161	606
Net decrease in cash and cash equivalents and restricted cash	<u>\$ (3,278)</u>	<u>\$ (152,555)</u>

Operating activities

During the nine months ended September 30, 2023, net cash used in operating activities was \$35.6 million, a decrease of \$11.3 million compared to the prior-year period. The lower use of net cash was primarily as a result of lower inventory purchases, the timing of payments to vendors, and increased receipts of our accounts receivable.

Investing activities

During the nine months ended September 30, 2023, net cash provided by investing activities was \$32.1 million, compared to net cash used in investing activities of \$106.3 million during the nine months ended September 30, 2022. The change was largely attributable to fewer purchases of investments and of property and equipment, as well as an increase in investment maturities.

Financing activities

During the nine months ended September 30, 2023, net cash provided by financing activities was \$0.2 million, a decrease of \$0.4 million compared to the nine months ended September 30, 2022, which was primarily related to a reduction in proceeds from stock option exercises.

Nasdaq Notice of Failure to Satisfy a Continued Listing Rule

On September 13, 2023, we received a notification letter from the Nasdaq Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC 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 thirty (30) consecutive business days (July 31, 2023 through September 11, 2023) 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"). On September 26, 2023, we were informed by the Staff that we regained compliance with the Bid Price Requirement following ten (10) consecutive business days (September 12, 2023 through September 25, 2023) during which the closing bid price of our common stock was equal to or greater than \$1.00 per share, and that this matter was closed.

Seasonality

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

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 2022 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 our 2022 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. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of disclosure controls and procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this 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, 2023, 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, 2023 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 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

Investing in our common stock involves a high degree of risk. Information regarding risk factors appears in "Part I, Item 1A. Risk Factors" of our 2022 Form 10-K. Aside from the below, there have been no material changes in our risk factors from those previously disclosed in our 2022 Form 10-K.

Risks Related to the Financial Services Industry

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 and Use of Proceeds

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

Not applicable.

Item 6. Exhibits

Exhibit Number	Description of Exhibit
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40952) filed on July 21, 2021)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40952) filed on July 21, 2021)
10.1	Amended and Restated Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39130) filed on August 10, 2023)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

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 3, 2023

RAPID MICRO BIOSYSTEMS, INC.

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

By: _____ /s/ Sean Wirtjes
Sean Wirtjes
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

**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 3, 2023

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 3, 2023

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, 2023 (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 3, 2023

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, 2023 (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 3, 2023

By: /s/ Sean Wirtjes
Name: Sean Wirtjes
Title: Chief Financial Officer
(principal financial officer and principal accounting officer)