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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, 2021

or

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

For the transition period from _____ to _____

Commission File Number: 001-40592

Rapid Micro Biosystems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	20-8121647
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

1001 Pawtucket Boulevard West, Suite 280
Lowell, MA 01854
(Address of Principal Executive Offices)

(978) 349-3200
(Registrant's telephone number)

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

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

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

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

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

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

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

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

As of November 1, 2021, there were 34,449,144 of the registrant's Class A common stock, par value $0.01, outstanding.
As of November 1, 2021, there were 6,903,379 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. These forward-looking statements are often, but not always, made through the use of words or phrases 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 future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management.

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. 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 II, Item 1A, "Risk Factors", in this Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. 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.

This Quarterly Report on Form 10-Q and the documents that we have filed as exhibits should be read with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by applicable law, we assume no obligation to publicly update or revise any forward-looking statements contained in this Quarterly Report on Form 10-Q, whether as a result of any new information, future events or otherwise.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part II Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. Investors should carefully consider these risks and uncertainties when investing in our Class A common stock. The principal risks and uncertainties affecting our business include the following:

- The COVID-19 pandemic has impacted, and may continue to impact, our operations and may materially and adversely affect our business and financial results;
- We have incurred significant losses since inception, we expect to incur losses in the future and we may not be able to generate sufficient revenue to achieve and maintain profitability;
- We may need to raise additional capital to fund our existing operations, improve our platform or develop and commercialize new products or expand our operations;
- To date, our revenue has been primarily generated from sales of our Growth Direct system, laboratory information management system, or LIMS, connection software, and validation services. The generation of our recurring revenue, comprised of sales of our proprietary consumables and service contracts, is dependent upon the sale, delivery and installation of a system as well as the completion of validation services. As a result, we require a substantial period of time to generate recurring revenue;
- We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy;
- We have limited experience in marketing and sales, and if we are unable to expand our marketing and sales organization to adequately address our customers’ needs or to expand our customer base, our business may be adversely affected;
- We must develop new products, adapt to rapid and significant technological change and respond to introductions of new products by competitors to remain competitive;
- The continued success of our business relies heavily on establishing and maintaining our position in the market as a leading provider of automated microbial quality control, or MQC, testing;
- If our sole manufacturing and development facility becomes damaged or inoperable or we are required to vacate our existing facility, our ability to conduct and pursue our manufacturing and development efforts will be jeopardized;
- Our manufacturing operations are dependent upon third-party suppliers, including single-source suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business;
- If we lose key management, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may be materially harmed;
- We may acquire businesses or form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders’ ownership, incur debt or cause us to incur significant expense;
- Our customers use our Growth Direct platform as part of their quality-control workflow, which is subject to regulation by the U.S. Food and Drug Administration, or FDA, and other comparable regulatory authorities;

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

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

- Because we do not anticipate paying any cash dividends on our Class A common stock in the foreseeable future, capital appreciation, if any, would be a stockholder's sole source of gain;

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

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

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

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 219,588	$ 30,079
Short-term investments	—	14,998
Accounts receivable	5,006	4,988
Inventory	14,167	8,965
Prepaid expenses and other current assets	5,400	3,120
Total current assets	244,161	62,150
Property and equipment, net	8,633	7,052
Other long-term assets	1,348	695
Restricted cash	284	100
Total assets	$ 254,426	$ 69,997
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,251	$ 4,468
Accrued expenses and other current liabilities	11,566	6,654
Deferred revenue	3,903	4,423
Total current liabilities	17,720	15,545
Preferred stock warrant liability	—	4,117
Notes payable, net of unamortized discount	—	24,810
Deferred rent, long term	728	705
Other long-term liabilities	1,233	—
Total liabilities	19,681	45,177
Commitments and contingencies (Note 16)		
Redeemable convertible preferred stock (Series A1, B1, C1, C2, D1, and D2), $0.01 par value; zero shares and 161,455,689 shares authorized at September 30, 2021 and December 31, 2020, respectively; zero shares and 133,021,640 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively.	—	151,826
Stockholders' equity (deficit):		
Class A common stock, $0.01 par value; 210,000,000 shares and 35,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 34,449,154 shares and 612,850 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	344	6
Class B common stock, $0.01 par value; 10,000,000 shares and zero shares authorized at September 30, 2021 and December 31, 2020, respectively; 6,903,379 shares and zero shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	69	—
Preferred stock, $0.01 par value: 10,000,000 shares and zero shares authorized at September 30, 2021 and December 31, 2020, respectively; zero shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	534,839	114,575
Accumulated deficit	(300,507)	(241,588)
Accumulated other comprehensive income	—	1
Total stockholders' equity (deficit)	234,745	(127,006)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 254,426	$ 69,997

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,	
	2021	2020	2021	2020
Revenue:				
Product revenue	$ 4,824	$ 4,069	$ 12,630	$ 6,921
Service revenue	1,479	895	4,152	2,060
Non-commercial revenue	596	283	1,242	1,858
Total revenue	6,899	5,247	18,024	10,839
Costs and operating expenses:				
Cost of product revenue	6,298	5,441	17,900	11,544
Cost of service revenue	1,516	772	3,997	2,478
Cost of non-commercial revenue	396	399	1,282	1,732
Research and development	2,441	2,224	6,926	4,906
Sales and marketing	3,063	1,447	8,460	4,149
General and administrative	5,308	2,541	12,135	6,855
Total costs and operating expenses	19,022	12,824	50,700	31,664
Loss from operations	(12,123)	(7,577)	(32,676)	(20,825)
Other income (expense):				
Interest expense	(775)	(886)	(2,631)	(2,463)
Change in fair value of preferred stock warrant liability	(8,160)	—	(19,643)	549
Loss on extinguishment of debt	(3,100)	—	(3,100)	(2,910)
Other income (expense)	(809)	18	(812)	24
Total other income (expense), net	(12,844)	(868)	(26,186)	(4,800)
Loss before income taxes	(24,967)	(8,445)	(58,862)	(25,625)
Income tax expense	20	20	57	114
Net loss	(24,987)	(8,465)	(58,919)	(25,739)
Accretion of redeemable convertible preferred stock to redemption value	210	(832)	(1,761)	(2,882)
Cumulative redeemable convertible preferred stock dividends	(451)	(1,412)	(2,747)	(2,987)
Net loss attributable to common stockholders — basic and diluted	$ (25,228)	$ (10,709)	$ (63,427)	$ (31,608)
Net loss per share attributable to Class A and Class B common stockholders — basic and diluted	$ (0.71)	$ (30.08)	$ (5.14)	$ (89.20)
Weighted average common shares outstanding — basic and diluted	35,316,099	356,074	12,344,619	354,341

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,	
	2021	2020	2021	2020
Net loss	$ (24,987)	$ (8,465)	$ (58,919)	$ (25,739)
Other comprehensive income:				
Unrealized loss on short-term investments, net of tax	—	—	(1)	—
Comprehensive loss	$ (24,987)	$ (8,465)	$ (58,920)	$ (25,739)

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

RAPID MICRO BIOSYSTEMS, INC.
Condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit)
(Unaudited)
(In thousands, except share amounts)

	Redeemable convertible preferred stock		Class A Common stock		Class B Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2020	133,021,640	$ 151,826	612,850	$ 6	—	$ —	$ 114,575	$ (241,588)	$ 1	$(127,006)
Issuance of Series D1 redeemable convertible preferred stock, net of issuance costs of $2,627	22,086,725	78,338	—	—	—	—	—	—	—	—
Issuance of Series D2 redeemable convertible preferred stock, net of issuance costs of $18	413,268	1,470	—	—	—	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	787	—	—	—	—	(787)	—	—	(787)
Cumulative redeemable convertible preferred stock dividends	—	1,411	—	—	—	—	(1,411)	—	—	(1,411)
Issuance of common stock upon exercise of stock options	—	—	67,418	1	—	—	66	—	—	67
Issuance of restricted common stock awards	—	—	248,903	2	—	—	(2)			—
Stock-based compensation expense	—	—	—	—	—	—	191	—	—	191
Net loss	—	—	—	—	—	—	—	(22,101)	—	(22,101)
Balances at March 31, 2021	155,521,633	$ 233,832	929,171	$ 9	—	$ —	$ 112,632	$ (263,689)	$ 1	$(151,047)
Series D1 issuance costs	—	(64)	—	—	—	—	—	—	—	—
Series D2 issuance costs	—	(1)	—	—	—	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	1,184	—	—	—	—	(1,184)	—	—	(1,184)
Cumulative redeemable convertible preferred stock dividends	—	885	—	—	—	—	(885)	—	—	(885)
Issuance of common stock upon exercise of stock options	—	—	37,146	1	—	—	31	—	—	32
Stock-based compensation expense	—	—	—	—	—	—	390	—	—	390
Net loss	—	—	—	—	—	—	—	(11,831)	—	(11,831)
Other comprehensive income	—	—	—	—	—	—	—	—	(1)	(1)
Balances at June 30, 2021	155,521,633	$ 235,836	966,317	$ 10	—	$ —	$ 110,984	$ (275,520)	$ —	$(164,526)
Accretion of redeemable convertible preferred stock to redemption value	—	(210)	—	—	—	—	210	—	—	210
Cumulative redeemable convertible preferred stock dividends	—	451	—	—	—	—	(451)	—	—	(451)
Conversion of preferred stock to common stock	(155,521,633)	(236,077)	24,200,920	242	6,903,379	69	235,766	—	—	236,077
Conversion of preferred stock warrants to class A common stock warrants	—	—	—	—	—	—	23,760	—	—	23,760
Issuance of class A common stock in initial public offering, net of issuance costs of $16,087	—	—	9,006,604	90	—	—	163,955	—	—	164,045
RSA liability accretion	—	—	—	—	—	—	5	—	—	5
Issuance of common stock upon exercise of common stock warrants	—	—	268,718	2	—	—	11	—	—	13
Issuance of common stock upon exercise of stock options	—	—	6,595	—	—	—	15	—	—	15
Stock-based compensation expense	—	—	—	—	—	—	584	—	—	584
Net loss	—	—	—	—	—	—	—	(24,987)	—	(24,987)
Balances at September 30, 2021	—	$ —	34,449,154	$ 344	6,903,379	$ 69	$ 534,839	$ (300,507)	$ —	$ 234,745

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

RAPID MICRO BIOSYSTEMS, INC.
Condensed consolidated statements of redeemable convertible preferred stock and stockholders' deficit
(Unaudited), continued
(In thousands, except share amounts)

	Redeemable convertible preferred stock		Class A Common stock		Class B Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2019	78,757,540	$ 81,850	353,465	$ 4	—	$ —	$ 121,931	$ (204,510)	$ —	$ (82,575)
Accretion of redeemable convertible preferred stock to redemption value	—	818	—	—	—	—	(818)	—	—	(818)
Cumulative redeemable convertible preferred stock dividends	—	788	—	—	—	—	(788)	—	—	(788)
Stock-based compensation expense	—	—	—	—	—	—	120	—	—	120
Net loss	—	—	—	—	—	—	—	(8,007)	—	(8,007)
Balances at March 31, 2020	78,757,540	83,456	353,465	$ 4	—	$ —	$ 120,445	$ (212,517)	$ —	$ (92,068)
Issuance of Series C1 redeemable convertible preferred stock, net of issuance costs of $261	23,611,208	26,891	—	—	—	—	—	—	—	—
Issuance of Series C2 redeemable convertible preferred stock, net of issuance costs of $303	20,301,829	23,044	—	—	—	—	—	—	—	—
Conversion of bridge notes to C1 redeemable convertible preferred stock	10,351,063	11,898	—	—	—	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	1,232	—	—	—	—	(1,232)	—	—	(1,232)
Cumulative redeemable convertible preferred stock dividends	—	787	—	—	—	—	(787)	—	—	(787)
Stock-based compensation expense	—	—	—	—	—	—	126	—	—	126
Net loss	—	—	—	—	—	—	—	(9,267)	—	(9,267)
Balances at June 30, 2020	133,021,640	147,308	353,465	$ 4	—	$ —	$ 118,552	$ (221,784)	$ —	$ (103,228)
Issuance of common stock upon exercise of stock options	—	—	5,000	—	—	—	5	—	—	5
Accretion of redeemable convertible preferred stock to redemption value	—	832	—	—	—	—	(832)	—	—	(832)
Cumulative redeemable convertible preferred stock dividends	—	1,412	—	—	—	—	(1,412)	—	—	(1,412)
Stock-based compensation expense	—	—	—	—	—	—	115	—	—	115
Net loss	—	—	—	—	—	—	—	(8,465)	—	(8,465)
Balances at September 30, 2020	133,021,640	149,552	358,465	$ 4	—	$ —	$ 116,428	$ (230,249)	$ —	$ (113,817)

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,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (58,919)	$ (25,739)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,079	1,190
Stock-based compensation expense	1,165	361
Change in fair value of preferred stock warrant liability	19,643	(549)
Provision recorded for inventory	44	—
Noncash interest expense	390	1,378
Gain on disposal of property and equipment	(18)	—
Accretion on investments	(4)	(11)
Loss on extinguishment of debt	3,100	2,910
Changes in operating assets and liabilities		
Accounts receivable	(18)	(2,036)
Inventory	(5,247)	(2,531)
Prepaid expenses and other current assets	(2,552)	(579)
Other long-term assets	(653)	(591)
Accounts payable	(2,216)	(1,613)
Accrued expenses and other current liabilities	2,646	618
Deferred revenue	(520)	1,295
Deferred rent, long term	22	72
Other long-term liabilities	(19)	—
Net cash used in operating activities	(42,077)	(25,825)
Cash flows from investing activities:		
Purchases of property and equipment	(1,251)	(566)
Proceeds from sale of property and equipment	20	—
Purchases of investments	—	(24,980)
Maturity of investments	15,000	—
Net cash provided by (used in) investing activities	13,769	(25,546)
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	79,743	49,935
Proceeds from issuance of common stock upon option exercise	294	5
Proceeds from issuance of restricted stock award	523	—
Proceeds from initial public offering of Class A common stock, net of issuance costs	165,453	—
Proceeds from exercise of common stock warrants	13	
Proceeds from issuance of convertible notes, net of issuance costs	—	9,500
Proceeds from issuance of notes payable, net of issuance costs	—	25,000
Payments of debt issuance costs	—	(857)
Repayment of term loans	(26,159)	(18,000)
Payment of debt extinguishment fees	(1,866)	(1,398)
Net cash provided by financing activities	218,001	64,185
Net increase in cash, cash equivalents and restricted cash	189,693	12,814
Cash, cash equivalents and restricted cash at beginning of period	30,179	12,611
Cash, cash equivalents and restricted cash at end of period	$ 219,872	$ 25,425

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,	
	2021	2020
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,891	$ 979
Supplemental disclosure of non-cash investing activities		
Establishment of property and equipment retirement cost asset	$ 188	$ —
Purchases of property and equipment in accounts payable	$ 857	$ 14
Supplemental disclosure of non-cash financing activities		
Conversion of convertible notes to Series C1 preferred stock	$ —	$ 9,523
Issuance of preferred stock warrants in connection with redeemable convertible preferred stock	$ —	$ 652
Initial fair value of derivative liability	$ —	$ 2,375
Assets acquired under capital lease	$ 372	$ —
Offering costs included in accounts payable and accrued expenses	$ 1,408	$ —
Conversion of preferred stock to common stock	$ 235,766	$ —
Conversion of preferred stock warrants to common stock warrants	$ 23,760	$ —
Accretion of redeemable convertible preferred stock to redemption value	$ 1,761	$ 2,882
Cumulative redeemable convertible preferred stock dividends	$ 2,747	$ 2,987

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)

1. Nature of the business and basis of presentation

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

The Company is subject to risks and uncertainties common to companies in the pharmaceutical and biotech quality control laboratory testing and instrumentation industry including, but not limited to, the successful development, commercialization, marketing and sale of products, fluctuations in operating results and financial risks, protection of proprietary knowledge and patent risks, dependence on key personnel, competition, technological and medical risks, customer demand, compliance with governmental regulations and management of growth. Potential risks and uncertainties also include, without limitation, uncertainties regarding the duration and magnitude of the impact of the ongoing COVID-19 pandemic on the Company's business and the economy in general. Products currently under development will require additional research and development efforts prior to commercialization and will require additional capital and adequate personnel and infrastructure. The Company's research and development may not be successfully completed, adequate protection for the Company's technology may not be obtained, the Company may not obtain necessary government regulatory approval, and approved products may not prove commercially viable. The Company operates in an environment of rapid change in technology and competition.

In March 2020, the World Health Organization declared the global novel coronavirus disease 2019 ("COVID-19") outbreak a pandemic. The impact of this pandemic has been and may continue to be extensive in many aspects of society, which has resulted in and may continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. The Company cannot at this time predict the ultimate extent, duration, or full impact that the COVID-19 pandemic will have on its future financial condition and operations. The impact of the ongoing COVID-19 pandemic on the Company's financial performance will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of COVID-19, and its variants, on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be materially adversely affected.

Future impacts to the Company's business as a result of COVID-19, and its variants, could include disruptions to the Company's manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; limitations on its employees' and customers' ability to travel, and delays in shipments to and from affected countries and within the United States. While the Company maintains an inventory of finished products and raw materials used in its products, a prolonged pandemic could lead to shortages in the raw materials necessary to manufacture its products.

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, 2020, included in the Company's prospectus, dated July 14, 2021, filed with the Securities and Exchange Commission ("SEC") in accordance with Rule 424(b) of the Securities Act on July 16, 2021 (the "Prospectus"). 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, 2021 and the results of its operations for the three and nine months ended September 30, 2021 and 2020, and its cash flows for the nine months ended September 30, 2021 and 2020. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2021 and 2020 are also unaudited. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period.

Reverse split

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

Initial public offering

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

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

Going concern

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued.

Through September 30, 2021, the Company has funded its operations primarily with proceeds from product, service and non-commercial revenue, proceeds from sales of its redeemable convertible preferred stock, including borrowings under convertible debt arrangements that subsequently converted into redeemable convertible preferred stock, and from the issuance of term loans, and proceeds from the IPO. The Company has incurred recurring losses since its inception, including net losses of $25.0 million and $8.5 million for the three months ended September 30, 2021 and 2020, respectively, and net losses of $58.9 million and $25.7 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, the Company had an accumulated deficit of $300.5 million. The Company expects to continue to generate significant operating losses for the foreseeable future. As of November 15, 2021, the date these interim condensed consolidated financial statements were issued, the Company expects that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months following the date these condensed consolidated financial statements were issued.

The consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

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, the valuation of common stock and stock-based awards, and the valuation of the preferred stock warrant liability. 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.

Due to the COVID-19 pandemic, there has been uncertainty and disruption in the global economy and financial markets. The Company is not aware of any specific event or circumstance that would require an update to its estimates or judgments or a revision of the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information is obtained.

Other than policies noted below, there have been no significant changes to the significant accounting policies disclosed in Note 2 of the audited consolidated financial statements as of December 31, 2020 and 2019 and for the years ended December 31, 2020 and 2019, included in the Prospectus.

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 investments and accounts receivable. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company maintains its cash and cash equivalents with financial institutions that management believes to be of high credit quality. The Company has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. 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 normal credit risk associated with commercial banking relationships.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Customer A	32.1 %	40.8 %	16.4 %	21.2 %
Customer B	*	*	*	17.1 %
Customer C	*	*	*	10.1 %
Customer D	11.4 %	*	*	*
Customer E	*	18.8 %	*	*
	43.5 %	59.6 %	16.4 %	48.4 %

* – less than 10%

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

	September 30, 2021	December 31, 2020 2020
Customer A	21.7 %	41.9 %
Customer D	20.2 %	*
Customer E	11.1 %	*
Customer F	*	10.1 %
Customer G	*	13.4 %
Customer H	*	18.7 %
	53.0 %	84.1 %

* – less than 10%

The Company relies on third parties for the supply and manufacture of its products as well as third-party logistics providers. In instances where these parties fail to perform their obligations, the Company may be unable to find alternative suppliers to satisfactorily deliver its products to its customers on time, if at all, which could have a material adverse effect on the Company's operating results, financial condition and cash flows and damage its customer relationships. There are no significant concentrations around a single third-party supplier or manufacturer for the three and nine months ended September 30, 2021 or 2020.

Deferred offering costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering or as a reduction to the carrying value of redeemable convertible preferred stock. If the in-process equity financing is abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations. As of September 30, 2021 and December 31, 2020, the Company had zero and $0.1 million, respectively, in deferred offering costs in the condensed consolidated balance sheets.

Debt issuance costs

The Company capitalizes certain legal and other third-party fees that are directly associated with the issuance of debt as debt issuance costs. Debt issuance costs are recorded as a direct reduction of the carrying amount of the associated debt on the condensed consolidated balance sheets and amortized as interest expense on the condensed consolidated statements of operations using the effective interest method, which approximates the straight-line method. As of September 30, 2021 and December 31, 2020, debt issuance costs totaled zero and $1.3 million, respectively. During the three months ended September 30, 2021 and 2020, the Company recorded $0.1 million in the respective periods, and during the nine months ended September 30, 2021 and 2020, the Company recorded $0.4 million and $0.7 million, respectively, of interest expense related to amortization of debt issuance costs in the condensed consolidated statement of operations.

Cash equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less at the time of purchase to be cash equivalents. Cash equivalents that are readily convertible to cash are stated at cost, which approximates fair value. At September 30, 2021 and December 31, 2020, the Company held cash of $0.4 million and $0.1 million, respectively, in banks located outside of the United States.

Restricted cash

As of September 30, 2021 and December 31, 2020, the Company was required to maintain guaranteed investment certificates of $0.3 million and $0.1 million, respectively, with maturities of three months to one year that are subject to an insignificant risk of changes in value. The guaranteed investment certificates are held for the benefit of the landlord in connection with an operating lease which has a remaining term 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 would be capitalized, provided these costs are expected to be recoverable. There was $1.1 million of software development costs capitalized in other long-term assets at September 30, 2021. Additionally, the related asset was not yet placed in service as of September 30, 2021.

Fair value measurements

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

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

The Company's cash equivalents, short-term investments and its redeemable convertible preferred stock warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

Product warranties

The Company offers a one-year limited assurance warranty on System sales, which is included in the selling price. The warranty accrual 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,	
	2021	2020	2021	2020
Balance, beginning of the period	$ 612	$ 757	$ 637	$ 848
Warranty repairs	—	(3)	(25)	(94)
Balance, end of the year	$ 612	$ 754	$ 612	$ 754

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 unbilled amounts in customer arrangements when revenue recognized exceeds the amount billed to the customer and the Company's right to payment is conditional and not only subject to the passage of time. The Company had $1.1 million and $0.5 million in contract assets as of September 30, 2021 and December 31, 2020, respectively, included in prepaid expenses and other current assets. These balances relate to the BARDA (as defined below) agreements, as well as unbilled amounts with commercial customers.

Contract liabilities represent the Company's obligation to transfer goods or services to a customer for which it has received consideration (or the amount is due) from the customer. The Company has a contract liability related to service revenue, which consists of amounts that have been invoiced but that have not been recognized as revenue. Amounts expected to be recognized as revenue within 12 months of the balance sheet date are classified as current deferred revenue and amounts expected to be recognized as revenue beyond 12 months of the balance sheet date are classified as noncurrent deferred revenue. The Company did not record any non-current deferred revenue as of September 30, 2021 or December 31, 2020. Deferred revenue was $3.9 million and $4.4 million at September 30, 2021 and December 31, 2020. Revenue recognized during the three months ended September 30, 2021 and 2020 that was included in deferred revenue at the prior period-end was $0.7 million and $0.2 million, respectively. Revenue recognized during the nine months ended September 30, 2021 and 2020 that was included in deferred revenue at the prior period-end was $3.6 million and $0.8 million, respectively.

Non-commercial revenue

The Company generates revenue from a long-term contract with the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority ("BARDA") a part of the U.S. government. The Company's contracts with the U.S. government typically are subject to the Federal Acquisition Regulation ("FAR") and are priced based on estimated or actual costs of producing goods or providing services. The FAR provides guidance on the types of costs that are allowable in establishing prices for goods or services provided under U.S. government contracts. In September 2017, the Company signed a contract with BARDA, which was subsequently modified on multiple occasions to increase the contract value and adjust the cost share reimbursement rate. Modifications were accounted for in accordance with the contract modification framework. The contract is a cost-reimbursable, cost- sharing arrangement, whereby BARDA reimburses the Company for a percentage of the total costs that have been incurred including indirect allowable costs. Revenue on the BARDA contract is recognized over time using an input method based on cost incurred to date in relation to total estimated cost. Due to the structure of the arrangement, the transaction price is variable in nature based on actual cost incurred. As such the amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur.

Disaggregated revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product and service revenue — recurring	$ 2,171	$ 855	$ 5,539	$ 2,712
Product and service revenue — non-recurring	4,132	4,109	11,243	6,269
Non-commercial revenue — non-recurring	596	283	1,242	1,858
Total revenue	$ 6,899	$ 5,247	$ 18,024	$ 10,839

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
United States	$ 4,313	$ 2,067	$ 10,086	$ 4,401
Germany	298	312	1,263	1,547
Switzerland	899	2,765	2,989	3,574
All other countries	1,389	103	3,686	1,317
Total revenue	$ 6,899	$ 5,247	$ 18,024	$ 10,839

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 and nine months ended September 30, 2021 and 2020.

Stock-based compensation

The Company measures all stock-based awards granted to employees, officers and directors based on their fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company issues stock-based awards with only

service-based vesting conditions and records the expense for these awards using the straight-line method. Forfeitures are accounted for prospectively as they occur.

The Company measures all restricted common stock granted to employees based on the common stock value on the date of grant. The purchase price of the restricted common stock is the common stock value on the date of grant. The restricted common stock includes a repurchase right, whereas upon the occurrence of a specific event, the Company shall have the right to repurchase unvested restricted common stock shares. At September 30, 2021 and December 31, 2020, the Company has $0.7 million and zero, respectively, in unvested restricted Class A common stock liability included in other long-term liabilities.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the three months ended September 30, 2021 and 2020, there were no other adjustments to comprehensive income or loss, and for the nine months ended September 30, 2021 and 2020, comprehensive loss included less than $0.1 million and zero, respectively, of unrealized gains on short-term investments, net of tax.

Recently adopted accounting pronouncements

In August 2018, the FASB issued ASU No. 2018-15, Intangibles — Goodwill and Other — Internal-Use Software (Topic 35): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract, which requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The Company adopted this guidance effective on January 1, 2021 and adoption did not have a material impact on the condensed consolidated financial statements and related disclosures.

Recently issued accounting pronouncements

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

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326)* ("ASU 2016- 13"). The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available for sale, and trade receivables. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For public business entities except smaller reporting companies, the guidance is effective for annual reporting periods beginning after December 15, 2019 and for interim periods within those fiscal years. For non-public entities and smaller reporting companies, the guidance was effective for annual reporting periods beginning after December 15, 2021. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for non-public entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. Early application is allowed. The Company expects to adopt this guidance effective January 1, 2023, and it is currently evaluating the impact on its condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e.,

lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For public business entities, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted.

For nonpublic entities, this guidance is effective for annual periods beginning after December 15, 2021. The Company expects to adopt this guidance effective January 1, 2022, and it is currently evaluating the impact on its condensed consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (ASC 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various areas related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application. For public business entities the guidance is effective for annual reporting periods beginning after December 15, 2020 and for interim periods within those fiscal years. For non-public entities, the guidance is effective for annual reporting periods beginning after December 15, 2021 and for interim periods within years beginning after December 15, 2022, with early adoption permitted. The Company expects to adopt this guidance effective January 1, 2022, and it is currently evaluating the impact on its condensed consolidated financial statements and related disclosures.

3. Fair value of financial assets and liabilities

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

	Fair value measurements as of September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 212,833	$ —	$ —	$ 212,833
	$ 212,833	$ —	$ —	$ 212,833

	Fair value measurements at December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents	$ 23,456	$ —	$ —	$ 23,456
Short-term investments	14,998	—	—	14,998
	$ 38,454	$ —	$ —	$ 38,454
Liabilities				
Preferred stock warrant liability	$ —	$ —	$ 4,117	$ 4,117
	$ —	$ —	$ 4,117	$ 4,117

During the three and nine months ended September 30, 2021 and 2020, respectively, there were no transfers between Level 1, Level 2 and Level 3.

Valuation of short-term investments

Short-term investments, which consisted of U.S. Treasury bonds were valued by the Company using quoted prices in active markets for similar securities, which represents a Level 1 measurement within the fair value hierarchy.

Valuation of preferred stock warrant liability

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

The Company used the Black-Scholes option-pricing model, which incorporates assumptions and estimates, to value the warrant liability. Key estimates and assumptions impacting the fair value measurement include (i) the fair value per share of the underlying shares of applicable series of redeemable convertible preferred stock issuable upon exercise of the Warrants, (ii) the remaining contractual term of the Warrants, (iii) the risk-free interest rate, (iv) the expected dividend yield and (iv) expected volatility of the price of the underlying applicable series of redeemable convertible preferred stock. The Company estimated the fair value per share of the underlying applicable series of redeemable convertible preferred stock based, in part, on the results of third-party valuations and additional factors deemed relevant. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the Warrant. The Company estimated a zero expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future. As the Company has historically been a private company and lacks company-specific historical and implied volatility information of its stock, the expected stock volatility was based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the Warrant.

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

The table below quantifies the weighted average of the unobservable inputs used to fair value the preferred stock warrant liability prior to their conversion into common stock warrants:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Fair value of Series A1 preferred stock	$ 4.00	$ 0.39	$ 3.01	$ 0.45
Fair value of Series B1 preferred stock	$ 4.00	$ 1.17	$ 3.26	$ 1.13
Fair value of Series C1 preferred stock	$ 4.00	$ 1.15	$ 3.30	$ 1.15
Remaining contractual term (in years)	6.6	7.4	6.8	7.7
Risk-free interest rate	1.0 %	0.6 %	1.2 %	0.6 %
Expected dividend yield	— %	— %	— %	— %
Expected volatility	42.2 %	40.3 %	42.0 %	39.3 %

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Balance, beginning of period	$ 15,600	$ 3,499	$ 4,117	$ 3,396
Initial fair value of Series C1 preferred stock warrants	—	—	—	652
Change in fair value of preferred stock warrants	8,160	—	19,643	(549)
Conversion of preferred stock warrants to common stock warrants	(23,760)	—	(23,760)	—
Balance, end of period	$ —	$ 3,499	$ —	$ 3,499

4. Short-term investments

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

	December 31, 2020			
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Fair value
U.S. Treasury bonds	$ 14,997	$ 1	$ —	$ 14,998
	$ 14,997	$ 1	$ —	$ 14,998

The Company did not have short-term investments at September 30, 2021.

5. Inventory

Inventory consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 10,315	$ 6,754
Work in process	689	1,190
Finished goods	3,163	1,021
Total	$ 14,167	$ 8,965

Raw materials, work in process and finished goods were net of adjustments to net realizable value.

6. Prepaid expenses and other current assets

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

	September 30, 2021	December 31, 2020
Prepaid insurance	$ 2,621	$ 355
Prepaid commitment fee on notes payable	—	275
Contract asset	1,065	471
Deposits	1,415	1,148
Lease receivables, current portion	282	325
Other	17	546
	$ 5,400	$ 3,120

7. Property and equipment, net

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

	September 30, 2021	December 31, 2020
Manufacturing and laboratory equipment	$ 13,198	$ 12,961
Computer hardware and software	1,637	1,088
Office furniture and fixtures	723	343
Leasehold improvements	3,012	2,996
Construction-in-process	1,454	—
	20,024	17,388
Less: Accumulated depreciation	(11,391)	(10,336)
	$ 8,633	$ 7,052

Depreciation and amortization expense related to property and equipment was $0.4 million and $0.3 million for the three months ended September 30, 2021 and 2020, respectively. Depreciation and amortization expense related to property and equipment was $1.1 million and $1.2 million for the nine months ended September 30, 2021 and 2020, respectively. The Company had zero fully depreciated assets disposed of during the three months ended September 30, 2021 and 2020, and less than $0.1 million and zero fully depreciated assets disposed of during the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021 and December 31, 2020, the Company's office furniture and fixtures shown in the above table included assets under a capital lease in the amount of $0.4 million and zero, respectively, and accumulated depreciation of less than $0.1 million and zero as of September 30, 2021 and December 31, 2020, respectively. As of September 30, 2021, future minimum lease payments under the capital lease were $0.6 million, with $0.2 million representing interest. The capital lease obligation is recorded in other long-term liabilities within the consolidated balance sheet.

8. Accrued expenses and other current liabilities

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

	September 30, 2021	December 31, 2020
Accrued employee compensation and benefits expense	$ 3,500	$ 3,083
Accrued vendor expenses	5,885	1,685
Accrued warranty expense	612	637
Accrued interest	—	330
Deferred rent, current portion	127	118
Accrued taxes	748	688
Other	694	113
	$ 11,566	$ 6,654

9. Long-term debt

The components of the Company's long-term debt consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Notes payable	$ —	$ 25,000
Payment in kind interest	—	1,145
Less: Unamortized discount	—	(1,335)
Long-term debt, net of discount	$ —	$ 24,810

Term loan agreements

2018 Term Loan

In April 2018, the Company entered into an $18.0 million term loan with a lender (the "2018 Term Loan").

The Company repaid the 2018 Term Loan in full in May 2020 using the proceeds from the 2020 Term Loan as discussed below. The Company paid $19.4 million to extinguish the outstanding principal and accrued interest owed, including the non-refundable end-of-term exit fee of $1.3 million (out of which $0.6 million was accrued for in prior years as interest expense) and an early termination fee of $0.1 million.

The loss on extinguishment of debt was $2.9 million which included the write-off of unamortized financing and end-of-term exit fee costs of $0.7 million and $0.1 million in early payment and documentation fees, and was included as a component of other income (expense) in the condensed consolidated statements of operations during the nine months ended September 30, 2020. Interest expense on the 2018 Term Loan totaled less than $0.1 million and $0.8 million for three and nine months ended September 30, 2020, respectively, which includes amortization of the debt discount of less than $0.1 million and $0.2 million during the three and nine months ended September 30, 2020, respectively.

2020 Term Loan

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

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

The Company incurred debt issuance costs of $1.5 million in connection with the 2020 Term Loan including $0.9 million of professional fees and $0.6 million for the fair value of the warrants issued with the debt. Interest expense on the 2020 Term Loan totaled $0.7 million and $2.5 million for the three and nine months ended September 30, 2021, respectively, which includes amortization of the debt discount of less than $0.1 million and $0.3 million during the three and nine months ended September 30, 2021, respectively.

In September 2021, the Company repaid the 2020 Term Loan and incurred a debt extinguishment loss of $3.1 million, which was comprised of a $1.8 million prepayment penalty, $1.1 million expense related to unamortized discounts, and $0.2 million in unamortized prepaid facility fees and other charges. As of September 30, 2021, the Company had no outstanding balance on the 2020 Term Loan.

Convertible Notes

In February 2020, the Company issued Convertible Notes to several investors in the aggregate amount of $9.5 million with a stated interest rate of 1.5% per annum and a maturity date of February 28, 2021. The Convertible Notes provided a conversion option whereby upon the closing of a financing event, in which the aggregate gross proceeds of the issuance of preferred stock totaled at least $20.0 million, the notes would automatically convert into shares of the same class and series of capital stock of the Company issued to other investors in the financing at a conversion price equal to 80% of the price per share paid by the other investors. The conversion option met the definition of an embedded derivative and was required to be bifurcated and accounted for separately from the notes. The proceeds from the Convertible Notes were allocated between the derivative liability, with a fair value at issuance of $2.4 million, and the notes, with an initial carrying value of $7.1 million, included in long-term liabilities on the Company's condensed consolidated balance sheets. The difference between the initial carrying value of the notes and the stated value of the notes represented a discount and that was accreted to interest expense over the term of the Convertible Notes using the effective interest method.

In April 2020, the Convertible Notes, including outstanding principal and accrued interest totaling $9.5 million, were automatically converted into 10,351,063 shares of Series C1 Preferred Stock. Upon conversion, the remaining unamortized discount was recognized as loss on extinguishment of debt in the condensed consolidated statement of operations.

Interest expense on the Convertible Notes was zero and $0.4 million for the three and nine months ended September 30, 2020, respectively, which consists primarily of amortization of the debt discount.

10. Redeemable convertible preferred stock

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

In April 2020, the Company issued and sold 23,611,208 shares of Series C1 Preferred Stock and 20,301,829 shares of Series C2 Preferred Stock to new and existing investors at a price of $1.15 per share for gross proceeds of $27.2 million and $23.3 million, respectively. Additionally, the Company's Convertible Notes, including outstanding principal and accrued interest totaling $9.5 million (see Note 9), were automatically converted into 10,351,063 shares of Series C1 Preferred Stock. The Company incurred issuance costs in connection with this transaction of $0.6 million and recorded them as a reduction to the carrying value of the Series C1 Preferred Stock and Series C2 Preferred Stock.

In March 2021, the Company issued and sold 22,086,725 shares of Series D1 Preferred Stock and 413,268 shares of Series D2 Preferred Stock to new and existing investors at a price of $3.60 per share for gross proceeds of $79.5 million and $1.5 million, respectively. The Company incurred issuance costs in connection with this transaction of $2.7 million and recorded them as a reduction to the carrying value of the Series D1 Preferred Stock and Series D2 Preferred Stock.

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

On July 14, 2021, the IPO resulted in the automatic conversion Series A1, Series B1, Series C1 and Series D1 preferred stock to 24,200,920 shares of Class A common stock and Series C2 and Series D2 converted into 6,903,379 shares of Class B common stock. On July 19, 2021, the Company restated its certificate of incorporation and authorized 10,000,000 shares of $0.01 par value Preferred Stock. As of September 30, 2021, there was no Preferred Stock outstanding.

As of December 31, 2020, Preferred Stock consisted of the following (in thousands, except for share data):

	December 31, 2020				
	Preferred stock authorized	Preferred stock issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A1 Preferred Stock	22,563,639	18,740,115	$ 18,542	$ 21,176	3,748,022
Series B1 Preferred Stock	61,217,425	60,017,425	68,511	90,026	12,003,474
Series C1 Preferred Stock	57,372,796	33,962,271	40,632	58,585	6,792,445
Series C2 Preferred Stock	20,301,829	20,301,829	24,141	35,021	4,060,365
	161,455,689	133,021,640	$ 151,826	$ 204,808	26,604,306

11. Preferred stock warrants

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

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

As of December 31, 2020, warrants to purchase the following classes of preferred stock outstanding consisted of the following:

	December 31, 2020					
Issuance date	Contractual term (in years)	Series of redeemable convertible preferred stock	Balance sheet classification	Preferred shares issuable upon exercise of warrant	Weighted average exercise price	Warrant fair value
April 24, 2017	10	Series A1	Liability	3,823,524	$ 0.01	$ 1,875
April 12, 2018	10	Series B1	Liability	1,199,994	$ 0.01	1,501
May 14, 2020	10	Series C1	Liability	1,195,652	$ 1.15	741
				6,219,170		$ 4,117

12. Common stock and common stock warrants

As of September 30, 2021 and December 31, 2020, the Company's restated certificate of incorporation authorized the issuance of 210,000,000 shares and 35,000,000 shares, respectively, of $0.01 par value Class A common stock.

On June 25, 2021, the Company filed an amended and restated certificate of incorporation, which effected a recapitalization of the Company's then outstanding common stock to Class A common stock and authorized an additional new class of common stock (Class B common stock). Rights of the holders of Class A common stock and Class B common stock are identical, except with respect to voting and conversion. On July 19, 2021, the Company filed an amended and restated certificate of incorporation which authorized Class A common stock and Class B common

stock to 210,000,000 shares and 10,000,000 shares, respectively. As of September 30, 2021, there were 34,449,154 shares of Class A common stock issued and outstanding, and 6,903,379 shares of Class B common stock issued and outstanding.

Each share of Class A common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. The Company's Class B common stock is non-voting. Class A and Class B common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of Preferred Stock. As of September 30, 2021 and December 31, 2020, no cash dividends had been declared or paid.

As of September 30, 2021 and December 31, 2020, the Company had reserved 9,991,141 and 32,574,029 shares, respectively, of common stock for the conversion of the outstanding Preferred Stock (see Note 10), exercise of outstanding stock options, the number of shares remaining available for grant under the Company's 2010 Stock Incentive Plan and 2021 Incentive Award Plan (see Note 13) and the exercise of outstanding warrants to purchase shares of preferred stock (see Note 11) and Class A common stock.

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

As of September 30, 2021, outstanding warrants to purchase common stock consisted of the following:

	September 30, 2021			
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	25,835	$ 295.15
April 12, 2018	10	Equity	30,000	$ 1.00
July 14, 2021	10	Equity	975,109	$ 1.46
			1,030,944	

As of December 31, 2020, outstanding warrants to purchase common stock outstanding consisted of the following:

	December 31, 2020			
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	25,835	$ 295.15
April 12, 2018	10	Equity	30,000	$ 1.00
			55,835	

13. 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.

At December 31, 2020, a total of 4,945,783 shares of common stock were reserved for issuance under the 2010 Plan. In March 2021, the Board of Directors approved an increase to the 2010 Plan shares by 382,889 shares. Upon the effectiveness of the IPO, no additional awards will be granted under the 2010 Plan and shares of existing outstanding options that are returned will be returned and can be granted under the 2021 Incentive Award Plan (described below).

2021 Incentive Award Plan

In July 2021, the Board of Directors adopted, and the Company's stockholders approved, the 2021 Incentive Award Plan (the "2021 Plan"), which became effective in connection with the IPO of Class A common stock. The 2021 Plan provides for the grant of stock options, including incentive stock options and non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based and cash-based awards. The 2021 Plan has a term of ten years. The aggregate number of shares of Class A common stock available for issuance under the 2021 Plan is equal to (i) 4,200,000 shares; (ii) any shares which are subject to the 2010 Plan awards that become available for issuance under the 2021 Plan; and (iii) an annual increase for ten years on the first day of each calendar year beginning on January 1, 2022, equal to the lesser of (A) 5% of the aggregate number of shares of Class A common stock outstanding on the last day of the immediately preceding calendar year and (B) such smaller amount of shares as determined by the Board of Directors. No more than 33,900,000 shares of Class A common stock may be issued under the 2021 Plan upon the exercise of incentive stock options. As of September 30, 2021, there are 4,187,990 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,	
	2021	2020	2021	2020
Risk-free interest rate	0.96 %	0.34 %	0.90 %	0.36 %
Expected term (in years)	5.8	6.0	6.0	6.0
Expected volatility	43.7 %	90.4 %	51.5 %	90.3 %
Expected dividend yield	0 %	0 %	0 %	0 %

Stock options

The following table summarizes the Company's stock option activity since December 31, 2020 (in thousands, except for share and per share data):

	Number of shares	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding as of December 31, 2020	3,604,584	$ 0.92	8.12	$ 4,272
Granted	1,732,182	9.15		
Exercised	(111,149)	2.67		
Expired	(34,447)	1.00		
Forfeited	(667,866)	2.12		
Outstanding as of September 30, 2021	4,523,304	$ 3.88	7.68	$ 66,231
Options vested and expected to vest as of September 30, 2021	4,523,304	$ 3.88	7.68	$ 66,231
Options exercisable as of September 30, 2021	2,134,381	$ 1.25	6.17	$ 36,777

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock (or Class A common stock as of September 30, 2021) 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, 2021 and 2020 was $0.4 million and zero, respectively.

The weighted average grant-date fair value per share of stock options granted during the three months ended September 30, 2021 and 2020 was $8.33 and $0.55, respectively, and during the nine months ended September 30, 2021 and 2020 was $4.05 and $0.55, respectively.

Restricted stock

In February 2021, the Company granted 248,903 shares of restricted stock to an employee under the 2010 Plan with a four-year vesting term. In connection with the grant, the employee paid $0.5 million, which represents the $2.10 per share fair value of the common stock on the date of the restricted stock grant. The restricted common stock includes a repurchase right, whereas upon the occurrence of the employee's resignation or termination for cause or good reason the Company shall have the right to repurchase unvested restricted common stock shares. At September 30, 2021 and December 31, 2020, the Company has $0.7 million and zero in unvested restricted common stock liability included in other long-term liabilities, respectively.

The following table summarizes the Company's restricted stock activity since December 31, 2020 (in thousands except for share and per share data):

	Number of shares	Weighted average fair value (in years)
Unvested as of December 31, 2020	-	
Granted	248,903	$ 2.10
Vested	-	
Forfeited	-	
Unvested as of September 30, 2021	248,903	$ 2.10

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. As of September 30, 2021, no offering periods have been initiated.

Stock-based compensation expense

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,	
	2021	2020	2021	2020
Cost of revenue	$ 106	$ 20	$ 221	$ 62
General and administrative	345	72	680	223
Sales and marketing	76	11	158	42
Research and development	57	12	106	34
Total stock-based compensation expense	$ 584	$ 115	$ 1,165	$ 361

As of September 30, 2021, total unrecognized compensation expense related to unvested stock options held by employees and directors was $6.2 million, which is expected to be recognized over a weighted average period of 1.4 years.

14. Income taxes

During the three and nine months ended September 30, 2021 and 2020, 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 ("AETR"), adjusted for the effect of discrete items arising in that quarter.

The impact of such inclusions 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, 2021 and December 31, 2020 the Company has recorded a full valuation allowance against its net deferred tax assets.

The Company files U.S. income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations in the U.S. The Company has not received notice of examination by any jurisdictions in the U.S.

The Company has a branch in Germany that is under examination in its local country for tax years 2016-2018. Any adjustments that may result from the examinations are not expected to have a material impact on the financial position, liquidity, or results of operations of the Company.

15. Net loss per share

Net loss per share attributable to common stockholders.

As of September 30, 2021, the Company has Class A common stock and Class B common stock. According to the Company’s restated certificate of incorporation, both classes have the same rights to the Company’s earnings and neither of the shares have any prior or senior rights to dividends to other shares.

The Company reported a net loss attributable to common stockholders for the three and nine months ended September 30, 2021 and 2020, as such basic net loss per share attributable to common stockholders was the same as

diluted net loss per share attributable to common stockholders. Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (24,987)	$ (8,465)	$ (58,919)	$ (25,739)
Accretion of redeemable convertible preferred stock to redemption value	210	(832)	(1,761)	(2,882)
Cumulative redeemable convertible preferred stock dividends	(451)	(1,412)	(2,747)	(2,987)
Net loss attributable to common stockholders—basic and diluted	$ (25,228)	$ (10,709)	$ (63,427)	$ (31,608)
Denominator:				
Weighted average Class A common shares outstanding—basic and diluted	29,463,234	356,074	10,372,225	354,341
Weighted average Class B common shares outstanding—basic and diluted	5,852,865	—	1,972,394	—
Total shares for EPS—basic and diluted	35,316,099	356,074	12,344,619	354,341
Net loss per share attributable to Class A common stockholders—basic and diluted	(0.71)	(30.08)	(5.14)	(89.20)
Net loss per share attributable to Class B common stockholders—basic and diluted	(0.71)	—	(5.14)	—

The Company's potentially dilutive securities, which include stock options, redeemable convertible preferred stock, common stock warrants and preferred stock warrants, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	September 30,	
	2021	2020
Options to purchase common stock	4,772,207	4,005,581
Warrants to purchase common stock	294,965	55,872
Redeemable convertible preferred stock (as converted to common stock)	—	26,604,306
Warrants to purchase preferred stock (as converted to warrants to purchase common stock)	—	1,243,834
	5,067,172	31,909,593

16. Commitments and contingencies

Lease agreements

In October 2013, the Company 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 early termination of the lease in July 2024 and a one-time, five-year extension of the lease following its expiration as well as a $0.7 million tenant improvement allowance, which was fully utilized as of September 30, 2021.

In June 2021, the Company entered into a Sublease agreement for office and manufacturing space in Lexington, Massachusetts, which expires in June 2029. The Sublease agreement includes an option to terminate the sublease in July 2026, subject to an early termination fee. The Company also has the right to use furniture and equipment specified in the Sublease agreement for $0.6 million in future payments over the term of the sublease with the option to purchase the

furniture and equipment at the end of the sublease term. Additionally, the Sublease requires the Company to return part of the leased space back to its original condition upon termination. As a result, the Company recognized an asset retirement obligation in the amount of $0.2 million which is classified in other long-term liabilities within the consolidated balance sheet. Concurrent with entering into the Sublease agreement, the Company executed an Option Agreement with the property owner which provides the Company the option to enter into a new direct lease for the Lexington facility for an additional five years following expiration of the sublease.

The Company recognizes rent expense on a straight-line basis over the respective lease period. The Company has recorded deferred rent for rent expense incurred but not yet paid. Rent expense was $0.2 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively, and rent expense was $0.4 million and $0.3 million for the nine months ended September 30, 2021 and 2020, respectively.

Future minimum lease commitments under operating leases as of September 30, 2021 are as follows (in thousands):

Year ending December 31,		
2021	$	169
2022		1,139
2023		1,169
2024		1,199
2025		1,229
Thereafter		2,997
Total	$	7,902

Exit fee

In December 2016, in connection with the amendment of a then-outstanding loan agreement with the lender, the Company entered into an agreement under which it was obligated to pay the lender an exit fee in the amount of $0.8 million in the event of a qualifying exit event prior to December 31, 2026. A qualifying event was defined as any (i) liquidation, dissolution or winding up whether voluntary or involuntary; (ii) consolidation, merger or reverse merger; (iii) sale, lease, transfer, exclusive license, exchange, dividend or other disposition of all or substantially all of the Company's assets; (iv) issuance and/or sale of the Company's stock that is greater than 50% of the shares of common stock immediately following such issuance; (v) any other form of acquisition or business combination that results in a change of control at the Company; or (vi) the consummation of any public offering of shares of common stock. There were no amounts accrued for the exit fee at December 31, 2020, as the occurrence of a qualifying exit event was not deemed probable. The Company paid the exit fee following the IPO, which was considered a qualifying event. The exit fee expense is included in Other income (expense) on the condensed consolidated statements of operations for the three and nine months ended September 30, 2021.

Supply agreement

In March 2020, the Company entered into an agreement with a supplier to provide raw materials used in the manufacturing process. As of September 30, 2021, the Company had committed to minimum payments under these arrangements totaling $0.8 million through December 31, 2022. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company had $0.3 million and $0.1 million accrued for the supply agreement as of September 30, 2021 and December 31, 2020. respectively.

Software subscription

During the year ended December 31, 2020, the Company entered into a non-cancelable agreement with a service provider for software as a service and cloud hosting services. As of September 30, 2021, the Company had committed to minimum payments under these arrangements totaling $1.1 million through January 31, 2026. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such

expenditures can be reasonably estimated. There were no amounts accrued for the software subscription as of September 30, 2021 and December 31, 2020.

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, 2021 and December 31, 2020.

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 such legal proceedings.

17. Benefit plans

The Company established a defined contribution savings plan under Section 401(k) of the Code. This plan covers all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the plan may be made at the discretion of the Company’s board of directors. The Company made contributions of $0.1 million and less than $0.1 million to the plan during the three months ended September 30, 2021 and 2020, respectively, and $0.2 million and $0.1 million to the plan during the nine months ended September 30, 2021 and 2020, 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, 2020, included in our prospectus, dated July 14, 2021, filed with the Securities and Exchange Commission, or the SEC, in accordance with Rule 424(b) of the Securities Act on July 16, 2021, or the Prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on 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, or MQC, detection platform. We develop, manufacture, market and sell the Growth Direct system and related proprietary consumables, and value-added services to enable rapid MQC testing in the manufacture of biologics, cell and gene therapies, vaccines, sterile injectables, and other healthcare products. Our system delivers the power of industrial automation to bioprocessing and pharmaceutical manufacturing firms by modernizing and digitizing their MQC operations. Our Growth Direct platform, developed with over 15 years of active feedback from our customers, was purpose-built to meet the growing demands posed by the increasing scale, complexity, and regulatory scrutiny confronting global pharmaceutical manufacturing. Our Growth Direct platform comprises the Growth Direct system, optional laboratory information management system, or LIMS, connection software (which the majority of our customers purchase), proprietary consumables, and comprehensive field service, validation services and post-warranty service contracts. Once embedded and validated in our customers' facilities, our Growth Direct platform provides for recurring revenues through ongoing sales of consumables and service contracts.

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

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

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

Since our inception, we have incurred net losses in each year. We generated revenue of $6.9 million and $5.2 million for the three months ended September 30, 2021 and 2020, respectively, and incurred net losses of $25.0 million and $8.5 million for those same periods, respectively. We generated revenue of $18.0 million and $10.8 million for the nine months ended September 30, 2021 and 2020, respectively, and incurred net losses of $58.9 million and $25.7 million for those same periods, respectively. As of September 30, 2021, we had an accumulated deficit of $300.5 million. We expect to continue to incur net losses in connection with our ongoing activities, including:

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

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

We believe that the net proceeds from the IPO, together with our cash and cash equivalents as of September 30, 2021, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. 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.”

COVID-19 update

In response to the COVID-19 pandemic and various resulting government directives, we took proactive measures to protect the health and safety of our employees, customers, and partners, while maintaining our ability to supply and service our customers. We continue to monitor the implications of the ongoing COVID-19 pandemic on our business, as well as our customers’ and suppliers’ businesses. Some of the measures we have taken follow:

- During this pandemic, we moved quickly to implement several business continuity initiatives aimed at maintaining uninterrupted manufacturing and supply capabilities while keeping our workforce safe, including instituting a COVID-19 task force, forming multiple manufacturing teams with staggered shifts, increasing inventory safety stock levels, and establishing appropriate protective equipment and distancing policies for essential on-site personnel.
- We have been designated an essential business that can continue operations during the COVID-19 pandemic. In early March 2020, we promptly instituted protocols to have many personnel work remotely. At the same time, because of our continued designation as an essential business, many employees continue to work on-site at our facility in Lowell, MA to undertake manufacturing activities that support essential operations to provide mission-critical MQC testing products to global pharmaceutical customers manufacturing life-saving drugs. We have also restricted business travel and have limited access to our facilities to outside visitors other than customers, vendors, suppliers and partners who are integral to supporting our business. To date, these arrangements have not materially affected our ability to maintain our business operations, including the operation of financial reporting systems, internal control over financial reporting and disclosure controls and procedures.

- Our production, shipping and customer service functions remain operational to maintain a continuous supply of products to our customers. We are communicating regularly with our suppliers and logistics partners so that our supply chain remains intact and we have not experienced any material supply issues to date. Our customer service teams around the world are operating remotely and remain available to assist our customers and partners as needed.

- As a result of travel restrictions and shelter-in-place orders, we experienced an impact on our ability to ship, install and validate systems, as well as train customers in certain geographies, which negatively impacted our product and service revenues during 2021 and 2020. Despite these restrictions, we were able to implement several measures including remote and customer-assisted support activities to support the continued growth of our business.

- We are actively reviewing and managing costs to navigate the current environment. However, to date, the COVID-19 pandemic has not had a material adverse effect on results of operations.

While the disruption due to COVID-19, and its variants, is currently expected to be temporary, there is considerable uncertainty around its duration. We expect these disruptions to continue to impact our operating results. However, the related financial impact and duration of these disruptions cannot be reasonably estimated at this time.

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. These factors also pose important challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address these challenges is subject to various risks and uncertainties, including those described under the heading “Risk Factors.”

New customer adoption of the Growth Direct platform

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

We are investing substantially in these organizations and expect to continue to do so in the future. As part of this effort, we increased our direct sales and marketing team by 69% for the nine months ended September 30, 2021 compared to the prior year-end.

Expansion within our existing customer base

There is an opportunity to increase broader adoption and utilization of our Growth Direct platform throughout our existing customers’ organizations by their purchasing of more systems to convert more of their test volume at existing locations, to support multiple locations, to meet redundancy requirements, or driven by a need to increase capacity. As of September 30, 2021, approximately 50% of our customers have purchased Growth Direct systems for multiple sites, and approximately 60% 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.

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.

Expanding Growth Direct into adjacent end markets

We have identified adjacent end markets that conduct high volumes of MQC testing under regulatory control and derive value from improving operational efficiency via MQC automation and we may opportunistically enter these markets. We could expand into these markets through our existing technologies, through adapting our existing technologies, or through developing new products to specifically address the unmet needs of these adjacent markets. We may drive our expansion into these markets by building commercial infrastructure to specifically target customers in those markets, or by partnering with other participants in those markets.

Revenue mix

Our revenue is derived from sales of our Growth Direct systems, our LIMS connection software, proprietary consumables, services and our cost-reimbursement contract with BARDA. During the three and nine months ended September 30, 2021 and 2020, Growth Direct system revenue was the single largest component of our revenue. Because Growth Direct system revenue involves a capital selling process and tends to be somewhat concentrated within a small (but different) group of customers each year, it is subject to variability from quarter to quarter. While we expect Growth Direct systems revenue to continue to be the largest contributor to our revenue over the near- to mid-term, as our base of validated Growth Direct systems continues to grow, we expect our recurring revenue (consumables and service contracts) to grow at a faster rate than our non-recurring revenues (Growth Direct systems, validation and other services), which we expect to drive variability and longer-term trends in our revenue mix.

Our non-commercial revenue is generated from long-term contracts with governmental agencies and third parties that are typically fixed in terms of scope and value. As a result, the amount of non-commercial revenue recognized in each period is subject to variability depending on factors such as the number of active contracts as well as the work performed and value remaining under each contract.

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	
	2021	2020	Amount	%
	(dollars in thousands)			
Systems placed:				
Systems placed in period	10	11	(1)	(9.1)%
Cumulative systems placed	113	77	36	46.8 %
Systems validated:				
Systems validated in period	5	4	1	25.0 %
Cumulative systems validated	68	37	31	83.8 %
Product and service revenue — total	$ 6,303	$ 4,964	$ 1,339	27.0 %
Product and service revenue — recurring	$ 2,171	$ 855	$ 1,316	153.9 %

	Nine Months Ended September 30,		Change	
	2021	2020	Amount	%
	(dollars in thousands)			
Systems placed:				
Systems placed in period	26	16	10	62.5 %
Cumulative systems placed	113	77	36	46.8 %
Systems validated:				
Systems validated in period	17	10	7	70.0 %
Cumulative systems validated	68	37	31	83.8 %
Product and service revenue — total	$ 16,782	$ 8,981	$ 7,801	86.9 %
Product and service revenue — recurring	$ 5,539	$ 2,712	$ 2,827	104.2 %

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 COVID-19 related restrictions). 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 validating placed systems. We expect our validated Growth Direct systems to continue to grow over time as we increase our base of cumulative systems placed and then validate those systems. After a Growth Direct system is placed with a customer and installed, we work with the customer to validate the system, which typically takes anywhere from three to nine months. Once a validation has been completed, we generally expect our customers to transition from their legacy manual method to our automated method and begin regular utilization of consumables over a period of up to three months.

The number of validated Growth Direct systems and rate of growth varies from period-to-period due to factors including, but not limited to, Growth Direct system order volume and timing, whether customers have previously validated Growth Direct systems within their site or network, access to customer sites (including as a result of COVID-19 related restrictions and delays in 2021 and 2020), customer site readiness and the time to install and validate each individual system. As a result, we expect to experience continued fluctuations in our period-to-period number of Growth Direct systems validated due to the aforementioned factors.

Product and service revenue

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

During the three and nine months ended September 30, 2021 and 2020, travel restrictions related to COVID-19, and its variants, negatively impacted our ability to ship, install and validate Systems, as well as train customers in certain geographies. This negatively impacted our product and service revenue in those periods. While we expect these disruptions to continue to impact our operating results, the related financial impact and duration of these disruptions cannot be reasonably estimated at this time.

Recurring revenue

We regularly assess trends relating to recurring revenue, which is the revenue from consumables and service contracts, based on our product offerings, our customer base and our understanding of how our customers use our products. Recurring revenue was 31.5% and 16.3% of our total revenue for the three months ended September 30, 2021 and 2020, respectively. Recurring revenue was 30.7% and 25.0% of our total revenue for the nine months ended September 30, 2021 and 2020, respectively. Our recurring revenue as a percentage of the total product and service revenue will generally vary based upon the cumulative number of validated Growth Direct 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 those Growth Direct systems. As our base of validated systems continues to grow, we expect our recurring revenue streams to grow at a faster rate that will ultimately result in them constituting the majority of our revenue over the longer term.

Components of results of operations

Revenue

We generate revenue from sales of our Growth Direct system including our LIMS connection software, consumables, validation services, service contracts and field service as well as our contractual arrangement with BARDA. We primarily sell our products and services through direct sales representatives. The arrangements are generally noncancelable and nonrefundable after ownership passes to the customer.

	Three Months Ended September 30, 2021	Percentage of total revenue	Three Months Ended September 30, 2020	Percentage of total revenue
	(in thousands)		(in thousands)	
Product revenue	$ 4,824	69.9 %	$ 4,069	77.5 %
Service revenue	1,479	21.4 %	895	17.1 %
Non-commercial revenue	596	8.6 %	283	5.4 %
Total revenue	$ 6,899	100.0 %	$ 5,247	100.0 %

	Nine Months Ended September 30, 2021	Percentage of total revenue	Nine Months Ended September 30, 2020	Percentage of total revenue
	(in thousands)		(in thousands)	
Product revenue	$ 12,630	70.1 %	$ 6,921	63.9 %
Service revenue	4,152	23.0 %	2,060	19.0 %
Non-commercial revenue	1,242	6.9 %	1,858	17.1 %
Total revenue	$ 18,024	100.0 %	$ 10,839	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, 2021, we had sold over 100 Growth Direct systems to over thirty customers globally, including over half of the top twenty pharmaceutical companies as measured by revenue and 30% of globally approved cell and gene therapies.

Growth Direct systems

Growth Direct system revenue is a non-recurring product revenue stream that we recognize as revenue upon transfer of control of the system to the customer. The Growth Direct system is fully functional for use by the customer upon delivery, as such transfer of control occurs at shipment or delivery, depending on contractual terms.

We expect our Growth Direct system revenue to continue to grow over time as we increase system placements in our existing customers and markets and expand into new customers and markets.

Consumables

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

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

LIMS Connection Software

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

Service revenue

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

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

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

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

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

Non-commercial revenue

We generate non-commercial revenue from long-term contracts with governmental agencies and third parties. To date, our non-commercial revenue has been derived from contracts with BARDA. Our current contract with BARDA is a cost-reimbursable, cost-sharing arrangement, whereby BARDA reimburses us for a percentage of the total cost incurred which includes allowable indirect costs. We recognize revenue from non-commercial revenue over time using an input method based on cost incurred to date in relation to total estimated cost.

Since the underlying contracts are typically fixed in terms of scope and value, the amount of non-commercial revenue recognized in each period is subject to variability depending on factors such as the number of active contracts as well as the work performed and value remaining under each contract. We received additional funding in April 2021 from BARDA. The Company expects our current funding to be fully earned by the end of 2021.

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 associated with training, and other expenses related to service revenue recognized in the period.

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

We expect that our cost of revenue will generally increase or decrease to the extent that our revenue increases or decreases, but that such costs will increase more slowly than the related revenue streams over time.

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

- information technology and facilities expenses, which include direct and allocated expenses for rent, maintenance of facilities and insurance as well as related depreciation and amortization.

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

Sales and marketing

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

General and administrative

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

Other income (expense)

Interest expense

Interest expense is comprised of interest cost associated with outstanding borrowings under our loan and security agreements, amortization of deferred financing costs and debt discounts associated with such arrangements.

Change in fair value of preferred stock warrant liability

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

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

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

Loss on extinguishment of debt

Loss on extinguishment of debt recognized in the nine months ended September 30, 2020, includes a loss from the conversion of the 2020 Convertible Notes into Series C1 Preferred Stock in April 2020. In addition, the loss on extinguishment of debt includes unamortized issuance costs, back-end fees and early payment fees related to the refinancing of our $18.0 million term loan with a new $25.0 million term loan in May 2020. We determined the loss on extinguishment of debt to be the difference between the reacquisition price of the debt and net carrying value of the extinguished debt.

Loss on extinguishment of debt recognized in the three and nine months ended September 30, 2021, includes a loss from the extinguishment of the 2020 Term Loan. In addition, the loss on extinguishment of debt includes unamortized issuance costs, unamortized prepaid commitment fees, and early payment fees associated with the 2020 Term Loan repayment.

Other income

Other income primarily consists of interest income as well as other miscellaneous income unrelated to our core operations.

Income tax expense

We generated significant taxable losses during the three and nine months ended September 30, 2021 and 2020, and, therefore, have not recorded any U.S. federal or state income tax expense during those periods. However, we did record an immaterial amount of foreign income tax expense during each of those periods.

Results of operations

Comparison of the three months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended			
	September 30, 2021	September 30, 2020	Change	
			Amount	%
	(in thousands)			
Revenue:				
Product revenue	$ 4,824	$ 4,069	$ 755	18.6 %
Service revenue	1,479	895	584	65.3 %
Non-commercial revenue	596	283	313	110.6 %
Total revenue	6,899	5,247	1,652	31.5 %
Costs and operating expenses:				
Cost of product revenue	6,298	5,441	857	15.8 %
Cost of service revenue	1,516	772	744	96.4 %
Cost of non-commercial revenue	396	399	(3)	(0.8)%
Research and development	2,441	2,224	217	9.8 %
Sales and marketing	3,063	1,447	1,616	111.7 %
General and administrative	5,308	2,541	2,767	108.9 %
Total costs and operating expenses	19,022	12,824	6,198	48.3 %
Loss from operations	(12,123)	(7,577)	(4,546)	60.0 %
Other income (expense):				
Interest expense	(775)	(886)	111	(12.5)%
Change in fair value of preferred stock warrant liability	(8,160)	—	(8,160)	*
Loss on extinguishment of debt	(3,100)	—	(3,100)	*
Other income (expense)	(809)	18	(827)	(4,594.4)%
Total other income (expense), net	(12,844)	(868)	(11,976)	1,379.7 %
Loss before income taxes	(24,967)	(8,445)	(16,522)	195.6 %
Income tax expense	20	20	—	— %
Net loss	$ (24,987)	$ (8,465)	$ (16,522)	195.2 %

* Not Meaningful

Revenue

Product revenue increased by $0.8 million, or 18.6%, with a net increase of $1.2 million primarily attributable to increased utilization of consumables attributable to both recently validated systems as well as those at existing customer sites. Partially offsetting the increase in product revenue volume was a negative impact of consumable product mix of $0.4 million.

Service revenue increased by $0.6 million, or 65.3%. The increase in service revenue was primarily due to a $0.3 million increase in validation revenue due to the increase in Growth Direct systems placed during 2021, as well as a $0.2 million increase in service contract revenue, driven by an increase in cumulative Growth Direct systems validated.

During the quarters ended September 30, 2021 and 2020, travel restrictions and shelter-in-place orders related to COVID-19, and its variants, negatively impacted our ability to ship, install and validate systems, as well as train customers in certain geographies. This negatively impacted our product and service revenue in the periods. While we expect these disruptions to continue to impact our operating results, the related financial impact and duration of these disruptions cannot be reasonably estimated at this time.

Non-commercial revenue increased by $0.3 million, or 110.6%. The increase in non-commercial revenue was primarily due to a final adjustment, approved by BARDA in September 2021, which closed out our previous contract with them.

Costs and operating expenses

Costs of revenue

Cost of product revenue increased by $0.9 million, or 15.8%. The increase was primarily driven by increased product volume of $1.0 million partially offset by a reduction in product cost of $0.9 million and mix of $0.2 million. Also contributing to the increase was an increase of $0.5 million in personnel-related costs resulting from higher headcount to support increased production volume and manufacturing support activities as well as to provide redundancy in the event of potential disruptions from COVID-19 and its variants, a $0.2 million increase in facilities and information technology, or IT, costs, and a net increase of $0.3 million in other costs.

Cost of service revenue increased by $0.7 million, or 96.4%. This increase was driven by an increase of $0.5 million due to higher headcount-related costs associated with additional validation and field service employees hired in 2021 and 2020 to support increased service activity. Also contributing to the increase was higher material, supplies and IT related costs of $0.2 million driven by higher service activity.

Cost of non-commercial revenue remained relatively flat, decreasing 0.8%. There was no significant change in costs incurred under our BARDA contract.

Research and development

	Three Months Ended September 30,		Change	
	2021	2020	Amount	%
	(dollars in thousands)			
Research and development	$ 2,441	$ 2,224	$ 217	9.8 %
Percentage of total revenue	35.4 %	42.4 %		

Research and development expenses increased by $0.2 million, or 9.8%. This increase was primarily due to an increase of $0.4 million in employee-related costs due primarily to higher headcount partially offset by a reduction in consulting expenses of $0.3 million, and an increase in other general research and development costs of $0.1 million.

Sales and marketing

	Three Months Ended September 30,		Change	
	2021	2020	Amount	%
	(dollars in thousands)			
Sales and marketing	$ 3,063	$ 1,447	$ 1,616	111.7 %
Percentage of total revenue	44.4 %	27.6 %		

Sales and marketing expenses increased by $1.6 million, or 111.7%. This increase was due to an increase in marketing consulting of $0.7 million, an increase in employee-related costs (including commissions earned) of $0.8 million primarily due to the expansion of our sales organization, and a $0.1 million increase in other expenses to support our sales and marketing organizations.

General and administrative

	Three Months Ended			
	September 30,		Change	
	2021	2020	Amount	%
	(dollars in thousands)			
General and administrative	$ 5,308	$ 2,541	$ 2,767	108.9 %
Percentage of total revenue	76.9 %	48.4 %		

General and administrative expenses increased by $2.8 million, or 108.9%. This increase was driven by a $1.5 million increase in employee-related costs due to business growth, including the transition to a public company beginning in July 2021, and higher benefit costs, a $0.6 million increase in business insurance, and increase of $0.7 million in professional fees related to legal, audit, accounting, and consulting activities due to an increase in underlying business activity, including public company operating costs.

Other income (expense)

Interest expense

Interest expense for the three months ended September 30, 2021 and 2020 was $0.8 million and $0.9 million, respectively. The decrease of $0.1 million, or 12.5%, was primarily due to $0.1 million in term loan interest expense, which decreased primarily due to the repayment of our 2020 Term loan in September 2021.

Change in fair value of preferred stock warrant liability

The change in fair value of preferred stock warrant liability was a loss of $8.2 million for the three months ended September 30, 2021, compared no change in the fair value of preferred stock warrant liability for the three months ended September 30, 2020. The change was due to an increase in the fair value of the underlying preferred stock, which is used to determine the value of preferred stock warrants, to reflect the IPO price. The increase in fair value was recorded upon the IPO prior to the conversion to Class A common stock warrants and the reclassification to equity.

Loss on extinguishment of debt

The loss on extinguishment of debt was $3.1 million for the three months ended September 30, 2021, compared to no loss for the three months ended September 30, 2020. The $3.1 million loss is comprised of a $1.8 million prepayment penalty, $1.1 million in expense related to unamortized discounts, and $0.2 million in unamortized prepaid facility fee and other charges. We determined the loss on extinguishment of debt to be the difference between the reacquisition price of the debt and net carrying value of the extinguished debt.

Other income (expense)

Other expense was $0.8 million for the three months ended September 30, 2021 compared to less than $0.1 million for the three months ended September 30, 2020. The increase was due to the expense related to the Exit Fee described in Note 16 to our condensed consolidated financial statements.

Income tax expense

Income tax expense was $20 thousand for the three months ended September 30, 2021 and September 30, 2020. The expense relates to tax expense recorded for our German entity.

Comparison of the nine months ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended		Change	
	September 30, 2021	September 30, 2020	Amount	%
	(in thousands)			
Revenue:				
Product revenue	$ 12,630	$ 6,921	$ 5,709	82.5 %
Service revenue	4,152	2,060	2,092	101.6 %
Non-commercial revenue	1,242	1,858	(616)	(33.2)%
Total revenue	18,024	10,839	7,185	66.3 %
Costs and operating expenses:				
Cost of product revenue	17,900	11,544	6,356	55.1 %
Cost of service revenue	3,997	2,478	1,519	61.3 %
Cost of non-commercial revenue	1,282	1,732	(450)	(26.0)%
Research and development	6,926	4,906	2,020	41.2 %
Sales and marketing	8,460	4,149	4,311	103.9 %
General and administrative	12,135	6,855	5,280	77.0 %
Total costs and operating expenses	50,700	31,664	19,036	60.1 %
Loss from operations	(32,676)	(20,825)	(11,851)	56.9 %
Other income (expense):				
Interest expense	(2,631)	(2,463)	(168)	6.8 %
Change in fair value of preferred stock warrant liability	(19,643)	549	(20,192)	(3,678.0)%
Loss on extinguishment of debt	(3,100)	(2,910)	(190)	6.5 %
Other income	(812)	24	(836)	(3,483.3)%
Total other income (expense), net	(26,186)	(4,800)	(21,386)	445.5 %
Loss before income taxes	(58,862)	(25,625)	(33,237)	129.7 %
Income tax expense	57	114	(57)	(50.0)%
Net loss	$ (58,919)	$ (25,739)	$ (33,180)	128.9 %

Revenue

Product revenue increased by $5.7 million, or 82.5%. The increase is attributable to a higher number of Growth Direct system placements during the nine months ended September 30, 2021, as well as higher volume of consumable shipments due to increased utilization of consumables attributable to both recently validated systems as well as those at existing customer sites, partially offset by an unfavorable impact of consumable product mix of $0.6 million.

Service revenue increased by $2.1 million, or 101.6%. The increase in service revenue was primarily due to a $1.3 million increase in validation revenue, a $0.7 million increase in service contract revenue, driven by an increase in cumulative Growth Direct systems validated, as well as a $0.1 million increase in field service revenue due to the increase in Growth Direct systems placed.

Non-commercial revenue decreased by $0.6 million, or 33.2%. The decrease in non-commercial revenue was primarily due to a reduction in billable costs due to a lower level of reimbursable activity under our contract with BARDA.

Costs and operating expenses

Costs of revenue

Cost of product revenue increased by $6.4 million, or 55.1%. The increase was driven by a $4.6 million increase in volume of Growth Direct systems and consumables sold, an increase of $2.0 million in personnel-related costs resulting from higher headcount to support increased production volume and manufacturing support activities, as well as to provide redundancy in the event of potential COVID-19 related disruptions, an increase in IT and facilities related costs of $0.9 million, an increase in freight costs of $0.3 million, and a $0.1 million increase in other non-direct costs. Partially offsetting the cost increase was a decrease in cost and mix of product sold of $1.5 million.

Cost of service revenue increased by $1.5 million, or 61.3%. This increase was primarily due to higher headcount-related costs of $1.2 million associated with additional validation and field service employees hired in the later part of 2020 and in 2021 to support increased service activity. Additionally, an increase in IT and facility related costs of $0.2 million, and materials used for increased validations and customers under service contracts, were partially offset by a net reduction in other cost of service revenue expenses of $0.1 million.

Cost of non-commercial revenue decreased by $0.5 million, or 26.0%. This decrease was primarily due to a reduction in spend due to the timing and extent of development activities under our contract with BARDA, with consulting activities down $0.5 million.

Research and development

	Nine Months Ended September 30,		Change	
	2021	2020	Amount	%
	(dollars in thousands)			
Research and development	$ 6,926	$ 4,906	$ 2,020	41.2 %
Percentage of total revenue	38.4 %	45.3 %		

Research and development expenses increased by $2.0 million, or 41.2%. This increase was primarily due to an increase of $1.9 million in employee-related costs due primarily to higher headcount to support increased activity, an increase of $0.3 million in IT and facility costs, and a net increase of $0.2 million in other general research and development expenses, partially offset by a reduction in consulting expenses of $0.4 million.

Sales and marketing

	Nine Months Ended September 30,		Change	
	2021	2020	Amount	%
	(dollars in thousands)			
Sales and marketing	$ 8,460	$ 4,149	$ 4,311	103.9 %
Percentage of total revenue	46.9 %	38.3 %		

Sales and marketing expenses increased by $4.3 million, or 103.9%. This increase was primarily due to a $2.0 million increase in employee-related costs (including commissions earned) due to higher headcount, and increase in marketing consulting expenses of $1.8 million, an increase of $0.3 million in other marketing activities and a net increase of $0.2 million in other sales and marketing expenses.

General and administrative

	Nine Months Ended September 30,		Change	
	2021	2020	Amount	%
	(dollars in thousands)			
General and administrative	$ 12,135	$ 6,855	$ 5,280	77.0 %
Percentage of total revenue	67.3 %	63.2 %		

General and administrative expenses increased by $5.3 million, or 77.0%. This increase was primarily due to a $3.1 million increase in employee-related costs driven by higher headcount and a $1.7 million increase in professional fees related to legal, audit, accounting, recruiting and consulting activities due to an increase in underlying business activity, including IPO preparation costs and public company operating costs, and an increase of $0.6 million in business insurance. The increase was partially offset by a net decrease of $0.1 million in other general and administrative expenses.

Other income (expense)

Interest expense

Interest expense for the nine months ended September 30, 2021 and 2020 was $2.6 million and $2.5 million, respectively. The increase of $0.1 million, or 6.8%, was primarily due to a larger long-term debt principal balance incurring interest expense during 2021.

Change in fair value of preferred stock warrant liability

The change in fair value of preferred stock warrant liability was a loss of $19.6 million for the nine months ended September 30, 2021, compared to a gain of $0.5 million for the nine months ended September 30, 2020. The change was due primarily to an increase in the fair value of the underlying preferred stock, which is used to determine the value of preferred stock warrants, to reflect the IPO price. The increase in fair value was recorded upon the IPO prior to the conversion to Class A common stock warrants and reclassification to equity.

Loss on extinguishment of debt

The loss on extinguishment of debt was $3.1 million for the nine months ended September 30, 2021, compared to $2.9 million for the nine months ended September 30, 2020. The $3.1 million loss is comprised of a $1.8 million prepayment penalty, $1.1 million in expense related to unamortized discounts, and $0.2 million in unamortized prepaid facility fee and other charges, and was incurred as a result of the repayment of the 2020 Term Loan. We determined the loss on extinguishment of debt to be the difference between the reacquisition price of the debt and net carrying value of the extinguished debt. The loss for the nine months ended September 30, 2020 is comprised of unamortized issuance costs, unamortized prepaid commitments fees, and early payment fees, and was incurred as result of the conversion of the 2020 Convertible Notes into Series C1 Preferred Stock in April 2020.

Other income (expense)

Other expense was $0.8 million for the nine months ended September 30, 2021 compared to less than $0.1 million income for the nine months ended September 30, 2020. The increase was due to the expense related to the Exit Fee described in Note 16 to our condensed consolidated financial statements.

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, proceeds from our IPO, borrowings under loan agreements and revenue from sales of our products, services and contracts. As of September 30, 2021, we had

cash and cash equivalents of $219.6 million. In July 2021, we completed our IPO and received net proceeds of approximately $143.8 million. Additionally, in August 2021, the underwriters exercised their overallotment option in part which resulted in net proceeds of approximately $20.2 million. We believe that our cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least twelve months following the date these condensed consolidated financial statements were issued.

Cash flows

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

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (42,077)	$ (25,825)
Net cash provided by (used in) investing activities	13,769	(25,546)
Net cash provided by financing activities	218,001	64,185
Net increase in cash and cash equivalents and restricted cash	$ 189,693	$ 12,814

Operating activities

During the nine months ended September 30, 2021, operating activities used $42.1 million in cash, primarily resulting from our net loss of $58.9 million, net cash used by changes in our operating assets and liabilities of $8.6 million, which were partially offset by non-cash charges of $25.4 million, which included a non-cash change in fair value of preferred stock warrant liability of $19.6 million and debt extinguishment loss of $3.1 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2021 consisted primarily of increases in inventory of $5.2 million driven by an increase in finished good and raw material inventory to support increased production volume and to build safety stock, an increase in prepaid and other assets of $2.6 million driven by an increase in prepaid business insurance, as well as a decrease in accounts payable of $2.2 million and deferred revenue of $0.5 million. The cash used by operating assets and liabilities was partially offset by an increase in accrued expenses and other liabilities of $2.6 million, and an increase long term deferred rent of less than $0.1 million.

During the nine months ended September 30, 2020, operating activities used $25.8 million in cash, primarily resulting from our net loss of $25.7 million, and net cash used by changes in our operating assets and liabilities of $5.4 million, which were partially offset by non-cash charges of $5.3 million, which included a non-cash loss on extinguishment of debt of $2.9 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2020 consisted primarily of increases in accounts receivable of $2.0 million, increase in inventory of $2.5 million to support increased production volume and to build safety stock, an increase in prepaid expenses and other current and long-term assets of $1.2 million, decreases of $1.6 million in accounts payable, and a decrease in prepaid and other current assets of $0.3 million. The cash used by operating assets and liabilities was partially offset by an increase in deferred revenue of $1.3 million and accrued expense and other liabilities of $0.6 million.

Investing activities

During the nine months ended September 30, 2021, net cash provided by investing activities was $13.8 million, maturities of investments of $15.0 million, net of purchases of property and equipment of $1.3 million.

During the nine months ended September 30, 2020, net cash used in investing activities was $25.5 million, consisting of purchases of investments of $25.0 million and purchases of property and equipment of $0.6 million.

Financing activities

During the nine months ended September 30, 2021, net cash provided by financing activities was $218.0 million, consisting of net proceeds from the IPO of $165.5 million, net proceeds of $79.7 million from the issuance of

redeemable convertible preferred stock in March 2021 and $0.8 million proceeds from issuance of restricted common stock purchased by an employee and stock option exercises. The proceeds were partially offset by the repayment of the 2020 Term loan of $26.2 million and payment of debt extinguishment fees of $1.9 million in September 2021.

During the nine months ended September 30, 2020, net cash provided by financing activities was $64.2 million, consisting primarily of net proceeds of $49.9 million from the issuance of redeemable convertible preferred stock in April 2020, $9.5 million proceeds from issuance of convertible notes in February 2020, and $25.0 million in proceeds from the issuance of long-term debt in May 2020. Partially offsetting the proceeds from financing activities were $18.0 million for the repayment of term loans, $1.4 million payments to extinguish debt, and $0.9 million in payment of debt issuance costs.

Long-term debt

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

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

The 2020 Term Loan's interest rate could be elected each quarter by us, as either (a) 12%, up to 7% of which may be Payment in Kind, or PIK, interest or (b) 13% PIK interest.

In September 2021, we repaid the 2020 Term Loan and incurred a debt extinguishment loss of $3.1 million, which was comprised of a $1.8 million prepayment penalty, $1.1 million in expense related to unamortized discounts, and $0.2 million in unamortized prepaid facility fee and other charges. For additional information on the 2020 Term Loan, see Note 9 —Long-term Debt to our condensed consolidated financial statements.

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. Future minimum commitments under this lease through July 2026 are $2.3 million and $2.6 million as of September 30, 2021 and December 31, 2020, respectively.

In December 2016, in connection with the amendment of a then-outstanding loan agreement with the lender, we entered into an agreement under which we are obligated to pay the lender an exit fee in the amount of $0.8 million in the event of a "qualifying exit event" prior to December 31, 2026. As defined in the agreement, a "qualifying exit event" includes but is not limited to a liquidation, merger, sale or change of control of the company or a public offering of its common stock. No amounts were accrued at December 31, 2020 as a "qualifying exit event" was not deemed probable. The IPO was a qualifying event and we expensed and paid the exit fee in July 2021.

In March 2020, we entered into an agreement with a supplier to secure future supply of certain materials used in the manufacturing of our Growth Direct systems. As of September 30, 2020, we had committed to minimum payments under these arrangements totaling $0.9 million through December 31, 2022. We had $0.3 million and $0.1 million accrued for the supply agreement as of September 30, 2021 and December 31, 2020, respectively.

In December 2020, we entered into a non-cancelable agreement with a service provider for software as a service and cloud hosting services. As of September 30, 2021, we had committed to minimum payments under these arrangements totaling $1.1 million through January 31, 2026. There were no amounts accrued for this agreement as of September 30, 2021 and December 31, 2020.

In June 2021, we entered into a Sublease agreement for office and manufacturing space in Lexington, Massachusetts, which expires in June 2029. The Sublease agreement includes an option to terminate the sublease in July 2026, subject to an early termination fee. Monthly rent payments are fixed and future minimum lease payments over the term of the sublease is $5.6 million. We also have the right to use furniture and equipment specified in the Sublease agreement for an additional $0.6 million in future payments over the term of the sublease with the option to purchase the furniture and equipment at the end of the sublease term. Concurrent with entering into the Sublease agreement, we executed an Option Agreement with the property owner which provides us the option to enter into a new direct lease for the Lexington facility for an additional five-years following expiration of the Sublease.

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

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 could impact our ability to deliver products and provide onsite services to our customers during those periods that could impact our ability to deliver product and provide onsite services to our customer during those periods. We expect this volatility to continue for the foreseeable future, which may cause fluctuations in our operating results and financial metrics. However, trends may vary in the future as our revenue mix shifts from non-recurring to recurring revenues.

Critical accounting policies and significant judgments and estimates

Our 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 Prospectus.

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

revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

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

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

Interest rate risk

As of September 30, 2021, we had cash and cash equivalents of $219.6 million, which consisted of cash equivalents. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

Foreign currency exchange risk

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

Inflation risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition or results of operations.

Item 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 Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2021, 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, 2021 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

We are not subject to any material legal proceedings.

Item 1A. Risk Factors

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

Risks Related to Our Financial Position and Need for Capital

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

We have incurred significant losses since our inception. As of September 30, 2021, we had an accumulated deficit of $300.5 million. We expect that our operating expenses will continue to increase as we grow our business and will also increase as a result of our becoming a public company. Since our inception, we have financed our operations primarily from private placements of our convertible preferred stock, the incurrence of indebtedness, our initial public offering, and to a lesser extent, revenue derived from our Growth Direct platform and non-commercial contracts. We have devoted substantially all of our resources to the development and commercialization of our Growth Direct platform and to development activities related to advancing and expanding our technological capabilities. We will need to generate significant additional revenue to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. We may never be able to generate sufficient revenue to achieve or sustain profitability and our recent and historical growth should not be considered indicative of our future performance.

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

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

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

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

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

- significant acceptance by drug manufacturers of automated microbial quality control, or MQC, testing;

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

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

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

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

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

- lead time needed for validation prior to our customers' using and purchasing our consumables;
- changes in demand for our consumables;
- the timing and cost of, and level of investment in, technology development and commercialization activities, which may change from time to time;
- the start and completion of manufacturing runs;
- the relative reliability and robustness of our platform;
- the introduction of new products or product enhancements by us or others in our industry;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- expenditures involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims;
- future accounting pronouncements or changes in our accounting policies; and
- general market conditions and other factors, including factors, such as inflation, unrelated to our operating performance or the operating performance of our competitors.

For example, we experienced a decrease in our installation of Growth Direct systems in 2020 due to the shutdown of a number of our customers due to the COVID-19 pandemic. The effect of one of the factors discussed above, or the cumulative effects of a combination of factors discussed above, could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

Our revenue has been primarily generated from sales of our Growth Direct system, proprietary consumables and laboratory information management system, or LIMS, connection software, which require a substantial period of time to generate recurring revenue.

Product revenue, comprised of sales of our Growth Direct system, proprietary consumables and LIMS connection software, accounted for 69.9%, and 77.5% of our revenue for the three months ended September 30, 2021 and 2020, respectively, and 70.1% and 63.9% for the nine months ended September 30, 2021 and 2020, respectively. We expect that sales of these products will continue to account for a substantial portion of our revenue and will increase as we grow our customer base and expand our business with existing customers. The Growth Direct system is fully functional for use by the customer upon delivery, as such we recognize revenue for sales of our Growth Direct system upon transfer of control of the system to the customer. After a system is placed with a customer and installed, validation services start to be provided, which typically can take anywhere from three to nine months. Once a system is validated, we generally expect our customers to transition from the traditional manual method of MQC testing to our automated method and begin regular utilization of consumables over a period of up to three months. Therefore, there can be a period of up to 12 months or more between installation of a system and revenue being generated from the regular sale of consumables for that system. As a result, it can be difficult for us to forecast our product revenue and there may be an extended period of time before we receive recurring revenue from sales of consumables. We may also experience fluctuations in our product revenue, which could have an adverse effect on our financial position.

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

In the three months ended September 30, 2021 and September 30, 2020, 43.5% and 59.6% of our revenue was generated from two customers, respectively. In the nine months ended September 30, 2021 and September 30, 2020, 16.4% of our revenue was generated from one customer and 48.4% of our revenue was generated from three customers,

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

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

We provide a one-year limited assurance warranty on Growth Direct systems, which is included in the sales price. Existing and future warranties place us at the risk of incurring future repair or replacement costs. We establish our accrual for estimated warranty expenses based on historical information, current cost data and future forecasts. We exercise judgment in determining the expected product warranty costs, using estimated material, labor and other costs. While we believe that historical experience provides a reliable basis for estimating such warranty cost, unforeseen quality issues or component failure rates could result in future costs in excess of such estimates. As of September 30, 2021, we had an amount reserved for warranty costs of $0.6 million. Substantial amounts of warranty claims could have a material adverse effect on our business, financial condition and results of operations.

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

We expect to spend significant amounts to expand our existing operations, to continue to improve our Growth Direct platform and to develop new products and consumables. Based upon our current operating plan, we believe that the net proceeds from our initial public offering, or IPO, and our existing cash and cash equivalents, and anticipated cash flow from operations, will enable us to fund our operating expenses and capital expenditure requirements through at least 2023. This estimate and our expectation regarding the sufficiency of the net proceeds from the IPO are based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Until such time, if ever, as we can generate sufficient revenues, we may finance our cash needs through a combination of equity offerings and debt financings or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

- our ability to achieve revenue growth;
- the cost of expanding our operations, including our manufacturing facilities, and our offerings, including our sales and marketing efforts;
- our rate of progress in launching and commercializing new products, and the cost of the sales and marketing activities associated with, establishing adoption of our Growth Direct system;
- our rate of progress in, and cost of research and development activities associated with, products in research and development;
- the effect of competing technological and market developments;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- costs related to domestic and international expansion.

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

Risks Related to Our Business and Strategy

The ongoing COVID-19 pandemic has impacted, and may continue to impact, our operations and may materially and adversely affect our business and financial results.

Since late 2019, the COVID-19 pandemic has spread globally, including to the Boston, Massachusetts area, where our primary office and manufacturing facility is located. The COVID-19 pandemic is evolving, and has led to the implementation of various responses, including government-imposed, quarantines, travel restrictions, vaccination mandates and other public health safety measures. In response to the spread of COVID-19, and its variants, and in accordance with direction from state and local government authorities, we have limited access to our facilities to vaccinated personnel, unvaccinated personnel who are tested weekly, and third parties who must perform critical activities that must be completed on-site. While Massachusetts is engaged in a phased re-opening of businesses, in the event that government authorities were to halt the re-opening or modify current restrictions, our employees conducting development or manufacturing activities may not be able to access our manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

As a result of the COVID-19 pandemic, we have and may in the future experience severe disruptions, including:

- interruption of or delays in receiving products and supplies from the third parties we rely on to, among other things, manufacture components for our Growth Direct system and consumables, due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, which may impair our ability to sell our products;
- limitations on our business operations by local, state, or the federal government that could impact our ability to sell our products;
- on-site visit limitations and prohibitions imposed by customers that could impact our ability to engage in pre-sales activities, such as in-person meetings and site visits, and to provide post-sale activities, such as installation and verification, training and service and support;
- delays in customers' purchasing decisions and negotiations with customers and potential customers;
- business disruptions caused by workplace, laboratory and office closures and an increased reliance on employees working from home, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions; and

- limitations on employee resources that would otherwise be focused on the conduct of our activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

Any of these factors could severely impact our development activities, business operations and sales, or delay necessary interactions with manufacturing sites and other important contractors and customers. For example, we experienced a disruption in receiving supplies from third parties and a decrease in installations as a result of the shutdown of our customers' businesses. These and other factors arising from the ongoing COVID-19 pandemic could worsen in countries that are already afflicted with COVID-19, and its variants, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, and could further adversely impact our ability to conduct our business generally and have a material adverse impact on our operations and financial condition and results.

The extent to which the outbreak may negatively impact our operations and results of operations or those of our third party manufacturers, suppliers, collaborators or customers will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, additional or modified government actions, new information that emerges concerning the severity and impact of COVID-19, and its variants, the availability and utilization of vaccines and treatments for COVID-19, and actions to contain the pandemic or treat its impact, such as social distancing, quarantines, lock-downs or business closures.

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

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

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

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

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

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

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

The size of the markets and forecasts of market growth for automated MQC testing and other of our key performance indicators are based on a number of complex assumptions and estimates, and may be inaccurate.

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

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

Products from our development programs will take time and considerable resources to develop, and may include improvements or changes to our systems, software and consumables. We may not be able to complete development and commercialize them on a timely basis, or at all. There can be no assurance that our development programs will produce commercial products and solutions and before we can commercialize any new products, we will need to expend significant funds in order to:

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

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

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

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

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

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

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

If we are unable to support demand for the Growth Direct platform, and for our future product offerings, including ensuring that we have adequate capacity to meet increased demand, our business could suffer.

As the number of customers using the Growth Direct platform grows and our volume of installed systems increases, we will need to continue to increase our capacity for customer service and support, including maintenance services of our systems, and expand our manufacturing capabilities. As a result, we will also need to purchase additional equipment, some of which can take several months or more to procure, setup and validate, and increase our personnel levels to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, manufacturing or services will be successfully implemented, or that we will have adequate space, including in our manufacturing facility, to accommodate such required expansion.

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

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

We have limited experience in marketing and selling our products and we currently rely on a small team to make direct sales in countries around the world. In order to support our planned growth, we will need to rapidly increase our sales and marketing team. Competition for employees capable of selling expensive instruments within the drug manufacturing industry is intense. There are significant expenses and risks involved with having our own sales and marketing team, including our ability to hire, train, retain, and appropriately incentivize a sufficient number of qualified individuals, generate sufficient sales leads and provide our sales and marketing team with adequate access to customers who may want to purchase our products, effectively manage a geographically dispersed sales and marketing team, and other unforeseen costs and expenses. We may not be able to attract and retain personnel or be able to build an efficient and effective sales organization, which could negatively impact sales and market acceptance of our products and limit our revenue growth and potential profitability. In addition, the time and cost of establishing a specialized sales, marketing and service force for a particular product or service may be difficult to justify in light of the revenue generated or projected.

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

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

We have experienced rapid growth in our product and service revenue and anticipate further growth in our business operations. Our growth has required significant time and attention from our management, and placed strains on our operational and manufacturing systems and processes, financial systems and internal controls and other aspects of our business. We expect to continue to increase headcount and to hire more specialized personnel in the future as we grow our business. We will need to continue to hire, train and manage additional qualified engineers, client and account services personnel and sales and marketing staff and improve and maintain our technology to properly manage our growth. We may also need to hire, train and manage individuals with expertise that is separate, supplemental or different from expertise that we currently have, and accordingly we may not be successful in hiring, training and managing such individuals. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees, or if we are not successful in retaining our existing employees, our business may be harmed.

Developing and launching new products and innovating and improving our existing products have required us to hire and retain additional engineering, sales and marketing, software, manufacturing, distribution and quality assurance personnel. As a result, we have experienced rapid headcount growth. As we have grown, our employees have become more geographically dispersed. We serve customers located in multiple countries and plan to continue to expand to new countries as part of our growth strategy, which will lead to increased dispersion of our employees, including sales employees and employees who are in our service and support groups. Moreover, we expect that we will need to hire additional accounting, finance, legal and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company. As a public company, our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. We may face challenges integrating, developing and motivating our rapidly growing and increasingly dispersed employee base.

We may not be able to maintain the quality, reliability or robustness of our platform, or the expected turnaround times of our services and support, or to satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. To effectively manage our growth, we must continue to improve our operational and

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

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

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

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

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

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

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

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

We sell our products in industries that are characterized by significant enhancements and evolving industry standards. As a result, our customers' needs are rapidly evolving. If we do not appropriately innovate and invest in new technologies, our products and services may become less desirable in the markets we serve, and our customers could move to new technologies offered by our competitors or decide to revert to the traditional MQC testing method. Though we believe customers in our markets display a significant amount of loyalty to their supplier of a particular product, we

also believe that because of the initial time investment required by many of our customers to reach a purchasing decision for a new product, it may be difficult to regain that customer once the customer purchases a product from a competitor. Without the timely introduction of new products, services and enhancements, our offerings will likely become less competitive over time, in which case our competitive position and operating results could suffer. Accordingly, we focus significant efforts and resources on the development and identification of new technologies, products and markets to further broaden our offerings. To the extent we fail to timely introduce new and innovative products or services, adequately predict our customers' needs or fail to obtain desired levels of market acceptance, our business may suffer and our operating results could be adversely affected.

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

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

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

Our Growth Direct platform includes the Growth Direct system, proprietary consumables and our LIMS connection software. While we rigorously test our platform and its components, there could be undetected errors or defects. Disruptions or other performance problems with our platform or with the components that comprise our platform may adversely impact our customers' manufacturing process, compliance work flow or business, harm our reputation and result in reduced revenue or increased costs associated with repairs or replacements. If that occurs, we may also incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise. We may also be subject to warranty claims or breach of contract for damages related to errors or defects in our products. Additionally, we may be subject to legal claims arising from any defects or errors in our platform, and in the systems, consumables and software that comprise our platform.

Our success depends on, among other things, the market's confidence that the Growth Direct platform is capable of substantially enhancing quality control in the conduct of manufacturing activities as compared to the traditional method of MQC testing, and will enable more efficient or improved drug manufacturing. Pharmaceutical companies and contract manufacturing organizations, or CMOs, are likely to be particularly sensitive to defects and errors in the use of our platform, including if our platform fails to deliver meaningful improvements in MQC testing with results at least as good as the results generated using the traditional method of MQC testing. There can be no guarantee that our platform will meet the expectations of these companies or CMOs.

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

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

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

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

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

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

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

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

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

Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business and our reputation.

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

In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information, intellectual property and proprietary business information owned or controlled by ourselves or our employees, customers and other parties. We manage and maintain our applications and data utilizing a combination of on-site systems and cloud-based data centers. We utilize external security and infrastructure vendors to manage parts of our data centers. These applications and data encompass a wide variety of business-critical information, including research and development information, customer information, commercial information and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, unauthorized access, inappropriate modification and the risk of our being unable to adequately monitor and audit and modify our controls over our critical information. This risk extends to the third-party vendors and subcontractors we use to manage this sensitive data or otherwise process it on our behalf. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may still be vulnerable to, and we have in the past experienced, attacks by hackers or viruses or breaches due to employee error, malfeasance or other malicious or inadvertent disruptions. Further, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, breach, or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, and regulatory penalties. Notice of breaches may be required to affected individuals or other state, federal or foreign regulators, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete. Although we have implemented security measures to prevent unauthorized access, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also disrupt our operations and damage our reputation, any of which could adversely affect our business.

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

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

In the United States, various federal and state regulators, including governmental agencies like the Consumer Financial Protection Bureau and the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act, or CCPA, which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted.

Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, the EU General Data Protection Regulation, or GDPR, which became effective in May 2018, greatly increased the European Commission's jurisdictional reach of its laws and adds a broad array of requirements for handling personal data. EU and the European Economic Area, or EEA, member states are tasked under the GDPR to enact, and have enacted, certain implementing legislation that adds to and/or further interprets the GDPR requirements and potentially extends our obligations and potential liability for failing to meet such obligations. The GDPR, together with national legislation, regulations and guidelines of the EU and EEA member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal data. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the European Economic Area, security breach notifications and the security and confidentiality of personal data. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. On June 28, 2021, the European Commission adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from member states in the European Union to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission renews or extends that decision and remains under review by the Commission during this period.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure or perceived failure by us to comply with any applicable federal, state or similar foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to

significant fines, sanctions, awards, penalties or judgments, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

We may acquire businesses or form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, incur debt or cause us to incur significant expense.

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

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

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

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

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

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

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

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

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, tariffs, economic sanctions and embargoes, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain approvals to conduct our business in various countries;
- differing intellectual property rights;
- complexities and difficulties in obtaining intellectual property protection, enforcing our intellectual property and defending against third-party intellectual property claims;
- difficulties in staffing and managing foreign operations;
- logistics and regulations associated with shipping systems and parts and components for systems and consumables, as well as transportation delays;
- travel restrictions that limit the ability of marketing, presales, sales, services and support teams to service customers;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- international trade disputes that could result in tariffs and other protective measures;

- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

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

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

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

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

We are exposed to the risk of fraud or other misconduct by our employees, consultants and collaborators. Misconduct by these parties could include intentional failures to comply with the applicable laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. These laws and regulations may restrict or prohibit a wide range of pricing, discounting and other business arrangements. Such misconduct could result in legal or regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct, and any precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, we could be subject to significant civil, criminal and administrative penalties, which could have a material adverse impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse impact on our business.

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

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

Risks Related to Manufacturing and Supply

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

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

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

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

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

We source the components of our Growth Direct system and consumables from third-party suppliers. We do not have supply agreements with most of our suppliers beyond purchase orders and, although we maintain an inventory of components, forecasted amounts may be inaccurate and we may experience shortages as a result of serious supply problems with these suppliers. There can be no assurance that our supply of components will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. For example, we have experienced disruptions to our supply chain as a result of the COVID-19 pandemic and may experience additional disruptions in the future.

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

Several other non-critical components and materials that comprise our Growth Direct platform are currently manufactured by a single supplier or a limited number of suppliers. In many of these cases, we have not yet qualified alternate suppliers and rely upon purchase orders, rather than long-term supply agreements. A supply interruption or an

increase in demand beyond our current suppliers' capabilities could harm our ability to manufacture our products unless and until new sources of supply are identified and qualified. Our reliance on these suppliers subjects us to a number of risks that could harm our business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- a modification or change in a manufacturing process or part that unknowingly or unintentionally negatively impacts the operation of our products;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers prioritizing other customer orders over ours;
- damage to our brand reputation caused by defective components produced by our suppliers;
- increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

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

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

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

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

Shipments of our products are subject to various regulations in the various countries in which we provide our products. For example, shipments of our growth media consumables may be required to comply with the shipping

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

We also currently rely on third-party vendors for our shipping. If we are not able to negotiate acceptable pricing and other terms with these entities or they experience performance problems or other difficulties, it could negatively impact our operating results and our customers' experience. Our products could sustain serious damage or be lost in transit. If a product is damaged in transit, it may result in a substantial delay in the fulfillment of the customer's order, and depending on the type and extent of the damage and whether the incident is covered by insurance, it may result in a substantial financial loss. If our products are not delivered in a timely fashion or are damaged or lost during the delivery process, our customers could become dissatisfied and cease using our products or services, which would adversely affect our business, financial condition, results of operations and prospects.

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

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

Risks Related to Our Intellectual Property

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

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

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

As is the case with other technology companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others, particularly patents, in the United States and other countries with respect to our products and technologies. We apply for patents covering our products and technologies and their uses, as we deem appropriate. However, obtaining and enforcing patents in our

industry is costly, time consuming and complex, and we may fail to apply for patents on important products, services and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights. We may not be able to patent the technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our products, or to block competitor products that are similar or adjacent to ours. Our earliest patent filings have been published. A competitor may review our published patents and arrive at the same or similar technology advances for our products as we developed. If the competitor files a patent application on such an advance before we do, then we may no longer be able to protect the technology, we may require a license from the competitor, and if the license is not available on commercially-viable terms, then we may not be able to launch our product. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products or services, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. It is possible that in the future some of our patents, licensed patents and patent applications may be challenged at the United States Patent and Trademark Office, or USPTO, or in proceedings before the patent offices of other jurisdictions. We may not be successful in defending any such challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in our patents being narrowed, invalidated or held unenforceable which could result in increased competition to our business. We may have to challenge the patents or patent applications of third parties. The outcome of patent litigation or other proceeding can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

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

Our current and future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights in the event of misuse.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products. If one of our products requires extended development or testing, patents protecting such products might expire before or shortly after such products are commercialized. For example, while our patents and, if issued, our patent applications have terms that will expire through 2039, certain of our U.S. patents covering the Growth Direct system and its use are scheduled to expire in 2024, and the corresponding foreign patents are scheduled to expire in 2022. Although we own other patents with later expiration dates that cover various improvements and consumables for the Growth Direct platform, these other patents may not provide the same protection as the earliest-filed patents As a result, our patent portfolio may not provide

us with sufficient rights to exclude others from commercializing products similar or identical to ours, which would have a material adverse effect on our business.

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

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

In addition to our current inventions developed using BARDA funds, we also sometimes collaborate with academic institutions to accelerate our research or development. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or in-license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

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

We rely heavily on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, including parts of our technology platform, and to maintain our competitive position and we expect our reliance to increase in the near term as the terms for certain of our patents expire. For example, while our patents and, if issued, our patent applications have terms that will expire through 2039, some of our U.S. patents covering the Growth Direct system and its use are expected to expire in 2024, and the corresponding foreign patents are scheduled to expire in 2022. Once these patents expire, we may have to rely more heavily on trade secrets to maintain our competitive advantage. Any disclosure, either intentional or unintentional, by our employees, consultants and vendors that we engage to perform research or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our products, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and know-how can be difficult to protect. In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, advisors, collaborators and customers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may

breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure, which could materially adversely impact our business and financial position. If we are required to assert our rights against such a party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, if we choose to go to court to stop a third party from using any of our trade secrets, it may result in a public disclosure of our trade secrets and corresponding loss of rights, which could have a material adverse effect on our business. In addition, courts outside the United States may be less willing to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

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

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

We are party to a royalty-bearing license agreement with Thermo CRS, Ltd., or Thermo Fisher, that grants us rights to exploit certain patent rights that are related to our Growth Direct platform. We may need to obtain additional licenses from others to advance our research, development and commercialization activities. These and other intellectual property license agreements that we enter into with third parties may impose various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations on us. Our rights to use the technology we license are subject to the continuation of and compliance with the terms of these agreements. If we fail to comply with our obligations under these agreements (including as a result of COVID-19, and its variants, impacting our operations), we use the licensed intellectual property in an unauthorized manner or we are subject to bankruptcy-related proceedings, the terms of the licenses may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate their respective agreement with us, which could limit our ability to implement our current business plan and materially adversely affect our business, financial condition, results of operations and prospects.

In some cases, we may not control the prosecution, maintenance or filing of the patents to which we hold licenses, or the enforcement of those patents against third parties. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Further, we may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the

manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control, and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Moreover, disputes may arise with respect to our licensing or other agreements, including:

- the scope of rights granted under the agreements and other interpretation-related issues;
- the extent to which our systems and consumables, technology and processes infringe on the intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreements and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us; and
- the priority of invention of patented technology.

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

In addition, our rights to certain technologies are licensed to us on a non-exclusive basis. The owners of these non-exclusively licensed technologies are therefore free to license them to third parties, including our competitors, on terms that may be superior to those offered to us, which could place us at a competitive disadvantage. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, certain of our agreements with third parties may provide that intellectual property arising under these agreements, such as data that could be valuable to our business, will be owned by the counterparty, in which case, we may not have adequate rights to use such data or have exclusivity with respect to the use of such data, which could result in third parties, including our competitors, being able to use such data to compete with us.

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

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries or regions may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

Generally, jurisdictions outside the United States have a "first to file" patent system. In the United States, prior to March 2013, the "first to invent" a claimed invention was entitled to the patent (assuming that all other requirements were met). After March 2013, following the passage of the Leahy-Smith America Invents Act, or the America Invents Act, the United States transitioned to a "first inventor to file" system, under which the first inventor to file a patent application on an invention is entitled to the patent (assuming that all other requirements are met) even if another party was the first to invent the claimed invention. The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and that also may affect patent litigation. These include the introduction of derivation proceedings; expansion of the permitted content of third-party submissions to the USPTO during patent prosecution; and additional procedures to challenge the validity of a patent after issuance, including post-grant review and *inter partes* review. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The America Invents Act and its continued implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent position of companies like us is particularly uncertain. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, various courts, including the United States Supreme Court have rendered decisions that affect the scope of patentability of certain inventions or discoveries. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature are not themselves patentable. Precisely what constitutes a law of nature or abstract idea is uncertain, and it is possible that certain aspects of our technology could be considered to be or apply laws of nature. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third party challenges to any owned or licensed patents.

Issued patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications (including licensed patents) may be challenged in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which could harm our business. In addition, in patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. Further, with respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on certain aspects of our platform technologies. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our products and our business. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a

license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

We may not be aware of all third-party intellectual property rights potentially relating to our products. Publications of discoveries often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until approximately 18 months after filing or, in some cases, not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. No assurance can be given that other patent applications will not have priority over our patent applications.

If we cannot acquire or license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may identify third-party intellectual property and technology we may need to license in order to engage in our business, including to develop or commercialize new products or services, and the growth of our business may depend in part on our ability to acquire, in-license or use this technology. However, such licenses may not be available to us on acceptable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater development or commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if such licenses are available, we may be required to pay the licensor in return for the use of such licensor's technology, lump-sum payments, payments based on certain milestones such as sales volumes, or royalties based on sales of our platform. In addition, such licenses may be non-exclusive, which could give our competitors access to the same intellectual property licensed to us. Our business, financial condition, results of operations and prospects could be materially and adversely affected if we are unable to enter into necessary agreements on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the acquired or licensed patents or other rights are found to be invalid or unenforceable. Moreover, we could encounter delays in the introduction of products or services while we attempt to develop alternatives.

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in some or all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products. Our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the misappropriation or other violations of

our intellectual property rights including infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, or that are initiated against us, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our products, services and other technologies and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can impact the validity and enforceability of patents issuing thereon. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to defend against these and other claims challenging inventorship of our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. Even if we are successful in defending against such claims,

litigation could result in substantial costs and be a distraction to management and other employees, and certain customers or partners may defer engaging with us until the particular dispute is resolved. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

In recent years, there has been significant litigation involving intellectual property rights. We may be involved with litigation or actions at the USPTO or foreign patent offices with various third parties that claim we or our collaborators or customers using our solutions and services have misappropriated or misused other parties' intellectual property rights. We expect that the number of such claims may increase as the number of our products grows, we expand our market share and the level of competition in our markets increases. Any infringement claim, regardless of its validity, could harm our business by, among other things, resulting in time consuming and costly litigation, diverting management's time and attention from the development of the business, requiring the payment of monetary damages (including treble damages, attorneys' fees, costs and expenses) or royalty payments, or result in potential or existing customers delaying purchases of our products or entering into engagements with us pending resolution of the dispute.

As we move into new markets and applications for our platform, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product or service revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties, or the invalidity of such patents or proprietary rights.

Our research, development and commercialization activities may in the future be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation and other patent challenges, both within and outside the United States, involving patent and other intellectual property rights, including patent infringement lawsuits, interferences, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products. As the automated MQC testing industry expands and more patents are issued, the risk increases that our products may be subject to claims of infringement of the patent rights of third parties. Numerous significant intellectual property issues have been litigated, are being litigated and will likely continue to be litigated, between existing and new participants in our existing and targeted markets, and one or more third parties may assert that our products or services infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets.

Third parties may assert that we are employing their proprietary technology without authorization. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our current or future products and services may infringe. In addition, similar to what other companies in our industry have experienced, we are aware of a patent, and there may be patents of which we are not aware or that are issued in future, that may cover our platform or its components. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our platform or its components. Under the applicable law of certain jurisdictions, the scope of a patent claim is

determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products.

There can be no assurance that we will prevail in any suit initiated against us by third parties, successfully settle or otherwise resolve patent infringement claims. Third parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products or services, and could result in the award of substantial damages against us, including treble damages, attorneys' fees, costs and expenses, if we are found to have willfully infringed. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products or services. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we could encounter delays and incur significant costs, in product or service introductions while we attempt to develop alternative products or services, or redesign our products or services, to avoid infringing third party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses or to develop a workaround could prevent us from commercializing products or services, and the prohibition of sale or the threat of the prohibition of sale of any of our products or services could materially affect our business and our ability to gain market acceptance for our products or services. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Further, even if we were successful in defending against a lawsuit, such a defense would distract our management team from our operations, which could have an adverse effect on our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

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

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

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

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

products or services. Even if resolved in our favor, any award of monetary damages or other remedy we receive may not be commercially valuable.

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

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our Class A common stock to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished.

Accordingly, the market price of shares of our Class A common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel using an outside service to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our vendors, can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business.

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

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

Further, some open-source software licenses require users who distribute software containing open-source software to publicly disclose all or part of the source code to the licensee’s software that incorporates, links or uses such open-source software, and make available to third parties for no cost, any derivative works of the open source code created by the licensee, which could include the licensee’s own valuable proprietary code. While we monitor our use of

open-source software and try to ensure that none is used in a manner that would require us to disclose our proprietary source code or that would otherwise breach the terms of an open source agreement, such use could inadvertently occur, or could be claimed to have occurred, in part because open source license terms are often ambiguous. Despite our efforts to monitor our use of open-source software to avoid subjecting our platform to conditions we do not intend, there is a risk that open source licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to provide or distribute our platform. Additionally, we may from time to time face claims from third parties claiming ownership of, or seeking to enforce the terms of, an open source license, including by demanding release of source code for the open-source software, derivative works or our proprietary source code that was developed using, or that is distributed with, such open-source software. These claims could also result in litigation and could require us to make our proprietary software source code freely available, require us to devote additional research and development resources to change re-engineer our platform, seek costly licenses from third parties or otherwise incur additional costs and expenses, any of which could result in reputational harm and would have a negative effect on our business and operating results. There is little legal precedent in this area and any actual or claimed requirement to disclose our proprietary source code or pay damages for breach of contract could harm our business and could help third parties, including our competitors, develop products and services that are similar to or better than ours.

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

Risks Related to Our Common Stock

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

Prior to our IPO, there was no public market for our Class A common stock. If an active market for our Class A common stock does not develop, it may be difficult for stockholders to sell our shares without depressing the market price for the shares, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of Class A common stock as consideration.

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

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

- actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results;
- the introduction of new products or product enhancements by us or others in our industry;
- variances in product and system reliability;
- overall conditions in our industry and the markets in which we operate;
- disputes or other developments with respect to our or others' intellectual property rights;
- actual or anticipated changes in our operating results or growth rate as a result of our competitors' operating results;

- our ability to develop and market new and enhanced products and expand into new markets on a timely basis;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- product liability claims or other litigation;
- announcement or expectation of additional financing effort;
- sales of our common stock by us or our stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- media exposure of our products or of those of others in our industry;
- changes in earnings estimates or recommendations by securities analysts;
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and
- the other factors described in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q.

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

Following our IPO, based on the number of shares of Class A common stock outstanding as of September 30, 2021, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before the IPO and their respective affiliates hold, in the aggregate, a majority of our outstanding voting stock. The holders of shares of our Class B common stock have the ability to convert any portion of their Class B common stock into Class A common stock. Our Class B common stock cannot be converted if, immediately following such conversion, the holder would beneficially own more than 4.9% of the issued and outstanding Class A common stock. Due to this conversion right, holders of our Class B common stock could, at any time, increase their voting control of us. As a result of their combined voting power, if our executive officers, directors and stockholders who own more than 5% of our outstanding common stock choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

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

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

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our Class A common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our Class A common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of Class A common stock intend to sell shares, could reduce the market price of our Class A common stock. As of November 1, 2021, we have 41,352,523 outstanding shares of Class A common stock and Class B common stock, collectively. This includes the shares that we sold in the IPO, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining shares are currently restricted as a result of applicable securities laws or lock-up agreements and will become eligible to be sold at various times beginning 180 days after the IPO, unless held by one of our affiliates, in which case the resale of those securities will be subject to certain restrictions under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder. Moreover, pursuant to an investors' rights agreement entered into with certain of our stockholders, holders of an aggregate of 32,348,126 shares of our Class A common stock (including shares issuable upon conversion of our Class B common stock) will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until the rights terminate. We have also registered shares of our common stock issued and available for issuance under our equity compensation plans, which can be freely sold in the public market, subject to vesting requirements, volume limitations applicable to affiliates and lock-up agreements. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

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

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

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

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

We are a "smaller reporting company" and are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as presenting 2 years of audited financial statements in our annual Form 10-K or reduced disclosure requirements for executive compensation. This reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our Class A common stock less attractive because we may rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock prices may be more volatile.

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

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act, or Section 404, and, therefore, we are not required to make a formal assessment of the effectiveness of our internal control over financial reporting. As a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Although we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we are not required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following our first annual report required to be filed with the SEC. As an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company and a "non-accelerated filer." At such time, our independent registered public accounting firm may issue a report that is adverse in the event material weaknesses have been identified in our internal control over financial reporting.

To comply with the requirements of being a public company, we will need to undertake actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. Testing and maintaining internal control can divert our management's attention from other matters that are important to the operation of our business. In addition, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal control over financial reporting or we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our Class A common stock could be materially adversely affected.

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

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

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be

detected, which could have a material adverse effect on investors' confidence in our reporting and the price of our Class A common stock.

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- the required approval of the holders of at least two-thirds of the shares entitled to vote thereon to (i) effect a reorganization, recapitalization, share exchange, share classification, consolidation, conversion or merger, (ii) sell, lease, exchange, transfer or otherwise dispose of all or substantially all of our assets, or (iii) dissolve our company or revoke a dissolution of our company;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

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

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

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

We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

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

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

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

As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $212.5 million and $106.7 million, respectively, which may be available to offset future taxable income, if any, that begin to expire in 2027 and 2025, respectively. Additionally, we had federal NOLs of $78.2 million which do not expire but are (for taxable years beginning after December 31, 2020) generally limited in their usage to an annual deduction equal to 80% of taxable income. In addition, we had federal and state research and development tax credits of $3.1 million and $2.0 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2028 and 2024, respectively. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change by

value in its equity ownership by one or more stockholders or groups of stockholders owning at least 5% of the corporation's stock over a rolling three-year period, is subject to limitations on its ability to utilize its pre-ownership change NOLs and tax credits to offset future taxable income or income tax liabilities for U.S. federal income tax purposes. Similar rules may apply under state tax laws. Our existing NOLs and tax credits may be subject to limitations arising from previous ownership changes. Future changes in our stock ownership, including as a result of the IPO, some of which might be beyond our control, could result in ownership changes. For these reasons, we may not be able to utilize a material portion of the NOLs and tax credits even if we attain profitability.

General risk factors

Changes in tax laws, including as a result of the 2020 United States presidential and congressional elections, may impact our future financial position and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. In particular, the recent presidential and congressional elections in the United States could result in significant changes in, and uncertainty with respect to, tax legislation, regulation and government policy directly affecting our business or indirectly affecting us because of impacts on our customers and suppliers. For example, the United States government may enact significant changes to the taxation of business entities including, among others, a permanent increase in the corporate income tax rate, an increase in the tax rate applicable to the global intangible low-taxed income and elimination of certain exemptions, and the imposition of minimum taxes or surtaxes on certain types of income. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, our suppliers or our customers, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows.

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

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

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

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

We could be subject to securities class action litigation.

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

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company and a non-accelerated filer, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practice.

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

(a) Issuance of capital stock

From July 1, 2021 through September 30, 2021, we did not issue any shares of our preferred stock to accredited investors.

On July 19, 2021, upon the closing of our IPO, all shares of our then-outstanding redeemable convertible preferred stock automatically converted into 24,200,920 shares of our Class A common stock and 6,903,379 shares of our Class B common stock. The issuance of such common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

(b) Equity grants

From July 1, 2021 through September 30, 2021, we granted stock options to purchase an aggregate of 150,000 shares of our Class A common stock with an exercise price of $20.00 per share.

From July 1, 2021 through September 30, 2021, we issued an aggregate of 25,790 shares of Class A common stock pursuant to stock options exercised by certain of our employees and consultants in connection with services provided to us by such parties, with exercise prices ranging between $0.20 and $10.85 per share.

The securities listed above were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

Use of Proceeds

On July 19, 2021, we completed our IPO, in which we issued and sold 7,920,000 shares of our Class A common stock at a price to the public of $20.00 per share. We raised net proceeds to us of approximately $143.8 million, after deducting the underwriting discount of $11.1 million and offering expenses of $3.7 million. On August 4, 2021, the underwriters exercised their option to purchase additional shares in part for 1,086,604 shares at the public offering price of $20.00 per share less underwriting discounts and commissions, for additional net proceeds to us of approximately $20.2 million. All shares sold were registered pursuant to a registration statement on Form S-1 (File No. 333-257431), as amended, or the "Registration Statement", declared effective by the SEC on July 14, 2021. J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC, Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated acted as representatives of the underwriters for the offering. The offering terminated after the sale of all securities registered pursuant to the Registration Statement. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The net proceeds from our IPO have been invested in cash and a highly liquid money market fund comprised of U.S. Government and U.S. Treasury securities to help ensure liquidity and capital preservation. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our 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	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation.	8-K	001-40592	3.1	7/21/21	
3.2	Amended and Restated Bylaws.	8-K	001-40592	3.2	7/21/21	
10.1	Payoff Letter, entered into as of September 17, 2021, by and between Rapid Micro Biosystems, Inc. and Kennedy Lewis Management LP, as collateral agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report Form 8-K (File No. 001-40592) filed on September 23, 2021, 2021).	8-K	001-40592	10.1	9/23/21	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).					*
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.					**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.					**
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 15, 2021

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)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

By: /s/ Robert Spignesi
Name: Robert Spignesi
Title: Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

By: /s/ Sean Wirtjes
Name: Sean Wirtjes
Title: Chief Financial Officer

Exhibit 32.1

Certification of CEO 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, 2021 (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 15, 2021

By: /s/ Robert Spignesi
Name: Robert Spignesi
Title: Chief Executive Officer

Exhibit 32.2

Certification of CFO 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, 2021 (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 15, 2021

By: /s/ Sean Wirtjes
Name: Sean Wirtjes
Title: Chief Financial Officer