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

Form 10-Q

(Mark One)

x 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

o 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 001-34899

Pacific Biosciences of California, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**16-1590339**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1305 O'Brien Drive Menlo Park, CA	**94025**
(Address of principal executive offices)	**(Zip Code)**

(650) 521-8000
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	PACB	The NASDAQ Stock Market LLC

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 x No o

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 x No o

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

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
Emerging growth company	o		

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. o

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

Number of shares outstanding of the issuer's common stock as of October 31, 2023: 267,443,887.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Condensed Consolidated Balance Sheets
(Unaudited)

(in thousands, except per share amounts)	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 385,648	$ 325,089
Investments	382,141	447,229
Accounts receivable, net	30,486	18,786
Inventory, net	68,256	50,381
Prepaid expenses and other current assets	15,466	10,289
Short-term restricted cash	300	300
Total current assets	882,297	852,074
Property and equipment, net	40,340	41,580
Operating lease right-of-use assets, net	34,610	39,763
Long-term restricted cash	2,422	2,922
Intangible assets, net	461,838	410,245
Goodwill	463,843	409,974
Other long-term assets	13,004	10,528
Total assets	$ 1,898,354	$ 1,767,086
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 16,106	$ 12,028
Accrued expenses	34,660	32,596
Deferred revenue, current	22,372	30,498
Operating lease liabilities, current	9,460	8,886
Other liabilities, current	5,170	7,233
Contingent consideration liability, current	96,193	172,094
Total current liabilities	183,961	263,335
Deferred revenue, non-current	5,053	1,794
Contingent consideration liability, non-current	18,450	—
Operating lease liabilities, non-current	34,100	41,070
Convertible senior notes, net, non-current	891,996	896,683
Other liabilities, non-current	1,051	1,300
Total liabilities	1,134,611	1,204,182
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value:		
Authorized 50,000 shares; No shares issued or outstanding	—	—
Common stock, $0.001 par value:		
Authorized 1,000,000 shares; issued and outstanding 258,374 and 226,505 shares at September 30, 2023 and December 31, 2022, respectively	258	227
Additional paid-in capital	2,522,382	2,099,782
Accumulated other comprehensive loss	(1,840)	(4,765)
Accumulated deficit	(1,757,057)	(1,532,340)
Total stockholders' equity	763,743	562,904
Total liabilities and stockholders' equity	$ 1,898,354	$ 1,767,086

See accompanying notes to the condensed consolidated financial statements.

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	$ 51,562	$ 27,509	$ 129,871	$ 85,928
Service and other revenue	4,129	4,802	12,293	15,023
Total revenue	55,691	32,311	142,164	100,951
Cost of Revenue:				
Cost of product revenue	33,735	15,752	87,697	46,437
Cost of service and other revenue	4,054	3,012	11,258	10,619
Total cost of revenue	37,789	18,764	98,955	57,056
Gross profit	17,902	13,547	43,209	43,895
Operating Expense:				
Research and development	47,514	47,092	142,626	150,377
Sales, general and administrative	43,431	36,795	123,822	115,851
Merger-related expenses	8,979	—	8,979	—
Amortization of acquired intangible assets	741	—	741	—
Change in fair value of contingent consideration	(271)	4,280	13,960	(2,221)
Total operating expense	100,394	88,167	290,128	264,007
Operating loss	(82,492)	(74,620)	(246,919)	(220,112)
Loss on extinguishment of debt	—	—	(2,033)	—
Interest expense	(3,588)	(3,664)	(10,772)	(11,042)
Other income, net	8,505	1,313	24,301	1,290
Loss before benefit from income taxes	(77,575)	(76,971)	(235,423)	(229,864)
Benefit from income taxes	(10,706)	—	(10,706)	—
Net loss	(66,869)	(76,971)	(224,717)	(229,864)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	846	(803)	2,925	(5,173)
Comprehensive loss	$ (66,023)	$ (77,774)	$ (221,792)	$ (235,037)
Net loss per share:				
Basic	$ (0.26)	$ (0.34)	$ (0.90)	$ (1.03)
Diluted	$ (0.26)	$ (0.34)	$ (0.90)	$ (1.03)
Weighted average shares outstanding used in calculating net loss per share:				
Basic	255,001	225,123	249,082	223,981
Diluted	255,001	225,123	249,082	223,981

See accompanying notes to the condensed consolidated financial statements.

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

(in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
For the three months ended September 30, 2023						
Balance at June 30, 2023	250,473	$ 250	$ 2,334,623	$ (2,686)	$ (1,690,188)	$ 641,999
Net loss	—	—	—	—	(66,869)	(66,869)
Other comprehensive income	—	—	—	846	—	846
Shares issuable following milestone achievement	—	—	84,761	—	—	84,761
Issuance of common stock in acquisition of Apton	6,121	6	76,636	—	—	76,642
Issuance of common stock in connection with liquidity event bonus plan	169	—	2,111	—	—	2,111
Issuance of common stock in conjunction with equity plans	1,611	2	4,560	—	—	4,562
Share-based compensation expense	—	—	19,691	—	—	19,691
Balance at September 30, 2023	258,374	$ 258	$ 2,522,382	$ (1,840)	$ (1,757,057)	$ 763,743
For the three months ended September 30, 2022						
Balance at June 30, 2022	224,756	$ 225	$ 2,058,103	$ (5,457)	$ (1,370,985)	$ 681,886
Net loss	—	—	—	—	(76,971)	(76,971)
Other comprehensive loss	—	—	—	(803)	—	(803)
Issuance of common stock in conjunction with equity plans	1,160	1	3,542	—	—	3,543
Share-based compensation expense	—	—	18,936	—	—	18,936
Balance at September 30, 2022	225,916	$ 226	$ 2,080,581	$ (6,260)	$ (1,447,956)	$ 626,591
For the nine months ended September 30, 2023						
Balance at December 31, 2022	226,505	$ 227	$ 2,099,782	$ (4,765)	$ (1,532,340)	$ 562,904
Net loss	—	—	—	—	(224,717)	(224,717)
Other comprehensive income	—	—	—	2,925	—	2,925
Shares issuable following milestone achievement	—	—	84,761	—	—	84,761
Issuance of common stock in acquisition of Apton	6,121	6	76,636	—	—	76,642
Issuance of common stock in connection with liquidity event bonus plan	169	—	2,111	—	—	2,111
Issuance of common stock from Underwritten Public Equity Offering, net of issuance costs	20,125	20	189,180	—	—	189,200
Issuance of common stock in conjunction with equity plans	5,454	5	14,378	—	—	14,383
Share-based compensation expense	—	—	55,534	—	—	55,534
Balance at September 30, 2023	258,374	$ 258	$ 2,522,382	$ (1,840)	$ (1,757,057)	$ 763,743
For the nine months ended September 30, 2022						
Balance at December 31, 2021	220,978	$ 221	$ 2,009,945	$ (1,087)	$ (1,218,092)	$ 790,987
Net loss	—	—	—	—	(229,864)	(229,864)
Other comprehensive loss	—	—	—	(5,173)	—	(5,173)
Issuance of common stock in conjunction with equity plans	4,938	5	9,978	—	—	9,983
Share-based compensation expense	—	—	60,658	—	—	60,658
Balance at September 30, 2022	225,916	$ 226	$ 2,080,581	$ (6,260)	$ (1,447,956)	$ 626,591

See accompanying notes to the condensed consolidated financial statements.

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

(in thousands)	Nine Months Ended September 30, 2023	2022
Cash flows from operating activities		
Net loss	$ (224,717)	$ (229,864)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	8,487	6,937
Amortization of intangible assets	1,408	685
Amortization of right-of-use assets	4,940	5,152
Share-based compensation expense	55,534	60,658
Merger-related compensation expense	3,395	—
Accretion of discount and amortization of premium on marketable securities, net	(10,088)	1,069
Change in the estimated fair value of contingent consideration	13,960	(2,221)
Loss on extinguishment of debt	2,033	—
Inventory provision	4,691	2,667
Deferred income taxes	(10,706)	—
Other	667	562
Changes in assets and liabilities		
Accounts receivable, net	(11,700)	1,485
Inventory	(22,849)	(23,367)
Prepaid expenses and other assets	(7,287)	(5,685)
Accounts payable	1,706	1,511
Accrued expenses	2,055	(11,054)
Deferred revenue	(4,867)	(3,575)
Operating lease liabilities	(6,396)	(5,905)
Contingent consideration liability	(732)	—
Other liabilities	(1,147)	(1,700)
Net cash used in operating activities	(201,613)	(202,645)
Cash flows from investing activities		
Purchase of property and equipment	(6,819)	(11,846)
Cash paid for purchase of Apton, net of cash acquired	(102)	—
Purchases of investments	(553,748)	(307,899)
Sales of investments	595	—
Maturities of investments	631,253	355,425
Net cash provided by investing activities	71,179	35,680
Cash flows from financing activities		
Proceeds from issuance of common stock under equity offerings, net of issuance costs	189,200	—
Proceeds from issuance of common stock from equity plans	14,383	9,983
Payment of debt issuance costs	(7,325)	—
Payment of contingent consideration	(4,368)	—
Notes payable principal payoff	(1,397)	(1,180)
Net cash provided by financing activities	190,493	8,803
Net increase (decrease) in cash, cash equivalents, and restricted cash	60,059	(158,162)
Cash, cash equivalents, and restricted cash at beginning of period	328,311	465,817
Cash, cash equivalents, and restricted cash at end of period	$ 388,370	$ 307,655
Cash and cash equivalents at end of period	385,648	304,433
Restricted cash at end of period	2,722	3,222
Cash, cash equivalents, and restricted cash at end of period	$ 388,370	$ 307,655

See accompanying notes to the condensed consolidated financial statements.

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

NOTE 1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

We are a life science technology company that is designing, developing, and manufacturing advanced sequencing solutions that enable scientists and clinical researchers to improve their understanding of the genome and ultimately, resolve genetically complex problems. Our products and technology under development stem from two highly differentiated core technologies focused on accuracy, quality, and completeness, which include our existing HiFi long-read sequencing technology and our emerging short-read Sequencing by Binding (SBB™) technology. Our products address solutions across a broad set of applications including human genomics, plant and animal sciences, infectious disease and microbiology, oncology, and other emerging applications. Our focus is on providing our customers with advanced sequencing solutions with higher throughput and improved workflows that we believe will enable dramatic advancements in routine healthcare. Our customers include academic and governmental research institutions, commercial testing and service laboratories, genome centers, public health labs, hospitals and clinical research institutes, contract research organizations ("CROs"), pharmaceutical companies, and agricultural companies.

References in this report to “PacBio,” “we,” “us,” the “Company,” and “our” refer to Pacific Biosciences of California, Inc. and its consolidated subsidiaries.

Basis of Presentation and Consolidation

Our unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or U.S. GAAP, as set forth in the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC. The unaudited condensed consolidated financial statements include the accounts of Pacific Biosciences and our wholly owned subsidiaries. Certain information and footnote disclosures typically included in our audited financial statements have been condensed or omitted. The accompanying unaudited condensed consolidated financial statements have been prepared on a consistent basis with the December 31, 2022 audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state our financial position, results of operations, comprehensive loss, and cash flows for the period, but are not necessarily indicative of the results to be expected for the entire year or any future periods. All intercompany transactions and balances have been eliminated. Certain prior period amounts have been reclassified to conform to current period presentation.

The financial statements should be read in conjunction with the audited consolidated financial statements and notes included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes to the financial statements. On an ongoing basis, we evaluate our significant estimates including, but not limited to, the valuation of inventory, the determination of stand-alone selling prices for revenue recognition, the fair value of contingent consideration, the valuation of acquired intangible assets, the fair value of certain equity awards, the useful lives assigned to long-lived assets, the computation of provisions for income taxes, the borrowing rate used in calculating the operating lease right-of-use assets and operating lease liabilities, the probability associated with variable payments under partnership development agreements, and the valuations related to our convertible senior notes. While the extent of the potential impact of the current macroeconomic conditions on our business is highly uncertain, we considered information available related to assumptions and estimates used to determine the results reported and asset valuations as of September 30, 2023. Actual results could differ materially from these estimates.

Cash, Cash Equivalents, Restricted Cash and Investments

We consider all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. Cash equivalents may be comprised of money market funds, certificates of deposit, commercial paper, corporate bonds and notes, and government agencies’ securities.

We classify our investments in debt securities as available-for sale and report the investments at fair value in current assets. We evaluate our available-for-sale investments in unrealized loss positions and assess whether the unrealized loss is credit-related. Unrealized gains and losses that are not credit-related are recognized in accumulated other comprehensive loss in stockholders' equity. Realized gains and losses, expected credit losses, as well as interest income, on available-for-sale securities are also reported in other income (expense), net. The cost used in the determination of gains and losses of securities sold is based on the specific identification method. The cost of marketable securities is adjusted for the amortization of premiums and discounts to expected maturity. Premium and discount amortization is recorded in other income (expense), net.

Our investment portfolio at any point in time contains investments in cash deposits, money market funds, commercial paper, corporate debt securities and U.S. government and agency securities with high credit ratings. We have established guidelines regarding diversification and maturities of investments with the objectives of maintaining safety and liquidity, while maximizing yield.

Restricted cash includes cash that is not readily available for use in the Company's operating activities. Restricted cash is primarily comprised of cash pledged under letters of credit.

Concentration and Other Risks

For the three and nine months ended September 30, 2023, no customer exceeded 10% of total revenue during each of the respective periods. For the three and nine months ended September 30, 2022, one customer accounted for approximately 13% and 11% of total revenue during the period.

As of September 30, 2023, 45% of our accounts receivable were from domestic customers, compared to 57% as of December 31, 2022. As of September 30, 2023, no customer represented 10% or greater of our accounts receivable, while one customer represented approximately 10% of our net accounts receivable as of December 31, 2022.

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

In October 2021, the FASB issued Accounting Standards Update ("ASU") No. 2021-08, Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers. This ASU provides specific guidance on how to recognize contract assets and contract liabilities related to revenue contracts with customers acquired in a business combination. This amendment improves comparability for both the recognition and measurement of acquired revenue contracts with customers at the date of and after a business combination. We adopted this ASU on January 1, 2023. The adoption of this guidance did not have a material effect on our consolidated financial statements.

Significant Accounting Policies

There have been no changes to our significant accounting policies as disclosed in the Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

NOTE 2. BUSINESS ACQUISITIONS

Apton Biosystems

On August 2, 2023, we acquired Apton Biosystems, Inc. ("Apton"), a California-based genomics company focused on developing a high throughput short-read sequencer using highly differentiated optics and image processing, paired with novel clustering and chemistry (the "Apton acquisition").

In connection with the Apton acquisition, all outstanding equity securities of Apton were cancelled in exchange for shares of our common stock with a fair value of $76.6 million, cash of $0.2 million, and contingent consideration with a preliminary estimated fair value of $18.5 million. Excluded from consideration transferred was $1.3 million attributable to accelerated share-based compensation expense. The fair value of the 6,121,571 common shares issued was determined based on the closing market price of our common stock on the acquisition date.

In connection with the Apton acquisition, contingent consideration of $25.0 million, which we may elect to pay in cash, shares of our common stock or a combination of cash and shares of our common stock, is due upon the achievement of a milestone, defined as the achievement of $50.0 million in revenue associated with Apton's technology, provided that the milestone event occurs prior to the 5-year anniversary of the closing date of the acquisition. At this time, the number of shares, if any, to be issued in connection with the achievement of the specified milestone is not known and will be calculated based on the daily volume-weighted average price of our common stock for the twenty trading days ending on and including the fifth trading day immediately prior to the occurrence of the specified milestone. Upon achievement of the milestone, we may pay cash in lieu of our common stock to ensure that the issuance of our common stock does not exceed 19.9% of our outstanding shares of common stock then outstanding.

The contingent consideration is accounted for as a liability at fair value, with changes during each reporting period recognized in our Consolidated Statements of Operations and Comprehensive Loss. The fair value of the contingent consideration liability is calculated, with the assistance from a third-party valuation firm, using a Monte Carlo Simulation to estimate the volatility and systematic relative risk of revenues subject to sales milestone payments and discounting the associated cash payment amounts to their present values using a credit-risk-adjusted interest rate.

We allocated the consideration transferred to the identifiable assets acquired and liabilities assumed based on preliminary estimates of their respective fair values at the date of the completion of the Apton acquisition, and such allocation is subject to adjustment for up to one year after the close of the acquisition as additional information is obtained. The major classes of assets and liabilities to which we have allocated the total fair value of the consideration transferred, based on the preliminary estimated fair values were as follows (in thousands):

Cash and cash equivalents	$	97
In-process research and development		53,000
Goodwill		53,869
Other assets, current		153
Deferred income tax liability		(10,920)
Liabilities assumed		(2,191)
Total consideration transferred	$	94,008

The purchase price allocation is preliminary, primarily due to the pending finalization of the valuation analysis and review of various tax attributes. We continue to collect information regarding certain estimates and assumptions, including potential liabilities and contingencies. We will record adjustments to the fair value of the assets acquired, liabilities assumed and goodwill within the twelve months measurement period, if necessary.

We incurred costs related to the Apton acquisition of approximately $9.0 million during the nine months ended September 30, 2023, which are included in merger-related expenses on the Condensed Consolidated Statement of Operations and Comprehensive Loss. Merger-related expenses include $2.8 million relating to a liquidity event bonus plan that was treated as a separate transaction and included the issuance of 168,621 shares of common stock that were issued with a fair value of $2.1 million based on the closing market price of our common stock on the acquisition date. As a result, the total shares issued in connection with the Apton acquisition were 6.3 million shares of common stock.

The excess of the value of consideration paid over the aggregate fair value of those net assets has been recorded as goodwill. We recognized goodwill of $53.9 million, based on preliminary estimates, which is primarily attributable to the synergies expected to occur from the integration of Apton and is not deductible for income tax purposes. We preliminarily allocated $53.0 million of the purchase price to acquired in-process research and development ("IPR&D"). The fair value of the IPR&D was determined, with the assistance of a third-party valuation firm, using an income approach based on a forecast of expected future cash flows. Expected future cash flows utilize significant assumptions such as assumed revenue growth, discount rate and obsolescence factors.

NOTE 3. FINANCIAL INSTRUMENTS

Fair Value of Financial Instruments

Fair value is the exchange price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The fair value hierarchy established under GAAP requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of inputs that may be used to measure fair value are as follows:

- Level 1: quoted prices in active markets for identical assets or liabilities;
- Level 2: inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3: unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

We consider an active market as one in which transactions for the asset or liability occurs with sufficient frequency and volume to provide pricing information on an ongoing basis. Conversely, we view an inactive market as one in which there are few transactions for the asset or liability, the prices are not current, or price quotations vary substantially either over time or among market makers. Where appropriate, our non-performance risk, or that of our counterparty, is considered in determining the fair values of liabilities and assets, respectively.

We classify our cash deposits and money market funds within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted market prices. We classify our investments as Level 2 instruments based on market pricing and other observable inputs. We did not classify any of our investments within Level 3 of the fair value hierarchy.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the entire fair value measurement requires management to make judgments and consider factors specific to the asset or liability.

The carrying amount of our accounts receivable, prepaid expenses, other current assets, accounts payable, accrued expenses and other liabilities, current, approximate fair value due to their short maturities.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table sets forth the fair value of our financial assets and liabilities that were measured on a recurring basis (in thousands):

	September 30, 2023				December 31, 2022			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets								
Cash and cash equivalents	$ 196,621	$ 189,027	$ —	$ 385,648	$ 137,636	$ 187,453	$ —	$ 325,089
Investments:								
Commercial paper	—	16,771	—	16,771	—	127,302	—	127,302
Corporate debt securities	—	75,853	—	75,853	—	49,491	—	49,491
U.S. government & agency securities	—	289,517	—	289,517	—	270,436	—	270,436
Total investments	—	382,141	—	382,141	—	447,229	—	447,229
Short-term restricted cash	300	—	—	300	300	—	—	300
Long-term restricted cash	2,422	—	—	2,422	2,922	—	—	2,922
Total assets measured at fair value	$ 199,343	$ 571,168	$ —	$ 770,511	$ 140,858	$ 634,682	$ —	$ 775,540
Liabilities								
Contingent consideration	$ —	$ —	$ 18,450	$ 18,450	$ —	$ —	$ 172,094	$ 172,094
Total liabilities measured at fair value	$ —	$ —	$ 18,450	$ 18,450	$ —	$ —	$ 172,094	$ 172,094

We classify contingent consideration, which was incurred in connection with the acquisition of Apton, within Level 3, as factors used to develop the estimate of fair value include unobservable inputs that are not supported by market activity and are significant to the fair value. Estimates and assumptions used in the Monte Carlo simulation include risk-adjusted forecasted revenues for products and services leveraging Apton's technology and an estimated credit spread.

On September 20, 2023, we achieved the commercial milestone in connection with the acquisition of Omniome. Consequently, former Omniome securityholders were entitled to receive as milestone consideration, among other things, an aggregate of approximately $100.9 million in cash and approximately 9.0 million shares of our common stock, representing $95.9 million divided by the volume-weighted average of the trading prices of our common stock for the twenty trading days ending with and including the trading day that was two days immediately prior to the achievement of the milestone. The $95.9 million represents the $100.0 million that was to be paid in shares of our common stock offset by $4.1 million attributable to stock options issued by PacBio in replacement of Omniome’s unvested options as part of the transaction, pursuant to the terms of the Omniome merger agreement.

Following the achievement of the commercial milestone, $5.1 million of the contingent consideration was paid during the three and nine months ended September 30, 2023. Additionally, as the shares payable pursuant to the commercial milestone became fixed, and the contingency was resolved, the value attributable to the shares to be issued of $84.8 million was reclassified to additional paid-in capital on the Condensed Consolidated Balance Sheets. Such shares were issued to the former Omniome securityholders and the remainder of the cash payment was in October 2023. The remaining liability balance attributable to the achievement of the commercial milestone in September 2023 of $96.2 million is included in contingent consideration liability, current, in the Condensed Consolidated Balance Sheets as of September 30, 2023.

As a result of the achievement of the milestone, the contingent consideration liability incurred in connection with the acquisition of Omniome was no longer considered a Level 3 liability at September 30, 2023. There were no other transfers between Level 1, Level 2, or Level 3 assets or liabilities reported at fair value on a recurring basis for the nine months ended September 30, 2023, and our valuation techniques did not change compared to the prior year.

Changes in the estimated fair value of the contingent consideration liability for the nine months ended September 30, 2023 were as follows (in thousands):

	Level 3
Beginning balance as of December 31, 2022	$ 172,094
Additions	18,450
Change in estimated fair value	13,960
Achievement of milestone	$ (186,054)
Ending balance as of September 30, 2023	$ 18,450

Changes to the fair value are recorded as change in fair value of contingent consideration in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

The following tables summarize our cash, cash equivalents and investments (in thousands):

	As of September 30, 2023			
	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Cash and cash equivalents	385,619	29	—	385,648
Investments:				
Commercial paper	16,771	—	—	16,771
Corporate debt securities	76,161	3	(311)	75,853
U.S. government & agency securities	291,078	7	(1,568)	289,517
Total investments	384,010	10	(1,879)	382,141
Total cash, cash equivalents and investments	$ 769,629	$ 39	$ (1,879)	$ 767,789
Short-term restricted cash	$ 300	$ —	$ —	$ 300
Long-term restricted cash	$ 2,422	$ —	$ —	$ 2,422

	As of December 31, 2022			
	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Cash and cash equivalents	325,144	6	(61)	325,089
Investments:				
Commercial paper	127,626	9	(333)	127,302
Corporate debt securities	49,998	—	(507)	49,491
U.S. government & agency securities	274,315	1	(3,880)	270,436
Total investments	451,939	10	(4,720)	447,229
Total cash, cash equivalents and investments	$ 777,083	$ 16	$ (4,781)	$ 772,318
Short-term restricted cash	$ 300	$ —	$ —	$ 300
Long-term restricted cash	$ 2,922	$ —	$ —	$ 2,922

The following table summarizes the contractual maturities of our cash equivalents and available-for-sale investments, excluding money market funds, as of September 30, 2023 (in thousands):

	Fair Value
Due in one year or less	$ 498,366
Due after one year through five years	72,802
Total	$ 571,168

Actual maturities may differ from contractual maturities because issuers may have the right to call or prepay obligations without call or prepayment penalties.

Investment income included in other income, net on the Condensed Consolidated Statement of Operations and Comprehensive Loss was $9.2 million and $25.0 million for the three and nine months ended September 30, 2023, respectively, and $2.8 million and $4.3 million for the three and nine months ended September 30, 2022, respectively.

NOTE 4. BALANCE SHEET COMPONENTS

Inventory, net

Our inventory, net, consisted of the following components (in thousands):

	September 30, 2023	December 31, 2022
Purchased materials	$ 23,333	$ 24,139
Work in process	27,883	14,062
Finished goods	17,040	12,180
Inventory, net	$ 68,256	$ 50,381

Intangible Assets and Goodwill

Intangible assets include acquired in-process research and development ("IPR&D") of $53.0 million as a result of the Apton acquisition in August 2023. The IPR&D will remain on our Consolidated Balance Sheet as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development activities. During the development period following the acquisition, IPR&D will not be amortized, but instead will be tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. Upon completion of the development, we will begin to amortize the asset over the life of the product or record an impairment charge if the asset is determined to be impaired.

In addition to IPR&D, definite-lived intangible assets included the following (in thousands, except years):

		As of September 30, 2023			As of December 31, 2022		
	Estimated Useful Life (in years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Developed technology	15	$ 411,179	$ (2,341)	$ 408,838	$ 11,179	$ (1,039)	$ 10,140
Customer relationships	2	360	(360)	—	360	(255)	105
Total		$ 411,539	$ (2,701)	$ 408,838	$ 11,539	$ (1,294)	$ 10,245

The developed technology as of September 30, 2023 includes the completed IPR&D from the Omniome acquisition that was completed in September 2023.

The estimated future amortization expense of intangible assets with definite lives is as follows (in thousands):

Remainder of 2023	$ 6,854
2024	27,412
2025	27,412
2026	27,412
2027	27,412
2028 and thereafter	292,337
Total	$ 408,838

Amortization of intangible assets is included within our cost of revenue if the costs and expenses related to the intangible assets are attributable to revenue generating activities. Amortization expense for intangible assets that are not directly related to sales generating activities are amortized to operating expenses. The definite-lived intangible assets are amortized using the straight-line method over their estimated useful lives.

We review definite-lived intangible assets for impairment when indication of potential impairment exists, such as a significant reduction in cash flows associated with the assets.

We had goodwill of $463.8 million as of September 30, 2023, which preliminarily increased by $53.9 million, due to the Apton acquisition, of which $10.9 million relates to a deferred income tax liability, as compared to $410.0 million as of December 31, 2022. Goodwill is reviewed for impairment at least annually during the second quarter, or more frequently if an event occurs indicating the potential for impairment. We performed our annual assessment for goodwill impairment in the second quarter of 2023, noting no impairment.

Deferred Revenue

As of September 30, 2023, we had a total of $27.5 million of deferred revenue, $22.4 million of which was recorded as deferred revenue, current, and primarily relates to future performance obligations under the Amended and Restated Agreement with Invitae Corporation ("Invitae") and deferred service contract revenues. The deferred revenue, non-current balance of $5.1 million primarily relates to future performance obligations under the Amended and Restated Agreement with Invitae and deferred service contract revenues and is scheduled to be recognized in the next 5 years. The deferred revenue, non-current balance includes $3.0 million that was reclassified from deferred revenue, current to deferred revenue, non-current following receipt of a non-cancellable order from Invitae during the nine months ended September 30, 2023 for partial utilization of the available credits, which is expected to be recognized in revenue after 12 months from September 30, 2023. Revenue recorded in the three and nine months ended September 30, 2023 includes $3.7 million and $11.7 million, respectively, that was included in deferred revenue as of December 31, 2022, of which $2.1 million and $4.2 million was included in product revenue recognized from the partial utilization of available credits by Invitae during the three and nine months ended September 30, 2023, respectively. Refer to *Note 3 – Invitae Collaboration*, in Part II, Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2022 for more information.

Product Warranties

We generally provide a one-year warranty on instruments. In addition, we provide a limited warranty on consumables. At the time revenue is recognized, an accrual is established for estimated warranty costs based on historical experience as well as anticipated product performance. We periodically review the warranty reserve for adequacy and adjust the warranty accrual, if necessary, based on actual experience and estimated costs to be incurred. Warranty expense is recorded as a component of cost of product revenue. There were no material changes in estimates for the periods presented below.

Changes in the reserve for product warranties were as follows for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Balance at beginning of period	$ 2,862	$ 1,609	$ 1,651	$ 594
Additions charged to cost of product revenue	2,825	779	5,675	2,644
Repairs and replacements	(1,722)	(622)	(3,361)	(1,472)
Balance at end of period	$ 3,965	$ 1,766	$ 3,965	$ 1,766

Term loans

In connection with the acquisition of Omniome, we acquired $1.3 million in short-term debt and $3.0 million in long-term debt relating to a term loan facility that Omniome obtained in April 2020. Borrowings on the term loan facility were used to fund Omniome's purchases of equipment, which serves as collateral. Each term loan has a term of 43 months and bears a fixed interest rate of approximately 17% annually. The fee for the elective option to prepay all, but not less than all, of the borrowed amounts at any time after the 24th month and before the 43rd month after the commencement date, is 4% of the outstanding loan balance. Payments are made in equal monthly installments including principal and interest.

As of September 30, 2023, the carrying value of term loans outstanding was $0.9 million, recorded as part of other liabilities, current on the Condensed Consolidated Balance Sheet. The interest expense was $0.1 million and $0.2 million for the three and nine months ended September 30, 2023, which was included as part of interest expense in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

The following table presents the future principal payments on the term loans (in thousands):

Remainder of 2023	$	444
2024		490
Total	$	934

NOTE 5. CONVERTIBLE SENIOR NOTES

2030 Convertible Senior Notes

In June 2023, we entered into a privately negotiated exchange agreement with a holder of our outstanding 1.50% Convertible Senior Notes due 2028 (the "2028 Notes"), pursuant to which we issued $441.0 million in aggregate principal amount of our 1.375% Convertible Senior Notes due 2030 (the "2030 Notes") in exchange for $441.0 million principal amount of the 2028 Notes (the "Exchange Transaction"), pursuant to exemptions from registration under the Securities Act of 1933, as amended, and the rules and regulations thereunder. The 2030 Notes were issued on June 30, 2023.

The 2030 Notes are governed by an indenture (the "2030 Indenture") between the Company and U.S. Bank Trust Company, National Association, as trustee. The 2030 Notes bear interest at a rate of 1.375% per annum. Interest on the 2030 Notes is payable semi-annually in arrears on June 15 and December 15, commencing on December 15, 2023. The 2030 Notes will mature on December 15, 2030, subject to earlier conversion, redemption or repurchase.

The 2030 Notes are convertible at the option of the holder at any time until the second scheduled trading day prior to the maturity date, including in connection with a redemption by the Company. The 2030 Notes are convertible into shares of our common stock based on an initial conversion rate of 46.5116 shares of common stock per $1,000 principal amount of the 2030 Notes (which is equal to an initial conversion price of $21.50 per share of common stock), in each case subject to customary anti-dilution and other adjustments as a result of certain extraordinary transactions. Upon conversion of the 2030 Notes, we may elect to settle such conversion obligation in shares of our common stock, cash or a combination of shares of our common stock and cash.

On or after June 20, 2028, the 2030 Notes will be redeemable by the Company in the event that the closing sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide the redemption notice at a redemption price of 100% of the principal amount of such 2030 Notes, plus accrued and unpaid interest up to, but excluding, the redemption date.

Upon the occurrence of a Fundamental Change (as defined in the 2030 Indenture), the holders of the 2030 Notes may require that we repurchase all or part of the principal amount of the 2030 Notes at a purchase price equal to 100% of the principal amount of the notes to be repurchased, plus any accrued and unpaid interest up to, but excluding, the fundamental change repurchase date, and all unpaid interest from the fundamental change repurchase date thereon, but excluding, the maturity date.

The 2030 Indenture includes customary "events of default," which may result in the acceleration of the maturity of the 2030 Notes under the 2030 Indenture. The 2030 Indenture also includes customary covenants for convertible notes of this type.

To the extent we elect, the sole remedy for an event of default relating to our failure to comply with certain of our reporting obligations shall, for the first 360 calendar days after the occurrence of such an event of default, consist exclusively of the right to receive additional interest on the 2030 Notes at a rate equal to (i) 0.25% per annum of the principal amount of the 2030 Notes outstanding for each day during the first 180 calendar days of the 360-day period after the occurrence of such an event of default during which such event of default is continuing (or, if earlier, the date on which such event of default is cured or waived) and (ii) 0.50% per annum of the principal amount of the 2030 Notes outstanding for each day from, and including, the 181st calendar day to, and including, the 360th calendar day after the occurrence of such an event of default during which such event of default is continuing (or, if earlier, the date on which such event of default is cured or waived as provided for in the 2030 Indenture). On the 361st day after such event of default (if the event of default relating to our failure to comply with its obligations is not cured or waived prior to such 361st day), the 2030 Notes shall be subject to acceleration as provided for in the 2030 Indenture.

The 2030 Notes are accounted for in accordance with the authoritative guidance for convertible debt instruments that may be settled in cash upon conversion. Under ASU 2020-06, the guidance requires that debt with an embedded conversion feature is accounted for in its entirety as a liability and no portion of the proceeds from the issuance of the convertible debt instrument is accounted for as attributable to the conversion feature unless the conversion feature is required to be accounted for separately as an embedded derivative or the conversion feature results in a substantial premium. The conversion feature of the 2030 Notes is not accounted for as an embedded derivative because it is considered to be indexed to our common stock, and the 2030 Notes were not issued at a substantial premium; therefore, the 2030 Notes are accounted for in their entirety as a liability. Because we may elect to settle any conversions entirely in shares, and because settlement in shares is the default settlement method, the liability is classified as non-current.

The requirement to repurchase the 2030 Notes, including unpaid interest to the maturity date in the event of a Fundamental Change, is considered a put option for certain periods requiring bifurcation under ASC 815 – *Derivatives and Hedging.* However, given the low probability of such a Fundamental Change occurring during the applicable periods, the value of the embedded derivative is immaterial.

The additional interest feature in the event of our failure to comply with certain reporting obligations is also considered an embedded derivative requiring bifurcation under ASC 815. However, due to the nature and terms of the reporting obligations, the value of the embedded derivative is immaterial.

The Exchange Transaction was accounted for as an extinguishment driven by the change in fair value of the embedded conversion option. We recorded a loss on extinguishment of debt of approximately $2.0 million in connection with the Exchange Transaction during the nine months ended September 30, 2023, which represents the difference between the fair value and the principal amount of the 2030 Notes of the debt at the modification date, plus unamortized debt issuance costs of $1.5 million related to the respective portion of the 2028 Notes.

We incurred issuance costs related to the 2030 Notes of approximately $7.3 million, which were recorded as debt issuance costs and are presented as a reduction to the 2030 Notes on our Consolidated Balance Sheets and are amortized to interest expense using the effective interest method over the term of the 2030 Notes, resulting in an effective interest rate of 1.6%. We also paid accrued but unpaid interest of $2.5 million on the 2028 Notes in connection with the Exchange Transaction on June 30, 2023.

We did not receive any cash proceeds from the Exchange Transaction. In exchange for issuing the 2030 Notes pursuant to the Exchange Transaction, we received and cancelled the exchanged 2028 Notes. Following the closing of the Exchange Transaction, $459.0 million in aggregate principal amount of 2028 Notes remained outstanding with terms unchanged.

The net carrying amount of the liability for the 2030 Notes is included as convertible senior notes, net, non-current in the Condensed Consolidated Balance Sheets as follows (in thousands):

	September 30, 2023	December 31, 2022
Principal amount	$ 441,000	$ —
Unamortized debt premium	542	—
Unamortized debt issuance costs	(7,093)	—
Net carrying amount	$ 434,449	$ —

For the three and nine months ended September 30, 2023 and 2022, interest expense for the 2030 Notes was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Contractual interest expense	$ 1,516	$ —	$ 1,516	$ —
Amortization of debt issuance costs	229	—	229	—
Total interest expense	$ 1,745	$ —	$ 1,745	$ —

As of September 30, 2023, the estimated fair value (Level 2) of the 2030 Notes was $356.6 million. The fair value of the 2030 Notes is estimated using a binomial lattice model that is primarily affected by the trading price of our common stock, market interest rates and volatility.

2028 Convertible Senior Notes

On February 9, 2021, we entered into an investment agreement (the "Investment Agreement") with SB Northstar LP (the "Purchaser"), a subsidiary of SoftBank Group Corp., relating to the issuance and sale to the Purchaser of $900.0 million in aggregate principal amount of the 2028 Notes. The 2028 Notes were issued on February 16, 2021. As discussed above, in June 2023 we completed an exchange of $441.0 million in aggregate principal amount of our 2028 Notes for $441.0 million aggregate principal amount of the 2030 Notes, leaving approximately $459.0 million in aggregate principal amount of 2028 Notes outstanding.

The 2028 Notes are governed by an indenture (the "2028 Indenture") between the Company and U.S. Bank National Association, as trustee. The 2028 Notes bear interest at a rate of 1.50% per annum. Interest on the 2028 Notes is payable semi-annually in arrears on February 15 and August 15 and commenced on August 15, 2021. The 2028 Notes will mature on February 15, 2028, subject to earlier conversion, redemption or repurchase.

The 2028 Notes are convertible at the option of the holder at any time until the second scheduled trading day prior to the maturity date, including in connection with a redemption by the Company. The 2028 Notes are convertible into shares of our common stock based on an initial conversion rate of 22.9885 shares of common stock per $1,000 principal amount of the 2028 Notes (which is equal to an initial conversion price of $43.50 per share of common stock), in each case subject to customary anti-dilution and other adjustments as a result of certain extraordinary transactions. Upon conversion of the 2028 Notes, we may elect to settle such conversion obligation in shares of our common stock, cash or a combination of shares of our common stock and cash.

On or after February 20, 2026, the 2028 Notes will be redeemable by the Company in the event that the closing sale price of our common stock has been at least 150% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide the redemption notice at a redemption price of 100% of the principal amount of such 2028 Notes, plus accrued and unpaid interest up to, but excluding, the redemption date.

Upon the occurrence of a Fundamental Change (as defined in the 2028 Indenture), the holders of the 2028 Notes may require that we repurchase all or part of the principal amount of the 2028 Notes at a purchase price of par plus unpaid interest up to, but excluding, the maturity date.

The 2028 Indenture includes customary "events of default," which may result in the acceleration of the maturity of the 2028 Notes under the 2028 Indenture. The 2028 Indenture also includes customary covenants for convertible notes of this type.

To the extent we elect, the sole remedy for an event of default relating to our failure to comply with certain of our reporting obligations shall, for the first 360 calendar days after the occurrence of such an event of default, consist exclusively of the right to receive additional interest on the 2028 Notes at a rate equal to (i) 0.25% per annum of the principal amount of the 2028 Notes outstanding for each day during the first 180 calendar days of the 360-day period after the occurrence of such an event of default during which such event of default is continuing (or, if earlier, the date on which such event of default is cured or waived) and (ii) 0.50% per annum of the principal amount of the 2028 Notes outstanding for each day from, and including, the 181st calendar day to, and including, the 360th calendar day after the occurrence of such an event of default during which such event of default is continuing (or, if earlier, the date on which such event of default is cured or waived as provided for in the 2028 Indenture). On the 361st day after such event of default (if the event of default relating to our failure to comply with its obligations is not cured or waived prior to such 361st day), the 2028 Notes shall be subject to acceleration as provided for in the 2028 Indenture.

The 2028 Notes are accounted for in accordance with the authoritative guidance for convertible debt instruments that may be settled in cash upon conversion. Under ASU 2020-06, the guidance requires that debt with an embedded conversion feature is accounted for in its entirety as a liability and no portion of the proceeds from the issuance of the convertible debt instrument is accounted for as attributable to the conversion feature unless the conversion feature is required to be accounted for separately as an embedded derivative or the conversion feature results in a substantial premium. The conversion feature of the 2028 Notes is not accounted for as an embedded derivative because it is considered to be indexed to our common stock, and the 2028 Notes were not issued at a premium; therefore, the 2028 Notes are accounted for in their entirety as a liability.

Because we may elect to settle any conversions entirely in shares, and because settlement in shares is the default settlement method, the liability is classified as non-current.

The requirement to repurchase the 2028 Notes, including unpaid interest to the maturity date in the event of a Fundamental Change, is considered a put option for certain periods requiring bifurcation under ASC 815 – *Derivatives and Hedging.* However, given the low probability of such a Fundamental Change occurring during the applicable periods, the value of the embedded derivative is immaterial.

The additional interest feature in the event of our failure to comply with certain reporting obligations is also considered an embedded derivative requiring bifurcation under ASC 815. However, due to the nature and terms of the reporting obligations, the value of the embedded derivative is immaterial.

We incurred issuance costs related to the 2028 Notes of approximately $4.5 million, which were recorded as debt issuance costs and are presented as a reduction to the 2028 Notes on our Consolidated Balance Sheets and are amortized to interest expense using the effective interest method over the term of the 2028 Notes, resulting in an effective interest rate of 1.6%.

The net carrying amount of the liability for the 2028 Notes is included as convertible senior notes, net, non-current in the Condensed Consolidated Balance Sheets as follows (in thousands):

	September 30, 2023	December 31, 2022
Principal amount	$ 459,000	$ 900,000
Unamortized debt issuance costs	(1,453)	(3,317)
Net carrying amount	$ 457,547	$ 896,683

For the three and nine months ended September 30, 2023 and 2022, interest expense for the 2028 Notes was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Contractual interest expense	$ 1,721	$ 3,375	$ 8,415	$ 10,125
Amortization of debt issuance costs	80	154	392	462
Total interest expense	$ 1,801	$ 3,529	$ 8,807	$ 10,587

As of September 30, 2023, the estimated fair value (Level 2) of the 2028 Notes was $358.6 million. The fair value of the 2028 Notes is estimated using a binomial lattice model that is primarily affected by the trading price of our common stock, market interest rates and volatility.

NOTE 6. COMMITMENTS AND CONTINGENCIES

The Company has entered into various operating lease agreements, primarily relating to our corporate offices. See *Note 8 – Commitments and Contingencies*, subsection titled “Leases”, in Part II, Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2022 for information regarding the Company’s maturity of lease liabilities under its lease agreements.

Contingencies

We may become involved in legal proceedings, claims and assessments from time to time in the ordinary course of business. We accrue liabilities for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

We do not believe that the ultimate outcome of any such pending matters is probable or reasonably estimable, or that these matters will have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of litigation and settlement costs, diversion of management resources, and other factors.

Please see subsection titled Legal Proceedings, in Part II, Item 1 of this Quarterly Report on Form 10-Q.

Indemnification

Pursuant to Delaware law and agreements entered into with each of our directors and officers, we may have obligations, under certain circumstances, to hold harmless and indemnify each of our directors and officers against losses suffered or incurred by the indemnified party in connection with their service to us, and judgements, fines, settlements and expenses related to claims arising against such directors and officers to the fullest extent permitted under Delaware law, our bylaws and our certificate of incorporation. We also enter and have entered into indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law. In addition, we may have obligations to hold harmless and indemnify third parties involved with our fundraising efforts and their respective affiliates, directors, officers, employees, agents or other representatives against any and all losses, claims, damages and liabilities related to claims arising against such parties pursuant to the terms of agreements entered into between such third parties and us in connection with such fundraising efforts. To the extent that any such indemnification obligations apply to the lawsuits described above, any associated expenses incurred are included within the related accrued litigation expense amounts. No additional liability associated with such indemnification obligations has been recorded as of September 30, 2023 and December 31, 2022.

NOTE 7. STOCKHOLDERS' EQUITY

Underwritten Public Equity Offering

In January 2023, we entered into an underwriting agreement, relating to the public offering of 17.5 million shares of our common stock, $0.001 par value per share, at a price to the public of $10.00 per share. Under the terms of the underwriting agreement, we also granted the underwriters a 30-day option to purchase up to an additional 2.6 million shares of our common stock, which was subsequently exercised in full, and the offering, including the sale of shares of common stock subject to the underwriters' option, closed in January 2023. In total, we sold 20.1 million shares of our common stock. We paid a commission equal to 5.75% of the gross proceeds from the sale of shares of our common stock. The total net proceeds to us from the offering after deducting the underwriting discount were approximately $189.7 million, excluding approximately $0.5 million of offering expenses.

Refer to *Note 10 – Stockholders' Equity*, in Part II, Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2022 for more information on the Company's underwritten public equity offerings and private placement of common stock.

Equity Plans

As of September 30, 2023, the Company had share-based compensation awards outstanding under the 2020 Equity Incentive Plan (the "2020 Plan"), the 2020 Inducement Equity Incentive Plan (the "Inducement Plan"), the 2021 adopted Omniome Equity Incentive Plan of Pacific Biosciences of California, Inc. (the "Omniome Plan") and the 2010 Employee Stock Purchase Plan, from which we issued equity awards and employee stock.

As of September 30, 2023, we had 12.3 million shares remaining and available for future issuance under the 2020 Plan, Inducement Plan, and the Omniome Plan. Shares remaining and available for future issuance reflect shares that may become eligible to vest upon the achievement of maximum targets for certain equity awards.

Refer to *Note 10 – Stockholders' Equity*, in Part II, Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2022 for more information on the Company's equity plans.

Stock Options

Time-based Stock Options

The following table summarizes stock option activity for time-based awards (shares in thousands):

	Number of shares	Weighted average exercise price
Outstanding at December 31, 2022	14,618	$ 10.60
Granted	332	12.11
Exercised	(929)	4.70
Canceled	(810)	18.05
Outstanding at September 30, 2023	13,211	$ 10.60

Performance-based Stock Options

The following table summarizes stock option activity for performance-based awards (shares in thousands):

	Number of shares	Weighted average exercise price
Outstanding at December 31, 2022	258	$ 4.71
Granted	—	—
Exercised	(251)	4.71
Canceled	(4)	4.71
Outstanding at September 30, 2023	3	$ 4.74

Restricted Stock Units ("RSU") and Performance Stock Units ("PSU")

We issue RSUs for which the respective shares vest when the requisite service period is achieved. We issue PSUs for which the number of shares issuable in the third year of the performance period based on performance relative to specified revenue targets and continued employment through the vesting period. Maximum achievement of the revenue goal under the PSUs will result in up to 200% of the target number of shares subject to the PSUs to become eligible to vest, while not meeting the minimum achievement of the revenue goal under the PSUs will result in no shares subject to the PSUs becoming eligible to vest. The following table summarizes the time-based RSUs and PSUs activity (shares in thousands):

	Restricted Stock Units (RSU)	Performance Stock Units (PSU)	Weighted average grant date fair value	
			RSU	PSU
Outstanding at December 31, 2022	8,535	—	$ 15.16	$ —
Granted	6,970	564	9.71	9.43
Vested	(2,538)	—	14.19	—
Forfeited	(1,008)	(23)	14.73	9.43
Outstanding at September 30, 2023	11,959	541	$ 12.23	$ 9.43

Employee Stock Purchase Plan ("ESPP")

Shares issued under our ESPP were 1,735,058 and 1,878,168 during the nine months ended September 30, 2023 and 2022, respectively. In February 2023, an additional 4.0 million shares were reserved under the ESPP. As of September 30, 2023, 12.2 million shares of our common stock remain available for issuance under our ESPP.

Share-Based Compensation

The following table summarizes share-based compensation expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of revenue	$ 1,125	$ 934	$ 4,251	$ 3,680
Research and development	6,182	7,519	18,310	24,232
Sales, general and administrative	12,384	10,483	32,973	32,746
Total share-based compensation expense	$ 19,691	$ 18,936	$ 55,534	$ 60,658

Determining Fair Value

We estimate the fair value of stock options granted using the Black-Scholes valuation method and a single option award approach. When determining the current share prices underlying the stock options for calculating the grant-date fair value, we reference the observable market prices of our stock. This fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. The fair market value of RSUs and PSUs granted is the closing price of our shares on the date of grant and is generally recognized as compensation expense on a straight-line basis over the respective vesting period. For shares purchased under our ESPP, we estimate the grant-date fair value, and the resulting share-based compensation expense, using the Black-Scholes option-pricing model. We estimate forfeitures of stock options, RSUs and shares purchased under our ESPP which is utilized to determine the compensation expense to be recorded over the requisite service period.

- Expected Term - The expected term used in the Black-Scholes valuation method represents the period that the stock options are expected to be outstanding and is determined based on historical experience of similar awards, giving consideration to the contractual terms of the stock options and vesting schedules.
- Expected Volatility - The expected volatility used in the Black-Scholes valuation method is derived from the implied volatility related to our share price over the expected term.
- Expected Dividend - We have never paid dividends on our shares and, accordingly, the dividend yield percentage is zero for all periods.
- Risk-Free Interest Rate - The risk-free interest rate used in the Black-Scholes valuation method is the implied yield currently available on U.S. Treasury constant maturities issued with a term equivalent to the expected terms.

The fair value of employee stock options was estimated using the following assumptions:

	Nine Months Ended September 30,	
	2023	2022
Expected term in years	4.9	4.6
Expected volatility	78%	70% — 76%
Risk-free interest rate	3.73% - 4.21%	0.41% — 3.66%
Dividend yield	—	—
Weighted average grant date fair value per share	$7.89	$5.93

The fair value of shares to be issued under the ESPP was estimated using the following assumptions:

	Nine Months Ended September 30,	
	2023	2022
Expected term in years	0.5 — 2.0	0.5 — 2.0
Expected volatility	79% — 97%	70% — 97%
Risk-free interest rate	4.87% — 5.47%	0.60% — 3.51%
Dividend yield	—	—
Weighted average grant date fair value per share	$5.34	$4.28

NOTE 8. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares of common stock outstanding and potential shares assuming the dilutive effect of the convertible senior notes, using the if-converted method, and outstanding equity awards using the treasury stock method.

The following table presents the calculation of the basic and diluted net loss per share amounts presented in the Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss	$ (66,869)	$ (76,971)	$ (224,717)	$ (229,864)
Denominator:				
Basic				
Weighted average shares used in computing basic net loss	255,001	225,123	249,082	223,981
Basic net loss per share	$ (0.26)	$ (0.34)	$ (0.90)	$ (1.03)
Diluted				
Weighted average shares used in computing diluted net loss per share	255,001	225,123	249,082	223,981
Diluted net loss per share	$ (0.26)	$ (0.34)	$ (0.90)	$ (1.03)

The following shares issuable upon conversion of the convertible senior notes and outstanding equity awards were excluded from the computation of diluted net loss per share for the periods presented because the effect of including such shares would have been antidilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Shares issuable upon conversion of convertible senior notes	31,063	20,690	31,063	20,690
Equity Awards	28,100	28,087	28,100	28,087

NOTE 9. REVENUE

A summary of our revenue by geographic location is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Americas	$ 28,978	$ 16,743	$ 71,480	$ 57,547
Europe, Middle East and Africa	10,994	5,997	29,594	17,432
Asia-Pacific	15,719	9,571	41,090	25,972
Total	$ 55,691	$ 32,311	$ 142,164	$ 100,951

A summary of our revenue by category is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Instrument revenue	$ 34,694	$ 11,442	$ 85,317	$ 42,611
Consumable revenue	16,868	16,067	44,554	43,317
Product revenue	51,562	27,509	129,871	85,928
Service and other revenue	4,129	4,802	12,293	15,023
Total revenue	$ 55,691	$ 32,311	$ 142,164	$ 100,951

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

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited condensed consolidated financial statements and related notes that are included elsewhere in this Quarterly Report on Form 10-Q and the consolidated financial statements and the related notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the U.S. Securities and Exchange Commission, or the SEC, on February 28, 2023, or our Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current plans, expectations and beliefs that involve risks and uncertainties. The words "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "might," "plans," "potential," "predicts," "projects," "seeks," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including, but not limited to, those discussed in the section entitled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q, and you should not place undue reliance on our forward-looking statements. We do not assume any obligation to update any forward-looking statements. In preparing this MD&A, we presume that readers have access to and have read the MD&A in our Annual Report on Form 10-K, pursuant to Instruction 2 to paragraph (b) of Item 303 of Regulation S-K.

Our Management's Discussion and Analysis (MD&A) is organized into the following sections:

- Overview and Outlook
- Results of Operations
- Liquidity and Capital Resources
- Critical Accounting Policies and Estimates
- Recent Accounting Pronouncements
- Off Balance Sheet Arrangements

Overview and Outlook

About PacBio

We are a premier life science technology company that is designing, developing, and manufacturing advanced sequencing solutions that enable scientists and clinical researchers to improve their understanding of the genome and ultimately, resolve genetically complex problems.

Our products and technology under development stem from two highly differentiated core technologies focused on accuracy, quality and completeness which include our existing HiFi long-read sequencing solutions and our emerging Sequencing by Binding ("SBB") short-read sequencing solution. Our products address solutions across a broad set of research applications including human genomics, plant and animal sciences, infectious disease and microbiology, oncology, and other emerging applications.

Our focus is on providing our customers with advanced sequencing solutions with higher throughput and improved workflows that we believe will enable dramatic advancements in routine healthcare.

Our customers include academic and governmental research institutions, commercial testing and service laboratories, genome centers, public health labs, hospitals and clinical research institutes, contract research organizations ("CROs"), pharmaceutical companies and agricultural companies.

As of September 30, 2023, our commercial team consisted of approximately 208 employees, including 64 quota-carrying representatives, many with advanced degrees in biology and significant experience in the genomics industry.

Strategic Objectives

Our 2023 strategic objectives are to:

- Drive rapid adoption of Revio™ by converting existing Sequel® II/IIe customers and attracting new PacBio customers
- Demonstrate Onso's extraordinary level of accuracy in the field and show how it can transform research in needle-in-haystack applications

- Progress development of ultra-high-throughput and benchtop long-read sequencers and next generation SBB™ short-read sequencer
- Leverage current infrastructure to drive toward positive cash flow
- Expand partnerships across ecosystem and workflow to drive customer adoption of SBB short-read sequencing and HiFi long-read sequencing

We will continue to leverage our commercial organization and significantly improve our products' efficiency and usability to seek to reach a broader customer base. We believe the commercial investments we have recently made will further help drive growth in our business.

To increase the adoption of HiFi sequencing, we have various development programs in progress to expand our product portfolio, increase the throughput, and improve the usability of our existing sequencing solutions. We continue to focus on programs to accelerate new platform launches in the near to mid-term as well as increase applications for our technologies. In October 2022, we announced Revio, our new HiFi long-read sequencing system. We began taking orders in the fourth quarter of 2022 and commenced commercial Revio shipments in the first quarter of 2023. To address the oncology research markets with a highly differentiated alternative to existing third-party short-read sequencing products already on the market, we also progressed development of and, subsequent to the quarter ended June 30, 2023, commercialized Onso™, our SBB short-read platform. We began taking orders in the first quarter of 2023, and in August 2023, we commenced customer shipments of the Onso short-read sequencing instrument.

We continue to believe that with the capabilities of our HiFi chemistry and SMRT™ technology, we can be a market leader in whole-genome clinical sequencing. Leading institutions have adopted our products to study rare and inherited disease. We believe the market opportunity for clinical sequencing is significant and could drive substantial revenue growth for us. We plan to continue to pursue collaborations where the technologies being developed or applications being considered extend beyond whole-genome clinical sequencing. Collaborative arrangements add to the awareness of our products and service offerings and may drive new applications for use of our technology.

Financial Overview

Key highlights of the nine months ended September 30, 2023 consolidated financial results include the following:

- Revenue increased $41.2 million, or 41%, to $142.2 million for the nine months ended September 30, 2023, as compared to $101.0 million for the nine months ended September 30, 2022. Revenue was comprised of $85.3 million in instrument revenue, $44.6 million in consumables revenue and $12.3 million in service and other revenue for the nine months ended September 30, 2023. The increase was primarily driven by the launch of Revio in the first quarter of 2023, which is sold at a higher average selling price than our previous Sequel II and IIe platforms. We ended the quarter with an installed base of 129 Revio systems.

- Gross profit as a percentage of revenue (gross margin) was 30% for the nine months ended September 30, 2023, compared to 43% for the nine months ended September 30, 2022. Gross margin declined due in part to instrument mix, as Revio instruments sold during the nine months ended September 30, 2023 had a lower margin primarily due to loyalty discounts provided and higher initial manufacturing costs, including warranty costs, as well as adjustments of approximately $3.5 million recognized in the first quarter of 2023 primarily relating to excess consumables inventory resulting from a faster-than-expected decline in demand of Sequel II/IIe consumables due to the product transition to Revio. Our gross margin in future periods will depend on several factors, including new product transitions and offerings, strategic product pricing; product mix as a result of higher-margin consumables; supply chain constraints and inflation increasing the costs of raw materials; manufacturing capacity and production volumes impacting the cost of inventory; warranty costs; freight costs; and excess or obsolete inventories.

- Loss from operations increased $26.8 million, or 12%, to $246.9 million for the nine months ended September 30, 2023, as compared to $220.1 million for the nine months ended September 30, 2022, driven primarily by an increase of $26.1 million of operating expenses, including a $8.0 million increase in sales, general and administrative expenses, a $9.0 million increase in merger-related expenses, a $0.7 million increase in amortization of acquired intangible assets, and a $16.2 million increase in the change in the fair value of the contingent consideration, partially offset by a $7.8 million decrease in research and development expenses, and a decline in gross profit of $0.7 million.

- Cash, cash equivalents, and short-term investments were $767.8 million at September 30, 2023, which represents a 1% decrease compared to the balance at December 31, 2022.

Macroeconomic dynamics including rising inflation, global supply chain constraints, volatile capital markets, competition, and fluctuating exchange rates have adversely impacted our customers and lengthened customer sales cycles. These factors could continue to impact our revenues and results of operations throughout the remainder of 2023; however, the size and duration of these impacts is uncertain, and as a result, we cannot reasonably estimate the future impact to our operations and financial results.

See the *Risk Factors* section for further discussion of the possible impact of the COVID-19 pandemic and other macroeconomic factors on our business.

Recent Developments

Apton Merger Agreement

On August 2, 2023, we entered into an agreement and plan of reorganization (the “Merger Agreement”), pursuant to which we acquired Apton Biosystems, Inc., a privately held genomics company (“Apton”). The transaction closed on August 2, 2023.

Pursuant to the Merger Agreement, upon the closing of the acquisition, we, among other things, issued to holders of Apton’s outstanding equity interests approximately 6.3 million shares of our common stock. Additionally, subject to the terms and conditions of the Merger Agreement and the achievement of $50.0 million in revenue associated with a high throughput sequencer using Apton's technology, former holders of Apton's outstanding equity interests will also be entitled to receive $25.0 million, which we may elect to pay in cash, shares of our common stock or a combination of cash and shares of our common stock. At this time, the number of shares, if any, to be issued in connection with the achievement of the specified milestone is not known, and will be calculated based on the daily volume-weighted average price of shares of our common stock for the twenty trading days ending on and including the fifth trading day immediately prior to the occurrence of the specified milestone. Under the terms of the Merger Agreement, we may pay cash in lieu of common stock to ensure that the issuance of common stock as contemplated by the Merger Agreement does not exceed 19.9% of the shares of our common stock then outstanding.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

(in thousands, except percentages)	Three Months Ended September 30,			
	2023	2022	$ Change	% Change
Revenue:				
Product revenue	$ 51,562	$ 27,509	$ 24,053	87 %
Service and other revenue	4,129	4,802	(673)	(14) %
Total revenue	55,691	32,311	23,380	72 %
Cost of Revenue:				
Cost of product revenue	33,735	15,752	17,983	114 %
Cost of service and other revenue	4,054	3,012	1,042	35 %
Total cost of revenue	37,789	18,764	19,025	101 %
Gross profit	17,902	13,547	4,355	32 %
Operating Expense:				
Research and development	47,514	47,092	422	1 %
Sales, general and administrative	43,431	36,795	6,636	18 %
Merger-related expenses	8,979	—	8,979	100 %
Amortization of acquired intangible assets	741	—	741	100 %
Change in fair value of contingent consideration	(271)	4,280	(4,551)	(106) %
Total operating expense	100,394	88,167	12,227	14 %
Operating loss	(82,492)	(74,620)	(7,872)	11 %
Interest expense	(3,588)	(3,664)	76	(2) %
Other income, net	8,505	1,313	7,192	548 %
Loss before benefit from income taxes	(77,575)	(76,971)	(604)	1 %
Benefit from income taxes	(10,706)	—	(10,706)	100 %
Net loss	$ (66,869)	$ (76,971)	$ 10,102	(13 %)

Revenue

Revenue increased $23.4 million, or 72%, to $55.7 million for the three months ended September 30, 2023, as compared to $32.3 million for the three months ended September 30, 2022.

Instrument revenue increased $23.3 million, or 203%, to $34.7 million for the three months ended September 30, 2023, as compared to $11.4 million for the three months ended September 30, 2022, primarily due to the sale of 52 Revio systems during the three months ended September 30, 2023 compared to 34 Sequel IIe systems during the three months ended September 30, 2022, as well as Revio's higher average selling price as compared to the Sequel IIe platform. We continue to expect the installed base of Revio instruments to grow, reflecting customer demand for the new product. As a result of this product launch, we anticipate installed base and sales volumes of Sequel II/IIe to continue to decline compared to prior periods. We commenced the shipment of Onso products during the three months ended September 30, 2023 and expect the installed base to continue to grow.

Consumables revenue increased $0.8 million, or 5%, to $16.9 million for the three months ended September 30, 2023, as compared to $16.1 million for the three months ended September 30, 2022. The increase in consumable sales was primarily due to higher Revio consumables sales attributable to the growth in the Revio instrument installed base, partially offset by a decline in Sequel II and IIe consumables as customers transition to the new platform. We expect Revio consumable sales to increase as the installed base grows. While we expect to see a decline in Sequel II and IIe consumable sales resulting from the product transition, there is uncertainty as to the rate at which these sales will decline.

Service and other revenue decreased $0.7 million, or 14%, to $4.1 million for the three months ended September 30, 2023, as compared to $4.8 million for the three months ended September 30, 2022, primarily due to the change in our terms of the warranty provided with the instrument during the first quarter of 2022 to remove the service component. As a result, the warranty is no longer a separate performance obligation and, accordingly, we accrue for the cost of the assurance warranty when revenue of the instrument is recognized, and no longer recognize a component of the instrument revenue in service and other revenue over the warranty period. Service revenue also declined as customers transition to the Revio, which includes a first-year warranty, and opt not to renew their Sequel II/IIe plans. We expect service revenue to continue to decline during the remainder of the year as we anticipate customers transitioning their service contracts to Revio following the standard warranty period, with fewer customers renewing Sequel and Sequel II/IIe service contracts.

Cost of Revenue, Gross Profit and Gross Margin

Cost of product revenue increased $18.0 million, or 114%, for the three months ended September 30, 2023, compared to the three months ended September 30, 2022. The cost of product revenue increased primarily due to an increase in system placements and higher overall product costs on the Revio platform, including warranty costs, as compared to the Sequel II and IIe platforms. Cost of revenue included share-based compensation expense of $1.1 million and $0.9 million during the three months ended September 30, 2023 and 2022, respectively.

Gross profit increased $4.4 million, or 32%, to $17.9 million for the three months ended September 30, 2023, compared to $13.5 million for the three months ended September 30, 2022. Gross margin was 32% for the three months ended September 30, 2023, compared to gross margin of 42% for the three months ended September 30, 2022. The decrease in gross margin was due in part to instrument mix, as Revio instruments sold during the quarter had higher initial manufacturing and warranty costs, in addition to charges for scrap inventory. Gross margin could fluctuate depending on the pace at which Sequel II/IIe consumable revenue declines, Revio consumable revenue ramps, manufacturing efficiencies and warranty costs improve, as well as fluctuations in average selling prices.

Research and Development Expense

Research and development expense increased by $0.4 million, or 1%, to $47.5 million for the three months ended September 30, 2023, compared to $47.1 million for the three months ended September 30, 2022. The increase was primarily driven by an increase in personnel expenses, in part due to the Apton acquisition, offset by the transition of Revio from development to commercialization. Research and development expense included share-based compensation expense of $6.2 million and $7.5 million during the three months ended September 30, 2023 and 2022, respectively.

Sales, General and Administrative Expense

Sales, general and administrative expense increased by $6.6 million, or 18%, to $43.4 million for the three months ended September 30, 2023, compared to $36.8 million for the three months ended September 30, 2022. The increase was primarily driven by an increase in sales and marketing related personnel expenses in connection with the Revio and Onso product launches and as we continue to grow our commercial footprint. Sales, general, and administrative expense included share-based compensation expense of $12.4 million and $10.5 million during the three months ended September 30, 2023 and 2022, respectively.

Merger-Related Expenses

Merger-related expenses of $9.0 million during the three months ended September 30, 2023 consist of $4.9 million of transaction costs arising from the acquisition of Apton, $2.8 million of compensation expense resulting from the liquidity event bonus plan in connection with the Apton acquisition, and $1.3 million of share-based compensation expense resulting from the acceleration of certain equity awards in connection with the Apton acquisition. We recognized $1.3 million of share-based compensation expense for the acceleration that was not attributable to pre-combination services.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets of $0.7 million during the three months ended September 30, 2023 consists of amortization expense attributable to acquired intangible assets that are not directly related to sales generating activities.

Change in Fair Value of Contingent Consideration

Change in fair value of contingent consideration of $0.3 million during the three months ended September 30, 2023, represents the final remeasurement impact of the contingent consideration liability that became due upon the achievement of the milestone resulting from the Omniome acquisition, defined as the first commercial shipment to a customer of both an instrument and related consumables, utilizing SBB technology. As a result of the milestone achievement in September 2023, former Omniome securityholders were entitled to receive as milestone consideration, among other things, an aggregate of approximately $100.9 million in cash and approximately 9.0 million shares of our common stock.

Interest Expense

Interest expense for the three months ended September 30, 2023, was $3.6 million compared to $3.7 million for the three months ended September 30, 2022 and was primarily comprised of interest on the convertible senior notes.

Other Income, Net

Other income, net for the three months ended September 30, 2023, was $8.5 million compared to $1.3 million for the three months ended September 30, 2022. The $7.2 million increase was primarily due to investment income due to higher yields on investments.

Benefit from Income Taxes

A deferred income tax benefit of $10.7 million for the three months ended September 30, 2023, is related to the release of the valuation allowance for deferred tax assets due to the recognition of deferred tax liabilities in connection with the Apton acquisition. We maintain a full valuation allowance on the net deferred tax assets of our U.S. entities as we have concluded that it is more likely than not that we will not realize our deferred tax assets. Accordingly, this benefit from income taxes is reflected on our Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended September 30, 2023.

Comparison of the Nine Months Ended September 30, 2023 and 2022

(in thousands, except percentages)	Nine Months Ended September 30,			
	2023	2022	$ Change	% Change
Revenue:				
Product revenue	$ 129,871	$ 85,928	$ 43,943	51 %
Service and other revenue	12,293	15,023	(2,730)	(18) %
Total revenue	142,164	100,951	41,213	41 %
Cost of Revenue:				
Cost of product revenue	87,697	46,437	41,260	89 %
Cost of service and other revenue	11,258	10,619	639	6 %
Total cost of revenue	98,955	57,056	41,899	73 %
Gross profit	43,209	43,895	(686)	(2 %)
Operating Expense:				
Research and development	142,626	150,377	(7,751)	(5) %
Sales, general and administrative	123,822	115,851	7,971	7 %
Merger-related expenses	8,979	—	8,979	100 %
Amortization of acquired intangible assets	741	—	741	100 %
Change in fair value of contingent consideration	13,960	(2,221)	16,181	(729) %
Total operating expense	290,128	264,007	26,121	10 %
Operating loss	(246,919)	(220,112)	(26,807)	12 %
Loss on extinguishment of debt	(2,033)	—	(2,033)	100 %
Interest expense	(10,772)	(11,042)	270	(2) %
Other income, net	24,301	1,290	23,011	1784 %
Loss before benefit from income taxes	(235,423)	(229,864)	(5,559)	2 %
Benefit from income taxes	(10,706)	—	(10,706)	100 %
Net loss	$ (224,717)	$ (229,864)	$ 5,147	(2 %)

Revenue

Revenue increased $41.2 million, or 41%, to $142.2 million for the nine months ended September 30, 2023, as compared to $101.0 million for the nine months ended September 30, 2022.

Instrument revenue increased $42.7 million, or 100%, to $85.3 million for the nine months ended September 30, 2023, as compared to $42.6 million for the nine months ended September 30, 2022, primarily due to the sale of 129 Revio systems that have a higher average selling price as compared to the Sequel II/IIe platform. We expect the installed base of Revio instruments to grow, reflecting customer demand for the new product. As a result of this new product launch, we anticipate installed base and sales volumes of Sequel II/IIe to continue to decline compared to recent quarters. We commenced the shipment of Onso products during the nine months ended September 30, 2023 and expect the installed base to continue to grow.

Consumables revenue increased $1.3 million, or 3%, to $44.6 million for the nine months ended September 30, 2023, as compared to $43.3 million for the nine months ended September 30, 2022. The increase in consumable sales was primarily due to higher Revio consumables sales attributable to the growth in the Revio instrument installed base, partially offset by a decline in Sequel consumables as customers transition to the new platform.

Service and other revenue decreased $2.7 million, or 18%, to $12.3 million for the nine months ended September 30, 2023, as compared to $15.0 million for the nine months ended September 30, 2022, primarily due to the change in our terms of the warranty provided with the instrument during the first quarter of 2022 to remove the service component. As a result, the warranty is no longer a separate performance obligation and, accordingly, we accrue for the cost of the assurance warranty when revenue of the instrument is recognized, and no longer recognize a component of the instrument revenue in service and other revenue over the warranty period. Service revenue also declined as customers transition to the Revio, which includes a first-year warranty, and opt not to renew their Sequel II/IIe plans. We expect service revenue to continue to decline during the remainder of the year as we anticipate customers transitioning their service contracts to Revio following the standard warranty period, with fewer customers renewing Sequel and Sequel II/IIe service contracts.

Cost of Revenue, Gross Profit and Gross Margin

Cost of product revenue increased $41.3 million, or 89%, for the nine months ended September 30, 2023, compared to the nine months ended September 30, 2022. The cost of product revenue increased primarily due to an increase in system placements and higher overall product costs on the Revio platform, including warranty costs, as well as adjustments of approximately $3.5 million recognized during the first quarter of 2023 primarily relating to excess consumables inventory resulting from a faster-than-expected decline in demand of Sequel II/IIe consumables due to the product transition to Revio. Cost of revenue included share-based compensation expense of $4.3 million and $3.7 million during the nine months ended September 30, 2023 and 2022, respectively.

Gross profit decreased $0.7 million, or 2%, to $43.2 million for the nine months ended September 30, 2023, compared to $43.9 million for the nine months ended September 30, 2022. Gross margin was 30% for the nine months ended September 30, 2023, compared to gross margin of 43% for the nine months ended September 30, 2022. The decrease in gross margin was due in part to instrument mix, as Revio instruments sold during the period had a lower margin primarily due to loyalty discounts provided and higher initial manufacturing costs, including warranty costs, in addition to charges for scrap inventory, as well as adjustments of approximately $3.5 million recognized during the first quarter of 2023 primarily relating to excess consumables inventory resulting from a faster-than-expected decline in demand of Sequel II/IIe consumables due to the product transition to Revio. Gross margin could fluctuate depending on the pace at which Sequel II/IIe consumable revenue declines, Revio consumable revenue ramps, manufacturing efficiencies and warranty costs improve, as well as fluctuations in average selling prices.

Research and Development Expense

Research and development expense decreased by $7.8 million, or 5%, to $142.6 million for the nine months ended September 30, 2023, compared to $150.4 million for the nine months ended September 30, 2022. The decrease was primarily driven by the transition of Revio from development to commercialization. Research and development expense included share-based compensation expense of $18.3 million and $24.2 million during the nine months ended September 30, 2023 and 2022, respectively.

Sales, General and Administrative Expense

Sales, general and administrative expense increased by $8.0 million, or 7%, to $123.8 million for the nine months ended September 30, 2023, compared to $115.9 million for the nine months ended September 30, 2022. The increase in sales, general, and administrative expense was primarily driven by an increase in marketing expenses in connection with product launches and increased sales and marketing headcount as we continue to grow our commercial footprint. Sales, general, and administrative expense included share-based compensation expense of $33.0 million and $32.7 million during the nine months ended September 30, 2023 and September 30, 2022, respectively.

Merger-Related Expenses

Merger-related expenses of $9.0 million during the nine months ended September 30, 2023 consist of $4.9 million of transaction costs arising from the acquisition of Apton, $2.8 million of compensation expense resulting from the liquidity event bonus plan in connection with the Apton acquisition, and $1.3 million of share-based compensation expense resulting from the acceleration of certain equity awards in connection with the Apton acquisition. We recognized $1.3 million of share-based compensation expense for the acceleration that was not attributable to pre-combination services.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets of $0.7 million during the nine months ended September 30, 2023 consists of amortization expense attributable to acquired intangible assets that are not directly related to sales generating activities.

Change in Fair Value of Contingent Consideration

Change in fair value of contingent consideration of $14.0 million during the nine months ended September 30, 2023, represents the remeasurement impact of the contingent consideration liability that was due upon the achievement of a milestone, defined as the first commercial shipment to a customer of both an instrument and related consumables, utilizing SBB technology. The increase in contingent consideration liability was primarily due to the passage of time and changes in the discount rates and probabilities of milestone achievement. As a result of the milestone achievement in September 2023, former Omniome securityholders were entitled to receive as milestone consideration, among other things, an aggregate of approximately $100.9 million in cash and approximately 9.0 million shares of our common stock.

Loss on Extinguishment of Debt

Loss on extinguishment of debt of $2.0 million during the nine months ended September 30, 2023, represents the loss resulting from the difference in the fair value of the 2030 Notes and the principal, in addition to the write-off of the unamortized debt issuance costs on the portion of the 2028 Notes that were exchanged as part of the debt modification during the nine months ended September 30, 2023.

Interest Expense

Interest expense for the nine months ended September 30, 2023, was $10.8 million compared to $11.0 million for the nine months ended September 30, 2022 and was primarily comprised of interest on the convertible senior notes.

Other Income, Net

Other income, net for the nine months ended September 30, 2023, was $24.3 million compared to $1.3 million for the nine months ended September 30, 2022. The $23.0 million increase was primarily due to investment income.

Benefit from Income Taxes

A deferred income tax benefit of $10.7 million for the nine months ended September 30, 2023, is related to the release of the valuation allowance for deferred tax assets due to the recognition of deferred tax liabilities in connection with the Apton acquisition. We maintain a full valuation allowance on the net deferred tax assets of our U.S. entities as we have concluded that it is more likely than not that we will not realize our deferred tax assets. Accordingly, this benefit from income taxes is reflected on our Condensed Consolidated Statements of Operations and Comprehensive Loss for the nine months ended September 30, 2023.

Liquidity and Capital Resources

As of September 30, 2023, we had cash, cash equivalents and investments of $767.8 million compared to $772.3 million as of December 31, 2022. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our projected operating requirements beyond the next 12 months from the date of filing of this Quarterly Report on Form 10-Q for the quarter ended September 30, 2023.

Our primary sources of liquidity, other than our holdings of cash, cash equivalents, and investments, has primarily been through the issuance of debt or equity securities, together with cash flow from operating activities. We have historically incurred, and expect to continue to incur, operating losses and generate negative cash flows from operations on an annual basis, and as a result, we may require additional capital resources to execute our strategic initiatives to grow our business.

Factors that may affect our capital needs include, but are not limited to, the pace of adoption of our products, which affects the sales of our products and services; our ability to obtain new collaboration and customer arrangements and maintain existing collaborations and arrangements; the progress of our research and development programs; initiation or expansion of research programs and collaborations; the purchase of patent licenses; manufacturing costs; service costs; the impact of product quality; litigation costs, including the costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; costs of developing new and enhanced products; acquisitions of complementary businesses, technologies or assets; achievement of milestones in connection with acquisitions; and other factors. There can be no assurance that funds will be available on favorable terms, or at all.

Contingent Consideration

In connection with the acquisition of Omniome in the third quarter of 2021, we entered into an arrangement where we are obligated to pay approximately $200.0 million in cash and equity dependent upon the achievement of a milestone event upon the first commercial shipment of products developed from our acquired sequencing solution. See *Note 2 – Business Acquisitions,* in Part II, Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2022 for further information. In August 2023, we commenced customer shipments of the Onso short-read sequencing instrument. The milestone payment associated with PacBio's acquisition of Omniome was triggered in September 2023 once both the Onso instrument and related consumables had been shipped to one customer. Consequently, we paid the former Omniome securityholders milestone consideration of an aggregate of approximately $100.9 million in cash and approximately 9.0 million shares of our common stock in October 2023.

In connection with the acquisition of Apton, we entered into an arrangement where we are obligated to pay former holders of Apton's outstanding equity interests $25.0 million upon the achievement of $50 million in revenue associated with a high throughput sequencer using Apton's technology, provided that the milestone event occurs prior to the 5-year anniversary of the closing date of the acquisition, which we may elect to pay in cash, shares of our common stock or a combination of cash and shares of our common stock. See *Note 2. Business Acquisitions* in Part I, Item 1 of this Quarterly Report on Form 10-Q for further information.

Summary of Cash Flows

	Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**
Cash used in operating activities	$ (201,613)	$ (202,645)
Cash provided by investing activities	71,179	35,680
Cash provided by financing activities	190,493	8,803
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 60,059	$ (158,162)

Operating Activities

Our primary uses of cash in operating activities include the development of future products and product enhancements, manufacturing, and support functions related to our sales, general and administrative activities.

Cash used in operating activities for the nine months ended September 30, 2023 of $201.6 million was due primarily to a $224.7 million net loss that included non-cash items such as share-based compensation of $55.5 million, change in estimated fair value of contingent consideration of $14.0 million, depreciation expense of $8.5 million, amortization of right-of-use assets of $4.9 million, inventory provisions of $4.7 million, merger-related compensation expense of $3.4 million, and loss on extinguishment of debt of $2.0 million. This was offset by deferred income taxes of $10.7 million, the accretion of discount and amortization of premium on marketable securities, net of $10.1 million, and $51.2 million in net changes to operating assets and liabilities. Cash flow impact from changes in net operating assets and liabilities was primarily driven by increases in inventory, accounts receivable and prepaid and other assets, as well as decreases in operating lease liabilities, deferred revenue, other liabilities and the contingent consideration liability. These uses of cash were partially offset by an increase in accrued expenses and accounts payable.

Cash used in operating activities for the nine months ended September 30, 2022, of $202.6 million was due primarily to a $229.9 million net loss that included non-cash items such as share-based compensation of $60.7 million, depreciation expense of $6.9 million, amortization of right-of-use assets of $5.2 million, inventory provisions of $2.7 million, amortization of premium and accretion of discount on marketable securities, net of $1.1 million, partially offset by a $2.2 million decrease in liability due to the change in estimated fair value of contingent consideration, and a net cash outflow due to $48.3 million in net changes to operating assets and liabilities. Cash flow impact from changes in net operating assets and liabilities was primarily driven by increases in inventory and prepaid and other assets, as well as decreases in accrued expenses, operating lease liabilities, deferred revenue and other liabilities. These uses of cash were partially offset by a decrease in accounts receivable and an increase in accounts payable.

Investing Activities

Our investing activities consist primarily of capital expenditures and investment purchases, sales, and maturities. Cash provided by investing activities for the nine months ended September 30, 2023, was due to $631.8 million of maturities and sales of investments offset by $553.7 million in purchases of investments, $6.8 million in purchases of property and equipment, and $0.1 million of cash paid for the Apton acquisition, net of cash acquired.

Our investing activities consist primarily of capital expenditures and investment purchases, sales and maturities. Cash provided by investing activities for the nine months ended September 30, 2022, was due to $355.4 million of maturities and sales of investments offset by $307.9 million in purchases of investments, and $11.8 million in purchases of property and equipment.

Financing Activities

Cash provided by financing activities during the nine months ended September 30, 2023 primarily resulted from $189.2 million in net proceeds related to the issuance of common stock from the underwritten public equity offering and $14.4 million from the issuance of common stock through our equity compensation plans partially offset by $7.3 million from the payment of debt issuance costs and $4.4 million from the payment of contingent consideration.

Cash provided by financing activities during the nine months ended September 30, 2022 primarily resulted from proceeds of $10.0 million from the issuance of common stock through our equity compensation plans partially offset by $1.2 million of principal payoff of notes.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with the rules and regulations of the SEC. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. We evaluate our critical accounting policies and estimates on an ongoing basis. 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 and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no changes to our significant accounting policies as disclosed in the Annual Report on Form 10-K for the year ended December 31, 2022.

Recent Accounting Pronouncements

Please see *Note 1. Organization and Significant Accounting Policies*, subsection titled “Recent Accounting Pronouncements”, in Part I, Item 1 of this Quarterly Report on Form 10-Q for information regarding applicable recent accounting pronouncements.

Off-Balance Sheet Arrangements

As of September 30, 2023, we did not have any off-balance sheet arrangements.

In the ordinary course of business, we enter into standard indemnification arrangements. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology, or from claims relating to our performance or non-performance under a contract, any defective products supplied by us, or any acts or omissions, or willful misconduct, committed by us or any of our employees, agents or representatives. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these agreements is not determinable because it involves claims that may be made against us in future periods but have not yet been made. To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

We also enter and have entered into indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law. In addition, we may have obligations to hold harmless and indemnify third parties involved with our fundraising efforts and their respective affiliates, directors, officers, employees, agents or other representatives against any and all losses, claims, damages and liabilities related to claims arising against such parties pursuant to the terms of agreements entered into between us and such third parties in connection with such fundraising efforts. To the extent that such indemnification obligations apply to the lawsuits described in *Note 6. Commitments and Contingencies* in Part I, Item 1 of this Quarterly Report on Form 10-Q, any associated expenses incurred are included within the related accrued litigation expense amounts. No additional liability associated with such indemnification agreements has been recorded as of September 30, 2023.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate and Market Risk

The 2030 Notes were recorded at fair value as of the closing date of the Exchange Transaction, less debt issuance costs, on our Condensed Consolidated Balance Sheets. We carry our remaining 2028 Notes at the principal amount, less unamortized debt issuance costs, on our Condensed Consolidated Balance Sheets. Because the 2030 Notes and 2028 Notes have fixed annual interest rates of 1.375% and 1.50%, respectively, we do not have any economic interest rate exposure or financial statement risk associated with changes in interest rates. The fair value of the notes, however, may fluctuate when interest rates and the market price of our stock changes. See *Note 5. Convertible Senior Notes* in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

During the nine months ended September 30, 2023, we invested in cash equivalents, U.S. government and agency securities, U.S. Treasury securities, and corporate debt securities which were designated as cash equivalents and available-for-sale investments. Our cash equivalents and available-for-sale securities as of September 30, 2023 was $768 million.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio comprising of marketable securities. We invest in a number of securities including U.S. government and agency securities, U.S. Treasury securities, and corporate debt securities and money market funds. We attempt to ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in high grade investment securities. The fair market value of our fixed rate securities may be adversely impacted by increases in interest rates while income earned may decline as a result of decreases in interest rates. A hypothetical 100 basis-point (one percentage point) increase or decrease in interest rates compared to rates at September 30, 2023 would have affected the fair value of our investment portfolio by approximately $2.4 million.

There have been no other material changes in market risk from the information provided in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer, our Chief Financial Officer and our Chief Accounting Officer 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. Based on this evaluation, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control Over Financial Reporting

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer, Chief Financial Officer and Chief Accounting Officer to determine whether any change in our internal control over financial reporting occurred during the fiscal quarter ended September 30, 2023 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. There were no material changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2023, that have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

U.S. District Court Proceedings

On September 26, 2019, Personal Genomics of Taiwan, Inc. ("PGI") filed a complaint in the U.S. District Court for the District of Delaware against us for patent infringement (C.A. No. 19-cv-1810) (the "PGI District Court matter"). The matter from this complaint is based on PGI's U.S. Patent No. 7,767,441 (the "'441 Patent"). We plan to vigorously defend in this matter. On November 20, 2019, we filed our answer to the complaint, denying infringement and seeking a declaratory judgement of invalidity of the '441 Patent.

On June 22, 2020, we filed a petition requesting institution of an inter-partes review ("IPR") to the Patent Trial and Appeals Board (the "Board") at the United States Patent Office requesting the Board to find a set of claims in the '441 Patent invalid. On June 27, 2020, we filed a second petition requesting institution of an IPR requesting the Board to find another set of claims in the '441 Patent invalid. The two petitions (the "PacBio IPR Petitions") requesting IPRs assert that all of the claims relevant to the PGI complaint are invalid. On January 19, 2021, the Board ordered that both PacBio IPR Petitions be instituted on all grounds presented. On January 18, 2022, the Board issued decisions on the two IPRs. In one IPR, all challenged claims were found unpatentable, including PGI's core device claims. In the second IPR, the Board did not find the disputed claims unpatentable. We are appealing the decision in the second IPR to the U.S. Court of Appeals for the Federal Circuit, which has scheduled a hearing for December 7, 2023.

On August 19, 2020, the court ordered a stay of the PGI District Court matter based on a joint stipulation by the parties pending a final written decision on the IPRs. Following the final decision on the IPRs described above, on February 2, 2022, the judge ordered that the PGI District Court matter be reopened. However, in a subsequent order dated September 15, 2022, the judge stayed the PGI District Court matter pending a final decision by the U.S. Court of Appeals for the Federal Circuit regarding the appeal described above. We plan to vigorously defend against the remaining claims.

In December 2022, Take2 Technologies, Ltd. ("Take2") and the Chinese University of Hong Kong filed a complaint in the U.S. District Court for Delaware against us alleging infringement of U.S. Patent No. 11,091,794 (the "'794 Patent") (C.A. No. 22- cv-01595). The complaint alleges that our Sequel™ II systems, Sequel IIe Systems, and Revio™ Systems that operate version 11.0 or later of the SMRT™ Link software, infringe the '794 Patent. The complaint seeks unspecified monetary damages and an order enjoining us from infringing the '794 Patent. We filed a motion to dismiss on February 14, 2023. We also filed a motion to transfer the case to the Northern District of California which was granted on August 2, 2023 and the case was transferred on August 16, 2023 (C.A. No. 5:23-cv-04166). The hearing on the motion to dismiss is scheduled for December 13, 2023. Take2 filed a motion to disqualify our in-house legal department from representing PacBio in the district court action on September 20, 2023. We opposed Take2's disqualification motion on October 4, 2023. An oral hearing on the disqualification motion was held on October 26, 2023 and the court is expected to issue an order on the motion in due course. We filed a petition for inter parties review at the USTPO (IPR2024-00028) challenging the validity of all claims of the '794 patent on October 17, 2023. A hearing was held on August 9, 2023. We believe the infringement allegations in the complaint lack merit and we intend to vigorously defend in this matter.

Proceedings in China

On May 12, 2020, PGI filed a complaint in the Wuhan Intermediate People's Court in China alleging infringement of one or more claims of China patent No. CN101743321B (the "CN321 Patent"), which is related to the '441 Patent. On November 23, 2020 we filed an Invalidation Petition at the China National Intellectual Property Administration (CNIPA) demonstrating the invalidity of the claims in the CN321 Patent on grounds of insufficient disclosure, and the lack of support, essential technical features, clarity, novelty, and inventiveness. A hearing in the invalidation proceeding at the CNIPA was held on April 29, 2021. On September 2, 2021, the CNIPA issued its decision on the Invalidation Petition and determined that all claims (1-61) of the CN321 patent were invalid. On December 1, 2021, PGI filed an appeal with the Beijing IP Court, contesting the CNIPA decision. We filed a petition with the Wuhan Intermediate People's court requesting dismissal of the infringement action based on the CNIPA invalidation decision, and PGI filed a petition to withdraw its complaint. The Wuhan Intermediate People's court granted PGI's petition and dismissed the infringement action in May 2022.

Other Proceedings

From time to time, we may also be involved in a variety of other claims, lawsuits, investigations, and proceedings relating to securities laws, product liability, patent infringement, contract disputes, employment, and other matters that arise in the normal course of our business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications.

We record a provision for contingent losses when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. We currently do not believe that the ultimate outcome of any of the matters described above is probable or reasonably estimable, or that these matters will have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of litigation and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

You should carefully consider the risks and uncertainties described below, together with all of the other information in our public filings with the SEC, which could materially affect our business, financial condition, results of operations and prospects. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially affect our business, financial condition, results of operations and prospects. In addition, any worsening of the economic environment may exacerbate the risks described below, any of which could have a material impact on us. This situation is changing rapidly, and additional impacts may arise that we are not aware of currently.

Summary Risk Factors

The following is a summary of the principal risks that could adversely affect our business, operations, and financial results. Such risks are discussed more fully below and include, but are not limited to, risks related to:

- our ability to successfully market, commercialize, and sell current and future products and related maintenance services;
- our ability to achieve profitability for our business;
- our ability to repay our debt and fund our long-term planned operations;
- our ability to successfully leverage and integrate our acquisitions and future acquisitions;
- our ability to successfully research, develop and timely manufacture our current and future products;
- management of new product introductions and transitions, resultant costs, and ability of new products to generate promised performance;
- recent significant changes to our leadership team and resultant disruptions to our business;
- retention, recruitment, and training of senior management, key personnel, scientists and engineers;
- our ability to further penetrate nucleic acid sequencing applications, as well as grow product demand;
- our reliance on outsourcing to other companies for manufacturing certain components and sub-assemblies, some of which are sole-sourced;
- our ability to consistently manufacture our instruments and consumables to meet customers' specifications, quantity, cost, or performance requirements;
- the high amount of competition we face in our industry;
- our ability to attract customers and increase sales of current and future products;
- reliance on a limited number of customers for a significant portion of our revenues, including academic, research and government institutions;
- the complexity of our products giving rise to defects or errors;
- our unpredictable and lengthy sales cycles;
- adverse effects resulting from political and economic tensions between the United States and other countries, including China and Russia, and other geopolitical uncertainties;
- securing and maintaining patent or other intellectual property protection for our products and related improvements;
- current and future legal proceedings filed against us claiming intellectual property infringement;
- the potential adverse impact of health epidemics, including the ongoing COVID-19 pandemic;
- governmental regulations that burden operations or narrow the market for our products;
- evolving ethical, legal, privacy, social, and regulatory concerns regarding genetic testing;
- volatility of the price of our common stock; and
- our stock price falling as a result of future offerings or sales of securities.

Our risk factors are not guarantees that no such conditions exist as of the date hereof and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part.

Risks Related to Our Business

The commercialization and sales of our current or future products may be unsuccessful or less successful than anticipated. While we plan to continue pursuing new products and expand into adjacent markets, we have limited experience in managing and selling multiple products and, as a result, may face challenges selling in new markets and fail to successfully carry out these initiatives, which may adversely impact our business, financial condition or results of operation.

We have made and expect to continue making substantial investments to develop new products and enhance our existing products through our acquisitions and research and development efforts. For example, we recently announced our new Revio long-read sequencing system in the fourth quarter of 2022, and commenced commercial Revio shipments in the first quarter of 2023, and we also progressed development of and, in the quarter ended September 30, 2023, commenced commercial shipments of Onso, our SBB short-read platform. Our future success is substantially dependent on our ability to successfully develop and commercialize our products, including Revio and Onso, as well as acquired technologies, which are anticipated to be used in demanding scientific research that requires substantial levels of accuracy and precision. In addition, we may not be successful in transitioning our Revio product from our prior generation products, or transitioning users of other third party short-read sequencing platforms to Onso, and could incur related obsolete inventory charges. Customers may also be slower that we anticipate in making new capital equipment acquisitions, especially in the current economic environment. However, due to challenges we may experience in developing and marketing our existing products and launching new products, we may not be able to effectively:

- manage the timeliness of our new product introductions and the rate at which sales of our new products may cannibalize sales of our older products or manage sales and marketing of multiple sequencing platforms;
- drive adoption of our current and future products, including the Sequel II/IIe Systems, the Revio system, the Onso system, and products under development, including acquired technologies;
- maintain our competitive position by continuing to attract and retain customers for our products;
- provide appropriate levels of customer training and support for our products;
- implement an effective marketing strategy to promote awareness of our products;
- develop and implement an effective sales and distribution strategy for our current and future products;
- develop, manufacture and commercialize new products or achieve an acceptable return on our manufacturing or research and development efforts and expenses;
- comply with regulatory requirements applicable to our products;
- anticipate and adapt to changes in our market;
- accommodate customer expectations and demands with respect to our products, increase product adoption by our existing customers or develop new customer relationships;
- deliver our beta systems to our external beta testing sites or complete our external beta testing program on our currently expected timelines;
- overcome unexpected challenges discovered during beta testing;
- complete the scientific and technical validation of new products on our currently expected timeline or at all;
- deliver our future products in a timely manner to our customers;
- grow our market share by marketing and selling our products for new and additional applications;
- manage the significant burdens that expanding our existing or future products into current and new markets may impose on marketing, compliance, and other administrative and managerial resources;
- maintain and develop strategic relationships with vendors, manufacturers, and other industry partners to acquire necessary materials for the production of, and to develop, manufacture and commercialize, our existing or future products;
- adapt or scale our manufacturing activities to meet performance specifications and potential demand at a reasonable cost;
- avoid infringement and misappropriation of third-party intellectual property;
- obtain and maintain any necessary licenses to third-party intellectual property on commercially reasonable terms;
- obtain valid and enforceable patents that give us a competitive advantage or enforce existing patents;
- protect our proprietary technology; and
- attract, retain, and motivate qualified personnel.

The risks noted above, especially with respect to the marketing, sales, and commercialization of our products, may be heightened by the impact of current uncertain market and other conditions. In addition, a high percentage of our expenses is and will continue to be fixed. Accordingly, if we do not generate revenue as and when anticipated, we could suffer a material adverse effect on our business, financial conditions, results of operations and prospects.

We have incurred losses to date, and we expect to continue to incur significant losses as we develop our business and may never achieve profitability.

We have generally incurred net losses each quarter since inception, and we cannot be certain if or when we will produce sufficient revenue from our operations to support our costs. Even if profitability is achieved in the future, we may not be able to sustain profitability on a consistent basis. We expect to continue to incur substantial losses and negative cash flow from operations for the foreseeable future.

Our net losses since inception and our expectation of incurring substantial losses and negative cash flow for the foreseeable future could:

- make it more difficult for us to satisfy our obligations;
- increase our vulnerability to general adverse economic and industry conditions;
- limit our ability to fund future working capital, capital expenditures, research and development and other business opportunities;
- increase the volatility of the price of our common stock;
- limit our flexibility to react to changes in our business and the industry in which we operate;
- place us at a disadvantage to other companies that offer nucleic acid sequencing equipment or consumables; and
- limit our ability to borrow additional funds.

In addition, inflationary pressure, including as a result of supply shortages, has adversely impacted and could continue to adversely impact our financial results, and our operating costs may increase. We may not fully offset these cost increases by raising prices for our products and services, which could result in downward pressure on our margins. Further, our customers may choose to reduce their business with us if we increase our pricing.

Any or all of the foregoing may have a material adverse effect on our business, operations, financial condition, and prospects. An impairment in value of our tangible or intangible assets could also be recorded as a result of weaker economic conditions.

We are not cash flow positive and may not have sufficient cash to make required payments under the terms of our debt or fund our long-term planned operations.

Our operations have consumed substantial amounts of cash since inception, and we expect to continue to incur substantial losses and negative cash flow from operations for the foreseeable future. Additional funds may not be available on terms acceptable to us or at all. We have incurred significant debt, and we may incur additional debt in the future. As of September 30, 2023, we had outstanding approximately $459.0 million aggregate principal amount of 1.50% convertible senior notes due 2028 (the “2028 Notes”) and $441.0 million aggregate principal amount of our 1.375% convertible senior notes due 2030 (the “2030 Notes” and, together with the 2028 Notes, the “Notes”). We may not have sufficient cash to make required payments under the terms of this debt, and should this occur, debt holders have rights senior to common stockholders to make claims on our assets. We may not be able to issue equity securities due to unacceptable terms and conditions to us in the capital markets. To the extent that we intend to raise additional funds through the sale of our common stock, downward fluctuations in our stock price could adversely affect such fundraising efforts. Furthermore, equity financings normally involve shares sold at a discount to the current market price and fundraising through sales of additional shares of common stock or other equity securities will have a dilutive effect on our existing investors. We may be required to seek equity financing at a time when the market price for our common stock is low, which will further contribute to dilution for existing holders.

We believe that our growth will depend, in part, on our ability to fund our commercialization efforts and our efforts to develop new products, including any improvements to our existing products. To the extent our existing resources are not sufficient, it may require us to delay, or even not allow us to conduct any or all of these activities that we believe would be beneficial for our future growth. We may need to raise additional funds through public or private debt or equity financing or alternative financing arrangements, which may include collaborations or licensing arrangements. If we are unable to raise funds on favorable terms, or at all, we may have to reduce our cash burn rate and may not be able to support our commercialization efforts, launching of new products, or operations, or to increase or maintain the level of our research and development activities.

If we are unable to generate sufficient cash flows or to raise adequate funds to finance our forecasted expenditures, we may have to make significant changes to our operations, including delaying or reducing the scope of, or eliminating some or all of, our development programs. We also may have to reduce sales, marketing, engineering, customer support or other resources devoted to our existing or new products, or we may need to cease operations. Any of these actions could materially impede our ability to achieve our business objectives and could materially harm our operating results. If our cash, cash equivalents and investments are insufficient to fund our projected operating requirements and we are unable to raise capital, it could have a material adverse effect on our business, financial condition and results of operations and prospects.

We have made acquisitions and, in the future, may continue to acquire businesses, technologies or assets, form joint ventures or make other strategic investments with companies that could adversely affect our operating results, dilute our stockholders' ownership, or cause us to incur debt or significant expense.

As part of our business strategy, we have acquired and expect to continue to pursue acquisitions of complementary businesses, technologies, or assets. We may also pursue technology license arrangements, strategic alliances or investments that complement our business, as we have previously with our acquisitions of Circulomics, Omniome and Apton in July 2021, September 2021 and August 2023, respectively.

Acquisitions and strategic transactions involve numerous risks, any of which could harm our business and negatively affect our financial condition and results of operations, including:

- intense competition for suitable acquisition targets, which could increase prices and adversely affect our ability to consummate deals on favorable or acceptable terms;
- failure or material delay in closing a transaction;
- transaction-related lawsuits or claims;
- difficulties in integrating the technologies, operations, existing contracts, and personnel of an acquired company;
- difficulties in retaining key employees or business partners of an acquired company;
- difficulties in retaining suppliers, partners, or customers of an acquired company;
- challenges with integrating the brand identity of an acquired company with our own;
- diversion of financial and management resources from existing operations or alternative acquisition opportunities;
- failure to realize the anticipated benefits or synergies of a transaction;
- difficulties in developing technology post-acquisition;
- failure to identify the problems, liabilities, or other shortcomings or challenges of an acquired company or technology, including issues related to intellectual property, regulatory compliance practices, litigation, revenue recognition or other accounting practices, or employee or user issues;
- risks that regulatory bodies may enact new laws or promulgate new regulations that are adverse to an acquired company or business;
- risks that regulatory bodies do not approve our acquisitions or business combinations or delay such approvals;
- theft of our trade secrets or confidential information that we share with potential acquisition candidates or other potential strategic partners;
- risk that an acquired company or investment in new services cannibalizes a portion of our existing business; and
- adverse market reaction to an acquisition or other strategic transaction.

To finance any acquisitions or other strategic investments, we may raise additional funds, which could adversely affect our existing stockholders and our business. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. In addition, our stockholders may experience substantial dilution as a result of additional securities we may issue for acquisitions. Open market sales of substantial amounts of our common stock issued to stockholders of companies we acquire could also depress our stock price. Additional funds may not be available on terms that are favorable to us, or at all.

If we fail to address the foregoing risks or other problems encountered in connection with past or future acquisitions of businesses, new technologies, services, and other assets and strategic investments, or if we fail to successfully integrate such acquisitions or investments, our business, financial condition, and results of operations could be adversely affected, including potential impairments of goodwill and intangible assets.

If we are unable to successfully develop and timely manufacture our current and future products, including with respect to SMRT Cells, Sequel II/IIe Systems, Revio, Onso, and other SMRT Cell, HiFi, and SBB products under development, and related products, our business may be adversely affected.

In light of the highly complex technologies involved in our products, there can be no assurance that we will be able to manufacture and commercialize our current and future products on a timely basis or continue providing adequate support for our existing products. The commercial success of our products, including the Sequel, Sequel II/IIe, Revio and Onso Systems, and the products under development, including acquired technologies, depends on a number of factors, including performance and reliability of the systems, our anticipating and effectively addressing customer preferences and demands, the success of our sales and marketing efforts, effective forecasting and management of product demand, purchase commitments and inventory levels, effective management of manufacturing and supply costs, and the quality of our products, including consumables such as SMRT Cells and reagents. Should we face delays in or discover unexpected defects during the further development or manufacturing process of instruments or consumables related to our products, including with respect to SMRT Cells, reagents, Sequel II/IIe Systems, Revio, Onso, and other SMRT Cell, HiFi, and SBB products under development, including acquired technologies, and including any delays or defects in software development or product functionality, the timing and success of the continued rollout and scaling of our products may be significantly impacted, which may materially and negatively impact our revenue and gross margin. The ability of our customers to successfully utilize our products will also depend on our ability to deliver high quality SMRT Cells and reagents. We have designed SMRT Cells and other consumables specifically for the Sequel, Sequel II/IIe, and Revio Systems, and may need to develop in the future, other customized SMRT Cells and consumables for our future products. Our production of the SMRT Cells for the Sequel and Sequel II/IIe Systems has been and may in the future, including with respect to the Revio system, be below desired levels and yields, and we have experienced and may experience in the future manufacturing delays, product or quality defects, SMRT Cell variability, and other issues. For example, the COVID-19 pandemic has impacted and could result in more pronounced impacts to our manufacturing and our ability to supply products. The performance of our consumables is critical to our customers' successful utilization of our products, and any defects or performance issues with our consumables would adversely affect our business. All of the foregoing could materially negatively impact our ability to sell our products or result in other material adverse effects on our business, operations, financial condition, operations and prospects.

The development of our products is complex and costly. Problems in the design or quality of our products may have a material and adverse effect on our brand, business, financial condition, and operating results, and could result in us losing our certifications from the International Organization for Standardization ("ISO"). If we were to lose ISO certification, then our customers might choose not to purchase products from us and this could adversely impact our ability to develop products approved for clinical uses. Unanticipated problems with our products could divert substantial resources, which may impair our ability to support our new and existing products and could substantially increase our costs. If we encounter development challenges or discover errors in our products late in our development cycle, including during external beta testing, we may be forced to undertake design and/or production changes, delay product shipments or the scaling of manufacturing or supply. The completion of the production and external testing of our beta systems may also take longer than currently planned, cost more than currently expected and the scientific and technical validation may not be completed on our currently expected timelines or at all. Such testing may also expose fundamental flaws in our products that may cause us to abandon the further development of such products.

If the continued rollout of our current and future products, including with respect to the SMRT Cell, the Sequel II/IIe, Revio, and Onso Systems, is delayed or is not successful or less successful than anticipated, then we may not be able to achieve an acceptable return, if any, on our substantial research and development efforts, and our business may be materially and adversely affected. The expenses or losses associated with delayed or unsuccessful product development or lack of market acceptance of our existing and new products, including the SMRT Cell, Sequel II/IIe Systems, Revio, and Onso, could materially and adversely affect our business, operations, financial condition, and prospects.

Our research and development efforts may not result in the benefits that we anticipate, and our failure to successfully market, sell, and commercialize our current and future products could have a material adverse effect on our business, financial condition and results of operations.

We have dedicated significant resources to developing our current products, including sequencing systems and consumables based on our proprietary SMRT sequencing technology and our Sequel and Sequel II/IIe Systems. We are also engaged in substantial and complex research and development efforts, which, if successful, may result in the introduction of new products in the future, including in connection with the SMRT Cell, the Sequel II/IIe Systems, Revio and Onso, in addition to other products currently under development, including acquired technologies. Our research and development efforts are complex and require us to incur substantial expenses and we may not be able to develop, manufacture and commercialize new products or obtain regulatory approval if necessary. We may divert significant resources to research and development initiatives that do not result in commercialized products, and even if these efforts do result in commercialized products, there can be no assurance that such products will compete successfully in the market or achieve an acceptable return, if any, on our research and development efforts and expenses. Moreover, our joint research and development efforts with partners require significant management attention and operational resources. If we are unable to successfully manage such joint research and development efforts, our future results may be adversely impacted. Furthermore, we will need to continue to expand our internal capabilities or seek new partnerships or collaborations, or both, in order to successfully develop, market, sell and commercialize our products for and in the markets we seek to reach. If we are unable to do so or are delayed, then this could materially and adversely affect our business, operations, financial condition, and prospects.

We must successfully manage new product introductions and transitions, including with respect to the SMRT Cell, the Sequel II/IIe, Revio and Onso Systems, and the development of acquired technologies, and we may incur significant costs during these transitions and development, and these efforts may not result in the benefits we anticipate.

If our products and services fail to deliver the performance, scalability or results expected by our current and future customers, or are not delivered on a timely basis, our reputation and credibility may suffer, our current and future sales and revenue may be materially harmed and our business may not succeed. For instance, if we are not able to realize the benefits we anticipate from the development and commercialization of the SMRT Cell, Sequel II/IIe Systems, the Revio HiFi long-read sequencing system, and the Onso SBB short-read sequencing system, and any future products that may be developed for research, medical and clinical uses, including acquired technologies, it could have a material adverse effect on our business, financial condition and results of operations. In addition, the introduction of future products, including with respect to future long-read and short-read products, and related consumables, has and may in the future lead to our limiting or ceasing development of further enhancements to our existing products as we focus our resources on new products, and has resulted and could in the future result in reduced marketplace acceptance and loss of sales of our existing products, materially adversely affecting our revenue and operating results. The introduction of new products, including the recent announcement of our Revio system, has had and may in the future also have a negative impact on our revenue in the near-term as our current and future customers have delayed or cancelled and may in the future delay or cancel orders of existing products in anticipation of new products and we may also be pressured to decrease prices for our existing products. Our experience in managing product transitions is limited, and we have experienced, and may in the future experience, difficulty in managing or forecasting customer reactions, purchasing decisions or transition requirements with respect to newly launched products. We have incurred and may continue to incur significant costs in completing these transitions, including costs of write-downs of our products, as current or future customers transition to new products. If we do not successfully manage these product transitions, including with respect to the SMRT Cell, Sequel II/IIe Systems, the Revio and Onso Systems, and any future long-read and short-read products, our business, operations, financial condition, and prospects may be materially and adversely affected.

Our business may be adversely affected by health epidemics, including any resurgence of COVID-19 cases or other outbreaks.

Our business has been and could be further adversely impacted by the effects of COVID-19 or other epidemics or pandemics. Although it is not possible at this time to estimate the impact that health epidemics, including the results of the COVID-19 pandemic and any future resurgence of COVID-19 cases or other outbreaks, could have on our business, any pandemic or public health outbreaks or related disruptions and the measures taken by the governments of countries affected could disrupt the supply chain and the manufacture of our products.

Our manufacturing partners and suppliers have been and could continue to be disrupted by conditions related to COVID-19 or other epidemics or pandemics, possibly resulting in disruption to the production of our products. If our manufacturing partners or suppliers are unable or fail to fulfill their obligations to us for any reason, we may not be able to manufacture our products and satisfy customer demand or our obligations under sales agreements in a timely manner, and our business could be harmed as a result. There is significant uncertainty relating to the long-term effect of COVID-19 on our business. Infections may resurge or become more widespread and any ensuing disruptions to business activities or supply chains could have a negative impact on our business, financial condition, and operating results. Because our semiconductor manufacturers are located in a region where immunization rates in certain communities may be low, new and emerging variants of COVID-19 could impact workforce availability at those locations and disrupt supply. For example, the Chinese government may re-impose lockdowns or similar measures to combat the spread of COVID-19 and such measures have had, and may continue to have in the future, a negative impact on manufacturing and/or supply chains, as well as customer demand for our products and demand through certain distributors.

For example, the COVID-19 pandemic caused us to modify our business practices, including limiting certain of our commercial operations and limiting certain employees from working in the office. We offered, and if there is a resurgence of COVID-19 or other outbreak, we may again offer a significant percentage of our employees flexibility in the amount of time they work in an office, which could adversely impact the productivity of certain employees and harm our business, including our future operating results. This may also present risks for our strategy and may present operational, cybersecurity, and workplace culture challenges that may adversely affect our business.

Even after the COVID-19 pandemic has further subsided, we may continue to experience an adverse impact to our business as a result of its global economic impact, including recessionary effects and inflationary pressures. Specifically, difficult macroeconomic conditions, such as decreases in discretionary capital expenditure spending, changes to the government funding environment, a reduction in or the lapsing of COVID-19-related governmental stimulus measures, increased and prolonged unemployment or a decline in consumer confidence as a result of the COVID-19 pandemic, as well as limited or significantly reduced points of access of our products, could have a continuing adverse effect on the demand for some of our products and, consequently, related maintenance and support services. The degree of impact of COVID-19 on our business will depend on several factors, such as the duration and the extent of the pandemic, the risk of waning immunity among persons already vaccinated and an increase in fatigue or skepticism with respect to initial or booster vaccinations, as well as actions taken by governments, businesses, and consumers in response to the pandemic, all of which continue to evolve and remain uncertain at this time.

Significant changes to our leadership team and the resulting management transitions might harm our future operating results.

We have experienced significant changes to our leadership team. Our President and Chief Executive Officer Christian O. Henry was appointed effective September 14, 2020, succeeding Dr. Michael Hunkapiller who retired on December 31, 2020. Our Chief Financial Officer Susan G. Kim was appointed effective September 28, 2020, succeeding Susan K. Barnes who retired on August 7, 2020. Our Chief Operating Officer Mark Van Oene was appointed effective January 8, 2021. Jeff Eidel was appointed Chief Commercial Officer effective August 16, 2022, succeeding Peter Fromen who resigned effective May 20, 2022. Also, our Vice President and Chief Accounting Officer Michele Farmer was appointed effective May 17, 2021, and our Chair of the Board Dr. John F. Milligan was appointed effective September 14, 2020.

Although we believe these leadership transitions are in the best interest of our stakeholders, these transitions may result in the loss of personnel with deep institutional or technical knowledge. Further, the transition could potentially disrupt our operations and relationships with employees, suppliers, partners, and customers due to added costs, operational inefficiencies, decreased employee morale and productivity and increased turnover. We must successfully recruit and integrate our new leadership team members within our organization to achieve our operating objectives; as such, the leadership transition may temporarily affect our business performance and results of operations while the new members of our leadership team become familiar with our business. In addition, our competitors may seek to use this transition and the related potential disruptions to gain a competitive advantage over us. Furthermore, these changes increase our dependency on the other members of our leadership team that remain with us, who are not contractually obligated to remain employed with us and may leave at any time. Any such departure could be particularly disruptive given that we are already experiencing leadership transitions and, to the extent we experience additional management turnover, competition for top management is high such that it may take some time to find a candidate that meets our requirements. Our future operating results depend substantially upon the continued service of our key personnel and in significant part upon our ability to attract and retain qualified management personnel. If we are unable to mitigate these or other similar risks, our business, results of operations and financial condition may be materially and adversely affected.

We depend on the continuing efforts of our senior management team and other key personnel. If we lose members of our senior management team or other key personnel or are unable to successfully retain, recruit and train qualified scientists, engineers, sales personnel and other employees, our ability to maintain, develop and commercialize our products could be harmed and we may be unable to achieve our goals.

Our success depends upon the continuing services of members of our senior management team and scientific and engineering personnel. In particular, our scientists and engineers are critical to our technological and product innovations, and we will need to hire additional qualified personnel. Our industry is characterized by high demand and intense competition for talent, and the turnover rate has been and may continue to be high. We compete for qualified management and scientific personnel with other life science companies, academic institutions and research institutions, particularly those focusing on genomics. This competition had been exacerbated by the increase in employee resignations in 2021 and 2022, that had been experienced by us and reported by employers nationwide. In addition, we have experienced significant turnover in our senior management team in recent periods. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options and restricted stock units that vest over time. The value to employees of stock options and restricted stock units 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. We may face challenges in retaining and recruiting such individuals due to sustained declines in our stock price that could reduce the retention value of equity awards. The loss of qualified employees, or an inability to attract, retain, and motivate employees, could prevent us from pursuing collaborations and materially and adversely affect our support of existing products, product development and launches, business growth prospects, results of operations and financial condition. In addition, we will need to continue to recruit, hire and retain sales personnel to support the commercialization of our existing and new products. Our employees could leave our company with little or no prior notice and would be free to work for a competitor. In addition, changes to U.S. immigration policies, particularly to H-1B and other visa programs, could restrain the flow of technical and professional talent into the U.S. and may inhibit our ability to hire qualified personnel. If one or more of our senior executives or other key personnel were unable or unwilling to continue in their present positions, we may not be able to replace them easily or at all, and other senior management may be required to divert attention from other aspects of the business. In addition, we do not have “key person” life insurance policies covering any member of our management team or other key personnel. Further, our vaccination and return to office protocols related to COVID-19 may also impact the recruitment and retention of key employees. The loss of any of these individuals or any inability to attract or retain qualified personnel, including scientists, engineers, sales personnel and others, could prevent us from pursuing collaborations and materially and adversely affect our support of existing products, product development and introductions, business growth prospects, results of operations and financial condition.

Our success is highly dependent on our ability to further penetrate nucleic acid sequencing applications as well as on the growth and expansion of the demand for our products. If our products fail to achieve and sustain sufficient market acceptance, we will not generate expected revenue and our business may not succeed.

Although nucleic acid sequencing technology is well-established, our SMRT Sequencing technology is relatively new and evolving. We cannot be sure that our current or future products will gain acceptance in the marketplace at levels sufficient to support our costs. Our success depends, in part, on our ability to expand overall demand for nucleic acid sequencing to include new applications that are not practicable with other current technologies and to introduce new products that capture a larger share of growing overall demand for sequencing. To accomplish this, we must successfully commercialize, and continue development of, our proprietary SMRT Sequencing technology for use in a variety of life science and other research applications, including uses by academic, government and clinical laboratories, as well as pharmaceutical, diagnostic, biotechnology, and agriculture companies, among others. However, we may be unsuccessful in these efforts and the sale and commercialization of the SMRT Cell, Sequel II/IIe, Revio and Onso Systems, and related products may not grow sufficiently to cover our costs.

There can be no assurance that we will be successful in adding new products or securing additional customers for our current and future products, including with respect to the SMRT Cell, Sequel II/IIe Systems, Revio and Onso. If we are unable to successfully develop acquired technologies and sell acquired technology products, we may fail to achieve our strategic commercial initiatives in connection with the planned release of new products and anticipated entry into new markets. Our ability to further penetrate existing applications and any new applications depends on a number of factors, including the cost, performance and perceived value associated with our products, as well as customers' willingness to adopt a different approach to nucleic acid sequencing. Potential customers may have already made significant investments in other sequencing technologies and may be unwilling to invest in new technologies. We are experiencing pricing pressures caused by industry competition and increased demand for lower-priced instruments and lower operational costs. We have limited experience commercializing and selling products outside of the academic and research settings, and we cannot guarantee success in acquiring additional customers. Furthermore, we cannot guarantee that our products will be satisfactory to potential customers or that our products will perform in accordance with customer expectations.

Nucleic acid sequencing applications are new and dynamic, and there can be no assurance that they will develop as quickly as we anticipate, that they will reach their full potential or that our products will be appropriate or competitive for these applications. As a result, we may be required to refocus our marketing efforts, and we may have to make changes to the specifications of our products to enhance our ability to enter particular applications more quickly. We may also need to delay full-scale commercial deployment of new products as we develop them in order to perform quality control and early access user testing. We also need to maintain reliable supply chains for the various components in our new products and consumables to support large-scale commercial production. Even if we are able to implement our technology successfully, we and/or our sales and distribution partners may fail to achieve or sustain market acceptance of our current or future products across the full range of our intended life science and other applications. We need to continue to expand and update our internal capabilities or to collaborate with other partners, or both, in order to successfully expand sales of our products in the applications that we seek to reach, which we may be unable to do at the scale required to support our business.

If the demand for our products grows more slowly than anticipated, if we are unable to successfully scale or otherwise ensure sufficient manufacturing capacity for new products to meet demand, if we are not able to successfully market and sell our products, if competitors develop better or more cost-effective products, if our product launches and commercialization are not successful, or if we are unable to further grow our customer base or do not realize the growth with existing customers that we are expecting, our current and future sales and revenue may be materially and adversely harmed, or we may recognize an impairment loss, and our business may not succeed.

We rely on other companies for the manufacture of certain components and sub-assemblies and intend to outsource additional sub-assemblies in the future, some of which are sole sources. We may not be able to successfully scale the manufacturing process necessary to build and test multiple products on a full commercial basis, which could materially harm our business.

Our products are complex and involve a large number of unique components, many of which require precise manufacturing. The nature of our products requires customized components that are currently available only from a limited number of sources, and in some cases, single sources. We have chosen to source certain critical components from a single source, including suppliers for our SMRT Cells, reagents, and instruments. We cannot assure you that product supplies will not be limited or interrupted, especially with respect to our sole source third-party manufacturing and supply collaborators, or that product supplies will be of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. We may be unable to negotiate binding agreements with our current and future sole source third-party manufacturing and supply collaborators or, in the event that such collaborators' services become interrupted for any reason, find replacement manufacturers to support our development and commercial activities at commercially reasonable terms. We do not always have arrangements in place for a redundant or second-source supply for our sole source vendors in the event they cease to provide their products or services to us or fail to provide sufficient quantities in a timely manner. If we are required to purchase these components from alternative sources, it could take several months or longer to qualify the alternative sources. If we are unable to source these product components from sole-source third-party manufacturing and supply collaborators for any reason, including in connection with acts of terrorism, hostilities, military conflict and acts of war, including between China and Taiwan, or secure a sufficient supply of these product components on a timely basis, or if these components do not meet our expectations or specifications for quality and functionality, our operations and manufacturing would be materially and adversely affected, we could be unable to meet customer demand and our business and results of operations may be materially and adversely affected.

The operations of our third-party manufacturing partners and suppliers have been and could continue to be disrupted by conditions unrelated to our business or operations or that are beyond our control, including but not limited to international trade restrictions, inflation, supply chain disruptions, and conditions related to COVID-19 or other epidemics or pandemics. If our manufacturing partners or suppliers are unable or fail to fulfill their obligations to us for any reason, we may not be able to manufacture our products and satisfy customer demand or our obligations under sales agreements in a timely manner, and our business could be harmed as a result. For example, the global shortage of semiconductors, which has been reported since early 2021, has caused challenges for us in our supply chain and resulted in some cost increases that have and may continue to adversely impact margins. During these periods of shortages or delays, the price of components may increase, or the components may not be available at all. Our suppliers have raised their prices and may continue to raise prices that we may not be able to pass on to our customers, which could adversely affect our business, including our competitive position, market share, revenues, and profit margins in material ways. We may not be able to secure enough components at reasonable prices or of acceptable quality to build new products in a timely manner in the quantities or configurations needed. For example, the Chinese government may re-impose lockdowns or similar measures to combat the spread of COVID-19 and these measures have had, and may continue to have in the future, a negative impact on manufacturing and/or supply chains, in addition to customer demand for our products and demand through certain distributors. If as a result of global economic or political instability, such as the political uncertainty associated with the Israel and Hamas conflict, an escalation of the war in Ukraine, potential uncertainty related to Taiwan and its relationship with China, other disease outbreaks, or supply issues, we or our contractors could experience shortages, business disruptions or delays for materials sourced or manufactured in the affected countries, and their ability to supply us with instruments or product components may be affected. From time to time, certain components of our systems and reagents may reach the end of their life cycles or become obsoleted by our suppliers, and we would have to procure alternative sources for these end-of-life products. If we encounter delays or difficulties in securing the quality and quantity of materials we require for our products, our supply chain would be interrupted, which would adversely affect sales. If any of these events occur, our business and operating results could be harmed. Accordingly, if any of the foregoing occurs, our ability to commercialize our products, revenue and gross margins could suffer until lockdowns from COVID-19 infections are reduced, supply issues or business disruptions are resolved and/or other sources can be developed.

In addition, because our semiconductor suppliers are in regions that may have communities with low vaccination rates, any variants of COVID-19 that evolve in the future or other outbreaks could lead to increased infections among workers that could further disrupt the supply chain. Our current manufacturing process is characterized by long lead times between the placement of orders for and delivery of our products. If we do not accurately anticipate our needs or if we receive insufficient components to manufacture our products on a timely basis to meet customer demand, our sales and our gross margin may be adversely affected, and our business could be materially harmed. If we are unable to reduce our manufacturing costs and establish and maintain reliable, high-volume manufacturing suppliers as we scale our operations and expand our product offerings, our business, operations, financial condition, and prospects could be materially and adversely harmed.

We may be unable to consistently manufacture our instruments and consumables, including SMRT Cells and reagents, to the necessary specifications or in quantities necessary to meet demand at an acceptable cost or at an acceptable performance level.

In order to successfully generate revenue from our products, we need to supply our customers with products that meet their expectations for quality and functionality in accordance with established specifications. Our customers have experienced variability in the performance of our products. We have experienced and may continue to experience delays, quality issues or other difficulties leading to customer dissatisfaction with our products. Our production of SMRT Cells, flow cells, and of reagents for both our long- and short-read technologies, involve a long and complex manufacturing process and has been and may in the future be below desired yields and resulting output levels. We have experienced and may experience in the future manufacturing delays, product defects, variability in the performance of SMRT Cells, flow cells and other products, inadequate reserves for inventory, or other issues.

There is no assurance that we will be able to manufacture our products so that they consistently achieve the product specifications and quality that our customers expect, including any products developed for clinical uses. Problems in the design or quality of our products, including low manufacturing yields of SMRT Cells, flow cells, or sub-performing reagent lots, may have a material adverse effect on our brand, business, financial condition, and operating results, and could result in us losing our ISO certifications. If we were to lose our ISO certifications, then our customers might choose not to purchase products from us. There is also no assurance that we will be able to increase manufacturing yields and decrease costs, particularly if high rates of inflation continue, or that we will be successful in forecasting customer demand or manufacturing and supply costs, or that product supplies, including reagents or integrated chips, will not be limited or interrupted, or will be of satisfactory quality or continue to be available at acceptable prices. Furthermore, while we are undertaking efforts to increase our manufacturing scale and capability, we may not be able to increase manufacturing to meet anticipated demand or may experience downtime in our manufacturing facilities, including, for example, if we experience increased cases of COVID-19 or other outbreaks among our employees, or if our suppliers are unable to meet our increased demand at a time when the supply chain is under duress due to potential dislocations and disruptions in product and employee availability due to COVID-19 or other outbreaks. An inability to manufacture products and components that consistently meet specifications, in necessary quantities and at commercially acceptable costs, will have a negative impact, and may have a material adverse effect on our business, product development timelines, financial condition and results of operations.

Rapidly changing technology in life sciences and research diagnostics could make our products obsolete unless we continue to develop, manufacture and commercialize new and improved products and pursue new opportunities.

Our industry is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry standards. These new and evolving technologies may be superior to, impair, or render obsolete the products we currently offer or the technologies currently underlying our products. Our future success depends on our ability to continually improve our products, to develop and introduce new products that address the evolving needs of our customers on a timely and cost-effective basis and to pursue new opportunities. These new opportunities may be outside the scope of our proven expertise or in areas where demand is unproven, and new products and services developed by us may not gain market acceptance or may not adequately perform to capture market share. Our inability to develop and introduce new products and to gain market acceptance of our existing and new products could harm our future operating results. Unanticipated difficulties or delays in replacing existing products with new products or in commercializing our existing or new products in sufficient quantities and of acceptable quality to meet customer demand, including with respect to the SMRT Cell, Sequel II/IIe Systems, Revio and Onso, could diminish future demand for our products and may materially and adversely harm our future operating results.

The size of the markets for our products, including our Revio and Onso instruments, may be smaller than estimated, and new market opportunities may not develop as quickly as we expect, or at all, limiting our ability to successfully sell our products.

The market for sequencing systems and consumables products is evolving, making it difficult to accurately predict the size of the markets for our current and future products, including our Revio and Onso instruments. Our estimates of the total addressable market for our current and future products are based on a number of internal and third-party estimates and assumptions that may be incorrect, including the assumptions that academic, governmental, corporate, or other sources of funding will continue to be available to life sciences researchers at times and in amounts necessary to allow them to purchase our products. In addition, sales of new products may take time to develop and mature and we cannot be certain that these market opportunities will develop as we expect. While we believe our assumptions and the data underlying our estimates of the total addressable market for our products are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates, or those underlying the third-party data we have used, may change at any time, thereby reducing the accuracy of our estimates. As a result, our estimates of the total addressable market and growth opportunities for our products may be incorrect.

The future growth of the market for our current and future products depends on many factors beyond our control, including recognition and acceptance of our products by the research and scientific communities, the growth, prevalence and costs of competing products and solutions and the development of robust ecosystems supporting our products and their methodologies. For example, the market acceptance and growth of long-read sequencing technologies, like our Revio system, depends on a variety of factors, including the availability and cost-effectiveness of related tools for high-quality sample collection and preparation and advanced bioinformatic tools to process results, as well as the perceived advantages and disadvantages of long-read sequencing compared to short-read or other sequencing technologies; consequently, if potential customers conclude the costs of adopting long-read sequencing technologies outweigh the benefits, the market for our Revio systems may be negatively impaired. There can be no assurance that our current or future products will gain traction in the market. If the markets for our current and future products are smaller than estimated or do not develop as we expect, our growth may be limited, and it could materially and adversely affect our business, operations, financial condition and prospects.

Increased market adoption of our products by customers may depend on the availability of sample preparation and informatics tools, some of which may be developed by third parties.

Our commercial success may depend in part upon the development of sample preparation and software and informatics tools by third parties for use with our products. We cannot guarantee that product supplies, including reagents, will not be limited or interrupted, or will be of satisfactory quality or continue to be available at acceptable prices, or that third parties will develop tools that our current and future customers will find useful with our products, or that customers will adopt such third-party tools on a timely basis or at all. A lack of complementary sample preparation and informatics tools, or delayed updates of such tools, may impede the adoption of our products and may materially and adversely impact our business.

We operate in a highly competitive industry and if we are not able to compete effectively, our business and operating results will likely be harmed.

There are a significant number of companies offering nucleic acid sequencing products and/or services, including Illumina, BGI Genomics (also known as MGI or Complete Genomics), Thermo, ONT Ltd., Roche, Bionano, and Qiagen. Other companies recently entering the market include Ultima Genomics, Element Biosciences and Singular Genomics. Many of these companies currently have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater financial, technical, research and/or other resources, more experience in new product development, larger and more established manufacturing capabilities and marketing, sales, and support functions, and/or more established distribution channels to deliver products to customers than we do. These companies may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards, or customer requirements.

There are also several companies that are in the process of developing or have already developed and commercialized new, competing or potentially competing technologies, products and/or services, including ONT Ltd. and its subsidiaries, against whom we have filed complaints for patent infringement in the U.S. District Court for the District of Delaware and, previously, with the U.S. International Trade Commission, in the High Court of England and Wales and in the District Court of Mannheim, Germany. ONT Ltd. previously filed claims against us in the High Court of England and Wales and the District Court of Mannheim, Germany, also for patent infringement, and its subsidiary, Oxford Nanopore Technologies, Inc. ("ONT Inc."), filed counterclaims against us in the U.S. District Court for the District of Delaware seeking declaratory judgements of non-infringement, invalidity and unenforceability of the asserted patents, as well as antitrust, false advertising and unfair competition counterclaims that were subsequently dismissed by that court. Roche is developing potentially competing sequencing products. Increased competition may result in pricing pressures, which could harm our sales, profitability or market share. Our failure to further enhance our existing products and to introduce new products to compete effectively could materially and adversely affect our business, operations, financial condition, and prospects.

We may be unable to successfully increase sales of our current products or market and sell our future products.

Our ability to achieve profitability depends, in part, on our ability to attract customers for our current and future products, including Revio and Onso, and we may be unable to effectively market or sell our products or find appropriate partners to do so. To perform sales, marketing, distribution, and customer support functions successfully, we face a number of risks, including:

- our ability to attract, retain and manage qualified sales, marketing, and service personnel necessary to expand market acceptance for our technologies;
- the performance and commercial availability expectations of our existing and potential customers with respect to new and existing products;
- availability of potential sales and distribution partners to sell our technologies, and our ability to attract and retain such sales and distribution partners;
- the time and cost of maintaining and growing a specialized sales, marketing and service force for a particular application, which may be difficult to justify in light of the revenue generated; and
- our sales, marketing and service force may be unable to execute successful commercial activities.

We have enlisted and may continue to enlist third parties to assist with sales, distribution and customer support. There is no guarantee that we will be successful in attracting desirable sales and distribution partners, that we will be able to enter into arrangements with such partners on terms favorable to us or that we will be able to retain such partners on a going-forward basis. If our sales and marketing efforts, or those of any of our third-party sales and distribution partners, are not successful, or our products do not perform in accordance with customer expectations, our technologies and products may not gain market acceptance, which could materially and adversely impact our business, operations, financial condition, and prospects.

Large purchases by a limited number of customers represent a significant portion of our revenue, and any loss or delay of expected purchases has resulted, and in the future could result, in material quarter-to-quarter fluctuations of our revenue or otherwise adversely affect our results of operations.

We receive a significant portion of our revenue from a limited number of customers. For example, for the years ended December 31, 2022, 2021, and 2020, one of our customers, who is our primary distributor in China, accounted for approximately 12%, 13%, and 14% of our total revenue, respectively. Many of these customers make large purchases on a purchase-order basis rather than pursuant to long-term contracts. As a consequence of the concentrated nature of our customer base and their purchasing behavior, our quarterly revenue and results of operations have fluctuated, and may fluctuate in the future, from quarter to quarter and are difficult to forecast. For example, the cancellation of orders or acceleration or delay in anticipated product purchases or the acceptance of shipped products by our larger customers has materially affected, and in the future could materially affect, our revenue and results of operations in any quarterly period. We have been, and may in the future be, unable to sustain or increase our revenue from our larger customers, or offset any discontinuation or decrease of purchases by our larger customers with purchases by new or other existing customers. To the extent one or more of our larger customers experience significant financial difficulty, bankruptcy or insolvency, this could have a material adverse effect on our sales and our ability to collect on receivables, which could materially and adversely harm our financial condition and results of operations.

In addition, many of our customers, including some of our larger customers, have negotiated, or may in the future negotiate, volume-based discounts or other more favorable terms from us or our sales and distribution partners, which can and have had a negative effect on our gross margins or revenue.

We expect that such concentrated purchases will continue to contribute materially to our revenue for the foreseeable future and that our results of operations may fluctuate materially as a result of such larger customers' buying patterns. In addition, we may see consolidation of our customer base. The loss of one of our larger customers, a significant delay or reduction in its purchases, or any volume-based discount or other more favorable terms that we or our sales and distribution partner(s) may agree to provide, in light of the aggregated purchase volume or buying power resulting from such consolidation, has harmed, and in the future could harm, our business, financial condition, results of operations and prospects.

Our products are highly complex, have recurring support requirements and could have unknown defects or errors, which may give rise to claims against us or divert application of our resources from other purposes.

Products using our SMRT sequencing and SBB technology are highly complex and may develop or contain undetected defects or errors. Our customers have previously experienced reliability issues with our existing products, including the Sequel System and the Sequel II/IIe Systems. In addition, it is possible our customers could experience reliability issues with current or future products, including the Sequel II/IIe, Revio and Onso Systems. Despite internal and external testing, defects, or errors may arise in our products, which could result in a failure to obtain, maintain, or increase market acceptance of our products, diversion of development resources, injury to our reputation and increased warranty, service, and maintenance costs. New products, including Revio and Onso, or enhancements to our existing products, including the SMRT Cell and Sequel II/IIe Systems, in particular may contain undetected errors or performance problems that are discovered only after delivery to customers. If our products have reliability or other quality issues or require unexpected levels of support in the future, the market acceptance and utilization of our products may not grow to levels sufficient to support our costs and our reputation and business could be harmed. Low utilization rates of our products could cause our revenue and gross margins to be adversely affected. We provide a warranty for our sequencing instruments and consumables, which is generally limited to replacing, repairing, or at our option, giving credit for any sequencing instrument or consumable with defects in material or workmanship. Service contracts for our sequencing instruments may be separately purchased. Defects or errors in our products may also discourage customers from purchasing our products. The costs incurred in correcting any defects or errors may be substantial and could materially and adversely affect our operating margins. If our service and support costs increase, our business and operations may be materially and adversely affected.

In addition, such defects or errors could lead to the filing of product liability claims against us or against third parties whom we may have an obligation to indemnify against such claims, which could be costly and time-consuming to defend and result in substantial damages. Although we have product liability insurance, any product liability insurance that we have or procure in the future may not protect our business from the financial impact of a product liability claim. Moreover, we may not be able to obtain adequate insurance coverage on acceptable terms. Any insurance that we have or obtain will be subject to deductibles and coverage limits. A product liability claim could have a material adverse effect on our business, financial condition, and results of operations.

A significant portion of our sales depends on customers' spending budgets that may be subject to significant and unexpected variation which could have a negative effect on the demand for our products.

Our instruments represent significant capital expenditures for our customers in research applications. Current and potential customers for our current or future products include academic and government institutions, genome centers, medical research institutions, clinical laboratories, pharmaceutical, agricultural, biotechnology, diagnostic and chemical companies. Their spending budgets can have a significant effect on the demand for our products. Spending budgets are based on a wide variety of factors, including the allocation of available resources to make purchases, funding from government sources which is highly uncertain and subject to change, the spending priorities among various types of research equipment, policies regarding capital expenditures during economically uncertain periods and the potential impacts of COVID-19 or other outbreaks. Any decrease in capital spending or change in spending priorities of our current and potential customers could significantly reduce the demand for our products. Any delay or reduction in purchases by current or potential customers or our inability to forecast fluctuations in demand could materially and adversely harm our future operating results.

We may not be able to convert our orders in backlog into revenue.

Our backlog represents product orders from our customers that we have confirmed but have not been able to fulfill, and, accordingly, for which we have not yet recognized revenue. We may not receive revenue from these orders, and any order backlog we report may not be indicative of our future revenue.

Many events can cause an order to be delayed or not completed at all, some of which may be out of our control, including the potential impacts from COVID-19 or other outbreaks and our suppliers, especially our sole source suppliers, not being able to provide us with products or components. If we delay fulfilling customer orders or if customers reconsider their orders, those customers may seek to cancel or modify their orders with us. Customers may otherwise seek to cancel or delay their orders even if we are prepared to fulfill them. If our orders in backlog do not result in sales, our operating results may suffer.

Our sales cycles are unpredictable and lengthy, which makes it difficult to forecast revenue and may increase the magnitude of quarterly or annual fluctuations in our operating results.

The sales cycles for our sequencing instruments are lengthy because they represent a major capital expenditure and generally require the approval of our customers' senior management. This may contribute to substantial fluctuations in our quarterly or annual operating results, particularly during periods in which our sales volume is low. Because of these fluctuations, it is likely that in some future quarters our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease. Past fluctuations in our quarterly and annual operating results have resulted in decreases in our stock price. Such fluctuations also mean that investors may not be able to rely on our operating results in any particular period as an indication of future performance. Sales to existing customers and the establishment of a business relationship with other potential customers is a lengthy process, generally taking several months and sometimes longer. Following the establishment of the relationship, the negotiation of purchase terms can be time-consuming, including as a result of seasonal factors, as discussed below, and a potential customer may require an extended evaluation and testing period. Our sales cycles may also lengthen, and those sales cycles may result in lower units sold per cycle, as we introduce our Revio and Onso instruments and their associated consumables to the market, as our customers may have additional administrative, technical or other requirements associated with transitioning to new products and technologies. In anticipation of product orders, we may incur substantial costs before the sales cycle is complete and before we receive any customer payments. As a result, if a sale is not completed or is canceled or delayed, we may have incurred substantial expenses, making it more difficult for us to become profitable or otherwise negatively impacting our financial results. Even if our selling efforts are successful, the realization of revenue may be substantially delayed, our ability to forecast our future revenue may be more limited and our revenue may fluctuate significantly from quarter to quarter and year over year. For more information on the impact of these fluctuations on our results and stock price, see "*—Our operating results fluctuate from quarter to quarter and year over year, which makes our future results difficult to predict and could negatively impact the market price of our common stock*," below.

Because some of our customers and suppliers are based in China, our business, financial condition and results of operations could be adversely affected by the political and economic tensions between the United States and China.

We are subject to risks associated with political conflicts between the U.S. and China. A significant portion of our revenue is generated from China. For example, for the years ended December 31, 2022, 2021, and 2020, one of our customers, who is our primary distributor in China, accounted for approximately 12%, 13%, and 14% of our total revenue, respectively. In addition, certain components, some of which are critical components, of our products are manufactured in China. These components are either sourced directly from companies in China or indirectly from third parties that source from companies in China.

Consequently, we are subject to significant risks associated with the trading relationship between the U.S. and China, which is currently characterized by significant uncertainty. Tariffs imposed by the U.S. and China have increased, and may continue to increase, our costs. Additionally, export restrictions imposed by the U.S. may impact our ability to export certain products to customers or distributors in China and restrict our ability to use certain integrated circuits in our products, and it is possible that additional restrictions will be put in place that could impact our ability to provide our products to customers or distributors in China or source components from China. Moreover, the Chinese government may retaliate against U.S. trade restrictions in ways that could impact our business. Given the relatively fluid regulatory environment in China and the United States and uncertainty how the U.S. or foreign governments will act with respect to export controls, tariffs, international trade agreements and policies, there could be additional import, export, tax, or other regulatory changes in the future. Any such changes could directly and adversely impact our financial results and results of operations. For more information, see "*—Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers may materially harm our business*," below.

Other risks could include:

- interruptions to operations in China as a result of potential disease outbreaks, including any further COVID-19 related outbreaks, and natural catastrophic events, which have in the past and can result in the future in business closures, transportation restrictions, import and export complications and cause shortages in the supply of raw materials or disruptions in manufacturing;
- product supply disruptions and increased costs as a result of heightened exposure to changes in the policies of the Chinese government, political unrest or unstable economic conditions in China; and
- the nationalization or other expropriation of private enterprises or intellectual property by the Chinese government.

Difficulties in this relationship may require us to take actions adverse to our business to comply with governmental restrictions on business and trade with China.

We face significant risks associated with doing business with Taiwanese suppliers and manufacturers due to the tense relationship between Taiwan and mainland China.

Substantially all of our consumable chips are partly manufactured by a company based in Taiwan. Our supply of consumables chips and other critical components may be materially and adversely affected by diplomatic, geopolitical, military and other developments affecting the relationship between China and Taiwan. Recent military exercises in the Taiwan Strait have contributed to geopolitical uncertainty regarding the future of the relationship between China and Taiwan. Current or future diplomatic, geopolitical, military or other tensions between China and Taiwan may lead to circumstances that negatively affect the availability of such consumable chips and other critical components to us, which could limit or prohibit our ability to manufacture consumable chips and other critical components or lead to an increase in our supply costs if we cannot find a similar cost alternative supplier, which could materially and adversely impact our business, operations, prospects, financial condition and results, and results of operations.

Our operating results fluctuate from quarter to quarter and year over year, which makes our future results difficult to predict and could negatively impact the market price of our common stock.

We operate on a December 31st year-end and believe that there are significant seasonal factors which may cause sales of our products, and particularly our sequencing instruments, to vary on a quarterly or yearly basis, contribute to lengthy sales cycles for our sequencing instruments, and increase the magnitude of quarterly or annual fluctuations in our operating results. We believe that this seasonality results from a number of factors, including the procurement and budgeting cycles of many of our customers, especially government-funded customers, which often coincide with government fiscal year ends. For example, the U.S. government's fiscal year-end occurs in our third quarter and may result in increased sales of our products during this quarter if government-funded customers have unused funds that may be forfeited, or future budgets that may be reduced if funds remain unspent at fiscal year-end. Furthermore, Lunar New Year celebrations, which occur during our first quarter, and may last for a week or longer, resulting in closure of many of our customers' offices in China and across the Asia-Pacific region have caused, and may in the future cause, decreased sales of our consumables during our first quarter. These factors have contributed, and in the future may contribute, to substantial fluctuations in our quarterly operating results.

Our operating results during any given period can also be impacted by numerous other factors, including the following:

- market acceptance for our products;
- our ability to attract new customers;
- the length of our sales cycles, as discussed above;
- our ability to achieve economies of scale and other manufacturing efficiencies at the rate we anticipate;
- publications of studies by us, our competitors or third parties;
- the timing and success of new product introductions by us or our competitors or other changes in the competitive dynamics of our industry, such as consolidation;
- the amount and timing of our costs and expenses;
- changes in our pricing policies or those of our competitors;

- general economic, industry and market conditions;
- the regulatory environment in which we operate;
- expenses associated with warranty obligations or unforeseen product quality issues;
- the hiring, training, and retention of key employees, including our ability to grow our sales organization;
- litigation or other claims against us for intellectual property infringement or otherwise;
- our ability to obtain additional financing as necessary;
- changes or trends in new technologies and industry standards; and the potential impacts of COVID-19 or other outbreaks.

Consequently, it is possible that in some quarters our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our common stock would likely decrease. These fluctuations, among other factors, also mean that our operating results in any particular period may not be relied upon as an indication of future performance. Seasonal or cyclical variations in our sales have in the past, and may in the future, become more or less pronounced over time, and have in the past materially affected, and may in the future materially affect, our business, financial condition, results of operations, and prospects.

Our ability to use net operating losses to offset future taxable income may be subject to substantial limitations, and changes to U.S. tax laws may cause us to make adjustments to our financial statements.

Under Section 382 of the Internal Revenue Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses (“NOLs”) to offset future taxable income. We believe that we have had one or more ownership changes, and as a result, our existing NOLs are currently subject to limitation. Future changes in our stock ownership could result in additional ownership changes, including potentially material changes, under Section 382. Consequently, we may not be able to utilize some or all of our NOLs even if we attain profitability.

Our facilities in California are located near earthquake faults, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our facilities in California are located near earthquake fault zones and are vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously, or potentially completely, impaired. In addition, the nature of our activities could cause significant delays in our research programs and commercial activities and make it difficult for us to recover from a disaster. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

Risks Related to Our Intellectual Property

Failure to secure patent or other intellectual property protection for our products and improvements to our products may reduce our ability to maintain any technological or competitive advantage over our current and potential competitors.

Our ability to protect and enforce our intellectual property rights is uncertain and depends on complex legal and factual questions. Our ability to establish or maintain a technological or competitive advantage over our competitors may be diminished because of these uncertainties. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications or issued patents;
- we or our licensors might not have been the first to file patent applications for these inventions;
- it is possible that neither our pending patent applications nor the pending patent applications of our licensors will result in issued patents;
- the scope of the patent protection we or our licensors obtain may not be sufficiently broad to prevent others from practicing our technologies, developing competing products, designing around our patented technologies or independently developing similar or alternative technologies;

- our and our licensors' patent applications or patents have been, are and may in the future be, subject to interference, opposition or similar administrative proceedings, which could result in those patent applications failing to issue as patents, those patents being held invalid or the scope of those patents being substantially reduced;
- our enforcement of patents and proprietary rights in other countries may be problematic or unpredictable;
- we may not be able to prevent third parties from practicing our inventions 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;
- we or our partners may not adequately protect our trade secrets;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may limit our freedom to operate and prevent us from commercializing our technology in accordance with our plans.

The occurrence of any of these events could impair our ability to operate without infringing upon the proprietary rights of others or prevent us from establishing or maintaining a competitive advantage over our competitors.

Variability in intellectual property laws may adversely affect our intellectual property position.

Intellectual property laws, and patent laws and regulations in particular, have been subject to significant variability either through administrative or legislative changes to such laws or regulations or changes or differences in judicial interpretation, and it is expected that such variability will continue to occur. Additionally, intellectual property laws and regulations differ by country. Variations in the patent laws and regulations or in interpretations of patent laws and regulations in the United States and other countries may diminish the value of our intellectual property and may change the impact of third-party intellectual property on us. Accordingly, we cannot predict the scope of the patents that may be granted to us with certainty, the extent to which we will be able to enforce our patents against third parties or the extent to which third parties may be able to enforce their patents against us.

Some of the intellectual property that is important to our business is owned by other companies or institutions and licensed to us, and changes to the rights we have licensed may adversely impact our business.

We license from third parties some of the intellectual property that is important to our business. If the third parties who license intellectual property to us fail to maintain the intellectual property that we have licensed, or lose rights to that intellectual property, the rights we have licensed may be reduced or eliminated, which would eliminate barriers against our competition. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, or could subject us to claims of intellectual property infringement or contract breach in litigation or other administrative proceedings that could result in damage awards against us and injunctions that could prohibit us from selling our products. In addition, some of our licenses from third parties limit the field in which we can use the licensed technology. Therefore, in order for us to use such licensed technology in potential future applications that are outside the licensed field of use, we may be required to negotiate new licenses with our licensors or expand our rights under our existing licenses. We cannot be certain that we will be able to obtain such licenses or expanded rights on reasonable terms or at all. In the event a dispute with our licensors were to occur, our licensors may seek to renegotiate the terms of our licenses, increase the royalty rates that we pay to obtain and maintain those licenses, limit the field or scope of the licenses, or terminate the license agreements. In addition, we have limited rights to participate in the prosecution and enforcement of the patents and patent applications that we have licensed. If we fail to meet our obligations under these licenses, or if we have a dispute regarding the terms of the licenses, these third parties could terminate the licenses, which could subject us to claims of intellectual property infringement. As a result, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. Further, because of the rapid pace of technological change in our industry, we may need to rely on key technologies developed or licensed by third parties, and we may not be able to obtain licenses and technologies from these third parties at all or on reasonable terms. The occurrence of these events may have a material adverse effect on our business, financial condition or results of operations.

The measures that we use to protect the security of and enforce our intellectual property and other proprietary rights may not be adequate, which could result in the loss of legal protection for, and thereby diminish the value of, such intellectual property and other rights.

In addition to patents, we also rely upon trademarks, trade secrets, copyrights, and unfair competition laws, as well as license agreements and other contractual provisions, to protect our intellectual property and other proprietary rights. Despite these measures, any of our intellectual property rights could be challenged, invalidated, circumvented, or misappropriated. In addition, we attempt to protect our intellectual property and proprietary information by requiring our employees and consultants to enter into confidentiality and assignment of inventions agreements, and by entering into confidentiality agreements with our third-party development, manufacturing, sales, and distribution partners, who may also acquire, develop and/or commercialize alternative or competing products or provide services to our competitors. For example, Roche had certain access to our trade secrets and other proprietary information pursuant to an agreement we had entered into with Roche, subject to the confidentiality provisions thereof (certain of which provisions survive the termination of the agreement); however, Roche is developing potentially competing sequencing products. There can be no assurance that our measures have provided or will provide adequate protection for our intellectual property and proprietary information. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets and other proprietary information may be disclosed to others, or others may gain access to or disclose our trade secrets and other proprietary information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. Additionally, others may independently develop proprietary information and techniques that are substantially equivalent to ours. The occurrence of these events may have a material adverse effect on our business, financial condition, or results of operations.

Our intellectual property may be subject to challenges in the United States or foreign jurisdictions that could adversely affect our intellectual property position.

Our pending, issued and granted U.S. and foreign patents and patent applications have been, are and may in the future be, subject to challenges by ONT Ltd., ONT Inc. and Metrichor, Ltd. (“Metrichor” and, together with ONT Ltd. and ONT Inc., “ONT”) in addition to other parties asserting prior invention by others or invalidity on various grounds, through proceedings, such as interferences, reexaminations, or opposition proceedings. Addressing these challenges to our intellectual property has been, and any future challenges can be, costly and distract management’s attention and resources. For example, we previously incurred significant legal expenses to litigate and settle a complaint seeking review of a patent interference decision of the U.S. Patent and Trademark Office. Additionally, ONT previously requested that the U.S. Patent and Trademark Office institute *inter partes* reviews of certain patents that we have asserted against ONT Inc. and ONT Ltd. in litigation proceedings for patent infringement. While none of the *inter partes* reviews requested by ONT were instituted by the U.S. Patent and Trademark Office, challenges of this nature before the Patent Trial and Appeal Board (“PTAB”) in the future could result in determinations that our patents or pending patent applications are unpatentable to us, or are invalidated or unenforceable in whole or in part and could require us to expend significant time, funds, and other resources in litigating such challenges. Accordingly, adverse rulings in such proceedings could negatively impact the scope of our intellectual property protection for our products and technology and could materially and adversely affect our business. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and courts and may result in the revocation, cancellation, or amendment of any foreign patents we hold now or in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such products. Such a loss of patent protection would have a material adverse impact on our business.

Some of our technology is subject to "march-in" rights by the U.S. government.

Some of our patented technology was developed with U.S. federal government funding. When new technologies are developed with U.S. government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that such action is necessary to (i) achieve practical application of the U.S. government-funded technology, (ii) alleviate health or safety needs, (iii) meet requirements of federal regulations, or (iv) give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government and such government funding must be disclosed in any resulting patent applications. Furthermore, our rights in such inventions are subject to government license rights and foreign manufacturing restrictions. The U.S. government has generally denied requests to exercise its march-in rights, even to provide access to potentially life-saving medications; however, if the U.S. government were to exercise its march-in rights to our patent technologies funded by the U.S. government, particularly for the benefit of one of more of our competitors, that may have a material adverse effect on our business.

We are involved in legal proceedings to enforce our intellectual property rights.

Our intellectual property rights involve complex factual, scientific, and legal questions. We operate in an industry characterized by significant intellectual property litigation. Even though we may believe that we have a valid patent on a particular technology, other companies have from time to time taken, and may in the future take, actions that we believe violate our patent rights. For example, we were previously involved in legal proceedings with ONT and Harvard University in several United States and European jurisdictions. We have in the past received adverse rulings against us with respect to our complaint with the United States International Trade Commission for one of these proceedings. Legal actions to enforce our patent rights have been, and will continue to be, expensive, and may divert significant management time and resources. Adverse parties from previous legal actions have brought, and they and others may in the future bring, claims against us and/or our intellectual property. Litigation is a significant ongoing expense, recognized in sales, general and administrative expense, with an uncertain outcome, and has been, and may in the future be, a material expense for us. Our enforcement actions may not be successful, have given rise to legal claims against us and could result in some of our intellectual property rights being determined to be invalid or not enforceable. Furthermore, an adverse determination or judgement could lead to an award of damages against us, or the issuance of an injunction against us or our products that could prevent us from selling any products found to be infringing the intellectual property rights of another party.

We have been, are currently, and could in the future be, subject to legal proceedings with third parties who may claim that our products infringe or misappropriate their intellectual property rights.

Our products are based on complex, rapidly developing technologies. We may not be aware of issued or previously filed patent applications that belong to third parties that mature into issued patents that cover some aspect of our products or their use. In addition, because patent litigation is complex and the outcome inherently uncertain, our belief that our products do not infringe third-party patents of which we are aware or that such third-party patents are invalid and unenforceable may be determined to be incorrect. As a result, third parties have claimed, and may in the future claim, that we infringe their patent rights and have filed, and may in the future file lawsuits or engage in other proceedings against us to enforce their patent rights. For example, we are involved in legal proceedings for alleged patent infringement and related matters in the United States with Personal Genomics of Taiwan, Inc. ("PGI"), Take2 Technologies, Ltd., and the Chinese University of Hong Kong. In addition, ONT Ltd. and Harvard University have, in the past, filed claims against us in the High Court of England and Wales and the District Court of Mannheim, Germany for patent infringement, and PGI has filed claims against us in the U.S. District Court for the District of Delaware and in the Wuhan People's Court in China. We are aware of other issued patents and patent applications owned by third parties that could be construed to read on our products, and related maintenance and support services. Although we do not believe that our products or services infringe any valid issued patents, the third-party owners of these patents and applications may in the future claim that we infringe their patent rights and file lawsuits against us. In addition, as we enter new markets, our competitors and other third parties may claim that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which effectively could block our ability to further develop or commercialize products or services and could result in the award of substantial damages against us. Patent litigation between competitors in our industry is common. Additionally, we have certain obligations to many of our customers and suppliers to indemnify and defend them against claims by third parties that our products or their use infringe any intellectual property of these third parties. In defending ourselves against any of these claims, we have in the past incurred, and could in the future incur, to defend ourselves or our customers, substantial costs, and the attention of our management and technical personnel could be diverted. For example, we previously incurred significant legal expenses to litigate and settle a complaint alleging patent infringement. Even if we have an agreement that indemnifies us against such costs, the indemnifying party may be unable to uphold its contractual obligations. To avoid or settle legal claims, it may be necessary or desirable in the future to obtain licenses relating to one or more products or relating to current or future technologies, which could negatively affect our gross margins. We may not be able to obtain these licenses on commercially reasonable terms, or at all. We may be unable to modify our products so that they do not infringe the intellectual property rights of third parties. In some situations, the results of litigation or settlement of claims may require us to cease allegedly infringing activities which could prevent us from selling some or all of our products. The occurrence of these events may have a material adverse effect on our business, financial condition, or results of operations.

In addition, in the course of our business, we may from time to time have access or be alleged to have access to confidential or proprietary information of others, which, though not patented, may be protected as trade secrets. Others could bring claims against us asserting that we improperly used their confidential or proprietary information, or that we misappropriated their technologies and incorporated those technologies into our products. A determination that we illegally used the confidential or proprietary information or misappropriated technologies of others in our products could result in us paying substantial damage awards or being prevented from further developing or selling some or all of our products, which could materially and adversely affect our business.

We have not yet registered some of our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.

Some of our trademark applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, in the U.S. Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings.

Our use of "open source" software could adversely affect our ability to sell our products and subject us to possible litigation.

A portion of the products or technologies developed and/or distributed by us incorporate "open source" software, and we may incorporate open source software into other products or technologies in the future. Some open source software licenses require that we disclose the source code for any modifications to such open source software that we make and distribute to one or more third parties, and that we license the source code for such modifications to third parties, including our competitors, at no cost. We monitor the use of open source software in our products to avoid uses in a manner that would require us to disclose or grant licenses under our source code that we wish to maintain as proprietary; however, there can be no assurance that such efforts have been or will be successful. In some circumstances, distribution of our software that includes or is linked with open source software could require that we disclose and license some or all of our proprietary source code in that software, which could include permitting the use of such software and source code at no cost to the user. Open source license terms are often ambiguous and there is little legal precedent governing the interpretation of these licenses. Successful claims made by the licensors of open source software that we have violated the terms of these licenses could result in unanticipated obligations, including being subject to significant damages, being enjoined from distributing products that incorporate open source software and being required to make available our proprietary source code pursuant to an open source license, which could substantially help our competitors develop products that are similar to or better than ours or otherwise materially and adversely affect our business.

Risks Related to Regulation

We are, and may become, subject to governmental regulations that may impose burdens on our operations, and the markets for our products may be narrowed.

We are subject, both directly and indirectly, to the adverse impact of government regulation of our operations and markets. For example, export of our instruments may be subject to strict regulatory control in a number of jurisdictions, and we could experience disruption in our supply chain as a result of certain geopolitical events and conflicts and any related political or economic responses and counter-responses or otherwise by various global actors. Following Russia's invasion of Ukraine in February 2022, the United States and other countries imposed certain economic sanctions and severe export control restrictions against Russia and Belarus as well as certain Russian nationals and individuals and entities with ties to Russia, Belarus, and this conflict. These sanctions and restrictions have continued to increase as the conflict has further escalated and now cover the export of our products to Russia, and the United States and other countries could impose even wider sanctions and export restrictions and take other actions in the future that could further limit our ability to provide products in certain locations. Additionally, restrictions on the ability to send certain products and technology related to semiconductors, semiconductor manufacturing, and supercomputing to China without an export license may impact our ability to provide products to customers or distributors in China. We have expanded and are continuing to expand the international jurisdictions into which we supply products, which increases the risks surrounding governmental regulations relating to our business. The need to or failure to satisfy export control criteria or to obtain necessary clearances could delay or prevent shipment of products, which could materially and adversely affect our revenue and profitability. Moreover, the life sciences industry, which is expected to continue to be one of the primary markets for our technology, has historically been heavily regulated. There are, for example, laws in several jurisdictions restricting research in genetic engineering, which may narrow our markets. Given the evolving nature of this industry, legislative bodies or regulatory authorities may adopt additional regulations that may adversely affect our market opportunities. Additionally, if ethical and other concerns surrounding the use of genetic information, diagnostics or therapies become widespread, there may be less demand for our products.

Our business is also directly affected by a wide variety of government regulations applicable to business enterprises generally and to companies operating in the life science industry in particular. Failure to comply with government regulations or obtain or maintain necessary permits and licenses could result in a variety of fines or other censures or an interruption in our business operations which may have a negative impact on our ability to generate revenue and the cost of operating our business. In addition, changes to laws and government regulations could cause a material adverse effect on our business as we will need to adapt our business to comply with such changes. For example, a governmental prohibition on the use of human *in vitro* diagnostics or other regulations that negatively impact the research and development activities of our customers would adversely impact our commercialization of products on which we have expended significant research and development resources, which would in turn have a material adverse impact on our business and prospects.

Our products could become subject to government regulation as medical devices by the U.S. Food and Drug Administration or other domestic and international regulatory agencies even if we do not elect to seek regulatory clearance or approval to market our products for diagnostic purposes, which could increase our costs and impede or delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

Our products are currently labeled and promoted as research use only ("RUO") products, and are not currently designed, or intended to be used, for clinical diagnostic tests or as medical devices. However, in the future, certain of our products or related applications, such as those that may be developed for clinical uses, could be subject to regulation by the U.S. Food and Drug Administration ("FDA"), or the FDA's regulatory jurisdiction could be expanded to include our products. Also, even if our products are labeled, promoted, and intended as RUO, the FDA or comparable agencies of other countries could disagree with our conclusion that our products are intended for research use only or deem our sales, marketing and promotional efforts as being inconsistent with the FDA's guidance on RUO products. For example, our customers may independently elect to use our RUO labeled products in their own laboratory developed tests ("LDTs") for clinical diagnostic use, which could subject our products to government regulation, and the regulatory clearance or approval and maintenance process for such products may be uncertain, expensive, and time-consuming. Regulatory requirements related to marketing, selling, and distribution of RUO products could change or be uncertain, even if clinical uses of our RUO products by our customers were done without our consent. If the FDA or other regulatory authorities assert that any of our RUO products are subject to regulatory clearance or approval, our business, financial condition, or results of operations could be adversely affected. In the event that we fail to obtain and maintain necessary regulatory clearances or approvals for products that we develop for clinical uses, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations may be materially harmed. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. We do not have experience in obtaining FDA approvals and no assurance can be given that we will be able to obtain or to maintain such approvals. Furthermore, any approvals that we may obtain can be revoked if safety or efficacy problems develop.

The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against laboratories developing and offering LDTs. In 2017, the FDA announced that it would not issue final guidance on the oversight of LDTs, and manufacturers of products used for LDTs, but would seek further public discussion on an appropriate oversight approach, and give Congress an opportunity to develop a legislative solution. The FDA has issued warning letters to certain genomics labs for illegally marketing genetic tests that claim to predict patients' responses to specific medications, noting that the FDA has not created a legal "carve-out" for LDTs and retains discretion to take action when appropriate, such as when certain genomic tests raise significant public health concerns.

As manufacturers develop more complex diagnostic tests and diagnostic software, the FDA may increase its regulation of LDTs. Any future legislative or administrative rule making or oversight of LDTs, if and when finalized, may impact the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws. We cannot predict how these various efforts will be resolved, how Congress or the FDA will regulate LDTs in the future, or how that regulatory system will impact our business. Changes to the current regulatory framework, including the imposition of additional or new regulations, including regulation of our products, could arise at any time during the development or marketing of our products, which may negatively affect our ability to obtain or maintain FDA or comparable regulatory approval of our products, if required. Further, sales of devices for diagnostic purposes may subject us to additional healthcare regulation and enforcement by the applicable government agencies. Such laws include, without limitation, state and federal anti-kickback or anti-referral laws, healthcare fraud and abuse laws, false claims laws, privacy and security laws, Physician Payments Sunshine Act and related transparency and manufacturer reporting laws, and other laws and regulations applicable to medical device manufacturers.

Additionally, in 2013, the FDA issued Final Guidance “Distribution of In Vitro Diagnostic Products Labeled for Research Use Only.” The guidance emphasizes that the FDA will review the totality of the circumstances when it comes to evaluating whether equipment and testing components are properly labeled as RUO. The final guidance states that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA’s clearance, approval, and other regulatory requirements if the circumstances surrounding the distribution, marketing and promotional practices indicate that the manufacturer knows its products are, or intends for its products to be, used for clinical diagnostic purposes. These circumstances may include written or verbal sales and marketing claims or links to articles regarding a product’s performance in clinical applications and a manufacturer’s provision of technical support for clinical applications.

In August 2020, the Department of Health and Human Services ("HHS") announced rescission of guidance and other informal issuances of FDA regarding pre-market review of LDT absent notice-and-comment rulemaking, stating that, absent notice-and-comment rulemaking LDTs are not required to obtain FDA pre-market authorization. In November 2021, HHS under the Biden administration issued a statement that withdrew the August 2020 policy announcement stating that HHS does not have a policy on LDTs that is separate from FDA’s longstanding approach.

Legislative and administrative proposals to amend the FDA's oversight of LDTs have been introduced in recent years, including the Verifying Accurate Leading-edge IVCT Development Act of 2021 (the "VALID Act"), which aims to create a new category of medical products separate from medical devices called “in vitro clinical tests,” or IVCTs, and bring all such products within the scope of the FDA’s oversight. To date, Congress has not passed the VALID Act, but may revisit the VALID Act or similar policy riders and enact other FDA programmatic reforms in the future. In October 2023, through rulemaking, the FDA proposed to amend the definition of “in vitro diagnostic products” in FDA regulations to include laboratories that manufacture such products and to phase out the FDA’s general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would be regulated similarly to IVDs. It is unclear when the FDA will finalize and begin enforcing such rule and how future legislation by federal and state governments and FDA regulation will impact the industry, including our business and that of our customers.

If the FDA determines our products or related applications should be subject to additional regulation as in vitro diagnostic devices based upon customers’ use of our products for clinical diagnostic or therapeutic decision-making purposes, our ability to market and sell our products could be impeded and our business, prospects, results of operations and financial condition may be adversely affected. In addition, the FDA could consider our products to be misbranded or adulterated under the Federal Food, Drug, and Cosmetic Act and subject to recall and/or other enforcement action.

To the extent we elect to label and promote any of our products as medical devices, we would be required to obtain prior approval or clearance by the FDA or comparable foreign regulatory authority, which could take significant time and expense and could fail to result in a marketing authorization for the intended uses we believe are commercially attractive. Obtaining marketing authorization in one jurisdiction does not mean that we will be successful in obtaining marketing authorization in other jurisdictions where we conduct business.

If we elect to label and market our products for use as, or in the performance of, clinical diagnostics in the United States, thereby subjecting them to FDA regulation as medical devices, we would be required to obtain pre-market 510(k) clearance or pre-market approval from the FDA, unless an exception applies. It is possible, in the event we elect to submit 510(k) applications for certain of our products, that the FDA would take the position that a more burdensome pre-market application, such as a PMA or a *de novo* application is required for some of our products. If such applications were required, greater time and investment would be required to obtain FDA approval. Even if the FDA agreed that a 510(k) was appropriate, FDA clearance can be expensive and time consuming. It generally takes a significant amount of time to prepare a 510(k), including conducting appropriate testing on our products, and several months to years for the FDA to review a submission. Notwithstanding the effort and expense, FDA clearance or approval could be denied for some or all of our products for which we choose to market as a medical device or a clinical diagnostic device. Even if we were to seek and obtain regulatory approval or clearance, it may not be for the intended uses we request or that we believe are important or commercially attractive. There can be no assurance that future products for which we may seek pre-market clearance or approval will be approved or cleared by FDA or a comparable foreign regulatory authority on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our anticipated claims or adequate to support continued adoption of such products. Compliance with FDA or comparable foreign regulatory authority regulations will require substantial costs, and subject us to heightened scrutiny by regulators and substantial penalties for failure to comply with such requirements or the inability to market our products. The lengthy and unpredictable pre-market clearance or approval process, as well as the unpredictability of the results of any required clinical studies, may result in our failing to obtain regulatory clearance or approval to market such products, which would significantly harm our business, results of operations, reputation, and prospects.

If we sought and received regulatory clearance or approval for certain of our products, we would be subject to ongoing FDA obligations and continued regulatory oversight and review, including the general controls listed above and the FDA's QSRs for our development and manufacturing operations. In addition, we would be required to obtain a new 510(k) clearance before we could introduce subsequent material modifications or improvements to such products. We could also be subject to additional FDA post-marketing obligations for such products, any or all of which would increase our costs and divert resources away from other projects. If we sought and received regulatory clearance or approval and are not able to maintain regulatory compliance with applicable laws, we could be prohibited from marketing our products for use as, or in the performance of, clinical diagnostics and/or could be subject to enforcement actions, including warning letters and adverse publicity, fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions; and criminal prosecution.

Further, if we decide to seek regulatory clearance or approval for certain of our products in countries outside of the United States or if a foreign regulatory authority determines that our products are regulated as medical devices, we would be subject to extensive medical device laws and regulations outside of the United States. Sales of such products outside the United States will likely be subject to foreign regulatory requirements, which can vary greatly from country to country. As a result, the time required to obtain clearances or approvals outside the United States may differ from that required to obtain FDA clearance or approval and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. In Europe, we would need to comply with the Medical Device Regulation 2017/745 and In Vitro Diagnostic Regulation 2017/746, which became effective May 26, 2017, with application dates of May 26, 2021 (postponed from 2020) and May 26, 2022, respectively. This will increase the difficulty of regulatory approvals in Europe in the future. In addition, the FDA regulates exports of medical devices. The number and scope of these requirements are increasing. Unlike many of the other companies offering nucleic acid sequencing equipment or consumables, this is an area where we do not have expertise. We, or our other third-party sales and distribution partners, may not be able to obtain regulatory approvals in such countries or may incur significant costs in obtaining or maintaining our foreign regulatory approvals. In addition, the export by us of certain of our products, which have not yet been cleared for domestic commercial distribution, may be subject to FDA or other export restrictions. Failure to comply with these regulatory requirements or obtain and maintain required approvals, clearances and certifications could impair our ability to commercialize our products for diagnostic use outside of the United States. Any action brought against us for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations, or other trade barriers may materially harm our business.

We are continuing to expand our international operations as part of our growth strategy and have experienced an increasing concentration of sales in certain regions outside the United States, especially the Asia-Pacific region, as discussed above. There is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, government regulations and tariffs. Starting in September 2018, the U.S. Trade Representative (the "USTR") enacted various tariffs of 7.5%, 10%, 15%, and 25% on the import of Chinese products, including non-U.S. components and materials that may be used in our products. Additionally, China also has imposed tariffs on imports into China from the United States. These tariffs have and could continue to raise our costs. Furthermore, tariffs, trade restrictions, or trade barriers that have been, and may in the future be, placed on products such as ours by foreign governments, especially China, have raised, and could further raise, amounts paid for some or all of our products, which may result in the loss of customers and our business, and our financial condition and results of operations may be harmed. Further tariffs may be imposed that could cover imports of additional components and materials used in our products, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to components or materials used in our products or increased amounts that must be paid for our products, which could materially harm our business, financial condition, and results of operations.

Additionally, the U.S. government imposed controls restricting the ability to send certain products and technology related to semiconductors, semiconductor manufacturing, and supercomputing to China without an export license. These controls also apply to certain hardware containing these specified integrated circuits. In many cases, these licenses are subject to a policy of denial and will not be issued. It is possible that additional restrictions will be put in place. These existing and future controls may impact our ability to export certain products to customers or distributors in China or other locations and restrict our ability to use certain integrated circuits in our products. The U.S. government also continues to add additional entities in China to restricted party lists impacting the ability of U.S. companies to provide items to these entities. Moreover, in November 2018, the U.S. Commerce Department's Bureau of Industry and Security ("BIS") released an advance notice of proposed rulemaking to control the export of emerging technologies. This notice included "[b]iotechnology, including nanobiology; synthetic biology; genomic and genetic engineering; or neurotech" as possible areas of increased export controls. The Biden Administration has continued to provide updated lists of emerging technologies subject to national security consents. These lists continue to include biotechnologies including "[g]enome and protein engineering including design tools" and "[b]iomanufacturing and bioprocessing technologies." Therefore, it is possible that our ability to export our products to customers or distributors may be further restricted in the future.

It is possible that the Chinese government will retaliate in response to existing or future U.S. export controls or trade restrictions in ways that could impact our business. It also is possible that additional restrictions will be put in place that could impact our ability to provide our products to customers or distributors in China or source components from China. The continued threats of tariffs, trade restrictions and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our sales. Given the relatively fluid regulatory environment in China and the United States and uncertainty how the U.S. or foreign governments will act with respect to export controls, tariffs, international trade agreements and policies, there could be additional tax or other regulatory changes in the future. Any such changes could directly and adversely impact our financial results and results of operations.

Our international business could expose us to business, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.

Engaging in international business inherently involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws that are or may be applicable to our business in the future, such as the European Union's General Data Protection Regulation ("GDPR") and other data privacy requirements, labor and employment regulations, anti-competition regulations, the U.K. Bribery Act of 2010 and other anti-corruption laws, regulations relating to the use of certain hazardous substances or chemicals in commercial products, and require the collection, reuse, and recycling of waste from products we manufacture;
- required compliance with U.S. laws such as the Foreign Corrupt Practices Act, and other U.S. federal laws and trade and economic sanctions and other regulations established by the Office of Foreign Asset Control;
- export requirements and import or trade restrictions;

- laws and business practices favoring local companies;
- restrictions on both inbound and outbound cross-border investment;
- foreign currency exchange, longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- changes in social, economic, and political conditions or in laws, regulations and policies governing foreign trade, manufacturing, research and development, and investment both domestically as well as in the other countries and jurisdictions in which we operate and into which we may sell our products including as a result of the separation of the United Kingdom from the European Union ("Brexit") and ongoing geopolitical tensions related to the political uncertainty and military actions associated with the Israel and Hamas conflict, the war in Ukraine, resulting sanctions imposed by the U.S. and other countries, and retaliatory actions taken by Russia in response to such sanctions;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements, and other trade barriers;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting, maintaining, enforcing, or procuring intellectual property rights and defending against intellectual property claims under the law and judicial systems of other countries.

If one or more of these risks occurs, it could require us to dedicate significant resources to remedy such occurrence, and if we are unsuccessful in finding a solution, our financial results will suffer.

Our operations involve the use of hazardous materials, and we must comply with environmental, health and safety laws, which can be expensive and may adversely affect our business, operating results and financial condition.

Our research and development and manufacturing activities involve the use of hazardous materials, including chemicals and biological materials, and some of our products include hazardous materials. Accordingly, we are subject to federal, state, local and foreign laws, regulations, and permits relating to environmental, health and safety matters, including, among others, those governing the use, storage, handling, exposure to and disposal of hazardous materials and wastes, the health and safety of our employees, and the shipment, labeling, collection, recycling, treatment, and disposal of products containing hazardous materials. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. For example, under certain circumstances and under certain environmental laws, we could be held liable for costs relating to contamination at our or our predecessors' past or present facilities and at third-party waste disposal sites. We could also be held liable for damages arising out of human exposure to hazardous materials. There can be no assurance that violations of environmental, health and safety laws will not occur as a result of human error, accident, equipment failure or other causes. The failure to comply with past, present or future laws could result in the imposition of substantial fines and penalties, remediation costs, property damage and personal injury claims, investigations, the suspension of production or product sales, loss of permits or a cessation of operations. Any of these events could harm our business, operating results, and financial condition. We also expect that our operations will be affected by new environmental, health and safety laws and regulations on an ongoing basis, or more stringent enforcement of existing laws and regulations. New laws or changes to existing laws may result in additional costs and may increase penalties associated with violations or require us to change the content of our products or how we manufacture them, which could have a material adverse effect on our business, operating results, and financial condition.

Ethical, legal, privacy, data protection and social concerns or governmental restrictions surrounding the use of genetic information could reduce demand for our technology.

Our products may be used to provide genetic information about humans, agricultural crops and other living organisms. The information obtained from our products could be used in a variety of applications which may have underlying ethical, legal, privacy, data protection and social concerns, including the genetic engineering or modification of agricultural products or testing for genetic predisposition for certain medical conditions. Governmental authorities could, for safety, social or other purposes, call for limits on or regulation of the use of genetic testing, and may consider or adopt such regulations or other restrictions. Such concerns or governmental restrictions could limit the use of our products or be costly and burdensome to comply with, and actual or perceived violations of any such restrictions may lead to the imposition of substantial fines and penalties, remediation costs, claims and litigation, regulatory investigations and proceedings, and other liability, any of which could have a material adverse effect on our business, financial condition, and results of operations.

Regulations related to conflict minerals has caused us to incur, and will continue to cause us to incur, additional expenses and could limit the supply and increase the costs of certain materials used in the manufacture of our products.

We are subject to requirements under the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 that require us to conduct diligence and report on whether or not our products contain conflict minerals. The implementation of these requirements could adversely affect the sourcing, availability and pricing of the materials used in the manufacture of components used in our products. Furthermore, the complex nature of our products requires components and materials that may be available only from a limited number of sources and, in some cases, from only a single source. We have incurred, and will continue to incur, additional costs to comply with the disclosure requirements, including costs related to conducting diligence procedures to determine the sources of conflict minerals that may be used or necessary to the production of our products and, if applicable, potential changes to components, processes, or sources of supply as a consequence of such verification activities. We may face reputational harm if we determine that certain of our products contain minerals that are not determined to be conflict free or if we are unable to alter our processes or sources of supply to avoid using such materials. In such circumstances, the reputational harm could materially and adversely affect our business, financial condition, or results of operations.

Risks Related to Owning Our Common Stock

The price of our common stock has been, is, and may continue to be, highly volatile, and you may be unable to sell your shares at or above the price you paid to acquire them.

The market price of our common stock is highly volatile, and we expect it to continue to be volatile for the foreseeable future in response to many risk factors listed in this section, and others beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- announcements of new products, technological innovations or strategic partnerships by us or our competitors;
- announcements by us, our customers, partners, or suppliers relating directly or indirectly to our products, services or technologies;
- overall conditions in our industry and market;
- addition or loss of significant customers;
- changes in laws or regulations applicable to our products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments or achievement of significant milestones;
- additions or departures of key personnel;
- competition from existing products or new products that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters or our ability to obtain intellectual property protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us or our stockholders;
- stock price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- reports, guidance and ratings issued by securities or industry analysts;

- operating results below the expectations of securities analysts or investors; and
- general economic and market conditions, which could be impacted by various events including COVID-19, other outbreaks or interest rate fluctuations, increases in fuel prices, foreign currency fluctuations, international tariffs, acts of terrorism, hostilities or the perception that hostilities may be imminent, military conflict and acts of war, including further political uncertainty and military actions associated with the Israel and Hamas conflict and, the war in Ukraine, as well as responses to such events including sanctions or other restrictive actions, by the United States and/or other countries.

If any of the forgoing occurs, it would cause our stock price or trading volume to decline. Stock markets in general and the market for companies in our industry in particular have experienced price and volume fluctuations, which have been exacerbated by the COVID-19 pandemic, and current macroeconomic trends and geopolitical events, and have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We have been a party to this type of litigation in the past and may be the target of this type of litigation again in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could reduce the market price that our common stock might otherwise attain and may dilute your voting power and your ownership interest in us.

Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our common stock and may make it more difficult for existing stockholders to sell their common stock at a time and price that they deem appropriate and may dilute their voting power and ownership interest in us.

In addition, if our stockholders sell, or indicate an intent to sell, a large number of shares of our common stock in the public market, it could cause our stock price to fall, particularly if such sales occur over a short period time (for example, following delivery of shares upon achievement of milestones in our acquisition agreements). We may also issue shares of common stock or securities convertible into our common stock in connection with a financing, acquisition, our equity incentive plans, or otherwise. Any such issuances would result in dilution to our existing stockholders and the market price of our common stock may be adversely affected.

Concentration of ownership by our principal stockholders may result in control by such stockholders of the composition of our board of directors.

Our existing principal stockholders, executive officers, directors, and their affiliates beneficially own a significant number of our outstanding shares of common stock. In addition, such parties may acquire additional control by purchasing stock that we issue in connection with our future fundraising efforts. These parties may now and in the future be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors. This control could have the effect of delaying or preventing a change of control of our company or changes in management and will make the approval of certain transactions difficult or impossible without the support of these stockholders.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 50,000,000 shares of undesignated preferred stock and up to approximately 1,000,000,000 shares of authorized but unissued shares of common stock;

- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the Chair of the Board, the Chief Executive Officer or the President;
- establish advance notice procedures for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause; and
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Our amended and restated bylaws designate a state or federal court located within the State of Delaware as the exclusive forum for certain stockholder litigation matters, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders, or employees.

Our amended and restated bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) will, to the fullest extent permitted by law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, stockholders, officers, or other employees to us or our stockholders; (iii) any action arising pursuant to any provision of the Delaware General Corporation Law; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine, except as to each of (i) through (v) above, for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court.

Section 22 of 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 bylaws also provide that, unless we consent in writing to the selection of an alternative forum, 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 including, without limitation and for the avoidance of doubt, any auditor, underwriter, expert, control person or other defendant.

Any person or entity purchasing, holding or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or any of our directors, stockholders, officers or other employees, which may discourage lawsuits with respect to such claims against us and our current and former directors, stockholders, officers or other employees. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions which are subject to the exclusive forum provisions described above. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions. Further, in the event a court finds either exclusive forum provision contained in our bylaws to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our results of operations.

Our large number of authorized but unissued shares of common stock may potentially dilute existing stockholders' stockholdings.

We have a significant number of authorized but unissued shares of common stock. Our board of directors may issue shares of common stock from this authorized but unissued pool from time to time without stockholder approval, resulting in the dilution of our existing stockholders.

We do not intend to pay dividends for the foreseeable future.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. 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.

Risks Related to Our Notes

We may not have the ability to raise the funds necessary to settle conversions of the Notes in cash or to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Notes.

As of September 30, 2023, we had outstanding approximately $459.0 million aggregate principal amount of our 2028 Notes and $441.0 million aggregate principal amount of our 2030 Notes. The 2028 Notes will mature on February 15, 2028, subject to earlier conversion, redemption or repurchase, including upon a fundamental change.

The 2030 Notes will mature on December 15, 2030, subject to earlier conversion, redemption or repurchase, including upon a fundamental change. The 2030 Notes and 2028 Notes are collectively referred to as the Notes.

Holders of the Notes will have the right to require us to repurchase all or a portion of their Notes upon the occurrence of a fundamental change before the maturity date at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus unpaid interest to, but excluding, the maturity date. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to settle a portion or all of our conversion obligation in cash in respect of the Notes being converted. Moreover, we will be required to repay the Notes in cash at their maturity unless earlier converted, redeemed, or repurchased. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor or pay cash with respect to Notes being converted or at their maturity.

In addition, our ability to repurchase Notes or to pay cash upon conversions of Notes or at their maturity may be limited by law, regulatory authority or agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture or to pay cash upon conversions of Notes or at their maturity as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. Moreover, the occurrence of a fundamental change under the indenture could constitute an event of default under any such agreement. If the payment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness or to pay cash amounts due upon conversion, upon required repurchase or at maturity of the Notes.

If the Notes are converted, it may adversely affect our financial condition and operating results.

Holders of the Notes are entitled to convert their Notes at any time at their option. If one or more holders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation in cash, which could adversely affect our liquidity. In addition, issuances of shares of common stock upon conversion of our Notes could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. The existence of the Notes may encourage short selling by market participants because the conversion of the Notes could depress the price of our common stock.

General Risk Factors

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

General conditions in the global economy and in the global financial markets could adversely affect our results of operations, including the potential effects from the COVID-19 pandemic or other outbreaks as discussed above, and the overall demand for nucleic acid sequencing products may be particularly vulnerable to unfavorable economic conditions. A global financial crisis, inflation or a global or regional political disruption, as well as acts of terrorism, hostilities, military conflict and acts of war, including any further political uncertainty and military actions associated with the Israel and Hamas conflict and the war in Ukraine, as well as the related responses, could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our products and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our product and services. An impairment in value of our tangible or intangible assets could also be recorded as a result of weaker economic conditions. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

Delivery of our products could be delayed or disrupted by factors beyond our control, and we could lose customers as a result.

We rely on third-party carriers for the timely delivery of our products. As a result, we are subject to carrier disruptions and increased costs that are beyond our control. Any failure to deliver products to our customers in a safe and timely manner may damage our reputation and brand and could cause us to lose customers. If our relationship with any of these third-party carriers is terminated or impaired or if any of these carriers are unable to deliver our products, the delivery of our products by our customers may be delayed, which could harm our business and financial results. The failure to deliver our products in a safe and timely manner may harm our relationship with our customers, increase our costs and otherwise disrupt our operations.

Doing business internationally creates operational and financial risks for our business.

We currently conduct operations in various countries and jurisdictions, and continue to expand to new international jurisdictions as part of our growth strategy and have experienced an increasing concentration of sales in certain regions outside the U.S. We sell directly and through distribution partners throughout Europe, the Asia-Pacific region, Mexico, Brazil, and South Africa and have a significant portion of our sales and customer support personnel in Europe and the Asia-Pacific region. As a result, we or our distribution partners may be subject to additional regulations and increased diversion of management time and efforts. Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and time zones and consumes significant management resources. If we fail to coordinate and manage these activities effectively, our business, financial condition or results of operations could be materially and adversely affected and failure to comply with laws and regulations applicable to business operations in foreign jurisdictions may also subject us to significant liabilities and other penalties. International operations entail a variety of other risks, including, without limitation:

- limits to travel, which could result from further outbreaks of COVID-19 or other pandemics or epidemics;
- challenges in staffing and managing foreign operations;
- potentially longer sales cycles and more time required to engage and educate customers on the benefits of our platform outside of the United States;
- the potential need for localized software and documentation;
- reduced protection for intellectual property rights in some countries and practical difficulties of enforcing intellectual property and contract rights abroad;
- defending against intellectual property claims in other countries;
- restrictions on both inbound and outbound cross-border investment, including enhanced oversight by the Committee on Foreign Investment in the United States (“CFIUS”) and substantial restrictions on investment from China;
- U.S. and foreign government trade restrictions, including those which may impose restrictions on the importation, exportation, re-exportation, sale, shipment or other transfer of programming, technology, components, including semiconductors, and/or services to foreign persons;
- changes in diplomatic and trade relationships, including new tariffs, trade protection measures, import or export licensing requirements, trade embargoes, sanctions, and other trade barriers;
- tariffs imposed by the U.S. on goods from other countries and tariffs imposed by other countries on U.S. goods, including the tariffs by the U.S. government on various imports from China, Canada, Mexico, and the European Union (“E.U.”) and by the governments of these jurisdictions on certain U.S. goods, and any other possible tariffs that may be imposed on products such as ours, the scope and duration of which, if implemented, remains uncertain;
- deterioration of political relations between the U.S. and Russia, China, Japan, Korea, Canada, the United Kingdom (“U.K.”), and the E.U., which could have a material adverse effect on our sales and operations in these countries;
- changes in social, political, and economic conditions or in laws, regulations and policies governing foreign trade, manufacturing, development, and investment both domestically as well as in the other countries and jurisdictions into which we sell our products, including as a result of the withdrawal of the U.K. from the E.U.;
- difficulties in obtaining export licenses or in overcoming other trade barriers and restrictions resulting in delivery delays;
- fluctuations in currency exchange rates and the related effect on our results of operations;
- increased financial accounting and reporting burdens and complexities;
- disruptions to global trade due to disease outbreaks or conflicts;
- potential increases on tariffs or restrictions on trade generally; and
- significant taxes or other burdens of complying with a variety of foreign laws and regulations, including laws and regulations relating to privacy and data protection such as the E.U. General Data Protection Regulation which took effect in the E.U. in 2018.

In conducting our international operations, we are subject to U.S. laws relating to our international activities, such as the Foreign Corrupt Practices Act of 1977, as well as foreign laws relating to our activities in other countries, such as the United Kingdom Bribery Act of 2010. Additionally, the inclusion of one of our foreign customers on any U.S. Government sanctioned persons list, including but not limited to the U.S. Department of Commerce's List of Denied Persons and the U.S. Department of Treasury's List of Specially Designated Nationals and Blocked Persons List, could be material to our earnings. Failure to comply with these laws may subject us to claims or financial and/or other penalties in the United States and/or foreign countries that could materially and adversely impact our operations or financial condition. These risks have become increasingly prevalent as we have expanded our sales into countries that are generally recognized as having a higher risk of corruption.

We face risks related to the current global economic environment, which could delay or prevent our customers from purchasing our products, which could in turn harm our business, financial condition, and results of operations. The state of the global economy continues to be uncertain. The current global economic conditions and uncertain credit markets and concerns regarding the availability of credit pose a risk that could impact customer demand for our products, as well as our ability to manage normal commercial relationships with our customers, suppliers, and creditors, including financial institutions. If the current global economic environment deteriorates, our business could be negatively affected.

Moreover, changes in the value of the relevant currencies may affect the cost of certain items required in our operations. Changes in currency exchange rates may also affect the relative prices at which we are able to sell products in the same market. Our revenue from international customers may be negatively impacted as increases in the U.S. dollar relative to our international customers' local currencies could make our products more expensive, impacting our ability to compete or as a result of financial or other instability in such locations which could result in decreased sales of our products. Our costs of materials from international suppliers may also increase as the value of the U.S. dollar decreases relative to their local currency. Foreign policies and actions regarding currency valuation could result in actions by the United States and other countries to offset the effects of such fluctuations. Such actions may materially and adversely impact our financial condition and results of operations.

Violations of complex foreign and U.S. laws and regulations could result in fines and penalties, criminal sanctions against us, our officers, or our employees, prohibitions on the conduct of our business and on our ability to offer our products and services in one or more countries, and could also materially affect our brand, our international growth efforts, our ability to attract and retain employees, our business, and our operating results. Even if we implement policies or procedures designed to ensure compliance with these laws and regulations, there can be no assurance that our distribution partners, our employees, contractors, or agents will not violate our policies and subject us to potential claims or penalties.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our business and our stock price.

Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be evaluated frequently. We may in the future discover areas of our internal financial and accounting controls and procedures that need improvement. Operating as a public company requires sufficient resources within the accounting and finance functions in order to produce timely financial information, ensure the level of segregation of duties, and maintain adequate internal control over financial reporting customary for a U.S. public company.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our company will have been detected. Pursuant to Section 404 of the Sarbanes-Oxley Act, we perform periodic evaluations of our internal control over financial reporting. While we have in the past performed this evaluation and concluded that our internal control over financial reporting was operating effectively, there can be no assurance that in the future material weaknesses or significant deficiencies will not exist or otherwise be discovered. In addition, if we are unable to produce accurate financial statements on a timely basis, investors could lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

Our business could be negatively impacted by changes in the United States political environment.

There is significant ongoing uncertainty with respect to potential legislation, regulation and government policy at the federal level, as well as the state and local levels. Any such changes could significantly impact our business as well as the markets in which we compete. Specific legislative and regulatory proposals discussed during election campaigns and more recently that might materially impact us include, but are not limited to, changes to spending priorities and potential reductions in research funding. Uncertainty about U.S. government funding has posed, and may continue to pose, a risk as customers may choose to postpone or reduce spending in response to actual or anticipated restraints on funding. To the extent changes in the political environment have a negative impact on us or on our markets, our business, results of operation and financial condition could be materially and adversely impacted in the future.

Disruption of critical information technology systems or material breaches in the security of our systems could harm our business, customer relations and financial condition.

Information technology ("IT") helps us to operate efficiently, interface with customers, maintain financial accuracy and efficiently and accurately produce our financial statements. IT systems are used extensively in virtually all aspects of our business, including in our products, sales forecast, order fulfillment and billing, customer service, logistics, and management of data from running samples on our products. Our success depends, in part, on the continued and uninterrupted performance of our IT systems. Our IT systems, including those used in our products, may be vulnerable to damage from a variety of sources, including telecommunications or network failures, power loss, natural disasters, human acts, computer viruses, ransomware, computer denial-of-service attacks, unauthorized access to customer or employee data or company trade secrets, and other attempts to harm our systems. Furthermore, there may be a heightened risk of potential cybersecurity incidents and security breaches to which we could be vulnerable by state-sponsored or affiliated actors or others in connection with the political uncertainty and military actions associated with the Israel and Hamas conflict and the war in Ukraine. Certain of our systems are not redundant, and our disaster recovery planning is not sufficient for every eventuality. Despite any precautions we may take, such problems could result in, among other consequences, disruption of our operations, which could harm our reputation and financial results.

If we do not allocate and effectively manage the resources necessary to build and sustain the proper IT infrastructure, including those used in our products, we could be subject to transaction errors, processing inefficiencies, loss of customers, business disruptions or loss of or damage to intellectual property. If our data management systems do not effectively collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Any such impairment could materially and adversely affect our reputation, financial condition, results of operations, cash flows and the timeliness with which we report our internal and external operating results.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personal information of our customers and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our IT infrastructure may be vulnerable to attacks by hackers, computer viruses, malicious codes, ransomware, unauthorized access attempts, and cyber- or phishing-attacks, or breached or otherwise disrupted due to employee error, malfeasance, faulty password management or other disruptions. Third parties may attempt to fraudulently induce employees or other persons into disclosing usernames, passwords or other sensitive information, which may in turn be used to access our IT systems, commit identity theft or carry out other unauthorized or illegal activities. Any such breach or incident could compromise our systems and networks and the information stored or otherwise processed there could be accessed, publicly disclosed, lost, stolen or otherwise processed in an unauthorized manner. We engage third-party vendors and service providers to store and otherwise process some of our data, including sensitive and personal information. Our vendors and service providers may also be the targets of the risks described above, including cyberattacks, malicious software, ransomware, phishing schemes, and fraud. Our ability to monitor our vendors and service providers' data security is limited, and, in any event, third parties may be able to circumvent those security measures, resulting in the unauthorized access to, misuse, disclosure, loss or destruction of our data, including sensitive and personal information, and disruption of our or third-party service providers' systems. We and our third-party service providers may face difficulties in identifying, or promptly responding to, potential security breaches and other instances of unauthorized access to, or disclosure, other processing, or loss or unavailability of, information. Any hacking or other attack on our or our third-party service providers' or vendors' systems, and any unauthorized access to, or disclosure, other processing, or loss or unavailability of, information suffered by us or our third-party service providers or vendors, or the perception that any of these have occurred, could result in legal claims or proceedings, loss of intellectual property, liability under laws that protect the privacy of personal information, negative publicity, disruption of our operations and damage to our reputation, and data integrity issues, which could divert our management's attention from the operation of our business and materially and adversely affect our business, revenues and competitive position. Moreover, we may need to increase our efforts to train our personnel to detect and defend against cyber- or phishing-attacks, which are becoming more sophisticated and frequent, and we may need to implement additional protective measures to reduce the risk of potential security breaches and security incidents, which could cause us to incur significant additional expenses. Retaliatory acts by Russia in response to Western sanctions or otherwise in connection with the war in Ukraine could include cyber-attacks that could disrupt the economy generally or that may either directly or indirectly impact our operations specifically.

In addition, our insurance may be insufficient to cover our losses resulting from cyber-attacks, breaches, or other interruptions, and any incidents may result in loss of, or increased costs of, such insurance. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation.

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

In the ordinary course of our business, we currently, and in the future will, collect, store, transfer, use or process sensitive data, including personal information of employees, and intellectual property and proprietary business information owned or controlled by ourselves and other parties. The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy. We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, various federal and state regulators, including governmental agencies like the Consumer Financial Protection Bureau and the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act ("CCPA"), which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. In November 2020, California also passed the California Privacy Rights Act, or ("CPRA"), which significantly expanded the CCPA as of January 1, 2023, including by introducing additional obligations such as data minimization and storage limitations and granting additional rights to consumers, among others. The enactment of the CCPA has prompted similar legislative developments in other states, and numerous other states have proposed, and in certain cases enacted, legislation relating to privacy and data security, many of which are similar to the CCPA and CPRA. Similar laws are being considered by other state legislatures. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law. These and future laws and regulations may increase our compliance costs and potential liability.

Furthermore, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as "protected health information") and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or disrupted, breached or otherwise compromised due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or disruption could compromise our networks and the information stored there could be accessed, manipulated, publicly disclosed, lost, stolen, made unavailable, or otherwise processed without authorization. Any such disruption, access, breach, unavailability, theft, loss or other unauthorized processing of information, or the perception that any of these has occurred could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or state attorneys general. Such a notice could harm our reputation and our ability to compete.

While we have in place formal policies and procedures related to the storage, collection, and processing of information, and have conducted data privacy audits, we continue to evaluate our compliance needs, including the need to conduct additional internal and external data privacy audits or adopt additional policies and procedures, to ensure our compliance with all applicable data protection laws and regulations. Additionally, we do not currently have policies and procedures in place for assessing our third-party vendors' compliance with applicable data protection laws and regulations. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure or perceived failure by us or our third-party vendors, collaborators, contractors and consultants to comply with any applicable federal, state or similar foreign laws and regulations relating to data privacy and security, could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, penalties or judgments, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Increased scrutiny of our environmental, social or governance responsibilities may result in additional costs and risks, and may adversely impact our reputation, employee retention, and willingness of customers and suppliers to do business with us.

Investor advocacy groups, institutional investors, investment funds, proxy advisory services, stockholders, and customers are increasingly focused on environmental, social, and governance ("ESG") practices of companies. Additionally, public interest and legislative pressure related to public companies' ESG practices continues to grow. If our ESG practices fail to meet regulatory requirements or investor or other industry stakeholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, board and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, and employing ESG strategies in our operations, our brand, reputation and employee retention may be negatively impacted and customers and suppliers may be unwilling to do business with us. In addition, as we work to align our ESG practices with industry standards, we will likely continue to expand our disclosures in these areas and doing so may result in additional costs and require additional resources to monitor, report, and comply with our various ESG practices. If we fail to adopt ESG standards or practices as quickly as stakeholders desire, report on our ESG efforts or practices accurately, or satisfy the expectations of stakeholders, our reputation, business, financial performance, and growth may be adversely impacted.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

Other than as previously reported on our Current Reports on Form 8-K filed with the SEC on August 2, 2023 and September 22, 2023, there have been no unregistered sales of our equity securities during the three months ended September 30, 2023.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Securities Trading Plans of Directors and Executive Officers

During our last fiscal quarter, none of our directors or officers, as defined in Rule 16a-1(f), adopted and/or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408.

Item 6. Exhibits

Exhibit No.	Description	Incorporated by reference herein		
		Form	Exhibit No.	Filing Date
3.1	Amended and Restated Certificate of Incorporation of Pacific Biosciences of California, Inc.	10-K	3.1	March 23, 2011
3.2	Third Amended and Restated Bylaws of Pacific Biosciences of California, Inc.	8-K	3.2	November 7, 2022
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			Filed herewith
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			Furnished herewith
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			Furnished herewith
101.INS	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)			Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document			Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document			Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document			Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document			Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document			Filed herewith
104	Cover Page Interactive File (formatted as inline XBRL and contained in Exhibit 101)			Filed herewith

* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Pacific Biosciences of California, 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 of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

Signatures

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

Pacific Biosciences of California, Inc.

Date: November 3, 2023 By: /s/ Christian O. Henry

Christian O. Henry
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 3, 2023 By: /s/ Susan G. Kim

Susan G. Kim
Chief Financial Officer
(Principal Financial Officer)

Date: November 3, 2023 By: /s/ Michele Farmer

Michele Farmer
Vice President and Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 31.1

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

I, Christian Henry, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pacific Biosciences of California, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 3, 2023

By: /s/ Christian O. Henry

Christian O. Henry
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Susan Kim, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Pacific Biosciences of California, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 3, 2023

By: /s/ Susan G. Kim

Susan G. Kim
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification of CEO Furnished Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 of The Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Pacific Biosciences of California, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof, I, Christian Henry, Chief Executive Officer of the Company, certify for the purposes of section 1350 of chapter 63 of title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

(i) the Quarterly Report of the Company on Form 10-Q for the period ended September 30, 2023 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2023

By: /s/ Christian O. Henry

Christian O. Henry
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification of CFO Furnished Pursuant to 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 of The Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Pacific Biosciences of California, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof, I, Susan Kim, Chief Financial Officer of the Company, certify for the purposes of section 1350 of chapter 63 of title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

(i) the Quarterly Report of the Company on Form 10-Q for the period ended September 30, 2023 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2023

By: /s/ Susan G. Kim
Susan G. Kim
Chief Financial Officer
(Principal Financial Officer)