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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-40632

CYTEK BIOSCIENCES, INC.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

47215 Lakeview Blvd. Fremont, California

(Address of principal executive offices)

47-2547526

(I.R.S. Employer
Identification No.)

94538

(Zip Code)

Registrant's telephone number, including area code: **(877) 922-9835**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	CTKB	The Nasdaq Global Select Market

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

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

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

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

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

The number of shares of Registrant's Common Stock outstanding as of October 31, 2023 was 135,549,154.

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PART I - FINANCIAL INFORMATION
Item 1. Consolidated Financial Statements (Unaudited).
**Cytek Biosciences, Inc.
Consolidated Balance Sheets**

(In thousands, except share and per share data)	September 30, 2023 <i>(unaudited)</i>	December 31, 2022 <i>(audited)</i>
Assets		
Current assets:		
Cash and cash equivalents	\$ 163,629	\$ 296,601
Restricted cash	—	2,899
Marketable securities	124,392	44,548
Trade accounts receivable, net	55,402	48,864
Inventories	66,875	48,154
Prepaid expenses and other current assets	12,017	12,954
Total current assets	422,315	454,020
Deferred income tax assets, noncurrent	24,080	20,459
Property and equipment, net	17,415	13,682
Operating lease right-of-use assets	11,703	13,883
Goodwill	16,457	10,144
Intangible assets, net	24,292	4,331
Other noncurrent assets	3,168	2,957
Total assets	\$ 519,430	\$ 519,476
Liabilities and stockholders' equity		
Current liabilities:		
Trade accounts payable	\$ 4,711	\$ 4,805
Legal settlement liability, current	2,600	2,163
Accrued expenses	20,514	21,126
Other current liabilities	7,821	7,960
Deferred revenue, current	23,047	12,986
Total current liabilities	58,693	49,040
Legal settlement liability, noncurrent	16,095	15,596
Deferred revenue, noncurrent	14,958	13,124
Operating lease liability, noncurrent	10,139	12,312
Long term debt	1,736	2,271
Other noncurrent liabilities	2,285	1,587
Total liabilities	103,906	93,930
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Common stock, \$0.001 par value; 1,000,000,000 authorized shares as of September 30, 2023 and December 31, 2022, respectively; 135,545,663 and 135,365,381 issued and outstanding shares as of September 30, 2023 and December 31, 2022, respectively.	136	135
Additional paid-in capital	451,648	442,887
Accumulated deficit	(34,681)	(17,030)
Accumulated other comprehensive loss	(1,579)	(697)
Noncontrolling interest in consolidated subsidiary	—	251
Total stockholders' equity	415,524	425,546
Total liabilities and stockholders' equity	\$ 519,430	\$ 519,476

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

Cytek Biosciences, Inc.
Consolidated Statements of Operations and Comprehensive Income (Loss)
(unaudited)

(In thousands, except share and per share data)	Three Months Ended		Nine Months Ended	
	September 30, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Revenue, net:				
Product	\$ 38,441	\$ 36,389	\$ 110,065	\$ 104,963
Service	9,559	4,088	24,717	10,737
Total revenue, net	48,000	40,477	134,782	115,700
Cost of sales:				
Product	16,205	10,606	45,557	34,153
Service	4,617	3,009	12,847	9,947
Total cost of sales	20,822	13,615	58,404	44,100
Gross profit	27,178	26,862	76,378	71,600
Operating expenses:				
Research and development	11,171	8,650	33,282	25,111
Sales and marketing	12,076	8,810	37,587	24,201
General and administrative	10,351	8,042	33,217	24,176
Total operating expenses	33,598	25,502	104,086	73,488
Income (loss) from operations	(6,420)	1,360	(27,708)	(1,888)
Other income (expense):				
Interest expense	(595)	(649)	(1,677)	(1,886)
Interest income	1,622	1,584	4,965	1,993
Other income (expense), net	1,208	(445)	4,600	(1,073)
Total other income (expense), net	2,235	490	7,888	(966)
Income (loss) before income taxes	(4,185)	1,850	(19,820)	(2,854)
Provision for (benefit from) income taxes	2,271	224	(2,169)	(1,620)
Net income (loss)	(6,456)	1,626	(17,651)	(1,234)
Less: net loss allocated to noncontrolling interests	—	40	—	281
Net income (loss) attributable to common stockholders, basic and diluted	\$ (6,456)	\$ 1,666	\$ (17,651)	\$ (953)
Net income (loss) attributable to common stockholders per share, basic	\$ (0.05)	\$ 0.01	\$ (0.13)	\$ (0.01)
Net income (loss) attributable to common stockholders per share, diluted	\$ (0.05)	\$ 0.01	\$ (0.13)	\$ (0.01)
Weighted-average shares used in calculating net income (loss) per share, basic	136,173,278	134,711,701	135,862,905	134,342,059
Weighted-average shares used in calculating net income (loss) per share, diluted	136,173,278	138,709,335	135,862,905	134,342,059
Comprehensive income (loss):				
Net income (loss)	\$ (6,456)	\$ 1,626	\$ (17,651)	\$ (1,234)
Foreign currency translation adjustment, net of tax	165	(758)	(856)	(1,427)
Unrealized gain (loss) on marketable securities	15	-	(26)	-
Net comprehensive income (loss)	\$ (6,276)	\$ 868	\$ (18,533)	\$ (2,661)

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

Cytek Biosciences, Inc
Consolidated Statements of Stockholders' Equity
(unaudited)

(In thousands, except share data)	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Noncontrolling interest in consolidated subsidiary	Total stockholders' equity
	Shares	Amount					
Balances at December 31, 2022	135,365,381 \$	135 \$	442,887 \$	(17,030) \$	(697) \$	251 \$	425,546
Shares issued in connection with employee stock plans	283,856	1	203	-	-	-	204
Shares of Common Stock withheld related to net share settlement	(5,182)	-	(57)	-	-	-	(57)
Stock-based compensation	-	-	4,699	-	-	-	4,699
Unrealized gain on marketable securities	-	-	-	-	152	-	152
Foreign currency translation adjustment, net of tax	-	-	-	-	(42)	-	(42)
Net loss	-	-	-	(6,807)	-	-	(6,807)
Noncontrolling interest	-	-	16	-	-	(251)	(235)
Balances at March 31, 2023	135,644,055 \$	136 \$	447,748 \$	(23,837) \$	(587) \$	- \$	423,460
Shares issued in connection with employee stock plans	697,670	-	483	-	-	-	483
Proceeds from Employee Stock Purchase Plan	145,569	-	966	-	-	-	966
Shares of Common Stock withheld related to net share settlement	(16,604)	-	(111)	-	-	-	(111)
Repurchase of shares	(125,782)	-	(981)	-	-	-	(981)
Stock-based compensation	-	-	5,922	-	-	-	5,922
Unrealized loss on marketable securities	-	-	-	-	(192)	-	(192)
Foreign currency translation adjustment, net of tax	-	-	-	-	(980)	-	(980)
Net loss	-	-	-	(4,388)	-	-	(4,388)
Balances at June 30, 2023	136,344,908 \$	136 \$	454,027 \$	(28,225) \$	(1,759) \$	- \$	424,179
Shares issued in connection with employee stock plans	373,649	-	440	-	-	-	440
Shares of Common Stock withheld related to net share settlement	(17,665)	-	(149)	-	-	-	(149)
Repurchase of shares	(1,155,229)	-	(8,428)	-	-	-	(8,428)
Stock-based compensation	-	-	5,758	-	-	-	5,758
Unrealized gain on marketable securities	-	-	-	-	15	-	15
Foreign currency translation adjustment, net of tax	-	-	-	-	165	-	165
Net loss	-	-	-	(6,456)	-	-	(6,456)
Balances at September 30, 2023	135,545,663 \$	136 \$	451,648 \$	(34,681) \$	(1,579) \$	- \$	415,524

(In thousands, except share data)	Common stock					Noncontrolling interest in consolidated subsidiary	Total stockholders' equity
	Shares	Amount	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)		
Balances at December 31, 2021	133,749,663 \$	126 \$	423,625 \$	(19,606) \$	897 \$	343 \$	405,385
Exercise of stock options	493,267	8	356	-	-	-	364
Stock-based compensation	-	-	3,837	-	-	-	3,837
Foreign currency translation adjustment, net of tax	-	-	-	-	14	-	14
Net loss	-	-	-	(2,021)	-	-	(2,021)
Noncontrolling interest	-	-	-	-	-	(137)	(137)
Balances at March 31, 2022	134,242,930 \$	134 \$	427,818 \$	(21,627) \$	911 \$	206 \$	407,442
Shares issued in connection with employee stock plans	365,649	1	1,204	-	-	- \$	1,205
Shares of Common Stock withheld related to net share settlement	(6,908)	-	(67)	-	-	-	(67)
Stock-based compensation	-	-	3,934	-	-	-	3,934
Foreign currency translation adjustment, net of tax	-	-	-	-	(683)	-	(683)
Net loss	-	-	-	(598)	-	-	(598)
Noncontrolling interest	-	-	-	-	-	(104)	(104)
Balances at June 30, 2022	134,601,671 \$	135 \$	432,889 \$	(22,225) \$	228 \$	102 \$	411,129
Shares issued in connection with employee stock plans	252,496	-	224	-	-	-	224
Shares of Common Stock withheld related to net share settlement	(5,028)	-	(71)	-	-	-	(71)
Stock-based compensation	-	-	4,359	-	-	-	4,359
Foreign currency translation adjustment, net of tax	-	-	-	-	(758)	-	(758)
Net income	-	-	-	1,666	-	-	1,666
Noncontrolling interest	-	-	-	-	-	(40)	(40)
Balances at September 30, 2022	134,849,139 \$	135 \$	437,401 \$	(20,559) \$	(530) \$	62 \$	416,509

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

Cytek Biosciences, Inc
Consolidated Statements of Cash Flows
(unaudited)

(In thousands)	Nine months ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (17,651)	\$ (1,234)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,417	1,731
Amortization of operating lease-right-of use assets	2,388	2,064
Stock-based compensation	16,379	12,130
Loss on disposal of property and equipment	7	—
Increase in accounts receivable allowance for credit losses	55	—
Provision for excess and obsolete inventory	798	462
Gain on investments, accretion, and amortization, net	(5,265)	—
Interest expenses for accretion of the legal settlement liabilities	1,311	1,611
Change in operating assets and liabilities:		
Trade accounts receivable	(7,595)	(11,780)
Inventories	(2,047)	(19,537)
Prepaid expenses and other assets	(2,336)	(15,035)
Trade accounts payable	10	2,770
Accrued expenses and other liabilities	610	2,828
Legal settlement liabilities	(374)	478
Operating lease liabilities	(2,154)	(1,408)
Deferred revenue	7,216	6,496
Net cash used in operating activities	(4,231)	(18,424)
Cash flows from investing activities:		
Purchases of marketable securities	(152,563)	—
Proceeds from maturities of marketable securities	78,000	—
Purchase of property and equipment	(3,148)	(3,218)
Acquisition of business	(44,896)	—
Purchase of intangible assets	(118)	(40)
Payment of investment	—	(1,587)
Payment for additional investment in Cytek Japan	(235)	—
Net cash used in investing activities	(122,960)	(4,845)
Cash flows from financing activities:		
Repayment of loan	(425)	—
Proceeds from Employee Stock Purchase Plan	966	765
Payments for taxes related to net share settlement of equity awards	(317)	(138)
Proceeds from issuance of common stock under employee stock plans	1,127	1,036
Payments for repurchase of shares	(9,409)	—
Net cash provided by (used in) financing activities	(8,058)	1,663
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(622)	(1,489)
Cash, cash equivalents and restricted cash:		
Net decrease in cash, cash equivalents and restricted cash	(135,871)	(23,095)
Cash, cash equivalents and restricted cash at beginning of period	299,500	364,618
Cash, cash equivalents and restricted cash at end of period	\$ 163,629	\$ 341,523
Supplemental disclosure of cash flow information:		
Cash paid for taxes	\$ 810	\$ 9,930
Non-cash investing and financing activities:		
Fixed asset purchases in accounts payable at period end	\$ 96	\$ 235
Intangible asset in accrued expenses at period end	\$ 9	\$ 69

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

Cytek Biosciences, Inc.
Notes to consolidated financial statements

1. Description of business

Cytek Biosciences, Inc. (“Cytek” or the “Company”) is a leading cell analysis solutions company advancing the next generation of cell analysis tools by leveraging novel technical approaches. The Company has focused on becoming the premier cell analysis company through continued innovation that facilitates scientific advances in biomedical research and clinical applications.

The Company has successfully developed and manufactured its full spectrum flow cytometry platform (“instrument(s)” or “product(s)”). The Company believes its core instruments, the Aurora and Northern Lights™ systems, are the first full spectrum flow cytometers able to deliver high-resolution, high-content and high-sensitivity cell analysis by utilizing the full spectrum of fluorescence signatures from multiple lasers to distinguish fluorescent tags on single cells (“Full Spectrum Profiling™” or “FSP™”). The Company’s FSP platform includes instruments, accessories, reagents, software, and services to provide a comprehensive and integrated suite of solutions for its customers.

On February 28, 2023, the Company completed the acquisition of the flow cytometry and imaging (“FCI”) business unit of Luminex Corporation (“Luminex”), including relating to the business of manufacturing, marketing, selling, servicing and maintaining Amnis® and Guava® instruments, and flow cytometry reagent products and services.

The Company was incorporated in the state of Delaware in December 2014 and is headquartered in Fremont, California with offices, manufacturing facilities and distribution channels across the globe.

2. Basis of presentation and summary of significant accounting policies

The Company has prepared the accompanying unaudited interim consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“GAAP”). 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 Updates (“ASUs”) of the Financial Accounting Standards Board (“FASB”).

Principles of consolidation

The unaudited interim consolidated financial statements include the accounts of Cytek Biosciences, Inc., its wholly-owned subsidiaries, Cytek Limited (HK), Cytek Biosciences B.V. (Europe), Cytek (Shanghai) Biosciences Co., Ltd., Cytek Biosciences (Wuxi) Co., Ltd., Cytoville Biosciences Shanghai Co., Ltd., Cytek (Shanghai) Software Development Technology Co., Ltd., Cytek Japan Kabushiki Kaisha (“Cytek Japan”), Cytek Biosciences Ltd (UK), and Cytek Biosciences GmbH (Germany). All intercompany accounts and transactions have been eliminated in consolidation.

Use of estimates

The preparation of the unaudited interim consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in the Company’s unaudited interim consolidated financial statements and accompanying notes as of the date of the unaudited interim consolidated financial statements. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates.

Operating segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company’s Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating and evaluating financial performance. The Company operates and manages its business as one reportable and operating segment.

Foreign currency translation and transactions

The Company has determined that the functional and reporting currency for its operations across the globe is the functional currency of the Company’s international subsidiaries. Accordingly, all foreign balance sheet accounts have been translated into U.S. dollars using the rate of exchange at the respective balance sheet date. Components of the unaudited interim consolidated statements of operations and comprehensive income have been translated at the average exchange rate for the year or the reporting period. Translation gains and losses are recorded in accumulated other

comprehensive income as a component of stockholders' equity. Gains or losses arising from currency exchange rate fluctuations on transactions denominated in a currency other than the local functional currency are included in the unaudited interim consolidated statements of operations and comprehensive income.

Cash, cash equivalents, and restricted cash

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Cash equivalents are carried at cost, which approximates fair value.

The Company's cash and cash equivalents consist of money held in demand depositary accounts and money market funds. The carrying amount of cash and cash equivalents was \$163.6 million and \$299.5 million as of September 30, 2023 and December 31, 2022, respectively, which approximates fair value and was determined based upon Level 1 inputs. As of December 31, 2022, the \$2.9 million of restricted cash which related to the Wuxi building purchase was released in April 2023. The money market account is valued using quoted market prices with no valuation adjustments applied and is categorized as Level 1. The Company limits its credit risk associated with cash and cash equivalents by maintaining its bank accounts at major and reputable financial institutions. The Company's cash and cash equivalents balance exceeded the federally insured limit of \$250,000 as of September 30, 2023.

The Company classifies restricted cash as current on the accompanying unaudited interim consolidated balance sheets based upon the term of the remaining restrictions.

The following is a summary of cash, cash equivalents and restricted cash on the consolidated balance sheets (in thousands):

	September 30, 2023	December 31, 2022
Cash	\$ 14,725	\$ 123,371
U.S. Treasury	23,838	29,930
Federal agency securities	-	19,908
Commercial paper	-	5,955
Money market funds	125,066	117,437
Restricted cash	-	2,899
Total cash, cash equivalents and restricted cash as presented on the consolidated statements of cash flows	<u>\$ 163,629</u>	<u>\$ 299,500</u>

Investments

Available-for-sale investments. The Company's investments may consist of U.S. treasury and U.S. government agency securities, corporate notes and bonds, commercial paper, and money market funds. The Company has designated all investments as available-for-sale and, therefore, such investments are reported at fair value, with unrealized gains and losses recorded in accumulated other comprehensive loss. The Company generally holds securities until maturity; however, they may be sold under certain circumstances including, but not limited to, when necessary for the funding of acquisitions and other strategic investments. Realized gains and losses on the sale of investments are recorded in interest and other income, net in the consolidated statements of operations. Investments with remaining maturities at date of purchase greater than 90 days and remaining maturities as of the reporting period less than one year are classified as short-term investments. Investments with remaining maturities greater than one year are classified as long-term investments.

Equity Investment. The Company's investment consists of non-marketable equity investments in a privately held company. The Company's non-marketable equity investments do not have readily determinable fair values. Therefore, the Company elects to apply the measurement alternative and record these investments at cost, less any impairment, plus or minus observable price changes in orderly transactions for identical or similar investments of the same issuer. Investment is included within other noncurrent assets on our consolidated balance sheets and adjustments to their carrying amounts are recorded in other income (expense), net in the consolidated statements of operations. There were no material events or circumstances impacting the carrying amount of our strategic investments during the three months ended September 30, 2023.

Trade accounts receivable, net

The Company's accounts receivable consists principally of amounts due related to product sales of instrument systems and accessories, as well as installation and repair services. These receivables are generally due within 30 to 90 days of the period in which the corresponding sales occur and do not bear interest are classified as trade accounts

receivable, net on the consolidated balance sheets. Trade accounts receivable are reported at their estimated net realizable value.

Allowance for uncollectible receivables

The Company adopted ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13, Financial Instruments - Credit Losses”), on December 31, 2022, which was retroactively applied as of the first day of fiscal year 2022, as further described within the section below titled Recently Adopted Accounting Pronouncements. This accounting standard requires companies to measure expected credit losses on financial instruments based on the total estimated amount to be collected over the lifetime of the instrument. Prior to the adoption of this accounting standard, the Company recorded incurred loss reserves against receivable balances based on current and historical information.

Expected credit losses for uncollectible receivable balances consider both current conditions and reasonable and supportable forecasts of future conditions. Current conditions considered include pre-defined aging criteria, as well as specified events that indicate the balance due is not collectible. Reasonable and supportable forecasts used in determining the probability of future collection consider publicly available macroeconomic data and whether future credit losses are expected to differ from historical losses.

The Company is not party to any off-balance sheet arrangements that would require an allowance for credit losses in accordance with this accounting standard.

The changes in the allowance for uncollectible receivables for the nine months ended September 30, 2023 were as follows (in thousands):

Allowance for uncollectible receivables

Balance at December 31, 2022	\$	102
Utilization of allowance for uncollectible receivables		-
Provision for credit losses		55
Balance at September 30, 2023	\$	<u>157</u>

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is computed using standard cost, which approximates actual cost on a first-in, first-out basis. The Company regularly monitors inventory quantities on hand and records write-downs for excess and obsolete inventories based on an estimate of demand for products, potential obsolescence of technology, product life cycles, and whether pricing trends or forecasts indicate that the carrying value of inventory exceeds its estimated selling price. These factors are impacted by market and economic conditions, technology changes, and new product introductions and require estimates that may include elements that are uncertain. The Company's estimates of forecasted demand are based upon analysis and assumptions including, but not limited to, expected product lifecycles, product development plans and historical usage by product. If inventory is written down, a new cost basis is established that cannot be increased in future periods.

Property and equipment, net

Property and equipment are recorded at cost, net of accumulated depreciation. Depreciation is recorded using the straight-line method based on the estimated useful lives of the depreciable property or, for leasehold improvements, the remaining term of the lease, whichever is shorter. Assets not yet placed in use are not depreciated. The Company's estimated useful lives of its property and equipment are as follows:

	<u>Estimated Useful Lives</u>
Building	20 years
Furniture and fixtures	7 years
Laboratory equipment	5 years
Office and computer equipment	3 years
Leasehold improvements	Shorter of expected lease term or estimated useful life

Upon sale or retirement of the assets, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is recognized in the consolidated statement of operations and comprehensive loss. Expenditures for general maintenance and repairs are expensed as incurred.

Goodwill and intangible assets, net

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. Intangible assets resulting from the acquisition of entities are estimated by management based on the fair value of assets received. Intangible assets are amortized on a straight-line basis over the estimated useful lives. The Company's estimated useful lives of its intangible assets are as follows:

	Estimated Useful Lives
Patent	20 years
Trademarks	10 years
Tradenname	3 - 15 years
FCI developed technology	1 - 6 years
Customer relationship	7 - 8 years
Reagent licenses	7 years
IP license	5 years

Accounting for Impairment of Long-Lived Assets

Long-lived assets with finite lives include property and equipment and acquired intangible assets. The Company evaluates long-lived assets, including acquired intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by comparison of the carrying amount of an asset or an asset group to estimated undiscounted future net cash flows expected to be generated by the asset or asset group. If the carrying amount of an asset exceeds these estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the assets exceeds the fair value of the asset or asset group.

Goodwill and indefinite-lived intangible assets are not amortized but rather tested for impairment at least annually in the fourth quarter, or more frequently if events or changes in circumstances indicate that impairment may exist. Goodwill impairment is recognized when the quantitative assessment results in the carrying value of the reporting unit exceeding its fair value, in which case an impairment charge is recorded to goodwill to the extent the carrying value exceeds the fair value, limited to the amount of goodwill. The Company did not recognize any impairment of goodwill for all periods presented.

Fair value of financial instruments

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 and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The categorization of a financial instrument within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The Company recognizes transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer.

The carrying amounts reflected in the unaudited interim consolidated balance sheets for cash and cash equivalents, trade accounts receivable, net, trade accounts payable and accrued expenses approximate their fair values.

Revenue recognition

The Company's product revenue consists of sales of its instrument systems and accessories. The Company recognizes product revenue at the point in time when control of the product is transferred to the customer.

The Company's service revenue primarily consists of post-warranty service contracts, installations and repairs, which are recognized over time. Post-warranty service contracts are recognized ratably over the term of the contract and installations and repair services are recognized as they are delivered to the customer.

Revenue is recognized when control of promised goods or services is transferred to a customer in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for its arrangements with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Invoicing for products occurs upon delivery and payment terms are 30 to 90 days. Service contracts are invoiced upfront and payment terms are generally 30 days. For those arrangements that have terms greater than one year, any payments received upfront are for reasons other than financing. Revenue is recognized only to the extent that it is probable that a significant reversal of the cumulative amount recognized will not occur in future periods. Variable consideration is not material.

Certain of the Company's sales contracts involve the delivery or performance of multiple products and services within contractually binding arrangements. The Company has determined these performance obligations qualify as distinct performance obligations, as the customer can benefit from the good or service on its own or together with other resources that are readily available to the customer, and the Company's promise to transfer the good or service is separately identifiable from other promises in the contract. For these arrangements that contain multiple performance obligations, the Company allocates transaction price based on the relative standalone selling price ("SSP") method by comparing the SSP of each distinct performance obligation to the total value of the contract. The Company uses a range of amounts to estimate SSP for products and services sold together in a contract to determine whether there is a discount to be allocated based on the relative SSP of the various products and services. In instances where SSP is not directly observable, such as when the Company does not sell the product or service separately, the Company determines the SSP using information that may include market conditions and other observable inputs.

Sales, value-add and other taxes, collected from customers concurrent with revenue generating activities and remitted to governmental authorities are not included in revenue. Shipping and handling costs associated with outbound freight are accounted for as a fulfillment cost and are included in cost of sales.

The Company recognizes revenue in certain circumstances before product delivery occurs (commonly referred to as bill-and-hold transactions). When the Company enters into bill-and-hold arrangements, the Company determines if the customer obtains control of the product by determining (a) the reason for the bill-and-hold arrangement; (b) whether the product was identified separately as belonging to the customer; (c) whether the product was ready for physical transfer to the customer; and (d) whether the Company was unable to utilize the product or direct it to another customer. For bill-and-hold arrangements, the associated product inventory is identified separately by the Company as belonging to the customer and is ready for physical transfer.

As of the nine months ended September 30, 2023, \$2.8 million was included in revenue for products that had not shipped. As of the nine months ended September 30, 2022, the Company had \$6.1 million of revenue included under bill-and-hold arrangements.

Product revenue

The Company's standard arrangement for sales to end users is a purchase order or an executed contract. Revenue is recognized upon transfer of control of the product to the customer, which occurs at a point in time depending on the shipping terms.

The Company's arrangements with its distributors include a purchase order. The purchase order is governed by terms and conditions set forth in the applicable distribution agreement. Revenue is recognized upon transfer of control of the products to the distributor, which occurs at a point in time depending on the shipping terms.

Service revenue

The Company's service revenue primarily consists of post-warranty service contracts, installations and repairs, which are recognized over time. Post-warranty service contracts are recognized ratably over the term of the contract and installations and repair services are recognized as they are delivered to the customer. Service contracts are typically between one and three years.

Contract liabilities

Contract liabilities consist of fees invoiced or paid by the Company's customers for which the associated services have not been performed and revenue has not been recognized based on the Company's revenue recognition criteria described above. Such amounts are reported as deferred revenue for service and customer deposits for instruments on the consolidated balance sheets. Deferred revenue that is expected to be recognized during the following 12 months is recorded as a current liability and the remaining portion is recorded as noncurrent.

Assurance-type product warranties

The Company provides a one-year assurance-type warranty that is included with the sale of its instruments. At the time revenue is recognized for the products, the Company establishes an accrual for estimated warranty expense based on historical data and trends of product reliability and costs of repairing and replacing defective products. The Company exercises judgment in estimating the expected product warranty costs, using data such as the historical repair costs. While management believes 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, or alternatively, improved quality and reliability in the Company's products could result in actual expenses that are below those currently estimated.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses to date consist primarily of salaries, benefits, stock-based compensation, independent contractor costs, laboratory supplies, equipment maintenance, materials expenses, and software license fees. Payments made prior to the receipt of goods or services to be used in research and development activities are recorded as prepaid expenses until the related goods or services are received.

Advertising costs

The cost of advertising, marketing and media is expensed as incurred. For the three and nine months ended September 30, 2023, advertising, marketing and media expenses were \$0.5 million and \$2.7 million, respectively. For the three and nine months ended September 30, 2022, advertising, marketing and media expenses were \$0.5 million and \$1.6 million, respectively.

Stock-based compensation

The Company maintains an equity incentive compensation plan under which incentive stock options and nonqualified stock options to purchase common stock, and restricted stock units for common stock, are granted to employees and non-employee consultants. Stock-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as expense over the requisite service period. The fair value of stock options granted to employees is estimated using the Black-Scholes option pricing model. The Company records forfeitures as they occur. The weighted-average assumptions used in estimating the fair value of stock options granted during each of the periods presented are:

Expected Volatility—Expected volatility is estimated by studying the volatility of selected industry peers deemed to be comparable to the Company's business corresponding to the expected term of the awards.

Expected Term—Expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method.

Dividend Yield—The expected dividend yield is zero as the Company has never declared or paid cash dividends and has no current plans to do so in the foreseeable future.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero-coupon issued in effect at the time of grant for periods corresponding with the expected term of the option.

Income taxes

The Company accounts for income taxes under an asset and liability approach. Deferred income taxes comprise the impact of temporary differences between assets and liabilities recognized for financial reporting purposes and the amounts recognized for income tax reporting purposes, net operating loss carryforwards, and other tax credit carryforwards measured by applying currently enacted tax laws. A valuation allowance is provided when necessary to reduce deferred tax assets to an amount that is more likely than not to be realized.

The Company determines whether a tax position is more likely than not to be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The

Company uses a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon tax authority examination, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. The Company's policy for interest and penalties related to uncertain tax positions is to recognize interest and penalties, if any, in interest expense and other expense, respectively, in the accompanying consolidated statement of operations. Accrued interest and penalties, if any, are included in accrued expenses in the consolidated balance sheet.

The Company files income tax returns in the U.S. federal jurisdiction, various U.S. state jurisdictions and foreign jurisdictions. The U.S. state and foreign jurisdictions have statutes of limitations that generally range from three to five years. The Company's federal, state and foreign income tax returns are subject to examination unless the statutes of limitations close. The Company is not currently under examination for federal, state, and foreign income tax purposes.

The Company intends to reinvest its undistributed earnings of its foreign operations. Following enactment of the 2017 Tax Cuts and Jobs Act (the "Tax Act"), the repatriation of cash to the United States is generally no longer taxable for federal income tax purposes. However, the repatriation of cash held outside the United States could be subject to applicable foreign withholding taxes and state income taxes. The Company may remit foreign earnings to the United States to the extent it is tax efficient to do so. It does not expect the tax impact from remitting these earnings to be material. The Company adopted this guidance on January 1, 2021 on a prospective basis, and the adoption did not have a material impact to the Company's unaudited interim consolidated financial statements.

Net income (loss) attributable to common stockholders per share

Basic net income (loss) attributable to common stockholders per share and diluted net income (loss) attributable to common stockholders per share are computed using the weighted-average number of shares of common stock outstanding for the period. Net income (loss) per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net income (loss) per share for the holders of shares of the Company's common stock and participating securities. The Company's redeemable convertible preferred stock contains participation rights in any dividend paid by the Company and is deemed to be a participating security. The participating securities include a contractual obligation to participate in the income of the Company and are included in the calculation of net income (loss) per share in the periods in which net income (loss) is recorded.

Diluted net income (loss) attributable to common stockholders per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. The Company allocates earnings first to preferred stockholders based on non-cumulative dividend rights if and when declared and then to common and preferred stockholders based on ownership interests. The weighted-average number of shares of common stock included in the computation of diluted net income (loss) attributable to common stockholders per share gives effect to all potentially dilutive common stock equivalents, including outstanding options and redeemable convertible preferred stock.

Common stock equivalents are excluded from the computation of diluted net loss attributable to common stockholders per share if their effect is antidilutive.

Business Combinations

The Company uses the acquisition method of accounting under ASC 805, *Business Combinations*. Each acquired company's operating results are included in the Company's consolidated financial statements starting on the date of acquisition. The purchase price is equivalent to the fair value of consideration transferred. Tangible and identifiable intangible assets acquired and liabilities assumed as of the date of acquisition are recorded at the acquisition date fair value. Goodwill is recognized for the excess of purchase price over the net fair value of assets acquired and liabilities assumed.

Amounts allocated to assets and liabilities are based upon fair values. Such valuations require management to make significant estimates and assumptions, especially with respect to the identifiable intangible assets. Management makes estimates of fair value based upon assumptions believed to be reasonable and that of a market participant. These estimates are based on historical experience and information obtained from the management of the acquired companies and the estimates are inherently uncertain. The separately identifiable intangible assets generally include developed technology, customer relationships, trade names, and reagent licenses.

Recently adopted accounting pronouncements

There are no relevant recently issued accounting pronouncements that would materially impact the Company's consolidated financial statements and related disclosures. There were no new accounting pronouncements adopted during the nine months ended September 30, 2023 that materially impacted the Company's condensed consolidated financial statements and related disclosures.

3. Concentrations of credit risk and other risks and uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains accounts in federally insured financial institutions in excess of federally insured limits. Management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which these deposits are held and of the money market funds in which these investments are made. The Company holds marketable securities with high credit ratings.

4. Revenue from contracts with customers

Disaggregation of revenue

The following table depicts the disaggregation of revenue by sales channel mix and customer mix as defined by the nature of workflows (in thousands):

	Three months ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Sales channel mix				
Direct sales channel	\$ 36,916	\$ 30,204	\$ 100,223	\$ 94,725
Distributor channel	11,084	10,273	34,559	20,975
Total revenue, net	\$ 48,000	\$ 40,477	\$ 134,782	\$ 115,700
Customer mix				
Academia and government	\$ 20,118	\$ 18,983	\$ 55,721	\$ 48,796
Biotechnology, pharmaceutical, distributor and contract research organizations	27,882	21,494	79,061	66,904
Total revenue, net	\$ 48,000	\$ 40,477	\$ 134,782	\$ 115,700

Revenue by geographical markets is presented in Note 22, *Geographic areas*.

Remaining performance obligations

The following table includes estimated revenues expected to be recognized in the future related to performance obligations that are unsatisfied (or partially satisfied) as of September 30, 2023 (in thousands):

	Less than 1 year	Greater than 1 year	Total
Product revenue	\$ 1,006	\$ -	\$ 1,006
Service revenue	22,041	14,958	36,999
Total revenue	\$ 23,047	\$ 14,958	\$ 38,005

Contract balances

The following table provides information about receivables, deferred revenue from contracts with customers, and customer deposits (in thousands):

	September 30, 2023	December 31, 2022
Trade accounts receivable	\$ 55,402	\$ 48,864
Contract liabilities:		
Deferred revenue	\$ 38,005	\$ 26,110
Customer deposits, which are included in 'Other current liabilities'	1,645	1,555
Total contract liabilities	\$ 39,650	\$ 27,665

The following provides a roll-forward of the contract liabilities (in thousands):

Contract liabilities

Balance at December 31, 2021	\$	17,889
Revenue recognized		(24,686)
Revenue deferred		34,462
Balance at December 31, 2022	\$	27,665
Revenue recognized		(28,657)
Revenue deferred		40,642
Balance at September 30, 2023	\$	39,650

5. Balance sheet details

Inventories

The following table shows the components of inventory (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	\$ 37,265	\$ 26,925
Work in progress	11,932	4,897
Finished goods	17,678	16,332
Total inventories	\$ 66,875	\$ 48,154

Prepaid expenses and other current assets

The following table shows the components of prepaid expenses and other current assets (in thousands):

	September 30, 2023	December 31, 2022
Prepaid expenses:		
Prepaid inventory	\$ 559	\$ 621
Prepaid rent	423	293
Prepaid insurance	1,055	1,466
Prepaid income tax	2,578	2,080
Prepaid VAT tax	760	-
Prepaid tradeshow	201	-
Other	1,960	2,687
Other current assets:		
Tax refund receivable	2,231	2,011
Other	2,250	3,796
Total prepaid expenses and other current assets	\$ 12,017	\$ 12,954

Accrued expenses

The following table shows the components of accrued expenses (in thousands):

	September 30, 2023	December 31, 2022
Accrued expenses:		
Accrued compensation and related benefits	\$ 13,690	\$ 13,911
Professional service fees	775	1,276
Purchases	2,248	2,457
Product warranty	2,782	2,126
Other	1,019	1,356
Total accrued expenses	\$ 20,514	\$ 21,126

For the product warranty analysis refer to Note 20.

Other current liabilities

The following table shows the components of other current liabilities (in thousands):

	September 30, 2023	December 31, 2022
Other current liabilities:		
Customer deposits	\$ 1,645	\$ 1,555
Income tax payable	-	246
Sales and use tax payable	2,213	1,421
Operating lease liability, current	2,879	2,931
Current portion of loan	548	580
Other	536	1,227
Total other current liabilities	\$ 7,821	\$ 7,960

6. Fair value of financial instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The categorization of a financial instrument within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The following table sets forth the fair value of the Company's financial assets and liabilities by level within the fair value hierarchy (in thousands):

Description:	September 30, 2023	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Cash equivalents:				
Money market funds	\$ 125,066	\$ 125,066	\$ -	\$ -
U.S Treasury	23,838	23,838	-	-
Short-term investments:				
U.S. Treasury	35,401	35,401	-	-
Federal agency securities	47,347	-	47,347	-
Commercial paper	41,644	-	41,644	-
Total	\$ 273,296	\$ 184,305	\$ 88,991	\$ -

Description:	December 31, 2022	Quoted prices in active markets for identical assets (level 1)	Significant other observable inputs (level 2)	Significant unobservable inputs (level 3)
Cash equivalents:				
U.S. Treasury	\$ 29,930	\$ 29,930	\$ —	-
Federal agency securities	19,908	-	19,908	-
Commercial paper	5,955	-	5,955	-
Money market funds	117,437	117,437	-	-
Short-term investments:				
U.S. Treasury	9,786	9,786	-	-
Federal agency securities	11,626	-	11,626	-
Commercial paper	23,136	-	23,136	-
Total	<u>\$ 217,778</u>	<u>\$ 157,153</u>	<u>\$ 60,625</u>	<u>\$ -</u>

The Company did not have any transfers of financial assets measured at fair value on a recurring basis to or from Level 1, Level 2 or Level 3 for any of the periods presented.

The table above does not include the Company's investments in privately held equity securities. Non-marketable equity investments of \$1.6 million are included within Other noncurrent assets on the consolidated balance sheet as of September 30, 2023.

7. Investments

The following tables summarize the Company's investments in available-for-sale securities by significant investment category reported as short-term as of September 30, 2023 (in thousands):

	September 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Loss	Estimated Fair Value
U.S. Treasury	\$ 35,403	\$ 3	\$ (4)	\$ 35,402
Federal agency securities	47,357	12	(23)	47,346
Commercial paper	41,644	-	-	41,644
Total available-for-sale investments	<u>\$ 124,404</u>	<u>\$ 15</u>	<u>\$ (27)</u>	<u>\$ 124,392</u>

The following table summarizes the contractual maturities of the Company's available-for-sale securities at September 30, 2023 (in thousands):

	September 30, 2023	
	Amortized Cost	Fair Value
Mature in less than one year	\$ 124,404	\$ 124,392
Total	<u>\$ 124,404</u>	<u>\$ 124,392</u>

8. Property and equipment, net

The following table shows the components of property and equipment, net (in thousands):

	September 30, 2023	December 31, 2022
Laboratory equipment	\$ 8,900	\$ 4,777
Leasehold improvements	3,582	3,481
Building and land	6,541	5,553
Construction in progress	218	178
Office and computer equipment	1,210	890
Furniture and fixtures	2,017	1,962
Total property and equipment	22,468	16,841
Less: accumulated depreciation	(5,053)	(3,159)
Property and equipment, net	\$ 17,415	\$ 13,682

Total depreciation expense for the three and nine months ended September 30, 2023 was \$0.9 million and \$2.0 million, respectively. Total depreciation expense for three and nine months ended September 30, 2022 was \$0.4 million and \$1.2 million, respectively.

9. Acquisition

On February 28, 2023, the Company completed the acquisition of the Luminex FCI business unit, including relating to the business of manufacturing, marketing, selling, servicing and maintaining Amnis and Guava branded instruments, and flow cytometry reagent products and services, for an aggregate cash consideration of \$44.9 million.

The acquisition was accounted for as a business combination in accordance with ASC 805. The tangible and intangible assets acquired were recorded at estimated fair value on the acquisition date. The purchase price allocation is based upon preliminary valuations and estimates and assumptions which are subject to change within the purchase price allocation period, generally one year from the acquisition date.

During the three months ended September 30, 2023, we recorded the following changes as a result of measurement period adjustments to the fair value of the initial assets related to inventory, property and equipment, customer relationships and trade names as follows:

- Inventories decreased by \$0.2 million
- Property and equipment increased by \$1.4 million
- Customer relationships increased by \$1.7 million
- Developed technologies decreased by a total \$0.4 million
- Trade names increased by a total of \$0.2 million

The measurement period adjustments noted above decreased goodwill by \$2.7 million.

The Company identified the following areas as subject to change within the purchase price allocation period: intangible asset and inventory fair values recognized and measured in accordance with ASC 820, Fair Value Measurement, deferred income tax assets acquired and liabilities assumed are recognized and measured in accordance with

ASC 740 Income Taxes. The following table summarizes the preliminary estimated fair value of assets acquired and liabilities assumed at the date of the acquisition (in thousands):

	(in thousands)
Fair value of assets acquired and liabilities assumed:	
Inventories	\$ 18,491
Property and equipment	3,040
Prepaid expenses	70
Intangible assets	
Customer Relationships	10,200
Amnis ImageStream developed technology	8,900
Guava easyCyte and Muse developed technology	140
Amnis FlowSight and CellStream developed technology	20
Amnis tradename	2,900
Guava tradename	90
Goodwill	6,313
Deferred revenue	(4,952)
Other current liabilities	(316)
Fair value of net assets acquired	<u>\$ 44,896</u>

The \$6.3 million of goodwill arising from the acquisition is primarily attributed to significant time-to-market advantages, as the Company gained immediate access to Luminex's FCI products, existing relationships and business infrastructure and Luminex's knowledgeable and experienced FCI workforce. The goodwill is expected to be deductible for tax purposes. The Company is currently evaluating the amount of goodwill which is expected to be deductible and will finalize this amount in future periods. Management plans to integrate the acquired FCI business into its existing business structure, which is comprised of a single reportable segment and a single reporting unit.

Intangible assets identified for recognition separate from goodwill were those that satisfied either the contractual or legal criterion or the separability criterion in the accounting guidance. The identifiable intangible assets acquired and their estimated useful lives for amortization are as follows:

	Fair Value	Useful life (years)
	(In thousands, except for years)	
Customer relationships	\$ 10,200	8
Amnis ImageStream Developed Technology	8,900	6
Guava easyCyte and Muse Developed Technology	140	2
Amnis FlowSight and CellStream Developed Technology	20	1
Amnis Tradename	2,900	15
Guava Tradename	90	3
Total	<u>\$ 22,250</u>	

The customer relationships intangible asset represents the fair value of the underlying relationships with Luminex's FCI customers. The tradename intangible asset represents the fair value of brand and name recognition associated with the marketing of the acquired Luminex FCI product lines. The FCI developed technology intangible asset represents the fair value of access to certain imaging and microcapillary technologies.

The fair value of the intangible assets acquired were estimated using variations of the income approach. The fair value of the customer relationships intangible asset was determined based on the multi-period excess earnings method and the relief-from-royalty method was utilized to estimate the fair values of the tradename and FCI developed technology intangible assets. The key assumptions used in estimating the fair values of intangible assets included

forecasted financial information; customer retention rates; factors for technological obsolescence; royalty rates and discount rates. The cash flow projections were discounted using rates ranging from 29.0% to 39.0%. The cash flows were based on estimates used to price the transaction, including market participant considerations, and the discount rates applied were benchmarked with reference to the implied rate of return from the transaction model and the weighted average cost of capital.

All acquired intangibles are being amortized over their estimated useful lives using the straight-line method of amortization.

The fair value assigned to the assets acquired are based on reasonable assumptions and estimates that market participants would use. Actual results may differ from these estimates and assumptions.

The results of operations for the acquisition are included in the consolidated financial statements of the Company from the date of the acquisition. For the three and nine months ended September 30, 2023 \$6.8 million and \$18.8 million of the Company's revenue were attributable to the acquired business unit.

The following unaudited pro forma consolidated financial information reflects the results of operations of the Company for the three and nine months ended September 30, 2023 and 2022 as if the acquisition had occurred as of January 1, 2022, after giving effect to certain purchase accounting and financing adjustments. These amounts are based on financial information of the acquired business unit and are not necessarily indicative of what the Company's operating results would have been had the acquisition taken place on January 1, 2022:

(in thousands)	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenue	\$ 48,000	\$ 49,691	\$ 139,359	\$ 145,474
Income (loss) before income taxes	(4,185)	339	(19,180)	(7,104)
Net Income (loss)	\$ (6,456)	\$ 475	\$ (17,170)	\$ (4,471)

Pro forma financial information is presented as if the operations of the acquired business unit had been included in the consolidated results of the Company since January 1, 2022 and gives effect to transactions that are directly attributable to the acquisition. Adjustments include additional depreciation and amortization expense related to the fair value of acquired property and equipment and intangible assets as if such assets were acquired on January 1, 2022. Transaction costs incurred by the Company related to the acquisition totaled approximately \$1.5 million for the nine months ended September 30, 2023, respectively, which were expensed and recorded as a component of general and administrative expenses in the consolidated statement of operations.

10. Goodwill and intangible assets, net

The addition of goodwill for the nine months ended September 30, 2023 is discussed in Note 9.

The following table shows the components of intangible assets, net (in thousands):

	September 30, 2023	December 31, 2022
Patents and trademarks	\$ 579	\$ 534
Tradenname	3,769	700
FCI developed technology	9,060	-
IP license	476	476
Customer relationships	12,400	2,200
Reagent license	1,800	1,800
Total intangible assets	28,084	5,710
Less: accumulated amortization	(3,792)	(1,379)
Intangible assets, net	\$ 24,292	\$ 4,331

Total amortization expense for the three and nine months ended September 30, 2023 was approximately \$0.9 million and \$2.4 million, respectively. Total amortization expense for the three and nine months ended September 30, 2022 was approximately \$0.2 million and \$0.6 million, respectively.

11. Legal settlement liability

On February 13, 2018, Becton, Dickinson, and Company (“BD”) filed a lawsuit against the Company alleging trade secret misappropriation and copyright infringement. On October 6, 2020, the Company entered into a Settlement, License and Equity Issuance Agreement with BD pursuant to which the Company and BD agreed to a mutual release of all claims against each other as of the date thereof (the “BD Agreement”). Additionally, BD granted Cytek a non-exclusive, irrevocable, perpetual, worldwide and non-transferrable license to certain BD patents and covenanted that it would not enforce or permit or encourage the enforcement of BD patents against Cytek or its affiliates in connection with the development, manufacture, use, importation, offer for sale or sale of its then-current instruments. In exchange, the Company agreed that Cytek and its affiliates would not dispute or challenge in a legal proceeding the validity, enforceability or scope of the applicable BD patent claims and agreed to make certain payments to BD, including (i) a one-time upfront payment of \$2.0 million, (ii) a low single digit royalty payment for ten years, based on net sales of certain of its products, (iii) \$6.0 million milestone payment upon the occurrence of a certain sales threshold, and (iv) a specified payment upon the closing of a change of control transaction, if any. The Company also issued 2,087,545 shares of the Company’s common stock to BD during the year ended December 31, 2020 in connection with the BD settlement. The Company achieved the sales milestone and made the milestone payment in the quarter ended December 31, 2021.

The Company separated the settlement agreement into two elements, the litigation settlement and future licensing rights. The Company could not readily determine the fair value of the litigation settlement of prior infringement claims between the Company and BD. Therefore, the Company applied the residual method and allocated the difference between the total present value consideration payable under the BD Agreement and the estimated fair value of the future licensing rights to the litigation settlement element. The Company determined the estimated fair value of the future licensing rights based on the relief from royalty method. The significant assumptions used were the market royalty rate estimated as a royalty rate that a market participant would pay to license the BD intellectual property, forecasted sales subject to the market royalty rate and the discount rate.

The patents in question were determined to have an average useful life of 18 months. Accordingly, beginning the third quarter of 2022, the remaining contractual payments will be classified as operating expenses as they are considered to be represented of deferred litigation settlement. The Company did not record any product cost of sales related to the royalty expense for the three and nine months ended September 30, 2023, and recorded \$0.0 million and \$0.8 million of product cost of sales related to royalty expense for the three and nine months ended September 30, 2022, respectively. The Company recorded \$0.5 million and \$1.3 million of interest expense for the three and nine months ended September 30, 2023, respectively, and \$0.6 million and \$1.6 million of interest expense for the three and nine months ended September 30, 2022, respectively, to accrete the present value discount of the payment streams over the payment period of ten years from the settlement date using the effective interest rate method. The Company made a one-time upfront payment and issued 2,087,545 shares of the Company’s common stock to BD during the year ended December 31, 2020. The Company recorded legal settlement liability on the consolidated balance sheets of \$18.7 million and \$17.8 million as of September 30, 2023 and December 31, 2022, respectively, and will record licensing expense in future periods.

The following table shows the components of the legal settlement liability (in thousands):

	September 30, 2023	December 31, 2022
Current:		
Legal settlement liability	\$ 2,600	\$ 2,163
Noncurrent:		
Legal settlement liability	16,095	15,596
Total legal settlement liability	\$ 18,695	\$ 17,759

12. Debt

On November 7, 2022, Cytek (Wuxi) Biosciences Co., Ltd, the Company’s China subsidiary (“Cytek Wuxi”), entered a fixed asset loan agreement with Bank of Communications, China. The loan is denominated in Chinese renminbi and collateralized by Cytek Wuxi’s cash deposit to the bank. The deposit was in a separate account with Cytek Wuxi’s name, but the use of such account is restricted. The Company presented the deposit as restricted cash on the audited consolidated balance sheets as of December 31, 2022 and unaudited interim consolidated balance sheets as of March 31, 2023. In April 2023, the restricted cash account was released. The total loan amount is \$2.9 million and the loan term is five years. The current portion of the loan of \$548,000 is included in other current liabilities. The fixed interest rate on the loan was 4.5% as of September 30, 2023.

13. Common stock

As of September 30, 2023, the Company has authorized 1,000,000,000 shares of common stock at \$0.001 par value. Holders of common stock are entitled to one vote per share, and to receive dividends, only and if declared by the Board of Directors and, upon liquidation or dissolution, are entitled to receive all assets available for distribution to stockholders, subordinate to the rights, preferences and privileges of any outstanding Preferred Stock with respect to dividends and in connection with a liquidation, winding up and dissolution of the Company. The holders have no preemptive or other subscription rights.

On July 16, 2021, the Board and the Company's stockholders approved an amendment and restatement of the Company's certificate of incorporation to effect a 1.3333-for-1 stock split of its common stock and redeemable convertible preferred stock, which became effective upon filing with the Secretary of State of the State of Delaware on July 16, 2021.

On July 16, 2021, the Board and the Company's stockholders approved an amendment and restatement of the Company's certificate of incorporation, which became effective immediately following the closing of the Company's initial public offering ("IPO") and filing with the Secretary of State of the State of Delaware on July 27, 2021.

On August 26, 2022, the Company filed with the SEC an automatic shelf registration statement on Form S-3ASR (File No. 333-267118) (the "Registration Statement"). In connection with the filing of the Registration Statement, the Company also entered into a sales agreement (the "2022 Sales Agreement") with Piper Sandler & Co. ("Piper") as sales agent to sell from time to time up to \$150 million of the Company's common stock through an "at-the-market" offering program as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act").

Pursuant to the terms of the 2022 Sales Agreement, the aggregate compensation payable to Piper is up to 3% of the gross proceeds from the sale of common stock sold by Piper pursuant to the 2022 Sales Agreement. Each party agreed in the 2022 Sales Agreement to provide indemnification and contribution against certain liabilities, including liabilities under the Securities Act, subject to the terms of the 2022 Sales Agreement. As of September 30, 2023, the Company has not made any sales of common stock pursuant to the 2022 Sales Agreement.

On May 17, 2023, the Board approved a program for the repurchase by the Company of up to an aggregate of \$50 million of its outstanding common stock. During the three months ended September 30, 2023, the Company repurchased 1,155,229 shares of its outstanding common stock for a total cost of approximately \$8.4 million at an average price per share of \$7.42. During the nine months ended September 30, 2023, the Company repurchased 1,281,011 shares of its outstanding common stock for a total cost of approximately \$9.4 million at an average price per share of \$7.33. The repurchase program was used to return capital to shareholders and to minimize the dilutive impact of stock options and other share-based awards. The repurchased shares of common stock were retired.

14. Stock-based compensation plan

Stock Plans

As of September 30, 2023, the Company had three stock-based compensation plans (the "Plans") which are described below.

2015 Equity Incentive Plan

In March 2015, the Board approved the 2015 Equity Incentive Plan ("2015 Plan"), which provided for the granting of stock options to employees, directors and consultants of the Company. As of the effective date of the 2015 Plan described below, the 2015 Plan was terminated and no further equity awards may be granted pursuant to the 2015 Plan. Outstanding stock options granted under the 2015 Plan will continue to be governed by the provisions of the 2015 Plan until expiration or exercise, whichever is earlier.

2021 Equity Incentive Plan

In July 2021, the Board approved the 2021 Equity Incentive Plan (the "2021 Plan"), which provides for the granting of stock options, stock appreciation rights, restricted stock awards, restricted stock unit ("RSU") awards, performance awards, and other awards to employees, directors and consultants of the Company. The 2021 Plan became effective on July 22, 2021 in connection with the IPO. Upon the 2021 Plan's effective date, there were 18,000,000 shares of the Company's common stock reserved for issuance thereunder. On January 1 of each year commencing after the effective date of the IPO and continuing through and including January 1, 2031, the number of shares of the Company's common stock reserved for issuance under the 2021 Plan will increase automatically by an amount equal to 4% of the number of shares of the Company's common stock outstanding on the preceding December 31, unless the Company's

Board of Directors elects to authorize a lesser number of shares prior to the applicable January 1. As of September 30, 2023, the total number of shares of common stock available for issuance under the 2021 Plan was 21,204,295 shares.

2021 Employee Stock Purchase Plan

In July 2021, the Board approved the 2021 Employee Stock Purchase Plan (the “ESPP”). The ESPP became effective on July 22, 2021 in connection with the IPO. Upon the ESPP’s effective date, there were 2,000,000 shares of the Company’s common stock reserved for issuance thereunder. On January 1 of each year commencing after the effective date of the IPO and continuing through and including January 1, 2031, the number of shares of the Company’s common stock reserved for issuance under the ESPP will increase automatically by an amount equal to the lesser of (1) 1% of the number of shares of the Company’s common stock outstanding on the preceding December 31, (2) 5,000,000 shares and (3) a number of shares determined by the Board. During the nine months ended September 30, 2023, 145,569 shares were issued pursuant to purchases under the ESPP. As of September 30, 2023, the total number of shares of common stock available for issuance under the ESPP was 4,352,888 shares.

Stock option valuation assumptions

The Company estimates the fair value of each stock option grant on the date of grant using the Black-Scholes option pricing model. The model assumptions include expected volatility, expected term, dividend yield, and the risk-free interest rate. The expected volatility was based on the volatility of a group of similar entities. The Company derived expected term by using the “simplified” method (the expected term is determined as the average of the time-to-vesting and contractual life of the option), as the Company has limited historical information to develop expectations about future exercise patterns and post vesting employment termination behavior. The Company based the risk-free rate on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term of the option. The Company has never paid any dividends and does not anticipate paying dividends in the foreseeable future, and therefore used an expected dividend yield of zero in the valuation model.

Stock Options

The following table shows stock option activity during the periods indicated (in thousands except share and per share data):

	Number of options outstanding	Weighted-average exercise price	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value
Balance as of December 31, 2022	7,578,635	\$ 7.76	7.42	\$ 37,200
Options granted	1,295,948	10.09	-	-
Options exercised	(911,407)	1.24	-	-
Options forfeited	(337,754)	12.08	-	-
Options expired	(97,257)	15.22	-	-
Balance as of September 30, 2023	7,528,165	\$ 8.66	7.18	\$ 12,753
Options exercisable as of September 30, 2023	4,533,451	\$ 6.75	6.38	\$ 11,643

The weighted-average grant date fair value of options granted during the three months ended September 30, 2023 was \$4.91 and the company did not grant any stock options during the three months ended September, 2022. The weighted-average grant date fair value of options granted during the nine months ended September 30, 2023 and 2022 was \$6.64 and \$8.14 per share, respectively.

There was \$24.1 million and \$31.6 million of unrecognized stock-based compensation expense related to unvested stock options as of September 30, 2023 and 2022, respectively. The unrecognized stock-based compensation expense is estimated to be recognized over a period of 2.12 years and 2.42 years as of September 30, 2023 and 2022, respectively.

The Company currently uses authorized and unissued shares to satisfy option exercises.

The aggregate intrinsic value is calculated as the difference between the exercise price and the estimated fair value of the Company’s common stock as of September 30, 2023.

RSU Awards

The following table shows RSU awards activity during the periods indicated:

	Shares	Weighted-average grant date fair value per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Unvested balance at December 31, 2022	1,169,508	\$ 13.36	1.59	\$ 11,941
Granted	2,402,781	10.09		
Vested	(443,768)	12.22		
Forfeited	(313,399)	10.99		
Unvested balance at September 30, 2023	2,815,122	\$ 11.01	1.65	\$ 15,539

There was \$29.0 million and \$15.1 million of unrecognized stock-based compensation expense related to unvested RSU awards as of September 30, 2023 and 2022, respectively. The unrecognized stock-based compensation expense is estimated to be recognized over a period of 3.21 and 3.44 years as of September 30, 2023 and 2022, respectively.

Stock-based compensation expense

The following table shows the allocation of stock-based compensation expense related to the Company's stock-based awards (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Cost of sales	\$ 829	\$ 759	\$ 2,389	\$ 2,214
Research and development	1,739	1,248	4,978	3,600
Sales and marketing	1,085	1,097	3,191	2,731
General and administrative	2,105	1,255	5,821	3,585
Total stock-based compensation	\$ 5,758	\$ 4,359	\$ 16,379	\$ 12,130

The following table shows the weighted-average valuation assumptions used in determining the fair value of employee stock options:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Expected term (in years)	6.02	0.0	5.96	5.91
Expected volatility	73 %	-	71 %	75 %
Risk-free interest rate	4 %	-	4 %	2 %
Dividend yield	-	-	-	-

The following table summarizes the weighted-average assumptions used in estimating the fair value of the ESPP for the current offering period using the Black-Scholes option-pricing model:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	67 %	72 %	75 %	74 %
Risk-free interest rate	5 %	2 %	5 %	1 %
Dividend yield	-	-	-	-

15. Employee benefit plan

401(k) retirement savings plan

The Company currently maintains a 401(k) retirement savings plan that covers substantially all of its employees ("401(k) Plan"). The 401(k) Plan permits voluntary contributions by employees, a portion of which are matched

by the Company. The Company's contributions to the 401(k) Plan were approximately \$469,000 and \$1,238,000 for the three and nine months ended September 30, 2023, respectively. The Company's contributions to the 401(k) Plan were approximately \$273,000, and \$791,000 for the three and nine months ended September 30, 2022, respectively.

16. Income taxes

The Company's effective income tax rate from continuing operations was 11.0% and 56.8% for the nine months ended September 30, 2023 and 2022, respectively. The Company's effective income tax rate for the nine months ended September 30, 2023 is lower than the US federal statutory tax rate due to a loss projected for the year and the impact of state income taxes, non-deductible stock-based compensation, the Company's mix of earnings between various taxing jurisdictions, which are partially offset by a deduction for foreign-sourced revenue, stock compensation, and federal and state research credits. The effective income tax rate for the nine months ended September 30, 2022 was higher than the US federal statutory tax rate primarily due to non-deductible stock-based compensation, the Company's mix of earnings between various taxing jurisdictions, partially offset by a deduction for foreign-sourced revenue, and federal and state research credits.

Realization of the Company's deferred tax assets is dependent primarily on the generation of future taxable income. In considering the need for a valuation allowance, the Company considers its historical, as well as future projected, taxable income along with other objectively verifiable evidence. Objectively verifiable evidence includes the Company's realization of tax attributes, assessment of tax credits, and utilization of net operating loss carryforwards during the year.

17. Lease

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

The Company leases office facilities and equipment from unrelated parties under operating lease agreements that have initial terms ranging from 1 to 7.25 years. Some leases include one or more options to renew, generally at the Company's sole discretion, with renewal terms that can extend the lease term up to five years. In addition, certain leases contain termination options, where the rights to terminate are held by either the Company, the lessor, or both parties. These options to extend or terminate a lease are included in the lease terms when it is reasonably certain that the Company will exercise that option. The Company's leases generally do not contain any material restrictive covenants. The Company is a sub-lessor in an agreement with a term of three years.

Operating lease cost is recognized on a straight-line basis over the lease term. The components of lease expense are as follows (in thousands):

	Nine months ended September 30,	
	2023	2022
Operating lease cost	\$ 2,388	\$ 2,370
Short-term lease cost	639	37
Total lease cost	\$ 3,027	\$ 2,407

For the three and nine months ended September 30, 2023, sublease income were \$68,000 and \$204,000, respectively, recorded as other income.

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

	Nine months ended September 30,	
	2023	2022
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash outflows - payments on operating leases	\$ 2,412	\$ 1,629
Right-of-use assets obtained in exchange for new lease obligations:		
Operating leases	\$ -	\$ 16,741

Supplemental balance sheet information related to leases is as follows (in thousands):

	September 30, 2023	December 31, 2022
Operating lease right-of-use assets	\$ 11,703	\$ 13,883
Included in other current liabilities:		
Operating lease liabilities, current	\$ 2,879	\$ 2,931
Operating lease liabilities, noncurrent	10,139	12,312
Total operating lease liabilities	<u>\$ 13,018</u>	<u>\$ 15,243</u>
Weighted-average remaining lease term - operating leases:	4.81	5.47
Weighted-average discount rate - operating leases:	2.6%	2.6%

Future undiscounted cash flows for each of the next five years and thereafter and reconciliation to the lease liabilities recognized on the balance sheet as of September 30, 2023 is as follows (in thousands):

2023 (excluding the nine months ended September 30, 2023)	\$ 843
2024	3,063
2025	2,665
2026	2,571
2027	2,315
Thereafter	2,395
Total lease payments	<u>\$ 13,852</u>
Less imputed interest	(834)
Total present value of lease liabilities	<u>\$ 13,018</u>

18. Commitments and contingencies

Legal proceedings

The Company evaluates the status of each legal matter, if any, and assesses potential financial exposure. If the potential loss from any legal proceedings or litigation is considered probable and the amount can be reasonably estimated, the Company accrues a liability for the estimated loss. Significant judgment is required to determine the probability of a loss and whether the amount of the loss is reasonably estimated. The outcome of any proceeding is not determinable in advance. As a result, the assessment of a potential liability and the amount of accruals recorded are based on the information available at the time.

The Company is not currently involved in legal actions, nor is management aware of any potential claims or legal actions, for which the ultimate disposition could have a material effect on the Company's financial position, results of operations or liquidity.

19. Investment in Cytek Japan

In May 2019, the Company jointly formed Cytek Japan with TOMY Digital Biology ("TOMY"). Cytek Japan was created for the purpose of expanding the Company's presence in Japan. The Company and TOMY each purchased \$46,000 of common stock of Cytek Japan. The Company previously accounted for its 50% interest in Cytek Japan as an equity method investment. The Company recorded \$40,000 for its proportionate share of Cytek Japan's earnings prior to its additional investment, which is included in other income (expense), net in the consolidated statements of operations and comprehensive income for the year ended December 31, 2022.

In March 2021, the Company purchased an additional \$688,000 of common stock of Cytek Japan and TOMY purchased an additional \$229,000 of common stock of Cytek Japan. The Company's interest in Cytek Japan increased from 50% to 73% giving the Company controlling interest. The Company consolidated Cytek Japan as of March 31, 2021 under the VOE model as Cytek Japan does not meet the definition of a VIE and as TOMY does not have substantive voting, participating or liquidation rights.

The Company recognized net assets of \$1.1 million, consisting primarily of \$1.0 million cash. The Company recorded noncontrolling interest of \$315,000 on the unaudited interim consolidated financial statements as of March 31, 2021.

In January 2023, the Company purchased an additional \$235,000 of common stock of Cytek Japan. Cytek Japan became a wholly-owned subsidiary of the Company.

20. Product warranty

The following table shows the activity in the product warranty accrual included in accrued expenses on the consolidated balance sheets (in thousands):

	September 30, 2023	December 31, 2022
Balance, beginning of the period	\$ 2,126	\$ 1,760
Accrual for current year warranties	2,958	2,841
Warranty cost incurred	(2,302)	(2,475)
Balance, end of period	<u>\$ 2,782</u>	<u>\$ 2,126</u>

21. Net income (loss) attributable to common stockholders per share

The following table sets forth the computation of the Company's basic and diluted net income (loss) attributable to common stockholders per share for the three and nine months ended September 30, 2023 and 2022 (in thousands except share and per share data):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
<i>Numerator</i>				
Net income (loss)	\$ (6,456)	\$ 1,626	\$ (17,651)	\$ (1,234)
Less: noncontrolling interests	—	40	—	281
Net income (loss) attributable to common stockholders, basic and diluted	<u>\$ (6,456)</u>	<u>\$ 1,666</u>	<u>\$ (17,651)</u>	<u>\$ (953)</u>
<i>Denominator</i>				
Weighted-average common shares outstanding, attributable to common stockholders, basic	136,173,278	134,711,701	135,862,905	134,342,059
Effect of employee stock plans	-	3,997,634	-	-
Weighted-average common shares outstanding, attributable to common stockholders, diluted	<u>136,173,278</u>	<u>138,709,335</u>	<u>135,862,905</u>	<u>134,342,059</u>
Net income (loss) attributable to common stockholders per share, basic	<u>\$ (0.05)</u>	<u>\$ 0.01</u>	<u>\$ (0.13)</u>	<u>\$ (0.01)</u>
Net income (loss) attributable to common stockholders per share, diluted	<u>\$ (0.05)</u>	<u>\$ 0.01</u>	<u>\$ (0.13)</u>	<u>\$ (0.01)</u>

Stock-based compensation awards of approximately 7.2 million and 6.2 million shares for the three and nine months ended September 30, 2023, respectively, and 3.5 million and 4.1 million shares for the three and nine months ended September 30, 2022 respectively, were outstanding but were not included in the computation of diluted net loss per share attributable to common stockholders because the effect of including such shares would have been anti-dilutive in the periods presented.

22. Geographic areas

The Company sells its products worldwide and attributes revenue to the geography where the product is delivered. The geographical distribution of revenue for the three and nine months ended September 30, 2023 and 2022 was as follows (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
United States	\$ 26,789	\$ 22,811	\$ 74,948	\$ 67,896
EMEA	12,922	10,301	33,469	27,823
APAC	6,757	7,153	22,073	18,306
Other	1,532	212	4,292	1,675
Total revenue, net	\$ 48,000	\$ 40,477	\$ 134,782	\$ 115,700

EMEA includes Europe, the Middle East and Africa; APAC includes Asia and the Pacific countries; Other includes Canada and Latin America.

For the three and nine months ended September 30, 2023 and 2022, the Company had no major customers.

As of September 30, 2023 and December 31, 2022, the Company's long-lived assets by geographic area were as follows (in thousands):

	September 30, 2023	December 31, 2022
United States	\$ 9,287	\$ 6,426
APAC	8,128	7,256
Total	\$ 17,415	\$ 13,682

As of September 30, 2023 and December 31, 2022, substantially all of the Company's long-lived assets were located in the United States and in Wuxi, China.

23. Related party transactions

On May 7, 2022, the Company's wholly-owned Hong Kong subsidiary ("Cytek HK") completed an investment of \$1.6 million in Tianjin Deep Analysis Intelligent Technology Development Co., Ltd, a company incorporated under the laws of the People's Republic of China ("DeepCyto") in consideration for the issuance of Series A preferred shares of DeepCyto, representing an ownership interest of approximately 3.3%. At the time of the investment, an entity affiliated with Northern Light Venture Capital ("NLVC") had a significant ownership interest in DeepCyto and a representative serving on the DeepCyto board of directors. The founding managing partner of NLVC served as a member of the Company's board of directors until June 1, 2022.

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 in conjunction with our unaudited interim consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2022 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 1, 2023. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us" and "our" refer to Cytek Biosciences, Inc.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of 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"), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Overview

We are a leading cell analysis solutions company advancing the next generation of cell analysis tools by leveraging novel technical approaches. Our goal is to become the premier cell analysis company through continued innovation that facilitates scientific advances in biomedical research and clinical applications. We believe our core instruments, the Aurora and Northern Lights systems, are the first full spectrum flow cytometers able to deliver high-resolution, high-content and high-sensitivity cell analysis by utilizing the full spectrum of fluorescence signatures from multiple lasers to distinguish fluorescent tags on single cells ("Full Spectrum Profiling" or "FSP"). Our novel approach harnesses the power of information within the entire spectrum of a fluorescent signal to achieve a higher level of multiplexing with exquisite sensitivity. Our patented FSP technology optimizes sensitivity and accuracy through its novel optical and electronic designs that utilize an innovative method of light detection and distribution. Our FSP platform includes instruments, reagents, software and services to provide a comprehensive and integrated suite of solutions for our customers. Since our first U.S. commercial launch in mid-2017, we have sold and deployed over 1,997 organic Cytek instruments—primarily comprised of our Aurora and Northern Lights systems—to customers around the world, including the largest pharmaceutical companies, over 200 biopharma companies, leading academic research centers, and clinical research organizations ("CROs"). In June 2021, we began shipping the Aurora cell sorter ("Aurora CS"), which uses our FSP technology to further broaden our potential applications across cell analysis.

On February 28, 2023, we completed the acquisition of the flow cytometry and imaging ("FCI") business unit of Luminex Corporation ("Luminex"), including relating to the business of manufacturing, marketing, selling, servicing and maintaining Amnis and Guava branded instruments, and flow cytometry reagent products and services.

We manufacture our instruments in our facilities in Fremont, California, Seattle, Washington and Wuxi, China. We have designed our operating model to be capital efficient and to scale efficiently as our product volumes grow.

Total revenue for the three and nine months ended September 30, 2023 was \$48.0 million and \$134.8 million, respectively, representing a 19% and 16% increase compared to revenue for the three and nine months ended September 30, 2022 of \$40.5 million and \$115.7 million respectively. Total revenue for the three months ended September 30, 2023 included \$6.8 million of revenue from the FCI business unit. Excluding revenue from the FCI business unit for the three months ended September 30, 2023, organic revenue was \$41.2 million, a 2% increase compared to the same period of the prior year. The 2% increase in organic revenue was primarily related to sales to pharmaceutical and biotech customers in the United States, and revenue growth in EMEA.

To date, we have adopted a direct sales model in North America, Europe, China, and several other countries in the Asia-Pacific region, and also sell our products through third-party distributors in certain countries in China, Europe,

Latin America, the Middle East, Africa and the Asia-Pacific region. Revenue from direct sales represented 77% and 74% of total revenue for the three and nine months ended September 30, 2023 and 75% and 82% total revenue for the three and nine months ended September 30, 2022, respectively, and revenue from distributors represented 23% and 26% of total revenue for the three and nine months ended September 30, 2023 and revenue from distributors represented 25% and 18% of total revenue for the three and nine months ended September 30, 2022. If our sales in region outside United States increase, we expect revenue from our distribution channel to increase.

We focus a substantial portion of our resources on developing new products and solutions to meet our customers' needs. Our research and development efforts focus on developing new and complementary instruments, reagents and reagent kits, and continued operating software development. We incurred research and development expenses of \$11.2 million and \$33.3 million for the three and nine months ended September 30, 2023, respectively, and \$8.7 million and \$25.1 million for the three and nine months ended September 30, 2022, respectively. We intend to continue to make significant investments in research and development in the future.

We expect to continue to invest in our commercial infrastructure through hiring additional employees with strong scientific and technical backgrounds to support growth in sales of our instruments as well as our planned expansion of reagents offerings and panel design capabilities. We also plan to continue to invest in sales, marketing and business development across the globe to drive commercialization of our products. We incurred sales and marketing expenses of \$12.1 million and \$37.6 million for the three and nine months ended September 30, 2023, respectively, and \$8.8 million and \$24.2 million for the three and nine months ended September 30, 2022, respectively.

Since our inception in 2014, we have financed our operations primarily through sales of our securities and revenue from the sale of our products and services.

Our net loss was \$6.5 million and \$17.7 million for the three and nine months ended September 30, 2023, respectively, and net income was \$1.6 million and net loss of \$1.2 million for the three and nine months ended September 30, 2022, respectively. The change for the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 resulted primarily from expenses driven by an increase in headcount and salaries and efforts in research and development and marketing initiatives.

We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- attract, hire and retain qualified personnel;
- invest in processes, commercial infrastructure and supporting functions to scale our business and introduce new products and services;
- support our research and development efforts;
- continue to expand geographically;
- protect and defend our intellectual property; and
- make strategic investments in complementary businesses, services, products or technologies.

Key factors affecting our results of operations and future 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 to sustain our growth and improve our results of operations. Our ability to successfully address these challenges is subject to various risk and uncertainties, including those described under the heading "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q.

Global customer adoption

Our financial performance has largely been driven by our ability to increase the adoption of our FSP platform, a key factor on which our future success depends. We plan to drive global customer adoption through business development efforts, direct sales and marketing and third-party distributions. We are investing in our direct sales organization and commercial support functions and developing third-party distributor relationships to support global expansion and drive revenue growth. We intend to continue increasing our workforce in line with our growth.

Recurring revenues

We believe our expanding installed base of instruments to new and existing customers will provide us with greater leverage to drive pull-through for reagent and service revenue, which are recurring by nature. Furthermore, as we develop and identify new applications and products, we expect to further increase pull-through across our installed base.

We expect recurring revenue on an absolute basis to increase and become an increasingly important contributor to our revenue as our installed base expands.

Revenue mix and gross margin

Our revenue is primarily derived from sales of our instruments and services with our instruments recognizing higher gross margins than our services. Although we expect sales of our instruments to continue to represent the largest percentage of our revenue in the future, we expect reagent sales to increase as a percentage of our total revenue and our gross margins to experience a corresponding improvement as we grow our installed base and increase our focus on commercializing reagents. We also expect a higher gross margin on our instruments as we increase manufacturing efficiency, instrument reliability and training for personnel using our instruments, which we expect to lead to a reduction in warranty claims. Our sales in certain regions, particularly outside of the United States, are realized through third-party distribution partners that typically receive discounted prices, thus resulting in lower gross margins than those recognized by our direct sales organization. Furthermore, our gross margins and instrument selling prices may fluctuate in the future as we continue to grow our volume of third-party distribution partners in geographies outside of the United States, introduce new products and reduce our production costs as a result of variability in the timing of new product introductions.

In the near term, we expect the continued optimization of our manufacturing processes related to our instruments and the expansion of product manufacturing distribution facilities to have the greatest impact on our gross margin. In addition to the impact of competing products entering the market, the future gross margin profiles of our instruments, services and reagents will depend on the outcome of any royalties we are required to pay and the royalty rates and products to which such royalties apply.

Expansion into new markets

We focus our research and development efforts on the greatest value-additive products to meet the growing and unmet needs of the research and clinical markets. We work closely with researchers, clinicians and scientists to optimize and implement new panels and applications to meet their specific needs. We also gain valuable insight on potential new products, new applications and enhancements to existing products, as well as biomarker combinations that would be beneficial in different fields, through collaborations with our customers, academic laboratories, KOLs and industry partners. We plan to continue to invest in new product development and enhancements to support our expansion into new markets.

The Northern Lights CLC system was certified under the European Union In Vitro Diagnostic Medical Devices Directive in September 2020 and is registered as an in vitro diagnostic medical device under Northern Lights Clinical Flow Cytometer. The certification enables the Northern Lights CLC system to be sold into in vitro diagnostic laboratories in the European Union and in other countries around the world that accept this specific certification. The Northern Lights CLC system is also certified for in vitro diagnostic use as a Class II device in China.

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 will change or may be substituted for additional or different metrics as our business grows.

	Three months ended September 30,			Nine months ended September 30,		
	2023	2022	Dollar Change	2023	2022	Dollar Change
(In thousands)						
Sales channel mix						
Direct sales channel	\$ 36,916	\$ 30,204	\$ 6,712	\$ 100,223	\$ 94,725	\$ 5,498
Distributor channel	11,084	10,273	811	34,559	20,975	13,584
Total revenue, net	\$ 48,000	\$ 40,477	\$ 7,523	\$ 134,782	\$ 115,700	\$ 19,082
Customer mix						
Academia and government	\$ 20,118	\$ 18,983	\$ 1,135	\$ 55,721	\$ 48,796	\$ 6,925
Biotechnology, pharmaceutical, distributor and CRO	27,882	21,494	6,388	79,061	66,904	12,157
Total revenue, net	\$ 48,000	\$ 40,477	\$ 7,523	\$ 134,782	\$ 115,700	\$ 19,082

Distributors typically sell to end customers identified in other customer categories.

Known Trends, Events and Uncertainties

The recent trends towards rising inflation may adversely affect our business and corresponding financial position and cash flows. Inflationary factors, such as increases in the cost of materials and supplies, interest rates and overhead costs may adversely affect our operating results. The general consensus among economists suggests that we should expect a higher recession risk to continue over the next year, which could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience increases in the near future (especially if inflation rates continue to rise) on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with COVID-19 or future public health crises, the ongoing conflict between Russia and Ukraine, the Israel and Palestine conflict or liquidity concerns at, and failure of, banks and other financial institutions.

Many of our pharmaceutical and biotech customers based in the United States have been impacted by macro-economic uncertainties related to the weakening economy, liquidity concerns in the broader financial services industry, such as those caused by recent banking failures, disruptions to and volatility in the credit and equity markets, and rising interest rates. We believe these factors contributed to longer sales cycles, which adversely impacted our operating results for the three months ended September 30, 2023, and may adversely affect our operating results in the future.

Components of our results of operations

Total revenue, net

We currently generate our total revenue, net from product revenue and service revenue.

Product. Our product revenue primarily consists of sales of our instruments, including the Aurora, Northern Lights, Aurora CS, Amnis and Guava systems, instrument accessories, such as loaders, and consumables, such as reagents. We offer multiple versions of our FSP systems with different price points based on the number of lasers integrated in the systems. We also derive revenue from sales of our conventional flow cytometry system, which is available for sale in China. We recognize product revenue when control of the instrument is transferred to the customer.

Service. Our service revenue primarily consists of post-warranty service contracts, installations and repairs which are recognized over time. Post-warranty service contracts are recognized ratably over the term of the contract and installations and repair services are recognized as they are delivered to the customer.

We expect our revenue to increase in absolute dollars as we expand our sales organization and sales territories, broaden our customer base, and expand awareness of our products with new and existing customers. Our revenue was \$48.0 million and \$134.8 million for the three and nine months ended September 30, 2023, respectively, and \$40.5 million and \$115.7 million for the three and nine months ended September 30, 2022, respectively. A portion of our revenue for the three and nine months ended September 30, 2023 is attributable to the acquired FCI business unit.

Total cost of sales, gross profit and gross margin

Our total cost of sales is comprised of product cost of sales and service cost of sales.

Product. Cost of sales associated with our products primarily consist of manufacturing-related costs incurred in the production process, inventory write-downs, warranty costs, third party royalty costs, personnel and related costs, costs of component materials, overhead, packaging and delivery and depreciation expense.

Service. Cost of sales associated with our services primarily consists of personnel and related costs, expenses related to product replacements, product updates and qualification validation of our products and depreciation expense.

We expect our total cost of sales to increase in absolute dollars in future periods, corresponding to our anticipated growth in revenue and employee headcount to support our manufacturing, operations, field service team and support organizations.

Gross profit is calculated as revenue less total cost of sales. Gross margin is gross profit expressed as a percentage of revenue. Our gross profit in future periods will depend on a variety of factors, including market conditions that may impact our pricing, sales mix changes among our instruments and service agreements, product mix changes between established products and new products, excess and obsolete inventories, our cost structure for manufacturing operations relative to volume and product warranty obligations.

Operating expenses

Our operating expenses are primarily comprised of research and development, sales and marketing, and general and administrative expenses, depreciation and amortization, and related overhead.

Research and development. Our research and development expenses primarily consist of salaries, benefits, stock-based compensation costs for employees in our research and development department, independent contractor costs, laboratory supplies, equipment maintenance and materials expenses.

We plan to continue to invest in our research and development efforts, including hiring additional employees to enhance existing products and develop new products. We expect research and development expense will increase in absolute dollars in future periods and vary from period to period as a percentage of revenue due to our continuing investment in product development.

Sales and marketing. Our sales and marketing expenses consist primarily of salaries, benefits, and stock-based compensation costs for employees in our sales and marketing department, sales commissions, marketing material costs, travel expenses and costs related to trade shows, trainings and various workshops. We expect our sales and marketing expense to increase in absolute dollars as we expand our commercial sales, marketing, and business development teams, increase our presence globally and increase marketing activities to drive awareness and adoption of our platform. While these expenses may vary from period to period as a percentage of revenue, we expect these expenses to increase as a percentage of sales in the short-term as we continue to grow our commercial organization to support anticipated growth of the business.

General and administrative. Our general and administrative expenses primarily consist of salaries, benefits, and stock-based compensation costs for employees in our executive, accounting and finance, legal and human resource functions, as well as professional services fees, such as consulting, audit, tax, legal, general corporate costs and allocated overhead expenses. We expect our operating expenses to increase as a public company. In particular, we expect our accounting, legal, personnel-related expenses and directors' and officers' insurance costs reported within general and administrative expense to increase as we establish more comprehensive compliance and governance functions, maintain IT costs, review internal controls over financial reporting in accordance with the Sarbanes-Oxley Act and prepare and distribute periodic reports as required by the rules and regulations of the SEC. As a result, our historical results of operations may not be indicative of our results of operations in future periods.

We expect these expenses to vary from period to period as a percentage of revenue.

Other income (expense), net

Interest expense. Interest expense consists primarily of accretion of the present value of the litigation settlement liability. See Note 11 to our unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further details regarding the settlement.

Interest income. Our interest income consists primarily of interest earned on our cash and cash equivalents which are invested in cash deposits and in money market funds.

Other income (expense), net. Our other income (expense), net consists primarily of foreign exchange gains and losses.

Income taxes

Our provision for (benefit from) income taxes consists primarily of provision for federal taxes and local taxes in the United States as well as foreign taxes. As we plan to expand the scale and scope of our international business activities, any changes in the United States and foreign taxation of such activities may increase our overall provision for income taxes in the future.

Results of operations

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

The results of operations presented below should be reviewed in conjunction with the unaudited interim consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

The following table sets forth our consolidated results of operations and comprehensive income (loss) data for the periods presented:

(In thousands)	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Revenue, net:				
Product	\$ 38,441	\$ 36,389	\$ 110,065	\$ 104,963
Service	9,559	4,088	24,717	10,737
Total revenue, net	48,000	40,477	134,782	115,700
Cost of sales:				
Product	16,205	10,606	45,557	34,153
Service	4,617	3,009	12,847	9,947
Total cost of sales	20,822	13,615	58,404	44,100
Gross profit	27,178	26,862	76,378	71,600
Operating expenses:				
Research and development	11,171	8,650	33,282	25,111
Sales and marketing	12,076	8,810	37,587	24,201
General and administrative	10,351	8,042	33,217	24,176
Total operating expenses	33,598	25,502	104,086	73,488
Income (loss) from operations	(6,420)	1,360	(27,708)	(1,888)
Other income (expense):				
Interest expense	(595)	(649)	(1,677)	(1,886)
Interest income	1,622	1,584	4,965	1,993
Other income (expense), net	1,208	(445)	4,600	(1,073)
Income (loss) before income taxes	(4,185)	1,850	(19,820)	(2,854)
Provision for (benefit from) income taxes	2,271	224	(2,169)	(1,620)
Net income (loss)	(6,456)	1,626	(17,651)	(1,234)
Foreign currency translation adjustment, net of tax	165	(758)	(856)	(1,427)
Unrealized gain (loss) on marketable securities	15	-	(26)	-
Net comprehensive income (loss)	\$ (6,276)	\$ 868	\$ (18,533)	\$ (2,661)

Total revenue, net

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Revenue, net								
Product	\$ 38,441	\$ 36,389	\$ 2,052	6 %	\$ 110,065	\$ 104,963	\$ 5,102	5 %
Service	9,559	4,088	5,471	134 %	24,717	10,737	13,980	130 %
Total revenue, net	\$ 48,000	\$ 40,477	\$ 7,523	19 %	\$ 134,782	\$ 115,700	\$ 19,082	16 %

Total revenue, net increased by \$7.5 million to \$48.0 million, or 19%, and \$19.1 million to \$134.8 million, or 16%, for the three and nine months ended September 30, 2023 as compared to the three and nine months ended September 30, 2022, respectively.

Product revenue increased by \$2.1 million to \$38.4 million, or 6%, and \$5.1 million to \$110.1 million, or 5%, for the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022 due to an increase of new product sales.

Service revenue increased \$5.5 million to \$9.6 million, or 134%, and \$14.0 million to \$24.7 million, or 130%, for the three and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022. The increase was primarily due to instruments coming off warranty.

Revenue from the acquired FCI business was \$6.8 million for the three months ended September 30, 2023 and \$18.8 million for the nine months ended September 30, 2023, driven by product sales.

Total cost of sales, gross profit and gross margin

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Cost of sales:								
Product	\$ 16,205	\$ 10,606	\$ 5,599	53 %	\$ 45,557	\$ 34,153	\$ 11,404	33 %
Service	4,617	3,009	1,608	53 %	12,847	9,947	2,900	29 %
Total cost of sales	\$ 20,822	\$ 13,615	\$ 7,207	53 %	\$ 58,404	\$ 44,100	\$ 14,304	32 %
Gross profit	\$ 27,178	\$ 26,862			\$ 76,378	\$ 71,600		
Gross margin	57 %	66 %			57 %	62 %		

Total cost of sales increased by \$7.2 million, or 53%, for the three months ended September 30, 2023 as compared to the three months ended September 30, 2022, and increased by \$14.3 million, or 32%, for the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022. The increase in cost of sales was driven by increases in product and service revenue, primarily due to higher material costs and unfavorable product mix

for the three and nine months ended September 30, 2023 as compared to the three and nine months ended September 30, 2022.

Total gross profit margin was 57% and 66% as a percent of total revenue for the three months ended September 30, 2023 and 2022, respectively, and 57% and 62% for the nine months ended September 30, 2023 and 2022, respectively. Gross profit margin depends on many factors, including market conditions that might affect our pricing; services; product mix changes between instrument configurations; excess and obsolete inventories; our cost structure for manufacturing operations relative to volume, freight costs and product support.

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Product:								
Revenue	\$ 38,441	\$ 36,389	\$ 2,052	6 %	\$ 110,065	\$ 104,963	\$ 5,102	5 %
Cost of sales	16,205	10,606	5,599	53 %	45,557	34,153	11,404	33 %
Product gross profit	\$ 22,236	\$ 25,783	\$ (3,547)	-14 %	\$ 64,508	\$ 70,810	\$ (6,302)	-9 %
Gross margin	58 %	71 %			59 %	67 %		
Service:								
Revenue	\$ 9,559	\$ 4,088	\$ 5,471	134 %	\$ 24,717	\$ 10,737	\$ 13,980	130 %
Cost of sales	4,617	3,009	1,608	53 %	12,847	9,947	2,900	29 %
Service gross profit (loss)	\$ 4,942	\$ 1,079	\$ 3,863	358 %	\$ 11,870	\$ 790	\$ 11,080	1402 %
Gross margin	52 %	26 %			48 %	7 %		

Product revenue for three and nine months ended September 30, 2023 increased by 6% and increased by 5% respectively, as compared to the three and nine months ended September 30, 2022. Product cost of sales for the three and nine months ended September 30, 2023 increased by 53% and 33%, respectively, as compared to the same period in 2022. Product gross profit for the three and nine months ended September 30, 2023 decreased 14% and decreased by 9%, respectively, as compared to the three and nine months ended September 30, 2022. The lower product gross profit margins in the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 were driven primarily by higher material costs and by less favorable instrument product mix following the FCI acquisition.

Service revenue for the three and nine months ended September 30, 2023 increased 134% and 130%, respectively, as compared to the three and nine months ended September 30, 2022. Service cost of sales for the three and nine months ended September 30, 2023 increased by 53% and 29% as compared to the same period in 2022. Service gross profit for the three and nine months ended September 30, 2023 increased 358% and 1402%, respectively, as compared to the three and nine months ended September 30, 2022. The higher service gross margins in the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022 were mainly driven by continued growth in the instruments installed base with more instruments coming off warranty and the addition of the FCI acquisition.

Operating expenses

Research and development

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
	Research and development	\$ 11,171	\$ 8,650	\$ 2,521	29 %	\$ 33,282	\$ 25,111	\$ 8,171

Research and development expenses were \$11.2 million for the three months ended September 30, 2023 as compared to \$8.7 million for the three months ended September 30, 2022. The increase of \$2.5 million in research and development expenses was primarily due to an increase in headcount and personnel-related expenses of \$2.4 million, including stock-based compensation and other payroll costs. This was primarily due to increased headcount from the Luminex acquisition.

Research and development expenses were \$33.3 million for the nine months ended September 30, 2023 as compared to \$25.1 million for the nine months ended September 30, 2022. The increase of \$8.2 million in research and development expenses was primarily due to an increase in headcount and personnel-related expenses of \$7.8 million, including stock-based compensation and other payroll costs. This was primarily due to increased headcount from the Luminex acquisition.

The increase in research and development expenses for the three and nine months ended September 30, 2023 was primarily driven by costs relating to the FCI business. We expect our research and development expense to increase in absolute dollars as we continue to develop new products and enhance existing instruments and technologies.

Sales and marketing

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
	Sales and marketing	\$ 12,076	\$ 8,810	\$ 3,266	37 %	\$ 37,587	\$ 24,201	\$ 13,386

Sales and marketing expenses were \$12.1 million for the three months ended September 30, 2023 as compared to \$8.8 million for the three months ended September 30, 2022. The increase of \$3.3 million in sales and marketing expenses was primarily due to an increase in headcount and personnel-related expenses of \$2.4 million, including stock-based compensation and other payroll costs, and increase in trade shows and other sales and marketing costs of \$0.6 million, and an increase in fixed assets and intangible asset amortization costs of \$0.6 million. This was primarily due to increased headcount from the Luminex acquisition.

Sales and marketing expenses were \$37.6 million for the nine months ended September 30, 2023 as compared to \$24.2 million for the nine months ended September 30, 2022. The increase of \$13.4 million in sales and marketing expenses was primarily due to an increase in headcount and personnel-related expenses of \$9.7 million, including stock-based compensation and other payroll costs, and increase in trade shows and other sales and marketing costs of \$1.5 million, and an increase in depreciation and amortization costs of \$1.2 million. This was primarily due to increased headcount from the Luminex acquisition.

We expect our sales and marketing expenses to increase in absolute dollars as we hire additional sales and marketing personnel, expand our sales support infrastructure and invest in our brand and product awareness to further penetrate the United States and the international markets.

General and administrative

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
	General and administrative	\$ 10,351	\$ 8,042	\$ 2,309	29 %	\$ 33,217	\$ 24,176	\$ 9,041

General and administrative expenses were \$10.4 million for the three months ended September 30, 2023 as compared to \$8.0 million for the three months ended September 30, 2022. The increase of \$2.3 million in general and administrative expenses was primarily due to an increase in general corporate personnel-related costs of \$1.6 million,

including stock-based compensation and other payroll costs, and other outside service increase of \$0.7 million. This was primarily due to increased headcount from the Luminex acquisition.

General and administrative expenses were \$33.2 million for the nine months ended September 30, 2023 as compared to \$24.2 million for the nine months ended September 30, 2022. The increase of \$9.0 million in general and administrative expenses was primarily due to an increase in legal and other professional service fees of \$2.3 million, which includes \$1.5 million related to the FCI acquisition in February 2023, increase in general corporate personnel-related costs of \$5.4 million, including stock-based compensation and other payroll costs to support the growth of our overall operations. This was primarily due to increased headcount from the Luminex acquisition.

We expect to continue to incur additional general and administrative expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and the Nasdaq Stock Market, additional insurance costs, investor relations activities and other administrative and professional services. As a result, we expect general and administrative expenses to increase in absolute dollars in future periods.

Interest expense

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Interest expense	\$ (595)	\$ (649)	\$ 54	-8 %	\$ (1,677)	\$ (1,886)	\$ 209	-11 %

Interest expense was \$0.6 million and \$1.7 million for the three and nine months ended September 30, 2023, respectively, as compared to \$0.6 million and \$1.9 million for the three and nine months ended September 30, 2022, respectively. The decrease during the three and nine months ended September 30, 2023 as compared to 2022 was mainly due to the accretion of the present value discount related to the settlement agreement with Becton, Dickinson and Company (“BD”). See Note 11 to our unaudited interim consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for further details.

Interest income

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Interest income	\$ 1,622	\$ 1,584	\$ 38	2 %	\$ 4,965	\$ 1,993	\$ 2,972	149 %

Interest income was \$1.6 million and \$5.0 million for the three and nine months ended September 30, 2023, respectively, as compared to \$1.6 million and \$2.0 million for the three and nine months ended September 30, 2022, respectively. The increase in interest income was the result of higher interest earned on our cash and cash equivalents and short term investment due to an increase in interest rates as compared to 2022.

Other income (expense), net

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Other income (expense), net	\$ 1,208	\$ (445)	\$ 1,653	-371 %	\$ 4,600	\$ (1,073)	\$ 5,673	-529 %

Other income, net was \$1.2 million and \$4.6 million for the three and nine months ended September 30, 2023, respectively, as compared to other expense, net of \$0.4 million of expenses and \$1.1 million of expenses for the three and nine months ended September 30, 2022, respectively. The income was primarily from the short-term investment.

Income Taxes

(In thousands, except percentages)	Three months ended September 30,		Change		Nine months ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Provision for (benefit from) income taxes	\$ 2,271	\$ 224	\$ 2,047	914 %	\$ (2,169)	\$ (1,620)	\$ (549)	34 %

Provision for income taxes was \$2.3 million and benefit from income taxes was \$2.2 million for the three and nine months ended September 30, 2023, respectively, as compared to the provision for income taxes of \$0.2 million and benefit from income tax of \$1.6 million for the three and nine months ended September 30, 2022, respectively. The net change of provision of \$2.0 million for the three months ended September 30, 2023 was primarily a result of more taxable income in the current quarter. The net benefit of \$0.5 million for the nine months ended September 30, 2023 includes the third quarter tax increase offset by previous quarter tax benefit.

Non-GAAP Financial Measure

To supplement our unaudited interim consolidated financial statements presented in accordance with generally accepted accounting principles, we use constant currency revenue, which is a non-GAAP financial measure. We believe the presentation of revenue on a constant currency basis, in addition to results reported in accordance with U.S. GAAP, provides useful information about our operating performance because the constant currency presentation excludes the effects of foreign currency volatility and highlights our core operating results. The presentation of revenue on a constant currency basis should be considered in addition to, but not as a substitute for, measures of financial performance reported in accordance with U.S. GAAP. Revenue on a constant currency basis, as we present it, may not be comparable to similarly titled measures used by other companies.

The FX Impact is calculated as the difference between the current year amounts and the current year amounts translated at prior period average exchange rates. The FX Impact % represents the percentage change on a period-over-period basis adjusted for foreign currency impacts.

The following table presents a reconciliation of constant currency revenue to our reported net revenue for the periods indicated (in thousands, except percentages):

Revenue	Three months ended September 30, 2023	Three months ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
As reported	\$ 48,000	\$ 40,477	\$ 134,782	\$ 115,700
Non-GAAP constant currency	47,703	40,501	135,903	117,647
FX Impact [\$]	\$ (297)	\$ 24	\$ 1,121	\$ 1,947
FX Impact [%]	(0.6 %)	0.1 %	(0.8 %)	(1.7 %)

Liquidity and capital resources

Overview

To date, our primary sources of capital have been through sales of our securities and revenue from the sale of our products and services. As of September 30, 2023 and December 31, 2022, we had approximately \$288.0 million and \$344.0 million, respectively, in cash and cash equivalents and short term investments, which were primarily held in U.S. short-term bank deposit accounts, money market funds, U.S. Treasury notes, Federal agency security notes, and short term commercial paper.

Funding and material cash requirements

We anticipate continuing to expend significant amounts of cash in the foreseeable future as we continue to invest in research and development of our product offerings, commercialization of new products and services, and expansion into new markets. Our future capital requirements will depend on many factors including our revenue, research and development efforts, the timing and extent of additional capital expenditures to invest in existing and new facilities, as well as our manufacturing operations, the expansion of sales and marketing and the introduction of new products. We have entered into, and may in the future enter into, arrangements to acquire or invest in businesses, services and technologies, and any such acquisitions or investments could significantly increase our capital needs.

We currently anticipate making additional capital expenditures during the next 12 months, which is expected to primarily include equipment to be used for manufacturing and investment in research and development, as well as spend associated with the expansion of our facilities in Wuxi, China.

In addition, we lease certain office facilities under operating lease arrangements that expire on various dates through fiscal year 2027. Under the terms of the leases, we are responsible for certain expenses related to operations,

maintenance, repairs and management fees. Future minimum lease payments under non-cancelable operating leases totaled \$13.9 million as of September 30, 2023.

Based on our current business plan, we believe our existing cash and cash equivalents and anticipated cash flows from operations will be sufficient to meet our working capital and capital expenditure needs for at least the next 12 months from the date of this Quarterly Report on Form 10-Q.

Sources of liquidity

We have financed our operations primarily through sales of our securities. In July 2021, we completed our IPO, which resulted in net proceeds to us of approximately \$215.7 million. We have also benefited from operating cash flows from the sale of our products and services.

On August 26, 2022, we entered into a sales agreement (the “Sales Agreement”) with Piper Sandler & Co. (“Piper”) as sales agent to sell from time to time up to \$150 million of our common stock through an “at the market” offering program. To date, we have not made any sales of common stock pursuant to the Sales Agreement. The securities in this transaction were offered pursuant to an automatic shelf registration statement on Form S-3ASR (File No. 333-267118) that was filed with the SEC on August 26, 2022.

Cash flows

The following table summarizes our cash flows for the periods presented:

(In thousands)	Nine months ended September 30,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (4,231)	\$ (18,424)
Investing activities	(122,960)	(4,845)
Financing activities	(8,058)	1,663
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(622)	(1,489)
Net decrease in cash, cash equivalents and restricted cash	\$ (135,871)	\$ (23,095)

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2023 was \$4.2 million including net loss of \$17.7 million. We also incurred gain on investments, accretion and amortization, non-cash provision for excess and obsolete inventory, stock-based compensation expense, depreciation and amortization, amortization of right-of-use assets, and interest expenses for accretion of the legal settlement liabilities of \$5.3 million, \$0.8 million, \$16.4 million, \$4.4 million, \$2.4 million, and \$1.3 million, respectively. Usage of cash included a decrease in lease liability of \$2.2 million, an increase of inventories of \$2.0 million and an increase in legal settlement liability of \$0.4 million. Additionally, there was an increase of trade accounts receivable of \$7.6 million, an increase in prepaid expenses and other assets of \$2.3 million, an increase in accrued expenses and other liabilities of \$0.6 million, an increase in deferred revenue of \$7.2 million and an increase of trade accounts payables of \$0.01 million.

Net cash used in operating activities for the nine months ended September 30, 2022 was \$18.4 million. Net loss was \$1.2 million; we also incurred non-cash stock-based compensation expense, depreciation and amortization, amortization of right-of-use assets, and interest expenses for accretion of the legal settlement liabilities of \$12.1 million, \$1.7 million, \$2.1 million, and \$1.6 million, respectively. Usage of cash included an increase of inventories of \$19.5 million, an increase of trade accounts receivable of \$11.8 million due to an increase in sales, and a decrease in prepaid expenses and other assets of \$15.0 million. This was partially offset by an increase of trade accounts payables of \$2.8 million, an increase in deferred revenue of \$6.5 million, an increase in accrued expenses and other liabilities of \$2.8 million and an increase in the legal settlement liability of \$0.5 million.

Investing activities

Net cash used in investing activities during the nine months ended September 30, 2023 was \$123.0 million driven by purchase of property and equipment of \$3.1 million, proceeds from maturities of marketable securities of \$78.0 million, additional purchase of marketable securities of \$152.6 million and purchases of business of \$44.9 million, purchases of patents of \$0.1 million, and payment of additional investments in Cytek Japan of \$0.2 million.

Net cash used in investing activities during the nine months ended September 30, 2022 was \$4.8 million driven by purchases of property and equipment of \$3.2 million, purchase of patents \$0.04 million and payment of investments of \$1.6 million.

Financing activities

Net cash used in financing activities during the nine months ended September 30, 2023 was \$8.1 million driven by the issuance of our common stock under our equity incentive plans of \$1.1 million, offset by repayment of loan of \$0.4 million, payments for taxes related to net share settlement of equity awards of \$0.3 million and \$9.4 million costs related to the repurchase of our shares.

Net cash provided by financing activities during the nine months ended September 30, 2022 was \$1.7 million driven by issuance of our common stock under our equity incentive plans, as well as the shares issues related to purchase under the Employee Stock Purchase Plan, offset by taxes from net settlement of RSU release.

Contractual Obligations and Commitments

During the nine months ended September 30, 2023, there were no material changes to our contractual obligations and commitments from those described under “Management’s Discussion and Analysis of Financial Condition” which is contained in our 10-K and filed with the SEC on March 1, 2023.

Critical accounting policies, significant judgments and use of estimates

This management’s discussion and analysis of our financial condition and results of operations is based on our unaudited interim consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of our unaudited interim consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited interim consolidated financial statements and notes to the unaudited interim consolidated financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates are different assumptions and conditions. A summary of our critical accounting policies is presented in our audited financial statements and notes thereto as of and for the year ended December 31, 2022 included in our Annual Report on Form 10-K filed with the SEC on March 1, 2023. There were no material changes to our critical accounting policies during the nine months ended September 30, 2023.

Recently adopted accounting pronouncements

Information with respect to this item may be found in Note 2, *Basis of presentation and summary of significant accounting policies*, in our notes to unaudited interim consolidated financial statements included in Part I, Item 1, of this Quarterly Report on Form 10-Q, which information is incorporated herein by reference.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily the result of fluctuations in foreign currency exchange rates.

Interest rate risk

The market risk inherent in our financial instruments and in our financial condition represents the potential loss arising from adverse changes in interest rates or exchange rates. As of September 30, 2023, we had cash and cash equivalents of \$163.6 million, which consisted primarily of money market funds and bank deposits. The primary objective of our investment is to preserve principal and provide liquidity. These money market funds and bank deposits generate interest income at variable rates.

We therefore do not believe we are exposed to, nor do we anticipate being in the near future exposed to, material risk due to changes in interest rates because of the short-term nature of our cash and cash equivalents.

Foreign currency risk

Our revenue has been generated across the globe, mainly in the United States, Europe and Asia. Our foreign currency risk related to our revenue and operating expenses denominated in currencies other than the U.S. dollar, primarily the renminbi and the euro, causes both our revenue and our operating results to be impacted by fluctuations in the exchange rates.

As we expand our presence in international markets, our results of operations and cash flows may increasingly be subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. To date, we have not entered into any hedging arrangements intended to minimize the impact of these fluctuations in the exchange rates. As our international operations grow, we intend to continue to reassess our approach to manage our risk relating to fluctuations in currency rates.

We do not believe that either inflation or foreign currency risk had a material effect on our business, financial condition, or results of operations during the periods presented. See the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Non-GAAP Financial Measure” for a presentation of revenue on a constant currency basis, which provides information regarding our operating performance excluding the effects of foreign currency volatility.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as a result of the material weaknesses in our internal control, our disclosure controls and procedures were not effective as of September 30, 2023.

Material Weaknesses

In connection with our financial statement close process for the year ended December 31, 2022, we identified deficiencies in the control environment and control activities components of the Committee of Sponsoring Organizations (“COSO”) framework that constitute material weaknesses, either individually or in the aggregate.

- Control environment – Management did not maintain an effective control environment based on the criteria established in the COSO framework and identified deficiencies in the principles associated with the control environment of the COSO framework. Specifically, the Company does not have a sufficient number of qualified resources within our accounting and IT function with the appropriate level of technical accounting or other requisite knowledge to (1) timely identify and assess accounting implications of transactions and (2) perform assigned responsibilities and have appropriate accountability for the design and operation of internal control over financial reporting.
- Control activities – Management did not design and implement effective control activities based on the criteria established in the COSO framework and identified deficiencies in the principles associated with the control activities component of the COSO framework. Specifically, these related to: (i) selecting and developing control activities that contribute to the mitigation of risks and support achievement of objectives; (ii) selecting and developing general control activities over technology to support the achievement of objectives; and (iii) deploying control activities through policies that establish what is expected and procedures that put policies into action and relate to substantially all financial statement accounts and disclosures.

The following material weaknesses were contributing factors: (i) inadequate general information technology controls (GITCs) in the areas of access security and program change-management over certain information technology systems that support the Company’s financial reporting processes. Some of our business process controls (automated and manual) are dependent on the affected GITCs; they too were deemed ineffective because they could have been adversely impacted; and (ii) ineffective design and/or review procedures for journal entries and balance sheet account reconciliations.

Remediation Plan and Status

We are committed to remediating the control deficiencies that constituted the above material weaknesses by implementing changes to our internal control over financial reporting. Management has implemented, and continues to implement, measures designed to ensure that control deficiencies contributing to the material weaknesses are remediated, such that these controls are designed, implemented and operating effectively. During 2022 and the nine months ended September 30, 2023, we executed and will continue to execute the following steps intended to remediate the material weaknesses described above and strengthen our internal control over financial reporting:

- With support from external consultants, we will revise and improve the design of our controls, implement reviews and monitor the effectiveness of our system of internal controls, including GITCs.
- We will identify and assign qualified personnel to implement appropriate accountability for the design and operation of internal control over financial reporting and monitor the progress of remediation.
- We are committed to adding qualified personnel within our accounting and information technology functions.
- We will continue to revise and enhance the design of existing controls and implement new controls, update documentation, expand education and training, and strengthen supervisory reviews by our management.
- We strengthened, and will continue to strengthen, GITCs related to financial accounting and reporting systems including implementing monitoring controls as appropriate.
- We will continue to automate workflows and enhance oversight over the execution and review of manual journal entry controls and account reconciliations, and will continue to provide training for such enhanced oversight and review.

We plan to continue to devote significant time and attention to remediate the above material weaknesses as soon as reasonably practicable. As we continue to evaluate our controls, we will make the changes described above as well as any others needed to enhance our control environment and remediate the material weaknesses. We believe these actions will be sufficient to remediate the identified material weaknesses and strengthen our internal control over financial reporting; however, there can be no guarantee that such remediation will be sufficient. We will continue to evaluate the effectiveness of our controls and will make any further changes management determines appropriate.

Changes in Internal Control over Financial Reporting

We are taking actions to remediate the material weaknesses relating to our internal control over financial reporting. Other than the changes intended to remediate the material weaknesses noted above, there was no change in our internal control over financial reporting that occurred during the three months ended September 30, 2023 that materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II -- OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently engaged in any material pending legal proceedings. From time to time, we may be subject to legal proceedings and claims arising in the ordinary course of business.

ITEM 1A. Risk Factors

Our operations and financial results are subject to numerous risks and uncertainties, including those described below, which may have a material and adverse effect on our business, results of operations, cash flows, financial conditions, and the trading price of our common stock. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Quarterly Report on Form 10-Q. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects could be materially and adversely affected. You should not interpret our disclosure of any of the following risks to imply that such risks have not already materialized.

Summary Risk Factors

We may be unable for many reasons, including those that are beyond our control, to implement our business strategy successfully. Below is a summary of material factors that make an investment in our shares of common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, immediately follows this risk factor summary. The below risk factor summary is qualified in its entirety by that more complete discussion of such risks and uncertainties.

- We have a limited operating history and only recently launched our commercial products, which may make it difficult to evaluate the prospects for our future viability and predict our future performance. We have limited experience marketing and selling our products.
- We are highly dependent on a limited number of product offerings. Our revenue has been primarily generated from sales of our core Aurora and Northern Light systems, which require a substantial sales cycle and are prone to quarterly fluctuations in revenue. Our future success depends on our ability to develop and successfully introduce new and enhanced products that meet the needs of our customers.
- We rely on single source suppliers and, in some cases, sole source suppliers, for certain components and materials used in our systems and may not be able to find replacements or immediately transition to alternative suppliers, which could have an adverse effect on our business, financial condition and results of operations. On August 25, 2021, we and Cytek (Wuxi) Biosciences Co., Ltd, our China subsidiary (the “Subsidiary”), entered into a Supply Agreement (the “Coherent Agreement”) with Coherent NA, Inc. (“Coherent”). Pursuant to the Coherent Agreement, Coherent has agreed to sell and supply to us and the Subsidiary, on a non-exclusive basis, laser products manufactured by Coherent. Other than the Coherent Agreement, we do not currently have long-term supply contracts with our sole and single source suppliers of key components.
- Our results of operations will be harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.
- Our business is dependent on adoption of our products by academic and government institutions, clinical research organizations, pharmaceutical companies and clinical laboratories for their research and development activities focused on cell analysis. If academic and government institutions, clinical research organizations, pharmaceutical companies and clinical laboratories are unwilling to adopt our products, it will negatively affect our business, financial condition, prospects and results of operations.
- If we are unable to manufacture our products in high-quality commercial quantities successfully and consistently to meet demand, our growth will be limited.
- Our future success is dependent upon our ability to increase penetration in our existing markets and expand into adjacent markets. If we are unable to successfully expand our commercial operations, including hiring additional qualified sales representatives, technical applications specialists and customer support staff, our business may be adversely affected.
- We and our suppliers are subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements. Our products may become subject to more onerous regulation by the FDA or other regulatory agencies in the future, which could increase our costs and delay or prevent sales of our products or commercialization of new products and product enhancements.
- Concentration of ownership of our common stock among our executive officers, directors, principal stockholders and their respective affiliates may prevent new investors from influencing significant corporate decisions. Based on shares outstanding as of September 30, 2023, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates (based on filings with the SEC), in the aggregate, own approximately 39.6% of our common stock. These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval,

including the election and removal of directors and any merger or other significant corporate transaction.

- If we are unable to obtain and maintain patent or other intellectual property protection for any of our current or future products, or if the scope of the patent and other 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 current or future products may be harmed.
- Our business currently depends significantly on research and development spending by academic institutions and government-owned institutions, a reduction in which could limit demand for our solutions and adversely affect our business and operating results.
- International operations and expansion of our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- The market for cell analysis technologies and life sciences tools, including flow cytometry, is rapidly evolving and highly competitive. If we are unable to successfully develop new products, adapt to rapid and significant technological change, respond to introductions of new products by competitors, make strategic and operational decisions to prioritize certain markets, technology offerings or partnerships, and develop and capitalize on markets, technologies or partnerships, our business could suffer.
- If our products do not perform as expected, our operating results, reputation and business will suffer.
- We may acquire other businesses or form other joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.
- If we are unable to expand or leverage the number of peer-reviewed articles published using data generated by our products or otherwise increase brand awareness, the demand for our products and our business may be adversely affected.
- We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing our growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.
- We rely on distributors for sales of our products in certain geographies outside of the United States. If we are unable to secure additional distributors or maintain good relationships with our existing distributors, or if such distributors do not perform adequately or effectively, our business could suffer.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.
- We may need to raise additional capital to fund our existing operations, develop our products and/or expand our operations.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase the costs of our products and services, limit their use or adoption, and otherwise negatively affect our operating results and business.

Risks Related to Our Business and Strategy

We have a limited operating history and only recently launched our commercial products, which may make it difficult to evaluate the prospects for our future viability and predict our future performance. We have limited experience marketing and selling our products.

We have a limited operating history and may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown obstacles. We launched our first core commercial product, the Aurora system, in June 2017. Our limited commercial and operating history makes it difficult to evaluate our current business and predict our future performance. Although we have experienced significant revenue growth in recent periods, any assessment of our future revenue, profitability or prediction about our future success or viability is subject to significant uncertainty. We have encountered in the past, and will encounter in the future, risks and uncertainties frequently experienced by growing companies with limited operating histories in emerging and rapidly changing industries, including scaling up our infrastructure and headcount. If our assumptions regarding these risks and uncertainties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks successfully, our results of operations could differ materially from our expectations, and our business, financial condition and results of operations could be materially and adversely affected.

We are highly dependent on a limited number of product offerings. Our revenue has been primarily generated from sale of our core Aurora and Northern Lights systems, which require a substantial sales cycle and are prone to quarterly fluctuations in revenue.

Our Aurora system was commercially launched in June 2017, our Northern Lights system was commercially launched in October 2018 and our Aurora CS was first commercially shipped in June 2021. Sales of the Aurora, Northern Lights and Aurora CS systems together accounted for a substantial portion of our revenue for the periods presented. We expect that, for at least the foreseeable future, sales of our Aurora, Northern Lights and Aurora CS systems will continue to account for a substantial portion of our revenue. The sales cycle for our flow cytometer instruments is slow and can take up to six months or longer to complete. As a result of this lengthy and unpredictable sales cycle, we will be prone to quarterly fluctuations in our revenue as sales of the Aurora and Northern Lights systems are expected to continue to comprise a significant component of our revenue. Additionally, we experience seasonality in our business, with revenue in the fourth quarter typically being higher as a result of higher sales volume. Quarterly fluctuations may make it difficult for us to predict our future operating results. Consequently, comparisons of 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.

As a result of variability and unpredictability, we may also fail to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall short of the expectations of analysts or investors or any guidance we may provide, or if the guidance we provide falls short of the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met or exceeded any previously publicly stated guidance we may have provided.

We currently rely on single source suppliers and, in some cases, sole source suppliers, for certain components and materials used in our systems and may not be able to find replacements or immediately transition to alternative suppliers, which could have an adverse effect on our business, financial condition and results of operations.

We have sourced and will continue to source certain components of the Aurora, Northern Lights and Aurora CS systems from a limited number of suppliers and, in some cases, sole source suppliers. Key components in our products that are supplied by sole or single source suppliers include certain lasers, semiconductors and mechanical components that are used in our optical, electrical and fluidic subassemblies. On August 25, 2021, we and the Subsidiary entered into the Coherent Agreement with Coherent. Pursuant to the Coherent Agreement, Coherent has agreed to sell and supply to us and the Subsidiary, on a non-exclusive basis, laser products manufactured by Coherent. We and the Subsidiary provide Coherent with rolling forecasts of our and the Subsidiary's anticipated orders, which are non-binding. Purchase orders submitted by us and the Subsidiary pursuant to the terms of the Coherent Agreement will be deemed accepted upon written acknowledgement of acceptance by Coherent. Other than the Coherent Agreement, we do not currently have long-term supply contracts with our sole and single source suppliers of key components. Additionally, we believe we are not a major customer to most of our suppliers. Our suppliers may therefore give other customers' needs higher priority than ours, and we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms. While we are in the process of qualifying additional sources of supply, qualifications can take 12 to 24 months and, in some cases, longer. If we were to lose one or more of our sole or single source suppliers, it would take significant time and effort to qualify alternative suppliers, if available. Moreover, in the event that we transition to a new supplier, particularly from any of our single source suppliers, doing so could be time-consuming and expensive, may result in interruptions in our ability to supply our products to the market and could affect the performance of our products, resulting in increased costs and negative customer perception.

Although we believe that we have stable relationships with our existing suppliers, we cannot assure you that we will be able to secure a stable supply of components materials going forward. In the event that any adverse developments occur with our suppliers, in particular for those products that are sole-sourced, or if any of our suppliers modifies any of the components they supply to us, our ability to supply our products may be temporarily or permanently interrupted. Obtaining substitute components could be difficult, time and resource-consuming and costly. Also, there can be no assurance that we will be able to secure a supply of alternative components at reasonable prices without experiencing interruptions in our business operations. In addition, quarantines, shelter-in-place and similar government orders related to infectious disease outbreaks, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could impact the suppliers upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our products.

In addition, we cannot assure you that our suppliers have obtained and will be able to obtain or maintain all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations, and failure to do so by them may lead to interruption in their business operations, which in turn may result in shortages of components supplied to us.

Supply interruptions have in the past arisen and could arise in the future from effects of infectious disease outbreaks, shortages of raw materials, labor disputes or weather conditions affecting products or shipments, transportation disruptions, adjustments to our inventory levels or other factors within and beyond our control, and such supply interruption risk is increased by the limited number of suppliers for certain of the components we use in our products. Our failure to maintain a continued supply of components that meets our quality control requirements for any reason, including changes to or termination of our agreements with key suppliers, or to enter into new agreements with other suppliers, particularly in the case of single or sole source suppliers, could result in the loss of access to important components and materials used in our products and impact our ability to manufacture and sell our products. Any delay or interruption in the supply of our materials could delay or suspend sales of our products and increase the costs of manufacturing our products, which could have an adverse effect on our business, financial condition and results of operations.

Our results of operations will be harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

To ensure adequate supply of our instruments and other products, we must forecast the inventory needs of our current and prospective customers, and manufacture our products based on our estimates of future demand. Our ability to accurately forecast demand for our products could be negatively affected by many factors, many of which are beyond our control, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast market acceptance of new products, changes in general market conditions, including as a result of infectious disease outbreaks, seasonal demands, regulatory matters, inflation or weakening of general economic conditions.

We seek to maintain sufficient levels of inventory of our instruments and other products to protect ourselves from supply interruptions. We rely in part on our support organizations and distributors to supply forecasts of anticipated product orders in their respective territories. If we fail to accurately estimate customer demand for our products, our inventory forecasts may be inaccurate, resulting in shortages or excesses of inventory. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and negatively impact our business, prospects, financial condition and results of operations. Conversely, if we underestimate customer demand for our products, we may not be able to deliver products in a timely manner or at all, and this could result in reduced revenue and damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, we may not have adequate manufacturing capacity to meet such demand, and additional supplies may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity to meet our increased requirements, all of which would negatively affect our business, financial condition and results of operations. If we are unable to meet customer demand, we could lose our existing customers or lose our ability to acquire new customers, which would also negatively impact our business, financial condition and results of operations.

We have limited experience manufacturing our products and if we are unable to manufacture our products in high-quality commercial quantities successfully and consistently to meet demand, our growth will be limited.

We have limited experience manufacturing our products. We currently manufacture our instruments and reagents at our manufacturing facilities in Fremont, California, Seattle, Washington and Wuxi, China, and reagents at our facility in San Diego, California. To manufacture our products in the quantities that we believe will be required to meet the currently anticipated market demand beyond the next several years, we will need to increase manufacturing capacity, which will involve significant challenges and may require additional quality controls and regulatory approvals. We may not successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

If there is a disruption to our manufacturing operations, we will have no other means of producing our products until we resolve such issues with our manufacturing facilities, develop alternative manufacturing facilities, or contract with third-party manufacturers capable of producing our products. Additionally, any damage to or destruction of our manufacturing facilities or equipment may significantly impair our ability to manufacture products on a timely basis. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our products, changes to labor costs or less favorable terms with third-party suppliers. There can be no assurance that we will not encounter such problems in the future.

If we are unable to manufacture products consistently and in sufficient quantities to meet anticipated customer demand, our business, financial condition, results of operations and prospects would be harmed. As we continue to scale the commercial production of our products and increase our manufacturing capacity, we may encounter quality issues that could result in product defects, errors or recalls. Manufacturing delays related to quality control could negatively impact our ability to bring our products to market, harm our reputation and decrease our revenue. Any defects, errors or recalls could be expensive and generate negative publicity, which could impair our ability to market or sell our products, and adversely affect our results of operations.

In addition, the introduction of new products may require the development of new manufacturing sites, processes or procedures as well as new suppliers. Developing new processes and negotiating supply agreements can be very time consuming, and any unexpected difficulty in doing so could delay the introduction of a product.

Our future success is dependent upon our ability to increase penetration in our existing markets and expand into adjacent markets.

Our customer base includes academic and government institutions, pharmaceutical and biotechnology companies, clinical research organizations and clinical laboratories focused on cell analysis. Approximately 42% and 47% of our revenue came from sales to academic and government-owned institutions and 58% and 53% of our revenue came from sales to pharmaceutical and biotechnology companies, distributors and CROs in the three months ended September 30, 2023 and 2022, respectively. Our success will depend upon our ability to increase our market penetration. We cannot guarantee that we will be able to further penetrate our existing markets or that these markets will be able to sustain our current and future product and service offerings. Any failure to increase penetration in our existing markets would adversely affect our ability to improve our operating results.

Our success will also depend on our ability to further expand into adjacent markets, such as immunotherapy, immuno-oncology, bio-processing, infectious diseases and immune-deficiencies, as well as areas outside of healthcare, such as marine biology and alternative biofuels and other environmental fields. For example, in the United States, our products are currently labeled and promoted, and are, and in the near-future are expected to continue to be, sold primarily to academic and research institutions and biopharmaceutical companies as research use only products for non-diagnostic and non-clinical purposes, and are not currently designed, or intended to be used, for clinical diagnostic tests. We plan to continue generating supporting publications and data, as well as pursue any required regulatory approvals for clinical use for our products in the United States. Our ability to penetrate the clinical markets in the United States will depend in part on our ability to receive 510(k) clearance, *de novo* classification, or approval of a pre-market approval application from the FDA. Our failure to further expand in adjacent markets and attract new customers could adversely affect our ability to improve our operating results.

Our business is dependent on adoption of our products by academic and government institutions, clinical research organizations, pharmaceutical companies and clinical laboratories for their research and development activities focused on cell analysis. If academic and government institutions, clinical research organizations, pharmaceutical companies and clinical laboratories are unwilling to change current practices to adopt our products, it will negatively affect our business, financial condition, prospects and results of operations.

Our primary strategy to grow our revenue is to take a stepwise approach to market our products across key stakeholders in flow cytometry and cell analysis, such as academic and government institutions, clinical research organizations, pharmaceutical companies and clinical laboratories. While the number of customers using our products has increased in recent years, many academic and government institutions, clinical research organizations, pharmaceutical companies and clinical laboratories have not yet adopted our products, and such institutions and companies may choose not to adopt our products for a number of reasons, including:

- inadequate recruiting or training of talented sales force in existing and new markets to facilitate outreach and further adoption and awareness of our products;
- lack of experience with our products for cell analysis;

- perceived inadequacy of evidence supporting benefits or cost-effectiveness of our products over existing alternatives;
- liability risks generally associated with the use of new products and processes;
- the training required to use new products;
- a decrease or delay in the research and development activities using our products;
- competing products and alternatives; and
- introduction of other novel alternative products for cell analysis.

We believe that educating notable industry KOLs, representatives of academic and government institutions, clinical research organizations, pharmaceutical companies and clinical laboratories, about the merits and benefits of our products for flow cytometry and cell analysis is one of key elements of increasing the adoption of our products. If these institutions and companies do not adopt our products for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and it will negatively affect our business, financial condition, prospects and results of operations.

Our business currently depends significantly on research and development spending by academic and government-owned institutions, a reduction in which could limit demand for our solutions and adversely affect our business and operating results.

Approximately 42% and 47% of our revenue came from sales to academic and government-owned institutions in the three months ended September 30, 2023 and 2022, respectively. Much of their funding was, in turn, provided by various state, federal and foreign government agencies. In the near term, we expect that a large portion of our revenue will continue to be derived from sales to academic and government-owned institutions. As a result, the demand for our solutions may depend upon the research and development budgets of these customers, which are impacted by factors beyond our control, such as:

- decreases in government funding of research and development;
- changes to programs that provide funding to research laboratories, hospitals and related institutions, including changes in the amount of funds allocated to different areas of research or changes that have the effect of increasing the length of the funding process;
- macroeconomic conditions and the political climate;
- scientists' and customers' opinions of the utility of new products or services;
- changes in the regulatory environment;
- differences in budgetary cycles;
- competitor product offerings or pricing;
- market-driven pressures to consolidate operations and reduce costs; and
- market acceptance of relatively new technologies, such as ours.

In addition, various state, federal and foreign agencies that provide grants and other funding may be subject to stringent budgetary constraints that could result in spending reductions, reduced grant making, reduced allocations or budget cutbacks, including as a result of negative or worsening conditions in the general economy, which could jeopardize the ability of these customers, or the customers to whom they provide funding, to purchase our solutions. For example, congressional appropriations to the National Institutes of Health (the "NIH") have generally increased year-over-year in recent years, but the NIH also experiences occasional year-over-year decreases in appropriations. There is no guarantee that NIH appropriations will not decrease or halt in the future. A decrease in the amount or halt of, or delay in the approval of, appropriations to NIH or other similar United States or foreign organizations, such as the Medical Research Council in the United Kingdom, could result in fewer grants benefiting life sciences research. These reductions or delays could also result in a decrease in the aggregate amount of grants awarded for life sciences research or the redirection of existing funding to other projects or priorities, any of which in turn could cause our customers and potential customers to reduce or delay purchases of our solutions. Our operating results may fluctuate substantially due to any such reductions and delays. Any decrease in our customers' budgets or expenditures, or in the size, scope or frequency of their capital or operating expenditures, could materially and adversely affect our business, operating results and financial condition.

We rely on distributors for sales of our products in certain geographies outside of the United States. If we are unable to secure additional distributors or maintain good relationships with our existing distributors, or if such distributors do not perform adequately or effectively, our business could suffer.

In addition to selling our products through our direct sales force and support organizations in North America, Europe, China, and several other countries in the Asia-Pacific region, we sell our products through third-party distributors or sales agents in certain countries in Europe, Latin America, the Middle East and the Asia-Pacific region. If current or future distributors do not perform adequately or effectively or fail to obtain or maintain any required regulatory approvals, we may not realize long-term international revenue growth and our business, operating results and financial condition may be harmed. We have limited control over our distributors, which may not commit the necessary resources to market our products to the level of our expectations.

We intend to continue to grow our business internationally and to do so we may choose to partner with additional distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms, which could affect our ability to expand into or further penetrate certain geographies and adversely impact our business, operating results and financial condition.

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

We currently have significant international operations and our business strategy incorporates further international expansion. We currently maintain relationships with distributors and suppliers outside of the United States and may in the future enter into new distributor and supplier relationships outside of the United States. In addition, we currently have manufacturing operations in both the United States and China. 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 our products, 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 such as the ongoing war in Ukraine, the Israel and Palestine conflict, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act (the "FCPA"), its books and records provisions, or its anti-bribery provisions.

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 in which we currently or 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.

The market for cell analysis technologies and life sciences tools, including flow cytometry, is highly competitive, and if we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue, or achieve and sustain profitability.

We face significant competition in the cell analysis and life sciences tools markets. We currently compete with both established and early stage life sciences and in vitro diagnostics (“IVD”) companies that design, manufacture and market flow cytometry instruments, consumables and software for cell analysis and/or provide services related to the same. An increasing number of applications for cell analysis, and more particularly flow cytometry, is leading to more companies offering competitive products and services. Our competitors include Agilent Technologies, Beckman Coulter (Danaher Corporation), Becton, Dickinson and Company (“BD”), Bio-Rad Laboratories, Standard BioTools Inc., Miltenyi Biotec, Sony Biotechnology (Sony Corporation), and Thermo Fisher Scientific. Our target customers may also elect to develop their workflows using other technologies rather than implementing our platform or existing customers may decide to stop using our platform. In addition, there are many large, established companies in the life sciences tools market that could develop instruments or other products that will compete with us in the future. These large, established companies have substantially greater financial and other resources than us, including larger research and development, quality and regulatory staff or more established marketing and sales forces.

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 and capabilities;
- greater technological and research and development resources;
- larger intellectual property portfolios;
- better system reliability and robustness;
- greater selling and marketing capabilities; and
- better established, larger scale and lower cost manufacturing capabilities.

In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies. 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 products and services than we can, secure key components from suppliers on more favorable terms, adopt more aggressive pricing policies or sell their products or offer services competitive with our products at prices and margins designed to win significant levels of market share. We may not be able to compete effectively against these organizations. If we are unable to compete successfully against current and future competitors, we may be unable to increase market adoption and sales of our products, which could negatively impact our business, financial condition, results of operations and prospects.

Our future success depends on our ability to develop and successfully introduce new and enhanced products that meet the needs of our customers.

Our current products include instruments, consumables and services to advance high-content and high-sensitivity cell analysis. We cannot assure you that the market for our current products will continue to generate significant or consistent demand. Demand for our current products could be significantly diminished by competitive technologies or products that replace them or render them obsolete or less desirable. Accordingly, we must continue to invest in research and development to develop competitive products and enabling services.

Our future success depends on our ability to anticipate our customers’ needs and develop new products and enhance current products and services to address those needs. Introduction of new products and product enhancements will require that we effectively transfer production processes from research and development to manufacturing and coordinate our efforts with those of our suppliers to achieve the desired level of production. If we fail to transfer production processes effectively, develop product enhancements or introduce new products or enabling services in sufficient quantities to meet

the needs of our customers, or effectively coordinate with our suppliers, our net sales may be reduced and our business would be harmed.

The commercial success of all of our products and services will depend upon their acceptance by the life sciences and biopharmaceutical industries. Some of the products and services that we are developing are based upon new technologies or approaches. As a result, there can be no assurance that these new products and services, even if successfully developed and introduced, will be accepted by customers. If customers do not adopt our new products, services and technologies, our results of operations may suffer and, as a result, the market price of our common stock may decline.

If we are unable to successfully develop new products, adapt to rapid and significant technological change, respond to introductions of new products by competitors, make strategic and operational decisions to prioritize certain markets, technology offerings or partnerships, and develop and capitalize on markets, technologies or partnerships, our business could suffer.

We currently sell our products primarily in the cell analysis market, which is characterized by significant enhancements and evolving industry and regulatory standards. As a result, our customers' needs are rapidly evolving. If we do not appropriately innovate and offer our customers comprehensive solutions and otherwise invest in new technologies, our offerings may become less desirable in the markets we serve, and our customers could move to new technologies offered by our competitors or make products themselves. Without the timely introduction of new instruments, consumables, software, services and enhancements, our offerings may 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 products and applications to further drive adoption of our platform. To the extent we fail to timely introduce new and innovative products, offer enhancements to our existing products, 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.

We believe our products have potential applications across a wide range of markets and we have targeted certain markets in which we believe our technology has significant advantages, or for which we believe we have a higher probability of success or revenue opportunity. For example, we are committed to developing our platform's applications within the clinical market, and in particular, within disease detection, diagnosis, and treatment monitoring. 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 and use cases for our technology. However, due to the significant resources required for the development of products or 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 products or services and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain markets may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. In particular, if we are unable to accelerate adoption of our FSP solutions, it could slow or stop our business growth and negatively impact 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 research and development programs will take time and considerable resources to develop, and may include improvements or changes to our current products, and we may not be able to complete development and commercialization of new or enhanced products on a timely basis, or at all. There can be no assurance that our research and development efforts will produce commercially viable products and solutions and before we can commercialize any new products, we will need to expend significant funds to, for example:

- conduct substantial research and development;
- obtain necessary regulatory approval;
- further develop and scale our laboratory, engineering and manufacturing processes to accommodate different products;
- source and enter into agreements with new suppliers; and
- further develop and scale our infrastructure.

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 and failure to reliably demonstrate the advantages of the product.

Even if we are successful in developing new products, it will require us to make significant additional investments in marketing and selling resources 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 systems are complex in design and may contain defects that are not detected until deployed by our customers, which could increase our costs and reduce our net sales. If our products do not perform as expected or the reliability of the technology on which our products and services are based is questioned, our operating results, reputation and business will suffer.

Our success depends on our ability to provide reliable, high quality products that enable high-content and high-sensitivity cell analysis through flexible, efficient and cost-effective solutions. Our systems are complex in design and involve a highly complex and precise manufacturing process. As a result of the technological complexity of our systems, changes in our or our suppliers' manufacturing processes or the inadvertent use of defective materials by us or our suppliers could result in an adverse effect on our ability to achieve acceptable manufacturing yields and product reliability. To the extent that we do not achieve and maintain our projected yields or product reliability, our business, operating results, financial condition and customer relationships would be adversely affected. We provide warranties on a majority of our product sales, and reserves for estimated warranty costs are recorded during the period of sale. The determination of such reserves requires us to make estimates of failure rates and expected costs to repair or replace the products under warranty. We typically establish warranty reserves based on historical warranty costs for each product line. If actual repair and replacement costs differ significantly from our estimates, adjustments to cost of sales may be required in future periods which could have an adverse effect on our results of operations.

Our customers may discover defects in our products after the products have been fully installed and operated. In addition, some of our products include components from other vendors, which may contain defects. As a result, should problems occur, it may be difficult to identify the source of the problem. If we are unable to identify and fix defects or other problems, we could experience, among other things:

- loss of customers or orders;
- increased costs of warranty expenses;
- damage to our brand reputation;
- failure to attract new customers;
- diversion of development, engineering and manufacturing resources;
- regulatory actions by governmental authorities; and
- legal actions by our customers.

We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our products, services and technologies may be impaired if our products or services fail to perform as expected. If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation, and business will suffer, and we may also be subject to legal claims arising from product limitations, errors, or inaccuracies. Any of the foregoing could have an adverse effect on our business, financial condition and results of operations.

Although our products are tested prior to shipment, defects or errors could nonetheless occur. Our operating results depend on our ability to execute and, when necessary, improve our quality management strategy and systems and our ability to effectively train and maintain our employee base with respect to quality management. A failure of our quality control systems could result in problems with facility operations or preparation or provision of products. In each case, such problems could arise for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials or environmental factors and damage to, or loss of, manufacturing operations.

We provide a one-year assurance-type warranty on our instruments. Existing and future warranties place us at the risk of incurring future repair and/or replacement costs. At the time revenue is recognized, we establish an accrual for estimated warranty expenses based on historical data and trends of product reliability and costs of repairing and replacing defective products. We exercise judgment in estimating the expected product warranty costs, using data such as the actual and projected product failure rates, estimated repair costs, freight, material, labor and overhead 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, or alternatively, improved quality and reliability in our products and consumables could result in actual expenses that are below those currently estimated. As of September 30, 2023, we had accrued approximately \$2.8 million in expenses relating to product warranty accruals. Substantial amounts of warranty claims could have an adverse effect on our business, financial condition and results of operations.

Even after any underlying concerns or problems are resolved, any lingering concerns in our target markets regarding our technology or any manufacturing defects or performance errors in our products or services could continue to result in lost revenue, delayed market acceptance, damage to our reputation and claims against us.

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

From time to time, we may pursue acquisitions of businesses and assets. For example, in February 2023, we entered into an asset purchase agreement with Luminex Corporation (“Luminex”) and acquired certain assets related to the flow cytometry and imaging (“FCI”) business unit of Luminex (the “FCI Acquisition”). We may choose to further expand our business by acquiring additional businesses or assets in the future. We also may pursue strategic alliances and additional joint ventures that leverage products and industry experience to expand our offerings or distribution. We have limited experience with acquiring other companies and forming strategic partnerships. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. We may not be able to integrate acquisitions, including the recent FCI Acquisition, successfully into our existing business, and in certain cases 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 an adverse effect on our financial condition, results of operations and cash flows. In addition, any pursuit of an acquisition and any potential integration of an acquired company also may disrupt ongoing operations and divert management attention and resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a negative effect on our results of operations and financial condition. We may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

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.

We 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. Additionally, our manufacturing operations in Fremont and San Diego, California, Seattle, Washington, and Wuxi, China require global shipping services which are subject to certain factors outside of our control, such as increased costs due to fuel surcharges or otherwise, delays passing through customs and disruptions to global shipping routes. We experienced shipping delays and difficulties due to the COVID-19 pandemic and may again experience such delays or difficulties due to future pandemics, other infectious disease outbreaks or natural disasters. Moreover, there is no guarantee that our systems will not become damaged or lost in transit, and we have experienced, and expect to continue to experience, delivery difficulties. If a system 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 customer dissatisfaction and a substantial financial loss for us. If our products are not delivered in a timely fashion or are lost during the delivery process, our customers could also become dissatisfied and cease using our products or services, which would adversely affect our business, financial condition, results of operations and prospects. Additionally, delays in shipping could have an adverse impact on our ability to recognize revenue in a timely manner, which could have an adverse impact on our quarterly results of operations.

If we are unable to successfully expand our commercial operations, including hiring additional qualified sales representatives, technical applications specialists and customer support staff, our business may be adversely affected.

Our future sales will depend, in large part, on our ability to develop and substantially expand our sales infrastructure, particularly as we enter into new markets, rollout new solutions and applications and manage inbound interest from new customers. We distribute our products through our direct sales force and support organizations located in North America, Europe, China, and several countries in the Asia-Pacific region, and through distributors or sales agents in several countries in Europe, Latin America, the Middle East and the Asia-Pacific region. Our sales and marketing efforts are targeted at academic and governmental institutions, pharmaceutical and biotechnology companies, clinical research organizations and clinical laboratories focused on cell analysis. To continue driving adoption of our solutions and to support our global brand, we will need to further expand our sales infrastructure by hiring additional, highly qualified and reputable sales representatives, technical applications specialists and customer support staff, in addition to increasing advertising efforts.

Identifying and recruiting qualified personnel with sufficient industry experience and training them requires significant time, expense and attention. We have limited experience in training our personnel to successfully market and sell our products. If we provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop broad brand awareness in a cost-effective manner, our business may be harmed. In addition, if our efforts to expand do not generate a corresponding increase in revenue or result in a decrease in our operating margin, our financial results will be adversely impacted. If we are unable to hire, develop and retain talented sales personnel or if new sales personnel are unable to achieve desired productivity levels in a reasonable period of time, we may not be able to realize the expected benefits of this investment or increase our revenue.

Additionally, our technical applications specialists work closely with researchers and clinicians to optimize and implement new panels and applications to meet their specific needs. Hiring these highly skilled specialists is competitive due to the limited number of people available with the necessary scientific and technical backgrounds and ability to understand our products at a technical level, and training such individuals requires significant time, expense and attention. Furthermore, we face intense competition in the labor market for such highly skilled specialists from competitors in our industry as well as competition from companies in other industries. To effectively support current and potential customers, we will need to hire, maintain, train and grow the number of our technical application specialists and customer support staff. If we are unable to maintain, attract, train or retain the number of qualified support personnel that our business needs, our business and prospects will suffer.

If we are unable to expand or leverage the number of peer-reviewed articles published using data generated by our products or otherwise increase brand awareness, the demand for our products and our business may be adversely affected.

We rely on a significant base of peer-reviewed publications to showcase and validate the importance and application of our technology in academic and clinical research settings. As of September 30, 2023, there have been more than 1,450 peer-reviewed articles published, including many published in prominent journals, using data generated by our technology across a wide range of key scientific research areas, including immunology and inflammation, infectious diseases, immuno-oncology, oncology and others. We believe that expanding the base of these publications, and otherwise developing and maintaining awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our solutions and attracting new customers. Such publications and other brand promotion activities may not generate customer awareness or increase revenue and, even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the customers necessary to realize a sufficient return on our brand-building efforts, or to achieve the widespread brand awareness that is critical for broad customer adoption of our solutions.

We are highly dependent on our senior management team and key personnel and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management team and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales, marketing, scientific and technical professionals, and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales, marketing, scientific and technical professionals could result in lower than expected sales and delays in product development. If we are not successful in attracting and retaining highly qualified personnel, it would have a negative impact on our business, financial condition and results of operations.

Competition for skilled personnel in our market is intense and has recently intensified further due to macro-economic conditions and industry trends in many areas where our employees are located. This may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued, and will in the future issue, equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, they may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice.

Many of the other cell analysis technology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities, better chances for career advancement and higher compensation. Some of these characteristics are more appealing to high quality candidates than what we can offer. Further, if we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages.

In addition, job candidates and existing employees often consider the value of the equity awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Many of our employees have become or will soon become vested in a substantial amount of their equity awards. Our employees may be more likely to leave us if the equity they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees as we expand our business and operations. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

We have increased the size of our organization and expect to further increase it in the future, and we may experience difficulties in managing our growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

As of September 30, 2023, we had 688 full-time employees worldwide. As our sales and marketing strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Since our inception, we have experienced growth and anticipate further growth in our business operations both inside and outside the United States. This future growth could strain our organizational, administrative and operational infrastructure, including quality control, operational, finance, customer service and sales organization management. We expect to continue to increase our 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 scientists, engineers, technical personnel and sales and marketing staff and improve and maintain our products to properly manage our growth. Rapid expansion in personnel could mean that less experienced people develop, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. 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 employees, our business may be harmed. We may not be able to maintain the quality or expected turnaround times of our products, or 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. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a timely, efficient and effective manner could adversely affect our operations.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations.

In connection with our financial statement close process for the year ended December 31, 2022, we identified deficiencies in the control environment and control activities components of the Committee of Sponsoring Organizations (“COSO”) framework that constitute material weaknesses, either individually or in the aggregate. Deficiencies in the control environment related to (i) the lack of a sufficient number of qualified resources within our accounting and IT functions with the appropriate level of technical accounting or other requisite knowledge to (a) timely identify and assess accounting implications of transactions; and (b) perform assigned responsibilities and have appropriate accountability for the design and operation of internal control over financial reporting. Deficiencies related to control activities related to (i) selecting and developing control activities that contribute to the mitigation of risks and support achievement of objectives; (ii) selecting and developing general control activities over technology to support the achievement of objectives; and (iii) deploying control activities through policies that establish what is expected and procedures that put policies into action and relate to substantially all financial statement accounts and disclosures. See the section entitled “Item 4. Controls and Procedures” for additional information.

A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of its financial statements would not be

prevented or detected on a timely basis. These deficiencies could result in additional material misstatements to our consolidated financial statements that could not be prevented or detected on a timely basis.

We cannot be certain that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. We currently do not have an internal audit group, and we will need to hire additional accounting and finance staff and consultants with appropriate public company experience and technical accounting knowledge to remediate the control deficiencies. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be negatively impacted, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. Failure to remedy any material weakness or significant deficiency in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We may need to raise additional capital to fund our existing operations, develop our products and/or expand our operations.

Based on our current planned operations, we expect that our existing cash will enable us to fund our operating expenses for at least 12 months from the date hereof. However, if our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements or otherwise, we may seek to issue equity or convertible debt securities, enter into a credit facility or another form of third-party funding, seek other debt financing or enter into collaborations or licensing arrangements.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to further scale up our manufacturing of our products, to increase our sales and marketing efforts to drive market adoption of our products and address competitive developments, and to finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, some of which are beyond our control, including:

- our ability to achieve and maintain revenue growth;
- the cost of expanding our operations, 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 products;
- 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 potential cost of and delays in product development as a result of any regulatory oversight applicable to our products;
- the costs associated with any product recall that may occur;
- costs related to domestic and international expansion;
- the costs of attaining, defending and enforcing our intellectual property rights; and
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish.

Additional funding may not be available on acceptable terms, or at all. Weakness and volatility in the capital markets and the economy in general could limit our access to the capital markets and increase our cost of borrowing. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to 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 other third-party funding, collaborations agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to

relinquish valuable rights to our technologies, future revenue streams, research programs or products or grant licenses on terms that may not be favorable to us.

In addition, our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from geopolitical tensions, such as the ongoing war in Ukraine, the Israel and Palestine conflict, government actions implemented as a result of either of the foregoing, as well as tensions with and economic uncertainty in China, inflation, rising interest rates and liquidity concerns at, and failures of, banks and other financial institutions. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in economic growth, increases in inflation rates, higher interest rates and uncertainty about economic stability. If the equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development, manufacturing or commercialization of our products, or other research and development initiatives. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have an adverse effect on our business, financial condition and results of operations.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, 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:

- the level of demand for any of our products, which may vary significantly;
- the timing and cost of, and level of investment in, research, development, manufacturing, regulatory approval and commercialization activities relating to our products, which may change from time to time;
- the size, seasonality and customer mix of the cell analysis market;
- sales and marketing efforts and expenses;
- the rate at which we grow our sales force and the speed at which newly-hired salespeople become effective;
- changes in the productivity of our sales force;
- the effectiveness of our distribution partners in selling our products;
- positive or negative coverage in the media or publications of our products or competitive products;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our arrangements with our suppliers;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including the introduction of new products or enhancements or technologies by us or others in the cell analysis market and competition-related pricing pressures;
- changes in governmental regulations or in the status of our regulatory approvals or applications;
- future accounting pronouncements or changes in our accounting policies;
- general economic conditions, both domestically and internationally, as well as economic conditions specifically affecting the industry in which we do business, including those related to widespread health crises;
- future global financial crises and economic downturns, including those caused by widespread public health crises;
- economic factors, including changes in inflation, interest rates, foreign currency rates, liquidity concerns at, and failures of, banks and other financial institutions and the potential effect of such factors on revenues and expenses; and

- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

The cumulative effects 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. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

The sizes of the markets for our products may be smaller than we estimate.

Within the life sciences technology market, flow cytometry technologies currently provide solutions largely within cell proliferation, cell counting, cell identification, cell quality control and single-cell applications, representing an initial total addressable market (“TAM”) of nearly \$12 billion. However, we believe that the enhanced capabilities of our FSP platform has the potential to capture an increasingly greater share of the broader cell analysis TAM. Our Northern Lights system has been approved for clinical use in the European Union and China. In the United States, our products are currently labeled and promoted, and are, and in the near-future are expected to continue to be, sold primarily to academic and research institutions and biopharmaceutical companies as research use only products for non-diagnostic and non-clinical purposes, and are not currently designed, or intended to be used, for clinical diagnostic tests. We plan to continue generating supporting publications and data, as well as pursue any required regulatory approvals for clinical use for our products in the United States. Our ability to penetrate the clinical markets in the United States will depend in part on our ability to receive 510(k) clearance, *de novo* classification, or approval of a pre-market approval application from the FDA. Further, we believe our differentiated platform will enable us to expand the use of cell analysis into new markets, well beyond current applications addressed by prior flow cytometry technologies and other cell analysis technologies. While we believe our assumptions and the data underlying our estimates are reasonable, we have not independently verified the accuracy of the third-party data on which we have based our assumptions and estimates, and these assumptions and estimates may not be correct and significantly different than actual market sizes, and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. If the actual number of customers who would benefit from our products, the price at which we can sell products or the annual addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations.

In addition, our growth strategy involves launching new solutions and expanding sales of existing solutions into new markets and geographies in which we have limited experience. For example, we intend to develop our platform’s applications within the clinical market, and in particular, within disease detection, diagnosis, and treatment monitoring. Sales of new or existing solutions into new market opportunities may take several years to develop and mature, and we cannot be certain that these market opportunities will develop as we expect. As a result, the sizes of the annual total addressable market for new markets and new products are even more difficult to predict.

If we were to be sued for product liability, we could face substantial liabilities that exceed our resources, limit sales of our existing products and limit commercialization of any products that we may develop.

The marketing, sale and use of our products could lead to the filing of product liability claims where someone may allege that our products identified inaccurate or incomplete information or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability claim could result in substantial damages and be costly and time-consuming for us to defend. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- substantial litigation costs;
- distraction of management’s attention from our primary business;
- the inability to commercialize our products or new products;
- decreased demand for our products;
- damage to our business reputation;

- product recalls or withdrawals from the market;
- loss of sales; or
- termination of existing agreements by our partners and potential partners failing to partner with us.

We maintain product liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability claims. Any product liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We may not be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future and these efforts may not have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also harm our reputation with customers, which could negatively affect our business, financial condition and results of operations.

Litigation and other legal proceedings may harm our business.

We have been, and may become, involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal or state regulatory investigations, securities class actions and other legal proceedings or investigations, which could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

If our information technology systems or data, or those of third parties on which we rely, are compromised now, or in the future, we could experience adverse consequences resulting from such a compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, collect, use, store, safeguard, disclose, share, transfer, secure and otherwise process (collectively, "Process" or "Processing") proprietary, confidential and sensitive data, including personal information (such as key-coded data, health information and other special categories of personal information), intellectual property, trade secrets and proprietary business information owned or controlled by ourselves, our customers and other parties (collectively "Sensitive Information"). We rely upon third parties (such as service providers) for our data processing-related activities and share or receive Sensitive Information with or from third parties.

We face a variety of evolving threats, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our Sensitive Information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are becoming increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, attacks enhanced or facilitated by artificial intelligence, and other similar threats. In particular, severe ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are

becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, ability to provide our products or services, loss of Sensitive Information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Additionally, employees working from home, while in transit and in public locations poses increased risks to our information technology systems and data when utilizing network connections, computers, and devices outside our premises or network.

In addition to experiencing a security incident, third parties may gather, collect, or infer Sensitive Information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Sensitive information of the Company or our customers could also be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative AI ("AI") technologies. Furthermore, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. We may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process Sensitive Information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their data privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Sensitive Information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our platform. We may expend significant resources or modify our business activities in an effort to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and Sensitive Information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities in our information technology systems because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Unremediated high risk or critical vulnerabilities pose a material risk to our business.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing data (including personal information); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products and services, deter new customers from purchasing our products and services, and negatively impact our ability to grow and operate our business.

Further, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations (including our manufacturing operations) and the operations of our distribution partners could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Our ability to obtain components for our products could be disrupted if the operations of our suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Fremont, California and one of our reagents manufacturing facilities is located in San Diego, California, near major earthquake faults and fire zones, and the ultimate impact on us for being located near earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We manufacture our products at our manufacturing facilities located in Fremont and San Diego, California, Seattle, Washington, and Wuxi, China, and we rely on various suppliers in the United States, China and other countries. Should our manufacturing facilities or the facilities of our suppliers be damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, or should events such as political unrest unfold, it could take months to relocate or rebuild, during which time our manufacturing and the operations of our suppliers would cease or be delayed and our products may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and approval. Because of the time required to authorize manufacturing in a new facility under FDA and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event we lose our manufacturing capacity. The inability to perform our manufacturing activities, combined with our limited inventory of materials and components and manufactured products, or the inability of our suppliers to continue their operations, may cause us to be unable to meet customer demand or harm our reputation, and we may be unable to reestablish relationships with such customers in the future. Consequently, a catastrophic event or business interruption at our manufacturing facilities or at our suppliers' facilities could harm our business, financial condition and results of operations.

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

We do not carry insurance for all categories of risk that our business may encounter. Although we have general and product liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could negatively affect our business, financial condition and results of operations. We do not carry specific hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we carry cyber insurance, the coverage may not be sufficient to cover our losses in the event of a Security Breach. Additionally, no assurance can be given that such policies can be retained on acceptable terms or that litigation will not occur following an insurance claim.

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, on 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 negatively affect our business, financial condition and results of operations.

We use hazardous biological materials that require considerable expertise for handling, storage and disposal and may result in claims against us. We and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business, and could expose us to liability if our use of such hazardous materials cause injury.

Our research and development and manufacturing processes involve the controlled use of hazardous materials, including flammables, toxics, corrosives and biologics. Our research operations produce hazardous biological

and chemical waste products, and we largely contract with third parties for the disposal of these 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 the event of accidental contamination or injury from these materials or wastes, 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.

In addition, because our product contains metals and electronic components which are purchased from third-party vendors, we may be required under rules promulgated by the U.S. Securities and Exchange Commission ("SEC") governing disclosure of the use of "conflict minerals" (tin, tungsten, tantalum and gold) to determine whether those minerals are necessary to the functionality or production of our products and, if so, conduct a country of origin inquiry with respect to all such minerals. If any such minerals may have originated in the Democratic Republic of the Congo, or DRC, or any of its adjoining countries, or covered countries, then we must conduct diligence on the source and chain of custody of those conflict minerals to determine if they originated in one of the covered countries and, if so, whether they financed or benefited armed groups in the covered countries. Disclosures relating to the products that may contain conflict minerals, the country of origin of those minerals and whether they are "DRC conflict free" must be provided in a Form SD (and accompanying conflict minerals report, if required, to disclose the diligence undertaken by us in sourcing the minerals and our conclusions relating to such diligence). If we are required to submit a conflict minerals report, that report must be audited by an independent auditor pursuant to existing government auditing standards. Compliance with this disclosure rule may be very time-consuming for our management and personnel (as well as time-consuming for our suppliers) and could involve the expenditure of significant amounts of money by us and them. Disclosures mandated by this rule, which can be perceived by the market to be "negative," may cause customers to refuse to purchase our products. The cost of compliance with the rule could adversely affect our results of operations.

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. We do not currently maintain separate environmental liability coverage and any accidental contamination or discharge or any resultant injury from these materials could result in significant cost to us in penalties, damages and suspension of our operations.

We are subject to foreign currency exchange risk.

A substantial amount of our revenues is derived from international operations, and we anticipate that a significant portion of our sales will continue to come from outside the United States in the future. As we have experienced in the nine months ended September 30, 2023, where our prices are denominated in U.S. dollars, our sales and revenues could be adversely affected by declines in foreign currencies relative to the U.S. dollar. The revenues we report with respect to our operations outside the United States may be adversely affected by fluctuations in foreign currency exchange rates. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" for additional information on the financial impact of exchange rate fluctuations and the ways and extent to which we may attempt to address any impact. Any hedging activities we engage in may only offset a portion of the adverse financial impact resulting from unfavorable changes in foreign currency exchange rates. We cannot predict with any certainty changes in foreign currency exchange rates or the degree to which we can mitigate these risks.

Risks Related to Government Regulation and Our Industry

Our products may become subject to more onerous regulation by the FDA or other regulatory agencies in the future, which could increase our costs and delay or prevent sales of our products or commercialization of new products and product enhancements, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

Currently, our Northern Lights CLC system is available for clinical use in only China and the European Union. Our Aurora and Northern Lights systems are otherwise available to customers as research use only ("RUO") products. RUO products are regulated by the FDA as medical devices. Although medical devices are subject to stringent FDA oversight, products that are intended for RUO and are labeled as RUO are exempt from compliance with most FDA requirements, including premarket clearance or approval, manufacturing requirements and others. A product labeled RUO but which is actually intended for clinical diagnostic use may be viewed by the FDA as adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and subject to FDA enforcement action. The FDA has indicated that when determining the intended use of a product labeled RUO, the FDA will consider the totality of the circumstances surrounding distribution and use of the product, including how the product is marketed and to whom. The FDA could disagree with our assessment that our products are properly marketed as RUOs, or could conclude that products labeled as

RUO are actually intended for clinical diagnostic use, and could take enforcement action against us, including requiring us to stop distribution of our products until we are in compliance with applicable regulations, which would reduce our revenue, increase our costs and adversely affect our business, prospects, results of operations and financial condition. In the event that the FDA requires us to obtain marketing authorization of our RUO products in the future, there can be no assurance that the FDA will grant any clearance or approval requested by us in a timely manner, or at all.

As part of our growth strategy, we plan to seek approval to offer our Aurora and Northern Lights systems for clinical use in the United States and in other countries. In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the FDCA, or approval of a premarket approval application from the FDA, unless an exemption applies. The process of obtaining approval or clearance from the FDA for new products, or with respect to enhancements or modifications to existing products, could take a significant period of time, require the expenditure of substantial resources, involve rigorous pre-clinical and clinical testing, require changes to products or result in limitations on the indicated uses of products. There can be no assurance that we will receive the required approvals or clearances for any new products or for modifications to our existing products on a timely basis or that any approval or clearance will not be subsequently withdrawn or conditioned upon extensive post-market study requirements. Moreover, even if we receive FDA clearance or approval of new products or modifications to existing products, we will be required to comply with extensive regulations relating to the development, research, clearance, approval, distribution, marketing, advertising and promotion, manufacture, adverse event reporting, recordkeeping, import and export of such products, which may substantially increase our operating costs and have a material impact on our business, profits and results of operations. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters, fines, injunctions, civil penalties, termination of distribution, recalls or seizures of products, delays in the introduction of products into the market, total or partial suspension of production, refusal to grant future clearances or approvals, withdrawals or suspensions of current approvals, resulting in prohibitions on sales of our products, and in the most serious cases, criminal penalties. Occurrence of any of the foregoing could harm our reputation, business, financial condition, results of operations and prospects.

We and our suppliers are subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Any medical device we market will be subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, unless exempt, we and our suppliers are required to comply with the FDA's Quality System Regulation ("QSR") and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- withdrawal of 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these actions were to occur, our reputation would be harmed and our product sales and profitability would be adversely impacted. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Later discovery of previously unknown problems with our products, including manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations.

Our products or any component thereof may be subject to product recalls in the future. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products that are subject to FDA regulation. Manufacturers may, under their own initiative, recall a product if any deficiency is found. For reportable corrections and removals, companies are required to make additional periodic submissions to the FDA after initiating the recall, and often engage with the FDA on their recall strategy prior to initiating the recall. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable health risk, component failures, failures in laboratory processes, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and adversely affect our business, results of operations, financial condition and reputation. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the FDA. We may initiate voluntary recalls involving our products. A recall announcement by us could harm our reputation with customers and negatively affect our business, financial condition, and results of operations. In addition, the FDA or other agency could take enforcement action for failing to report the recalls when they were conducted.

If we initiate a recall, including a correction or removal, for one of our products, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our customers regarding the quality and safety of our products, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

The misuse or off-label use of our products may harm our reputation in the marketplace, or result in injuries that lead to product liability suits, which could be costly to our business. Moreover, we could be subject to FDA sanctions if we are deemed to have engaged in off-label promotion.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition on the promotion of an RUO device or medical device for an indication that has not been approved or cleared by the FDA, referred to as an off-label use. We cannot prevent our customers from using our products for off-label uses, including in laboratory developed tests for clinical use. If the FDA determines that our promotional materials constitute the unlawful promotion of an off-label use, it could subject us to regulatory or enforcement actions, including civil money penalties, criminal fines and penalties, and exclusion from participation in federal health programs, among others. Other federal, state or foreign governmental authorities might also take action if they consider our promotion or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities. In that event, our reputation could be damaged and the use of our products in the marketplace could be diminished.

Furthermore, off-label uses of our products may lead to performance issues or produce erroneous results, which could harm our reputation in the marketplace and increase the risk of product liability. Product liability claims are expensive to defend and could divert our management's attention from our primary business and result in substantial damage awards against us. Any of these events could harm our business, results of operations and financial condition.

Changes in tariffs or other government trade policies may materially adversely affect our business and results of operations, including by reducing demand for our products.

The imposition of tariffs and trade restrictions as a result of international trade disputes or changes in trade policies may adversely affect our sales and profitability. For example, in 2018 and 2019, the U.S. government imposed and

proposed, among other actions, new or higher tariffs on specified imported products originating from China in response to what it characterized as unfair trade practices, and China responded by imposing and proposing new or higher tariffs on specified U.S. products. There can be no assurance that a broader trade agreement will be successfully negotiated between the United States and China to reduce or eliminate these tariffs. These tariffs, and the related geopolitical uncertainty between the United States and China, may cause decreased demand for our products, which could have a material adverse effect on our business and results of operations. For example, certain of our foreign customers may respond to the imposition of tariffs or threat of tariffs on products we produce by delaying purchase orders or purchasing products from our competitors. Ongoing international trade disputes and changes in trade policies could also impact economic activity and lead to a general contraction of customer demand. In addition, tariffs on components that we may import from China or other nations will adversely affect our profitability unless we are able to exclude such components from the tariffs or we raise prices for our products, which may result in our products becoming less attractive relative to products offered by our competitors. Future actions or escalations by either the United States or China that affect trade relations may also negatively affect our business, or that of our suppliers or customers, and we cannot provide any assurances as to whether such actions will occur or the form that they may take. To the extent that our sales or profitability are negatively affected by any such tariffs or other trade actions, our business and results of operations may be materially adversely affected.

We are subject to governmental export controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.

Exports of our products are subject to export controls and sanctions laws and regulations imposed by the U.S. government and administered by the U.S. Departments of State, Commerce, and Treasury. U.S. export control laws may require a license or other authorization to export products to certain destinations and end users. In addition, U.S. economic sanctions laws include restrictions or prohibitions on the sale or supply of certain products and services to U.S. embargoed or sanctioned countries, governments, persons and entities. Obtaining export licenses can be difficult, costly and time-consuming and we may not always be successful in obtaining necessary export licenses, and our failure to obtain required export approval for our products or limitations on our ability to export or sell our products imposed by export control or sanctions laws may harm our revenues and adversely affect our business, financial condition, and results of operations. Noncompliance with these laws could have negative consequences, including government investigations, penalties and reputational harm.

We are subject to stringent and changing U.S. and foreign data privacy and security laws, regulations, rules, and standards as well as policies, contractual obligations, and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to government regulatory investigations or enforcement actions (that could include fines and penalties), a disruption of our business or commercialization of our products, private litigation (including class claims) and mass arbitration demands, harm to our reputation, loss of revenue or profits, and other adverse effects on our business or prospects.

In the course of our operations, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share sensitive, confidential, and proprietary information, including personal information, business data, trade secrets, intellectual property, and sensitive third-party data. Accordingly, we are, and may increasingly become, subject to various data privacy and security laws, the number and scope of which are changing, subject to differing applications and interpretations, may be inconsistent among jurisdictions, and may conflict with each other.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy and security laws, and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. The California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (“CPRA”), (collectively, “CCPA”) applies to personal information of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain rights related to their personal information, such as those noted below. The CCPA allows for statutory fines for noncompliance (up to \$7,500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, CPRA expanded the CCPA’s requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency, the California Privacy Protection Agency, to implement and enforce the law, which could increase the risk of an enforcement action. Other states, such as Virginia, Colorado, Utah, and Connecticut, have enacted comprehensive data privacy and security laws. Similar laws are being considered in several other states, as well as at the federal and local levels. These state laws and the CCPA provide individuals with certain rights concerning their

personal information, including the right to access, correct, or delete certain personal information, and opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. If we become subject to new data privacy and security laws, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals via a private right of action and state actors), increasing legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's General Data Protection Regulation ("UK GDPR"), (collectively, "GDPR") impose strict requirements for processing the personal information of individuals located, respectively within the European Economic Area ("EEA") and the United Kingdom ("UK"). For example, violations of the GDPR can result in, temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros (£17.5 million for the UK GDPR) or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Furthermore, in Europe, there is a proposed regulation related to artificial intelligence ("AI") that, if adopted, could impose onerous obligations related to the use of AI-related systems. Other countries outside of Europe have enacted or are considering enacting similar comprehensive data privacy and security laws and regulations, which could increase the cost and complexity of delivering our services and operating our business. For example, China's Personal Information Protection Law ("PIPL") broadly regulates data privacy and security practices and imposes strict requirements for processing personal information. As another example, Canada has enacted the Personal Information Protection and Electronic Documents Act and Canada's Anti-Spam Legislation, which broadly regulate the Processing of personal information and impose compliance obligations and penalties comparable to those of European data privacy and security laws. Complying with these and other similar laws and regulations (to the extent applicable) may cause us to incur substantial operational costs or require us to change our business practices, and could lead to material fines, penalties and liability.

In addition, many jurisdictions have enacted data localization laws and cross-border personal information transfer laws. These laws may make it more difficult for us to transfer personal information across jurisdictions, which could impede our business. For example, absent appropriate safeguards or other circumstances, the EU GDPR and UK GDPR generally restrict the transfer of personal information to the United States and other countries that are viewed by some regulators as to not generally provide an adequate level of data privacy and security. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal information to the United States or other countries. In addition to European restrictions on cross-border transfers of personal information, other jurisdictions have enacted or are considering similar cross-border personal information transfer laws and local personal information residency laws, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal information from Europe or elsewhere. The inability to import personal information to the United States could significantly and negatively impact our business operations, including by limiting our ability to collaborate with parties that are subject to European and other data privacy and security laws, requiring us to increase our personal information processing capabilities in Europe and/or elsewhere at significant expense; increased exposure to regulatory actions; and substantial fines and penalties. Additionally, companies that transfer personal information out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, privacy advocates and industry groups have proposed, and may propose in the future, standards with which we are legally or contractually bound to comply. For example, we may also be subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI DSS can result in penalties ranging from \$5,000 to \$100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses. We may also rely on vendors to process payment card data, who may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI

DSS noncompliance. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain data privacy and security laws, such as the EU/UK GDPR and the CCPA, require us to impose specific contractual restrictions on our service providers. We also publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security (and consumers' data privacy and security expectations) are quickly changing in an increasingly stringent fashion and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources), which may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change our business model. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations which could impact our compliance posture and business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight, bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers, interruptions or stoppages in our business operations, inability to process personal information or to operate in certain jurisdictions, limited ability to develop or commercialize our products, expenditure of time and resources to defend any claim or inquiry, adverse publicity, or revision or restructuring of our business model or operations.

We are subject to U.S. and certain foreign anti-corruption and anti-money laundering laws and regulations. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to anti-corruption and anti-money laundering laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct or may in the future conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other third-party collaborators from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to or from persons in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.

In addition to selling our products internationally directly through our sales teams, we currently engage third parties outside of the United States, and may engage additional third parties outside of the United States, to sell our products internationally and to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other third-party collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we fail to comply with U.S. federal and state fraud and abuse and other healthcare laws and regulations, including those relating to kickbacks and false claims, we could face substantial penalties and our business operations and financial condition could be harmed.

We are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our products. We have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the

precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations. The laws that may affect our ability to operate include, among others:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of a person, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the FCA. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti-Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities. Certain common business activities including, certain reimbursement support programs, educational and research grants or charitable donations, and practices that involve remuneration to those who prescribe, purchase or recommend medical devices, including discounts, providing items or services for free or engaging such people as consultants, advisors or speakers, may be subject to scrutiny if they do not fit squarely within any available exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute. Our business may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability;
- the federal civil False Claims Act, or the FCA, which prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Actions under the FCA may be brought by the government or as a qui tam action by a private person in the name of the government. These people, sometimes known as “relators” or, more commonly, as “whistleblowers,” may share in any monetary recovery. Many medical device manufacturers have been investigated and have reached substantial financial settlements with the federal government under the FCA for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, life sciences companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Settlements may require companies to enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. Medical device manufacturers and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs;
- HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or

document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and their implementing regulations, also impose obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for them or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- various state laws govern the privacy and security of personal information, including the California Consumer Protection Act, or CCPA, which became effective January 1, 2020, and gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways 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 data breaches;
- the federal Physician Payments Sunshine Act, implemented as Open Payments, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually, with certain exceptions to CMS, information related to payments or other “transfers of value” made to physicians, as defined by such law, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require medical device companies to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, which are state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, FCA and HIPAA’s healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices of our products, could be subject to challenge under one or more such laws. If an arrangement were deemed to violate the Anti-Kickback Statute, it may also subject us to violations under other fraud and abuse laws such as the federal civil FCA and civil monetary penalties laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling FCA, Anti-Kickback Statute or civil monetary penalties law cases also may enter into a Corporate Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General, or the OIG, to avoid exclusion from participation (such as loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may harm our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business, financial condition and results of operations.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (1) the laws of the FDA and other similar regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators, (2) manufacturing standards, (3) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or (4) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally.

We have adopted a code of business conduct and ethics that applies to our directors, officers and employees, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities 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 be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent or other intellectual property protection for any of our current or future products, or if the scope of the patent and other 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 current or future products may be harmed.

As with other flow cytometry companies, our success depends in large part on our ability to obtain, maintain and solidify a proprietary position for our current and any future products, which will depend upon our success in obtaining effective patent protection in the United States and other countries that cover, and other intellectual property with respect to, such products, their manufacturing processes and their intended methods of use and enforcing those patent claims once granted as well as our other intellectual property. In some cases, we may not be able to obtain issued patent claims or other intellectual property covering our technologies which are sufficient to prevent third parties, such as our competitors, from utilizing our products and negate any competitive advantage we may have. Any failure to obtain or

maintain patent and other intellectual property protection with respect to our current and any future products or other aspects of our business could harm our business, financial condition and results of operations.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek and obtain patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions.

Including rights acquired in connection with the acquisition of the FCI business unit, as of September 30, 2023, we own 33 issued U.S. utility patents, nine issued Japan utility patents, seven issued European utility patents, three issued China utility patents, one Canada utility patent, one India utility Patent, two Australian utility patents, and three Singapore utility patents. We have 54 pending utility patent applications, including 32 utility patent applications in the United States, two international utility patent applications, eight utility patent applications in the European Union, seven utility patent applications in China, and four utility patent applications in Japan. Assuming all maintenance fees are paid, the U.S. issued patents are expected to naturally expire between years 2025 and 2038. Patents covering intellectual property relating to design specific technologies invented by our researchers in Shanghai and Wuxi, China are filed in China and owned by our China subsidiaries, respectively. As of September 30, 2023, our Shanghai subsidiary owns 14 issued utility patents and three issued invention patent and has eight pending invention patent applications, and our Wuxi subsidiary owns 37 issued patents and has seven pending patent applications, including two pending utility model patent applications and five pending invention patent applications.

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 the scope, validity and enforceability of our patents, licensed patents, patent applications, trademarks, and trademark applications may be challenged at the United States Patent and Trademark Office (“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, patent applications, trademarks or trademark applications. Any successful third party challenge to our patents or trademarks could result in the unenforceability or invalidity of such patents or trademarks and increased competition to our business. We may have to challenge the patents, patent applications, trademarks, or trademark 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.

Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties or that we may jointly-own with third parties in the future and are therefore reliant on our licensors or licensees, and may be reliant on future joint-owners, licensors or licensees, to protect certain of our intellectual property used in our business. If our joint-owners, licensors or licensees fail to adequately protect this intellectual property or if we do not have exclusivity for the marketing of our products, whether because our joint-owners or licensors do not grant us exclusivity or they do not enforce the intellectual property against our competitors, our ability to commercialize products could suffer. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like. If we or any of our current or

future joint-owners, licensors or licensees fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If any current or future joint-owners, licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and/or unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may impact our ability to commercialize our products and materially harm our business.

The strength of patent rights generally, and particularly the patent position of life sciences companies, involves complex legal and scientific questions and can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to changes to statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents or the chances that patent applications will result in issued claims and the scope of any such claims. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our current and any future products. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of the exclusive rights necessary for the successful commercialization of our current and any future products, which may materially harm our business. Furthermore, even if they are unchallenged, our patents may not adequately protect our current and any future products, provide exclusivity for such products or prevent others from designing around the claims of our patents. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and products would be adversely affected and would materially harm our business. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our current and any future products is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our current and any future products.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our current and any future products and services, we may be open to competition, which may harm our business prospects. Further, if we encounter delays in our development efforts, the period of time during which we could market our current and any future products and services under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future products, patents protecting our current and any future products might expire before or shortly after such products are commercialized. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own now or in the future may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our current and any future products or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could harm our business, financial condition and results of operations.

Some of our patents and patent applications may in the future be jointly-owned with third parties, including certain universities and public institutions in the United States and China. If we are unable to obtain an exclusive license to any such third-party joint-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such joint-owners patents to enforce such patents against third

parties, and such cooperation may not be provided to us. Any of the foregoing could harm our business, financial condition and results of operations.

Additionally, we may find it necessary or prudent to acquire or obtain licenses from third-party intellectual property holders. However, we may be unable to acquire or secure such licenses to any intellectual property rights from third parties that we identify as necessary for our current and any future products. The acquisition or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant products, which could harm our business, financial condition and results of operations.

Patents covering our current, and any future products, or our technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, which could harm our business, financial condition and results of operations.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts, the USPTO or patent offices abroad and may not provide us with adequate proprietary protection or competitive advantage against competitors with similar products. We may be subject to a third-party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review (“IPR”), or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our current and any future products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our current and any future products or technologies. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us.

In addition, if we initiate legal proceedings against a third party to enforce a patent covering our current and any future products, the defendant could counterclaim that such patent is invalid or unenforceable. 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, including 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 relevant information from the USPTO or made a misleading statement during prosecution. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, derivation proceedings and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover or provide meaningful protection of our current and any future products or technologies. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant or other third-party 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 our current and any future products and technology. Such a loss of patent protection would harm our business, financial condition and results of operations.

We rely substantially on our trademarks and trade names. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be harmed.

We rely substantially upon trademarks to build and maintain the integrity of our brand. Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which

we rely upon to build name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion and asserting claims against such third parties may be prohibitively expensive. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks against us. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs and diversion of resources and could harm our business, financial condition and results of operations.

Obtaining and maintaining our intellectual property, including patent, protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government agencies, and our intellectual property, including patent, protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on intellectual property registrations and applications will be due to be paid to the applicable government agencies, including with respect to patents and patent applications the USPTO and similar agencies outside of the United States, over the lifetime of our intellectual property registrations and applications, including our patents and patent applications. The various applicable government agencies, including with respect to patents and patent applications the USPTO and similar agencies outside of the United States, require compliance with several procedural, documentary, fee payment and other similar provisions during the application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in the abandonment or lapse of the intellectual property registration or application, resulting in a partial or complete loss of intellectual property rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of an intellectual property registration or application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could harm our business, financial condition and results of operations.

We have limited foreign intellectual property rights outside the United States, selected countries in the European Union, Japan and China and may not be able to protect our intellectual property and proprietary rights throughout the world, which could harm our business, financial condition and results of operations.

We have limited intellectual property rights outside the United States, selected countries in the European Union, Japan and China. Filing, prosecuting and defending patents or trademarks on our current and any future products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions or utilizing our trademarks in 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, further, may export otherwise 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 current and any future products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put 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, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. 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 technology and the enforcement of our intellectual property.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our current and any future products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third-party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our current and any future products.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, IPR and derivation proceedings.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. 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. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations.

In addition, recent U.S. Supreme Court rulings have made and will likely continue to make changes in how the patent laws of the United States are interpreted. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violation against us, the joint-owners of our intellectual property, or our collaborators may prevent or delay the sale and marketing of our current and any future products.

The flow cytometry industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, we could become subject to significant intellectual property-related litigation and proceedings relating to our or third-party intellectual property and proprietary rights. Such litigation and proceedings may cause us to incur significant expense, including the payment of damages, settlement payments and/or royalty payments. For example, in February 2018, BD filed suit against us and certain of our employees in the United States District Court for the Northern District of California asserting a number of claims against us, including misappropriation of trade secrets and copyright infringement. In October 2020, we entered into a settlement agreement with BD resulting in a dismissal of all claims and a release of all claims between the parties. Pursuant to the settlement agreement with BD, we are required to make certain payments to BD, including royalty payments on sales of certain of our products.

Our commercial success depends in part on our and any potential future collaborators' ability to develop, manufacture, market and sell any products that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property or proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any potential collaborators to alter our

development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post-grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our current and any future products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our current and any future products, components of our current and any future products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates, increasing the risk that we will be required to incur significant expenses defending any such claims or lose patent protection for our current or future products.

We may also be subject to claims that current or former employees, collaborators or other third parties have an interest in our patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our current and any future products. Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our current and any future products. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our current and any future products. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and 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. Any of the foregoing could harm our business, financial condition and results of operations.

In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed by our current and any future products, which could harm our ability to commercialize any product we may develop and any other technologies covered by the asserted third-party patents. To successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe third-party intellectual property rights, including patents, and we are unsuccessful in demonstrating that such patents or other intellectual property rights are invalid or unenforceable, such third parties may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay significant license fees and/or royalties, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same technology. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize our current and any future products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products and/or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such intellectual property. Claims that we have misappropriated the confidential information or trade secrets of third parties could harm our

business, financial condition and results of operations. We also might have to redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure.

Engaging in litigation to defend against third-party infringement claims is very expensive, particularly for a company of our size, and time-consuming. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition and results of operations.

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

Competitors may infringe our patents, or the patents of any future licensing partners, or we may be required to defend against claims of infringement. In an infringement proceeding, a court may decide that our patent is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Any of the foregoing could harm our business, financial condition and results of operations.

Further, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be harmed.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Such claims could harm our business, financial condition and results of operations.

As is common in the life sciences industry, our employees, consultants and advisors may be currently or previously employed or engaged at universities or other life sciences companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may in the future become subject to claims that we or these people have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their current or former employer. Also, we may in the future be subject to claims that these people are violating non-compete agreements with their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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. Such claims could harm our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our current and any future products, we also rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position, especially where we do not believe patent protection is appropriate or obtainable. Trade secrets and know-how can be difficult to protect. We seek to protect such proprietary information, in part, through non-disclosure and confidentiality agreements with our employees, collaborators, contractors, advisors, consultants and other third parties and invention assignment agreements with our employees. We also have agreements with our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses containing invention assignment, to grant us ownership of technologies that are developed through a relationship with employees or third parties.

We cannot guarantee that we have entered into such agreements with each party that has or may have had access to our trade secrets or proprietary information. Additionally, despite these efforts, 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. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor or other third-party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to scientific industry positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these people, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known, or be independently discovered by, competitors. To the extent that our employees, consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could harm our business, financial condition and results of operations.

Failure of a key information technology system, process, or site could have an adverse effect on our business.

We rely extensively on information technology systems to conduct our business. These systems affect, among other things, ordering and managing materials from suppliers, shipping products, processing transactions, complying with regulatory, legal or tax requirements, data security and other processes necessary to manage our business. Our systems and the data contained on them may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, social engineering (including phishing), supply chain attacks, credential stuffing, efforts by individuals or groups of hackers and sophisticated organizations, including state-sponsored organizations, errors or malfeasance of our personnel, and security vulnerabilities in the software or systems on which we rely, and failures during the process of upgrading or replacing software, databases or components thereof. If the confidentiality, integrity, or availability of our systems or our data is compromised due to these, or any number of causes, ranging from catastrophic events and power outages to security breaches, and our business continuity plans do not effectively compensate on a timely basis, we may experience interruptions in our operations, including corruption of our data or release of our confidential information, which could have an adverse effect on our business. Furthermore, any breach in our information technology systems could lead to the unauthorized access,

disclosure and use of non-public information, which may be protected by applicable laws. Any such access, disclosure, or other loss of information could require substantial expenditures to remedy and could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and damage to our reputation.

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 in connection with the software integrated in our instruments. Companies that incorporate open source software into their products have, from time to time, faced claims challenging their use of open source software and compliance with open source license terms. As a result, we could be subject to lawsuits by parties claiming ownership of what we believe to be open source software or claiming noncompliance with open source licensing terms. 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. 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. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

Risks Related to Ownership of Our Common Stock

Our stock price may continue to be volatile, and our stockholders may not be able to resell shares of our common stock at or above the price they paid.

The market price of our common stock has been and may continue to be highly volatile and may further fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the degree and rate of market adoption of our products;
- variance in our financial performance from expectations of securities analysts or investors;
- actual or anticipated fluctuations in our financial condition and results of operations, including as a result of anticipated or unanticipated demand based on seasonal factors;
- changes in our projected operating and financial results;
- actual or anticipated fluctuations in our operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- significant lawsuits, including patent or stockholder litigation;
- negative publicity associated with issues related to our products;
- changes in senior management or key personnel;
- future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases;
- the trading volume of our common stock;
- our ability to obtain and maintain regulatory approvals for our products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning any of our third-party distribution partners and suppliers, including our single and sole-source suppliers;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- our inability to engage additional distribution partners and establish collaborations, if needed;
- performance or news releases by other companies in our industry including about adverse developments related to safety, effectiveness, accuracy and usability of their products, reputational concerns, regulatory compliance, and product recalls;

- general economic, regulatory and market conditions, including economic recessions or slowdowns, the ongoing war in Ukraine and the general inflationary environment; and
- other events or factors, many of which are beyond our control.

Broad market and industry fluctuations, as well as general economic, pandemic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small public float of shares of our common stock on the Nasdaq Global Select Market (the “Nasdaq”), the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against companies that have experienced volatility or following a decline in the market price of its securities. This risk is especially relevant for us, because life sciences 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 have broad discretion in the use of our cash and may invest or spend the funds in ways with which you do not agree and in ways that may not yield a return.

We have broad discretion over the use of our cash. Investors may not agree with our decisions, and our use of cash may not yield any return on your investment. We currently intend to use our cash to fund manufacturing activities, sales and marketing activities, including the hiring and training of additional sales and marketing personnel, and the remainder for working capital and general corporate purposes, including research and development activities. In addition, a portion of our cash may also be used to acquire assets or complementary businesses. Our failure to use our cash effectively could impair our ability to pursue our growth strategy or could require us to raise additional capital. In addition, pending their use, our cash may be placed in investments that do not produce income or that may lose value. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Substantial future sales of shares of our common stock or securities convertible into our common stock will result in additional dilution of the percentage of ownership of our stockholders and could cause the market price of our common stock to decline.

Sales and issuances of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales and issuances may have on the prevailing market price of our common stock.

In addition, we may offer and sell up to \$150 million shares of common stock registered under our universal shelf registration statement on Form S-3 pursuant to the Sales Agreement with Piper in one or more “at the market” offerings. To date, we have not made any sales of common stock pursuant to the Sales Agreement. The extent to which we utilize the Sales Agreement with Piper as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, general market conditions and other restrictions and the extent to which we are able to secure funds from other sources.

In addition, certain of our stockholders have registration rights that would require us to register shares owned by them for public sale in the United States. We have also filed a registration statement to register shares reserved for future issuance under our equity compensation plans. As a result, subject to the satisfaction of applicable exercise periods and applicable volume and restrictions that apply to affiliates, the shares issued upon exercise of outstanding stock options or upon settlement of outstanding restricted stock unit awards are available for immediate resale in the United States in the open market.

Sales of shares of our common stock could also impair our ability to raise capital through the sale of additional equity securities in the future and at a price we deem appropriate. These sales could also cause the trading price of our common stock to decline and make it more difficult for you to sell shares of our common stock.

Concentration of ownership of our common stock among our executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based on the number of shares of common stock outstanding as of September 30, 2023, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates (based on filings with the SEC), in the aggregate, own approximately 39.6% of our common stock. These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders. For example, because many of these stockholders purchased their shares at prices substantially below the current market price or our shares and have held their shares for a longer period, they may be more

interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and may be restricted by the terms of any then-current debt instruments. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

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 Securities Exchange Act of 1934 (the “Exchange Act”). We designed 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.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue redeemable convertible preferred stock on terms determined by the board of directors without stockholder approval and which redeemable convertible preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the

then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, (iv) any action or proceeding to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws, (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware and (vi) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933 (the "Securities Act") creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and our amended and restated bylaws will further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find either exclusive forum provision contained in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

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 common stock.

The preparation of our consolidated financial statements in conformity with generally accepted accounting principles 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. For example, in connection with the revenue accounting standard, Accounting Standards Codification, or ASC, Topic 606, management makes judgments and assumptions based on our interpretation of the new standard. The revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the

standard. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgments, 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 common stock.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of its securities. This risk is especially relevant for us because life sciences 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 compliance with our public company responsibilities and corporate governance practices.

As a public company, we have incurred and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. We expect such expenses to further increase as we are no longer an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, the senior members of our management team do not have significant experience with operating a public company. As a result, our management and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs, which could negatively affect our business, financial condition and results of operations.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

If securities or industry analysts do not publish research or publish unfavorable or inaccurate research about our business, our common stock price and trading volume could decline.

Our stock price and trading volume will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business or publish negative reports about our business, regardless of accuracy, our common stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline. Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline.

Our ability to use our net operating losses ("NOLs") to offset future taxable income may be subject to certain limitations.

As of December 31, 2022, we had no federal and state NOL carryforwards, except in California. The California NOLs will begin to expire in calendar year 2036, unless previously utilized. These California NOLs could expire unused and be unavailable to offset future income tax liabilities.

Separately, under Section 382 of the Internal Revenue Code of 1986, as amended (“Code”) if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Similar rules may apply under state tax laws. We determined that an ownership change occurred on September 7, 2018, October 23, 2020, and in connection with our IPO on July 23, 2021. As of December 31, 2022, we had not experienced an ownership change subsequent to the ownership change on July 23, 2021. In addition, we may in the future experience ownership changes, as a result of changes in our stock ownership (some of which are not in our control). If an ownership change occurs, our ability to utilize our NOL carryforwards and other tax attributes to reduce future tax liabilities may be limited. Many states have provisions similar to Code Section 382. Annual limitations may result in the expiration of the state net operating loss carryforwards before utilization.

Changes in our effective tax rate or tax liability may have an adverse effect on our results of operations.

Our effective tax rate could increase due to several factors, including:

- changes in the relative amounts of income before taxes in the various jurisdictions in which we operate that have differing statutory tax rates;
- changes in tax laws, tax treaties, and regulations or the interpretation of them;
- changes to our assessment about our ability to realize our deferred tax assets that are based on estimates of our future results, the prudence and feasibility of possible tax planning strategies, and the economic and political environments in which we do business;
- the outcome of current and future tax audits, examinations, or administrative appeals; and
- limitations or adverse findings regarding our ability to do business in some jurisdictions.

Additionally, a tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Changes in tax law and regulations may have a material adverse effect on our business, financial condition and results of operations.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by the Internal Revenue Service, the U.S. Treasury Department and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, financial condition, results of operations, and cash flow. We urge investors to consult with their legal and tax advisers regarding the implication of potential changes in tax laws on an investment in our common stock.

Changes and uncertainties in the tax system in the countries in which we have operations, could materially adversely affect our financial condition and results of operations, and reduce net returns to our shareholders.

We conduct business globally and file income tax returns in multiple jurisdictions. Our consolidated effective income tax rate could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms under consideration; the practices of tax authorities in jurisdictions in which we operate; the resolution of issues arising from tax audits or examinations and any related interest or penalties. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices in jurisdictions in which we operate, could increase the estimated tax liability that we have expensed to date and paid or accrued on our statement of financial position, and otherwise affect our financial position, future results of operations, cash flows in a particular period and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders and increase the complexity, burden and cost of tax compliance.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES.**Unregistered Sales of Equity Securities**

None.

Issuer Purchases of Equity Securities

On May 17, 2023, the Board approved a program for the repurchase by the Company of up to an aggregate of \$50 million of its outstanding common stock. As of September 30, 2023, there was approximately \$40.6 million remaining under this program.

The following table provides information with respect to the shares of the Company's common stock repurchased from the beginning of the repurchase start to the end of September 30, 2023.

(Except for the share amount and average price per share, dollar value in thousands)

	Total number of shares repurchased	Average price paid per share	Cost of buyback shares	Total number of shares purchased as part of publicly announced plans or programs	Cumulative Cost of buyback shares	Maximum dollar that may yet be purchased under the plans or programs
May 2023	100,623	\$ 7.72	\$ 782	100,623	\$ 782	\$ 49,218
June 2023	25,159	7.95	199	125,782	981	49,019
July 2023	—	—	—	125,782	981	49,019
August 2023	295,574	7.73	2,269	421,356	3,250	46,750
September 2023	859,655	7.14	6,159	1,281,011	9,409	40,590
Year to Date Total	1,281,011	\$ 7.33	\$ 9,409	1,281,011	\$ 9,409	\$ 40,590

The repurchase program was used to return capital to shareholders and to minimize the dilutive impact of stock options and other share-based awards. The repurchased shares of common stock were retired.

Use of Proceeds

In July 2021, we issued and sold an aggregate of 13,949,401 shares of common stock in connection with our IPO, including the full exercise by the underwriters of their option to purchase an additional 2,184,695 shares from us, and the selling stockholders sold 2,799,929 shares of common stock, at a public offering price of \$17.00 per share. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-257663), which was declared effective by the SEC on July 22, 2021. There has been no material change in the use of proceeds from our IPO from those disclosed in the final prospectus for our IPO dated July 22, 2021 and filed with the SEC pursuant to Rule 424(b)(4) of the Securities Act on July 23, 2021.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. Exhibits

Number	Exhibit Title	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-40632	3.1	07/27/2021	
3.2	Amended and Restated Bylaws	8-K	001-40632	3.2	07/27/2021	
31.1	Certification of Principal Executive Officer required by Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*					X
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*					X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibits 101).					X

* As contemplated by SEC Release No. 33-8212, these exhibits are furnished with this Quarterly Report on Form 10-Q and are not deemed filed with the SEC and are not incorporated by reference in any filing of Cytex Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language contained in such filings.

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Wenbin Jiang, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cytex Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(r) and 15d-15(r)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

By: /s/ Wenbin Jiang, Ph.D.

Wenbin Jiang, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Patrik Jeanmonod, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cytex Biosciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(r) and 15d-15(r)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

By: /s/ Patrik Jeanmonod
Patrik Jeanmonod
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION 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 on Form 10-Q of Cytex Biosciences, Inc. (the "Company") for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Wenbin Jiang, Ph.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to requirements set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; 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 14, 2023

By: /s/ Wenbin Jiang, Ph.D.
Wenbin Jiang, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION 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 on Form 10-Q of Cytex Biosciences, Inc. (the “Company”) for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Patrik Jeanmonod, Chief Financial Officer of the Company, hereby certifies, pursuant to requirements set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; 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 14, 2023

By: /s/ Patrik Jeanmonod

Patrik Jeanmonod
Chief Financial Officer
(Principal Financial Officer)