

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.
Form 10-Q
November 05, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

Or

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

For the transition period from _____ to _____

Commission File Number 001-34899

Pacific Biosciences of California, Inc.

(Exact name of registrant as specified in its charter)

Edgar Filing: PACIFIC BIOSCIENCES OF CALIFORNIA, INC. - Form 10-Q

(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)

1380 Willow Road

Menlo Park, CA 94025 94025
(Address of principal executive offices) (Zip Code)

(650) 521-8000

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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

Number of shares outstanding of the issuer's common stock as of October 31, 2014: 71,356,003

TABLE OF CONTENTS

	PAGE NO.
<u>PART I. FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements (unaudited):</u>	
<u>Condensed Consolidated Balance Sheets as of September 30, 2014 and December 31, 2013</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three- and Nine-Month Periods Ended September 30, 2014 and 2013</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Nine-Month Periods Ended September 30, 2014 and 2013</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	18
<u>Item 4. Controls and Procedures</u>	18
<u>PART II. OTHER INFORMATION</u>	19
<u>Item 1. Legal Proceedings</u>	19
<u>Item 1A. Risk Factors</u>	19
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
<u>Item 3. Default Upon Senior Securities</u>	31
<u>Item 4. Mine Safety Disclosures</u>	31
<u>Item 5. Other Information</u>	31
<u>Item 6. Exhibits</u>	31
<u>EXHIBIT INDEX</u>	33

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands except par value amounts)	September 30, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	\$ 35,411	\$ 26,362
Investments	63,901	86,166
Accounts receivable	2,370	2,746
Inventory, net	11,398	10,050
Prepaid expenses and other current assets	1,057	1,135
Total current assets	114,137	126,459
Property and equipment, net	7,034	9,236
Other long-term assets	471	490
Total assets	\$ 121,642	\$ 136,185
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 5,845	\$ 1,717
Accrued expenses	8,726	7,905
Deferred service revenue, current	5,307	4,046
Deferred contractual revenue, current	6,785	6,785
Other liabilities, current	2,477	2,102
Total current liabilities	29,140	22,555
Deferred service revenue, non-current	918	518
Deferred contractual revenue, non-current	21,431	26,519
Other liabilities, non-current	2,505	3,517
Notes payable	13,914	13,347
Financing derivative	699	549
Total liabilities	68,607	67,005
Commitments and contingencies		
Stockholders' equity		

Edgar Filing: PACIFIC BIOSCIENCES OF CALIFORNIA, INC. - Form 10-Q

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 70,976 shares at September 30, 2014 and 66,275 shares at December 31, 2013, respectively	71	66
Additional paid-in capital	715,439	684,413
Accumulated other comprehensive income	23	14
Accumulated deficit	(662,498)	(615,313)
Total stockholders' equity	53,035	69,180
Total liabilities and stockholders' equity	\$ 121,642	\$ 136,185
See accompanying notes to the condensed consolidated financial statements.		

3

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except per share amounts)	Three-Month Periods Ended		Nine-Month Periods Ended	
	September 30, 2014	2013	September 30, 2014	2013
Revenue:				
Product revenue	\$ 6,762	\$ 5,814	\$ 22,376	\$ 14,248
Service and other revenue	2,165	1,607	6,226	4,800
Contractual revenue	11,696	—	15,088	—
Total revenue	20,623	7,421	43,690	19,048
Cost of Revenue:				
Cost of product revenue	5,608	4,616	19,048	11,138
Cost of service and other revenue	1,853	1,564	5,678	4,680
Total cost of revenue	7,461	6,180	24,726	15,818
Gross profit	13,162	1,241	18,964	3,230
Operating Expense:				
Research and development	11,693	10,419	35,899	34,084
Sales, general and administrative	9,882	10,757	28,025	29,685
Total operating expense	21,575	21,176	63,924	63,769
Operating loss	(8,413)	(19,935)	(44,960)	(60,539)
Interest expense	(716)	(686)	(2,103)	(1,785)
Other income (expense), net	(34)	134	(122)	262
Net loss	(9,163)	(20,487)	(47,185)	(62,062)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	(19)	13	9	(19)
Comprehensive loss	\$ (9,182)	\$ (20,474)	\$ (47,176)	\$ (62,081)
Net loss per share:				
Basic and diluted net loss per share	\$ (0.13)	\$ (0.31)	\$ (0.68)	\$ (1.01)
Shares used in computing basic and diluted net loss per share	70,740	65,523	69,716	61,636

See accompanying notes to the condensed consolidated financial statements.

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)	Nine-Month Periods Ended September 30,	
	2014	2013
Cash flows from operating activities		
Net loss	\$ (47,185)	\$ (62,062)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	3,311	4,238
Amortization of debt discount and financing costs	579	418
Stock-based compensation	6,944	7,361
Other	242	(73)
Changes in assets and liabilities		
Accounts receivable	376	(992)
Inventory	(1,348)	171
Prepaid expenses and other assets	85	791
Accounts payable	4,128	425
Accrued expenses	821	544
Deferred service revenue	1,661	56
Deferred contractual revenue	(5,088)	35,000
Other liabilities	(637)	(1,136)
Net cash used in operating activities	(36,111)	(15,259)
Cash flows from investing activities		
Purchase of property and equipment	(1,132)	(807)
Purchase of investments	(97,468)	(141,549)
Maturities of investments	119,673	133,391
Net cash provided by (used in) investing activities	21,073	(8,965)
Cash flows from financing activities		
Proceeds from issuance of common stock from equity plans	3,319	2,731
Proceeds from issuance of common stock from at-the-market equity offering, net of issuance costs	20,768	19,954
Proceeds from issuance of Facility Agreement, net of issuance costs	—	19,766
Net cash provided by financing activities	24,087	42,451
Net increase in cash and cash equivalents	9,049	18,227
Cash and cash equivalents at beginning of period	26,362	46,540
Cash and cash equivalents at end of period	\$ 35,411	\$ 64,767

See accompanying notes to the condensed consolidated financial statements.

5

PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

NOTE 1. OVERVIEW

Pacific Biosciences of California, Inc. (referred to in this report as “Pacific Biosciences”, the “Company”, “we”, “us” or “our”) has commercialized high resolution genetic sequencing products that provide access to genetic information that was previously inaccessible. The PacBio RS II DNA Sequencing System helps scientists solve genetically complex problems. Based on our novel Single Molecule, Real-Time (SMRT) technology, our products enable: targeted sequencing to more comprehensively characterize genetic variations; de novo genome assembly to more fully identify, annotate, and decipher genomic structures; and DNA base modification identification to help characterize epigenetic regulation and DNA damage. By providing access to information that was previously inaccessible, we allow scientists to increase their understanding of biological systems.

The names “Pacific Biosciences,” “PacBio,” “SMRT,” “SMRTbell” and our logo are our trademarks.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

In the opinion of management, the accompanying unaudited Condensed Consolidated Financial Statements (“Financial Statements”) of Pacific Biosciences of California, Inc. have been prepared on a consistent basis with the December 31, 2013 audited Consolidated Financial Statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth herein. Certain prior year amounts in the Financial Statements and notes thereto have been reclassified to conform to the current year presentation. The Financial Statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and, as permitted by such rules and regulations, omit certain information and footnote disclosures necessary to present the statements in accordance with U.S. generally accepted accounting principles (“GAAP”). These Financial Statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2013. The results of operations for the nine-month period ended September 30, 2014 are not necessarily indicative of the results to be expected for the entire 2014 fiscal year or any future periods.

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. Our estimates include, but are not limited to, the valuation of inventory, the valuation of our financing derivative and the valuation of our long-term notes, the assumptions used to determine stock-based compensation, and estimates used to allocate proceeds received in revenue. We base our estimates on historical experience and various other assumptions that we believe are reasonable. Actual results could differ materially from these estimates.

Fair Value of Financial Instruments

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 measured on a recurring basis as of September 30, 2014 and December 31, 2013:

(in thousands)	September 30, 2014				December 31, 2013			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets								
Cash and cash equivalents:								
Cash and money market funds	\$ 16,513	\$ —	\$ —	\$ 16,513	\$ 12,963	\$ —	\$ —	\$ 12,963
Commercial paper	—	18,898	—	18,898	—	13,399	—	13,399
Total cash and cash equivalents	16,513	18,898	—	35,411	12,963	13,399	—	26,362
Investments:								
Commercial paper	—	37,812	—	37,812	—	61,264	—	61,264
Corporate debt securities	—	8,215	—	8,215	—	8,629	—	8,629
Asset backed securities	—	17,874	—	17,874	—	16,273	—	16,273
Total investments	—	63,901	—	63,901	—	86,166	—	86,166
Total assets measured at fair value	\$ 16,513	\$ 82,799	\$ —	\$ 99,312	\$ 12,963	\$ 99,565	\$ —	\$ 112,528
Liabilities								
Financing derivative	\$ —	\$ —	\$ 699	\$ 699	\$ —	\$ —	\$ 549	\$ 549
Total liabilities measured at fair value	\$ —	\$ —	\$ 699	\$ 699	\$ —	\$ —	\$ 549	\$ 549

Our cash deposits and money market funds are classified within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted market prices. Our investments are classified as Level 2 instruments based on market pricing and other observable inputs. None of our investments are classified within Level 3 of the fair value hierarchy.

During the nine-month periods ended September 30, 2014 and 2013, there were no impairments of our investments.

The estimated fair value of the Financing Derivative liability (as defined in Note 6. Debt) was determined using Level 3 inputs, or significant unobservable inputs. Changes to the estimated fair value of the Financing Derivative are recorded in "Other income (expense), net" in the condensed consolidated statements of operations and comprehensive loss. The following table provides the changes in the estimated fair value of the Financial Derivative during the nine-month period ended September 30, 2014 (in thousands):

Financial Derivative	Amount
Balance as of December 31, 2013	\$ 549
Loss on change in estimated fair value	150
Balance as of September 30, 2014	\$ 699

During the nine-month period ended September 30, 2014 there were no transfers between Level 1, Level 2, or Level 3 assets or liabilities reported at fair value on a recurring basis and valuation techniques did not change compared to established practice.

Financial assets and liabilities not measured at fair value on a recurring basis

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. The carrying value of our other liabilities, non-current approximates fair value due to the time to maturity and prevailing market rates.

We determined the estimated fair value of the Notes (as defined in Note 6. Debt) from the debt facility using Level 3 inputs, or significant unobservable inputs. The estimated fair value of the Notes was determined by comparing the difference between the estimated fair value of the Notes with and without the Financing Derivative by calculating the respective present values from future cash flows using an 18.8% and 20.4% weighted average market yield at September 30, 2014 and December 31, 2013, respectively. The estimated fair value and carrying value of the Notes are as follows (in thousands):

	September 30, 2014		December 31, 2013	
	Fair Value	Carrying Value	Fair Value	Carrying Value
Long-term notes payable	\$ 15,129	\$ 13,914	\$ 14,551	\$ 13,347

Net Loss per Share

The following table presents the computation of our basic and diluted net loss per share (in thousands, except per share amounts):

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2014	2013	2014	2013
Net loss per share				
Numerator:				
Net loss	\$ (9,163)	\$ (20,487)	\$ (47,185)	\$ (62,062)
Denominator:				
Weighted average shares used in computation of basic and diluted net loss per share	70,740	65,523	69,716	61,636
Basic and diluted net loss per share	\$ (0.13)	\$ (0.31)	\$ (0.68)	\$ (1.01)

The following were excluded from the computation of our diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	As of September 30,	
(in thousands)	2014	2013
Options outstanding	16,651	13,351
Warrants to purchase common stock	5,500	5,504

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, requiring entities to recognize revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either a retrospective or cumulative effect transition method. The updated standard is effective for the Company in the first quarter of fiscal year 2017 and early adoption is not permitted. We are evaluating the impact of adopting this ASU on our financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This ASU introduces an explicit requirement for management to assess if there is substantial doubt about an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. Disclosures are required if conditions give rise to substantial doubt. This ASU is effective for the Company in the first quarter of fiscal 2017. We are currently assessing the potential effects of this ASU on our consolidated financial statements.

NOTE 3. CONTRACTUAL REVENUE

During September 2013 we entered into a Development, Commercialization and License Agreement (the "Roche Agreement") with F. Hoffman-La Roche Ltd ("Roche"), pursuant to which we account for, and recognize as revenue, the up-front payment using the proportional performance method over the periods in which the delivery of elements of the agreement occurs. We recognize revenue using a straight line convention over the service periods of the deliverables as this method approximates our performance of services pursuant to the contract. Out of the \$35.0 million upfront cash payment received, \$1.7 million and \$5.1 million have been recognized as contractual revenue for the three- and nine-month periods ended September 30, 2014, respectively, and \$28.2 million remain deferred as of September 30, 2014 and will be recognized as contractual revenue over the estimated obligation periods.

In addition to the deliverables above, the Roche Agreement provides for additional payments totaling up to \$40.0 million upon the achievement of certain development milestones. During August 2014, we achieved the first development milestone and we recorded the related \$10.0 million as contractual revenue. Under the terms of the Roche Agreement, we may receive up to an additional \$30.0 million based on the achievement of additional development milestones in future periods.

NOTE 4. CASH, CASH EQUIVALENTS AND INVESTMENTS

The following table summarizes our investments as of September 30, 2014 and December 31, 2013 (in thousands):

	September 30, 2014			
	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Cash and cash equivalents:				
Cash and money market funds	\$ 16,513	\$ —	\$ —	\$ 16,513
Commercial paper	18,897	1	—	18,898
Total cash and cash equivalents	35,410	1	—	35,411
Investments:				
Commercial paper	37,806	6	—	37,812
Corporate debt securities	8,201	14	—	8,215
Asset backed securities	17,872	5	(3)	17,874
Total investments	63,879	25	(3)	63,901
Total cash, cash equivalents and investments	\$ 99,289	\$ 26	\$ (3)	\$ 99,312
	December 31, 2013			
	Amortized Cost	Gross unrealized gains	Gross unrealized losses	Fair Value
Cash and cash equivalents:				
Cash and money market funds	\$ 12,963	\$ —	\$ —	\$ 12,963
Commercial paper	13,398	1	—	13,399
Total cash and cash equivalents	26,361	1	—	26,362
Investments:				
Commercial paper	61,252	13	(1)	61,264
Corporate debt securities	8,620	12	(3)	8,629
Asset backed securities	16,281	2	(10)	16,273
Total investments	86,153	27	(14)	86,166
Total cash, cash equivalents and investments	\$ 112,514	\$ 28	\$ (14)	\$ 112,528

The following table summarizes the contractual maturities of our cash equivalents and available-for-sale investments, excluding money market funds, as of September 30, 2014:

(in thousands)

	Fair Value
Due in one year or less	\$ 69,387
Due after one year through five years	13,412
Total	\$ 82,799

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

NOTE 5. BALANCE SHEET COMPONENTS

Inventory, net

As of September 30, 2014 and December 31, 2013, our inventory, net, consisted of the following components:

(in thousands)	September 30, 2014	December 31, 2013
Purchased materials, net	\$ 2,553	\$ 3,019
Work in process, net	5,420	4,012
Finished goods, net	3,425	3,019
Inventory, net	\$ 11,398	\$ 10,050

NOTE 6. DEBT

Pursuant to a Facility Agreement (the “Facility Agreement”) we entered into with entities affiliated with Deerfield Management Company, L.P. (collectively, “Deerfield”) during February 2013, we issued promissory notes in the aggregate principal amount of \$20.5 million (the “Notes”). The Notes bear simple interest at a rate of 8.75% per annum, payable quarterly in arrears commencing on April 1, 2013. In connection with the execution of the Facility Agreement, we issued warrants to purchase an aggregate of 5,500,000 shares of common stock immediately exercisable at an exercise price per share initially equal to \$2.63 (the “Warrants”). In addition, we are required to maintain consolidated cash and cash equivalents on the last day of each calendar quarter of not less than \$2.0 million. As security for our repayment of our obligations under the Facility Agreement, we granted to Deerfield a security interest in substantially all of our property.

Notes

The Notes and Warrants were initially recorded at a value of \$14.1 million and \$6.4 million, respectively, based upon the relative fair value allocation of the \$20.5 million of proceeds. The carrying value of the Notes at the inception of the debt was \$12.8 million, resulting in an original issue discount of \$7.7 million. As of September 30, 2014, \$6.6 million remains to be amortized through February 2020, the maturity of the Notes.

Financing Derivative

A number of features embedded in the Notes issued pursuant to the Facility Agreement required accounting for as a derivative, including the indemnification of certain withholding taxes and the acceleration of debt upon (a) a qualified financing, (b) an Event of Default, (c) a Major Transaction, and (d) the exercise of the Warrant via offset to debt

principal. These features represent a single derivative (the “Financing Derivative”) that was bifurcated from the debt instrument and accounted for as a liability at fair value, with changes in fair value between reporting periods recorded in other income (expense), net. The estimated fair value of the Financing Derivative was determined by comparing the difference between the estimated fair value of the Notes with and without the Financing Derivative by calculating the respective present values from future cash flows using an 18.8% and 20.4% weighted average market yield at September 30, 2014 and December 31, 2013, respectively. The estimated fair value of the Financing Derivative as of September 30, 2014 and December 31, 2013 was \$0.7 million and \$0.5 million, respectively.

NOTE 7. STOCKHOLDERS’ EQUITY AND SHARE-BASED COMPENSATION

Equity Offering

During the nine-month period ended September 30, 2014, we issued 3.0 million shares of our common stock at an average price of \$7.11 per share through our “at-the-market” offering, resulting in net proceeds of \$20.8 million. As of September 30, 2014, under our “at-the-market” offering program, \$17.8 million of common stock remain available for future sales; however, we are not obligated to make sales under this program.

From October 1, 2014 through November 3, 2014, we issued 1.8 million shares of our common stock at an average price of \$6.41 per share through our “at-the-market” offering, resulting in net proceeds of \$11.1 million.

Warrants

As of September 30, 2014, we had outstanding warrants to purchase an aggregate of 5,500,000 shares of common stock.

Equity Plans

As of September 30, 2014, we had three active equity compensation plans, the 2010 Equity Incentive Plan, or 2010 Plan, the

2010 Outside Director Equity Incentive Plan, or 2010 Director Plan, and the 2010 Employee Stock Purchase Plan, or ESPP.

The following table summarizes stock option activity for all stock option plans for the nine-month period ended September 30, 2014 (in thousands, except per share amounts):

	Shares available for grant	Stock Options Outstanding Number of shares	Weighted average exercise price	
			Exercise price	
Balances, December 31, 2013	3,912	14,070	\$ 0.20 – 16.00	\$ 4.81
Additional shares reserved	3,977			
Options granted	(3,291)	3,291	4.21 – 7.05	5.96
Options exercised	—	(370)	0.20 – 6.96	2.65
Options canceled	340	(340)	1.16 – 15.98	5.22
Balances, September 30, 2014	4,938	16,651	\$ 0.70 – 16.00	\$ 5.08

As of September 30, 2014, no shares of our common stock remain available for issuance under our ESPP. The ESPP provides for an annual increase to the shares available for issuance at the beginning of each calendar year equal to two percent of the common shares then outstanding. Shares issued under the ESPP totaled 1,325,507 and 1,519,366 shares during the nine-month periods ended September 30, 2014 and 2013, respectively.

Stock-based Compensation

Total stock-based compensation expense consists of the following (in thousands):

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2014	2013	2014	2013
Cost of revenue	\$ 218	\$ 107	\$ 480	\$ 343
Research and development	893	835	2,601	3,077

Edgar Filing: PACIFIC BIOSCIENCES OF CALIFORNIA, INC. - Form 10-Q

Sales, general and administrative	1,341	1,229	3,863	3,941
Total stock-based compensation expense	\$ 2,452	\$ 2,171	\$ 6,944	\$ 7,361

We estimated the fair value of employee stock options on the grant date using the Black-Scholes option pricing model. The estimated fair value of employee stock options is amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the following weighted average assumptions:

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
Stock Option	2014	2013	2014	2013
Expected term in years	6.1	6.1	6.1	6.1
Expected volatility	70%	65%	70%	65%
Risk-free interest rate	1.9%	1.8%	1.9%	1.1%
Dividend yield	—	—	—	—

We estimate the value of the employee stock purchase rights on the grant date using the Black-Scholes option pricing model. The fair value of ESPP was estimated using the following assumptions:

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
ESPP	2014	2013	2014	2013
Expected term in years	0.5-2.0	0.5-2.0	0.5-2.0	0.5-2.0
Expected volatility	70%	70%	70%	70%
Risk-free interest rate	0.1%-0.5%	0.1%-0.4%	0.1%-0.5%	0.1%-0.4%
Dividend yield	—	—	—	—

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 our condensed consolidated financial statements and the related notes included in this report and those in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, including statements regarding our expected financial results in future periods. You should read the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We develop, manufacture and market an integrated platform for high resolution genetic analysis. Combining advances in nanofabrication, biochemistry, molecular biology, surface chemistry and optics, we created a technology platform called single molecule, real-time, or SMRT, technology. Our initial focus is to offer our SMRT technology to the DNA sequencing market where we have developed a third generation sequencing platform, the PacBio RS II sequencing system. The PacBio RS II is an instrument that uses our proprietary consumables, including our SMRT Cells and reagent kits that are used to prepare and sequence DNA samples.

Basis of Presentation

Revenue

During the three- and nine-month periods ended September 30, 2014 and 2013, product revenue was primarily derived from the sale of PacBio RS II instruments and associated consumables. Service and other revenue was primarily derived from product maintenance agreements sold on our installed instruments. Contractual revenue relates to the quarterly amortization of \$1.7 million from the non-refundable up-front payment of \$35.0 million we received during September 2013 pursuant to the Roche Agreement. In addition, for the three- and nine-month periods ended September 30, 2014, contractual revenue also included \$10.0 million relating to the achievement of a development milestone outlined in the Roche Agreement.

As of September 30, 2014, our backlog was comprised of 20 instruments. We define backlog as purchase orders or signed contracts for systems from customers which we believe are firm and for which we have not yet recognized revenue.

Cost of Revenue

Cost of revenue reflects the direct cost of product components, third-party manufacturing services and our internal manufacturing overhead and customer service infrastructure costs incurred to produce, deliver, maintain and support our instruments, consumables, and services. There are no incremental costs associated with our contractual revenue; all product development costs are reflected in research and development expense.

Manufacturing overhead is predominantly comprised of labor costs. We determine and capitalize manufacturing overhead into inventory based on a standard cost model that approximates actual costs. Prior to achieving manufacturing volumes that correlated with our estimated normal capacity (the production levels expected to be

achieved over a number of periods under normal circumstances with available resources), we based our capitalized overhead relative to our normal capacity. Prior to achieving normal capacity, excess manufacturing resources were engaged in research and development activities, including; next generation products, internal use research products, and general support activities. As such, manufacturing costs in excess of amounts reflected in inventory were expensed as a component of research and development expense. During 2014, manufacturing volumes trended towards and then approximated normal capacity, and excess manufacturing resources contributing to research and development activities declined significantly.

Service costs include the direct costs of components used in support, repair and maintenance of customer instruments as well as the cost of personnel, materials and support infrastructure necessary to support the installed customer base. Prior to the fourth quarter of 2013, the capacity of our existing service infrastructure exceeded the number of installed customer instruments. Therefore, management estimated the capacity of the existing service infrastructure and recognized the service-related cost of revenue based on the installed base. As a result, prior to the fourth quarter of 2013, total service infrastructure costs exceeded the costs associated with the support of customer instruments and such excess costs were included as a component of sales, general and administrative expense.

Research and Development Expense

Research and development expense consists primarily of expenses for personnel engaged in the development of our SMRT technology, the design and development of our future products and current product enhancements. These expenses also include prototype-related expenditures, development equipment and supplies, facilities costs and other related overhead.

Sales, General and Administrative Expense

Selling, general and administrative expenses include costs for sales, marketing and administrative personnel, sales and marketing activities, tradeshow expenses, legal expenses and general corporate expenses.

Interest Expense

Interest expense is primarily related to our debt facility and includes the amortization of debt discount and other related costs. To a lesser extent, amounts also include interest expense relating to our facility financing obligations resulting from a lease agreement entered into in 2010. We expect interest expense to increase during future periods as the recorded value accretes to the amount due at maturity.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash and investments, accretion of discounts and amortization of premiums related to investments, foreign currency translation, net gains or losses from disposal of fixed assets, net gains or losses resulting from changes in fair value of the Financing Derivative, and foreign income taxes.

Income Taxes

Since inception, we have incurred net losses and have not recorded any U.S. federal or state income tax benefits for such losses as they have been fully offset by valuation allowances.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our unaudited financial statements, which have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("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. On an ongoing basis, we evaluate our critical accounting policies and estimates. 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 material changes to our critical accounting policies and estimates discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013.

Results of Operations

Comparison of the Three-month Periods Ended September 30, 2014 and 2013

\$ Change % Change

(in thousands, except percentages)	Three-Month Periods			
	Ended September 30,			
	2014	2013		
	(unaudited)			
Revenue:				
Product revenue	\$ 6,762	\$ 5,814	\$ 948	16%
Service and other revenue	2,165	1,607	558	35%
Contractual revenue	11,696	—	11,696	—
Total revenue	20,623	7,421	13,202	178%
Cost of Revenue:				
Cost of product revenue	5,608	4,616	992	21%
Cost of service and other revenue	1,853	1,564	289	18%
Total cost of revenue	7,461	6,180	1,281	21%
Gross profit	13,162	1,241	11,921	961%
Operating Expense:				
Research and development	11,693	10,419	1,274	12%
Sales, general and administrative	9,882	10,757	(875)	(8%)
Total operating expense	21,575	21,176	399	2%
Operating loss	(8,413)	(19,935)	11,522	58%
Interest expense	(716)	(686)	(30)	(4%)
Other income (expense), net	(34)	134	(168)	(125%)
Net loss	\$ (9,163)	\$ (20,487)	\$ 11,324	55%

Revenue

Total revenue for the three-month period ended September 30, 2014 was \$20.6 million compared to \$7.4 million for the same period during 2013.

Product revenue during the three-month period ended September 30, 2014 consisted of \$3.5 million from sales of PacBio RS II instruments and \$3.3 million from sales of consumables compared to \$3.7 million from sales of instruments and \$2.1 million from sales of consumables for the same period during 2013. Instrument revenue during the three-month period ended September 30, 2014 reflects the delivery of six PacBio RS II instruments as compared to six instruments and \$0.5 million associated with instrument upgrades for the same period during 2013.

Service and other revenue of \$2.2 million and \$1.6 million for the three-month periods ended September 30, 2014 and 2013, respectively, was primarily derived from product maintenance agreements sold on our installed instruments.

Contractual revenue for the three-month period ended September 30, 2014 included the quarterly amortization of \$1.7 million from the non-refundable up-front payment of \$35.0 million we received in September 2013 pursuant to the Roche Agreement, and our achievement of a \$10.0 million milestone pursuant to the Roche Agreement.

Gross Profit

Gross profit increased \$12.0 million to \$13.2 million for the three-month period ended September 30, 2014, resulting in a gross margin of 63.8%, compared to gross profit of \$1.2 million and a gross margin of 16.7% for the three-month period ended September 30, 2013. The increase for both gross margin and gross profit is primarily due to the increase in Roche contractual revenue, specifically the \$10.0 million relating to the achievement of a development milestone.

Cost of product revenue of \$5.6 million for the three-month period ended September 30, 2014 reflects the costs primarily relating to the sale of six instruments and consumables shipped during the period while cost of product revenue of \$4.6 million for the same period during 2013 reflects the costs primarily relating to the sale of six instruments and consumables shipped during the period. The increase of \$1.0 million in cost of product revenue for the three-month period ended September 30, 2014 compared to the same period during 2013 was primarily due to the increase in consumable revenue and higher cost of product associated with instruments during three-month period ended September 30, 2014.

Cost of service and other revenue for the three-month period ended September 30, 2014 increased to \$1.9 million compared to \$1.6 million for the same period during 2013. The increase in cost of service and other revenue reflected higher service costs for personnel, materials and support infrastructure necessary to support the rising install base of our instruments.

Gross margin is expected to remain variable depending on the revenue mix; however in the short-term, we expect gross margin to decrease due to a higher mix of instrument revenue expected in the fourth quarter and the non-recurring nature of the milestone revenue recognized during the third quarter of 2014.

Research and Development Expense

During the three-month period ended September 30, 2014, research and development expense increased \$1.3 million, or 12%, compared to the same period during 2013. The increase in research and development expense was primarily attributed to an increase of \$1.1 million for higher product development expenses. Research and development expense included stock-based compensation expense of \$0.9 million and \$0.8 million during the three-month periods ended September 30, 2014 and 2013, respectively. We anticipate quarterly research and development expenses to remain consistent with recent quarters for the remainder of 2014.

Sales, General and Administrative Expense

For the three-month period ended September 30, 2014, selling, general and administrative expense decreased \$0.9 million, or 8%, compared to the same period during 2013. The decrease in sales, general and administrative expense was primarily attributed to a decrease of \$1.3 million in professional fees primarily due to higher expenses incurred associated with the Roche Agreement during the three-month period ended September 30, 2013 as compared to the expenses associated with the Roche Agreement during the three-month period ended September 30, 2014. Sales, general and administrative expense included stock-based compensation expense of \$1.3 million and \$1.2 million during the three-month periods ended September 30, 2014 and 2013, respectively. We anticipate quarterly sales, general and administrative expenses to remain consistent with recent quarters for the remainder of 2014.

Interest Expense

Interest expense for the three-month period ended September 30, 2014 remained flat compared to the same period during 2013. Interest expense related primarily to the debt facility entered into during the three-month period ended March 31, 2013.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash and investments, accretion of discounts and amortization of premiums related to investments, net gains or losses on foreign currency transactions, net gains or losses resulting from changes in the estimated fair value of the Financing Derivative and foreign income taxes.

Comparison of the Nine-month Periods Ended September 30, 2014 and 2013

(in thousands, except percentages)	Nine-Month Periods Ended September 30,		\$ Change	% Change
	2014	2013		
	(unaudited)			
Revenue:				
Product revenue	\$ 22,376	\$ 14,248	\$ 8,128	57%
Service and other revenue	6,226	4,800	1,426	30%
Contractual revenue	15,088	—	15,088	—
Total revenue	43,690	19,048	24,642	129%
Cost of Revenue:				
Cost of product revenue	19,048	11,138	7,910	71%
Cost of service and other revenue	5,678	4,680	998	21%
Total cost of revenue	24,726	15,818	8,908	56%
Gross profit	18,964	3,230	15,734	487%
Operating Expense:				
Research and development	35,899	34,084	1,815	5%
Sales, general and administrative	28,025	29,685	(1,660)	(6%)
Total operating expense	63,924	63,769	155	0%
Operating loss	(44,960)	(60,539)	15,579	26%
Interest expense	(2,103)	(1,785)	(318)	(18%)
Other income (expense), net	(122)	262	(384)	(147%)
Net loss	\$ (47,185)	\$ (62,062)	\$ 14,877	24%

Revenue

Total revenue for the nine-month period ended September 30, 2014 was \$43.7 million compared to \$19.0 million for the same period during 2013.

Product revenue in the nine-month period ended September 30, 2014 primarily consisted of \$13.5 million from sales of PacBio RS II instruments and \$8.9 million from sales of consumables compared to \$8.3 million from sales of

instruments and instrument upgrades and \$5.9 million from sales of consumables for the same period during 2013. Instrument revenue during the nine-month period ended September 30, 2014 reflects revenue from 23 PacBio RS II instruments as compared to 12 instruments and \$1.2 million associated with instrument upgrades for the same period during 2013.

Service and other revenue of \$6.2 million and \$4.8 million for the nine-month periods ended September 30, 2014 and 2013, respectively, was primarily derived from product maintenance agreements sold on our installed instruments.

Contractual revenue for the nine-month period ended September 30, 2014 related to the quarterly amortization of \$1.7 million from the non-refundable up-front payment of \$35.0 million we received during September 2013 pursuant to the Roche Agreement, and our achievement of a \$10.0 million milestone pursuant to the Roche Agreement.

Gross Profit

Gross profit increased \$15.7 million to \$19.0 million for the nine-month period ended September 30, 2014, resulting in a gross margin of 43.4%, compared to gross profit of \$3.2 million and a gross margin of 17.0% for the nine-month period ended September 30, 2013. The increase for both gross margin and gross profit is primarily due to the increase in Roche contractual revenue, specifically the \$10.0 million relating to the achievement of a development milestone.

Cost of product revenue of \$19.0 million for the nine-month period ended September 30, 2014 reflects the costs primarily relating to the sale of 23 instruments and consumables shipped during the period while cost of product revenue of \$11.1 million for the same period during 2013 reflects the costs primarily relating to the sale of 12 instruments and consumables shipped during the period. The increase of \$7.9 million in cost of product revenue for the nine-month period ended September 30, 2014 compared to the same

period during 2013 was primarily due to 11 more instruments recognized and an increase in consumable revenue during the nine-month period ended September 30, 2014.

Cost of service and other revenue for the nine-month period ended September 30, 2014 increased to \$5.7 million compared to \$4.7 million for the same period during 2013. The increase in cost of service and other revenue reflected higher service costs for the personnel, materials and support infrastructure necessary to support the rising install base of our instruments during the nine-month period ended September 30, 2014.

Research and Development Expense

During the nine-month period ended September 30, 2014, research and development expense increased \$1.8 million, or 5%, compared to the same period during 2013. The increase in research and development expense was primarily attributed to an increase of \$2.1 million for higher product development expenses. Research and development expense included stock-based compensation expense of \$2.6 million and \$3.1 million during the nine-month periods ended September 30, 2014 and 2013, respectively.

Sales, General and Administrative Expense

For the nine-month period ended September 30, 2014, selling, general and administrative expense decreased \$1.7 million, or 6%, compared to the same period during 2013. The decrease in sales, general and administrative expense was primarily attributed to a decrease of \$1.3 million in professional fees primarily due to higher expenses incurred associated with the Roche Agreement during the nine-month period ended September 30, 2013 as compared to the expenses associated with the Roche Agreement during the nine-month period ended September 30, 2014. Sales, general and administrative expense included stock-based compensation expense of \$3.9 million for both the nine-month periods ended September 30, 2014 and 2013.

Interest Expense

Interest expense for the nine-month period ended September 30, 2014 remained relatively flat compared to the same period during 2013. Interest expense related primarily to the debt facility entered into during the three-month period ended March 31, 2013.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on cash and investments, accretion of discounts and amortization of premiums related to investments, net gains or losses on foreign currency transactions, net gains or losses resulting from changes in the estimated fair value of the Financing Derivative and foreign income taxes.

Liquidity and Capital Resources

Since our inception we have financed our operations primarily through the issuance of common stock and convertible preferred stock, in addition to our debt facility. Cash and investments at September 30, 2014 totaled \$99.3 million, compared to \$112.5 million at December 31, 2013. During the nine-month period ended September 30, 2014, we received \$20.8 million, net, through the sale of common stock under our current “at-the-market” offering program.

Excluding proceeds from the “at-the-market” offering, cash and investments decreased by \$34.0 million compared to December 31, 2013, primarily reflecting \$36.1 million of cash used in operating activities and \$1.1 million of fixed asset purchases, partially offset by \$3.3 million of proceeds received from equity sales through our employee equity plans.

We believe that existing cash, cash equivalents and investments will be sufficient to fund our projected operating requirements for at least 12 months; however, we plan to raise additional capital in the future including, but not limited to, the financing arrangements as detailed under “Financing Activities” below. These expectations are based on our current operating and financing plans, which are subject to change. Factors that may affect our capital needs include, but are not limited to, slower than expected adoption of our products resulting in lower sales of our products and services; future acquisitions; our ability to maintain new collaboration and customer arrangements; the progress of our research and development programs; initiation or expansion of research programs and collaborations; the costs involved in preparing, filing, prosecuting, defending and enforcing intellectual property rights; the purchase of patent licenses; and other factors.

To the extent we raise additional funds through the sale of equity or convertible debt securities, the issuance of such securities will result in dilution to our stockholders. There can be no assurance that such funds will be available on favorable terms, or at all. If adequate funds are not available, we may be required to curtail operations significantly or to obtain funds by entering into collaboration agreements on unattractive terms. Our inability to raise capital could have a material adverse effect on our business, financial condition and results of operations.

Operating Activities

Our primary uses of cash in operating activities are for the manufacturing and sale of PacBio RS II instruments and consumables, development of ongoing product enhancements and future products, and support functions related to our selling, general

and administrative activities. The net cash used for the nine-month periods ended September 30, 2014 and 2013 primarily reflects the net loss for those periods, partially offset by non-cash operating expenses including depreciation, stock-based compensation, and changes in working capital.

We used \$36.1 million of cash from operating activities for the nine-month period ended September 30, 2014, compared to cash usage of \$15.3 million for the corresponding period in 2013. The cash used in operating activities for the nine-month period ended September 30, 2014 was due primarily to a net loss of \$47.2 million, partially offset by a stock-based compensation of \$6.9 million and depreciation and amortization of \$3.9 million. The cash used in operating activities for the nine-month period ended September 30, 2013 was due primarily to a net loss of \$62.1 million, partially offset by \$35.0 million collected relating to the Roche Agreement, stock-based compensation of \$7.4 million and depreciation and amortization of \$4.7 million.

Investing Activities

Our investing activities consist primarily of capital expenditures and investment purchases and maturities. We received \$21.1 million of cash from investing activities for the nine-month period ended September 30, 2014 compared to cash usage of \$9.0 million for the corresponding period in 2013. The receipt of cash of \$21.1 million from investing activities for the nine-month period ended September 30, 2014 was due primarily to net maturities of investments of \$22.2 million, partially offset by purchases of property and equipment of \$1.1 million. Net cash used in investing activities was \$9.0 million for the nine-month period ended September 30, 2013, comprised of net purchases of investments of \$8.2 million and purchases of property and equipment of \$0.8 million.

Financing Activities

We received \$24.1 million of cash from financing activities for the nine-month period ended September 30, 2014, due primarily to net proceeds of \$20.8 million from our common stock “at-the-market” offering and \$3.3 million from the issuance of common stock through our equity compensation plans. Under our current “at-the-market” offering program, \$17.8 million of common stock remains available for future sales; however, we are not obligated to make sales under this program. We received \$42.5 million of cash from financing activities for the nine-month period ended September 30, 2013. For the nine-month period ended September 30, 2013, we received net proceeds of \$19.8 million from the debt facility, net proceeds of \$20.0 million from our common stock “at-the-market” offering, and \$2.7 million from the issuance of our common stock through the sale of shares under our ESPP and stock option exercises.

Off-Balance Sheet Arrangements

As of September 30, 2014 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 negligent 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 fund raising 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 the Company in connection with such fund raising efforts. No additional liability associated with such indemnification agreements has been recorded as of September 30, 2014.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest rate and Market Risk

Our exposure to market risk is confined to our cash, cash equivalents and our investments, all of which have maturities of less than three years. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of high credit quality securities. The securities in our investment portfolio are not leveraged, are classified as available-for-sale, and are, due to their relatively short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a hypothetical 10% change in market interest rates would have any material negative impact on the value of our investment portfolio.

Foreign Exchange Risk

The majority of our expense and capital purchasing activities are transacted in U.S. dollars. However, a portion of our operations consists of sales activities outside of the United States; therefore we have foreign exchange exposures relating to non-U.S. dollar revenues, operating expenses, accounts receivable, accounts payable, and currency balances. Our primary exposure is with the Euro. Actual gains and losses in the future may differ materially from the hypothetical gains and losses discussed above based on changes in the timing and amount of foreign currency exchange rate movements and our actual exposure; however, we do not believe that the effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would have a material impact on our historical consolidated financial statements.

Our international operations are subject to risks typical of international operations, including, but not limited to, differing economic conditions, changes in political climate, differing tax structures, other regulations and restrictions and foreign exchange rate volatility.

Item 4. Controls and Procedures.

(a) Disclosure controls and procedures.

Our management, with the participation of our chief executive officer and our chief financial 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.

(b) Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

18

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

We may, from time to time, be party to litigation and subject to claims that arise in the ordinary course of business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. We currently believe that these ordinary course matters will not 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 defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, 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.

Risks Related to Our Business

We have limited experience as a commercial company.

Our first commercial product, the PacBio RS, launched in 2011 and our most recent product, the PacBio RS II, launched in 2013 and, as such, we have limited historical financial data upon which to base our projected revenue, planned operating expense or upon which to evaluate us and our commercial prospects. Based on our limited experience in developing and marketing new products, we may not be able to effectively:

- drive adoption of our products;
- 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;
- focus our research and development efforts in areas that generate returns on these efforts;
- comply with evolving regulatory requirements applicable to our products;
- anticipate and adapt to changes in our market;
- maintain and develop strategic relationships with vendors and manufacturers to acquire necessary materials for the production of our products;

- scale our manufacturing activities to meet potential demand at a reasonable cost;
- avoid infringement and misappropriation of third-party intellectual property;
- obtain licenses on commercially reasonable terms to third-party intellectual property;
- obtain valid and enforceable patents that give us a competitive advantage;
- protect our proprietary technology;
- protect our products from any equipment or software-related system failures; and
- attract, retain and motivate qualified personnel.

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, our losses may be greater than expected and our operating results will suffer.

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 incurred net losses 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, we may not be able to sustain profitability. We expect to incur substantial losses and negative cash flow from operations for the foreseeable future.

If our products fail to achieve and sustain sufficient market acceptance, we will not generate expected revenue and our business may not succeed.

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 the market for genetic analysis to include new applications that are not practical with other current technologies. To accomplish this, we must successfully commercialize, and continue development of, our SMRT technology for use in a variety of life science applications. There can be no assurance that we will be successful in securing additional customers for our products. Furthermore, we cannot guarantee that the design, performance or specifications of our products will be satisfactory to potential customers in the markets we seek to reach. These markets are dynamic, and there can be no assurance that they will develop as quickly as we expect or that they will reach their full potential. 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 markets more quickly. Even if we are able to implement our technology successfully, we may fail to achieve or sustain market acceptance of our products by academic and government research laboratories and pharmaceutical, biotechnology and agriculture companies, among others, across the full range of our intended life science applications. If the market for our products grows more slowly than anticipated, if competitors develop better or more cost-effective products or if we are unable to further grow our customer base, our future sales and revenue would be materially harmed and our business may not succeed.

Our development, commercialization and license arrangement with Roche may not result in the benefits we anticipate, and could have a material adverse effect on our business, financial condition and results of operations.

We have entered into an agreement with Roche, pursuant to which we will develop and manufacture diagnostic products for clinical use including sequencing systems and consumables based on our proprietary SMRT technology. There can be no assurance that we will be able to develop and manufacture products as provided by the terms of the Roche Agreement or that Roche will be able to commercialize and sell the developed diagnostic products. We may also be unable to meet the development milestones required for additional payments from Roche. We could also be involved in disputes with Roche, which could lead to delays in or termination of our development and manufacture of diagnostic products and result in time consuming and expensive litigation or arbitration. In addition, any such dispute could diminish Roche's commitment to us and reduce the resources they devote to commercializing the developed diagnostic products. If Roche terminates or breaches the Roche Agreement, or otherwise acquires, develops and/or commercializes alternative or competing products, the successful commercialization of our diagnostic products for clinical use would be materially and adversely affected. If we are not able to realize the expected benefits from the Roche Agreement, it could have a material adverse effect on our business, financial condition and results of operations.

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 and for which we have not yet recognized revenue. We may not receive revenue from these orders, and the 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. If we delay fulfilling customer orders, those customers may seek to cancel their orders with us. In addition, 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 indebtedness could adversely affect our financial condition and prevent us from fulfilling our obligations.

We have entered into a debt agreement pursuant to which we received \$20.5 million in funding. Our net losses since inception and our expectation of incurring substantial losses and negative cash flow for the foreseeable future, combined with indebtedness, could:

- make it more difficult for us to satisfy our obligations, including under the debt agreement;
- 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;
- require us to dedicate a substantial portion of our cash flow from operations to service payments on our indebtedness;
- 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 competitive disadvantage to our competitors that have less or no indebtedness; and
- limit, along with the financial and other restrictive covenants in our indebtedness, among other things, our ability to borrow additional funds.

Our debt agreement contains covenants which may adversely impact our business and the failure to comply with such covenants could cause our outstanding indebtedness to become immediately payable.

Our debt agreement contains various affirmative and negative covenants, including restrictions on our and our subsidiaries' ability to incur additional indebtedness or liens on our assets, except as permitted under the debt agreement, that impose significant operating and financial restrictions on us, including restrictions on our ability to take actions that may be in our best interests, some of which may be affected by events beyond our control.

A breach of any of the covenants contained in our debt agreement could result in a default under such agreement. If an event of default exists, debt holders could elect to declare all amounts outstanding under the debt agreement to be immediately due and payable. If we are unable to repay our indebtedness when due and payable, debt holders could proceed against the collateral granted to them to secure such indebtedness. We have pledged substantially all of our property and interests in property, including intellectual property, as collateral under the debt agreement. If the debt holders accelerate the repayment of borrowings, we may not have sufficient funds to repay our existing indebtedness, which could have a material adverse effect on our liquidity and ability to conduct our business.

Our products are highly complex and have recurring support requirements.

In light of the highly complex technology involved in our products, there can be no assurance that we will be able to continue providing adequate support for our products. Our customers have in the past experienced reliability issues with our products. 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. We deliver our PacBio RS II instruments with one year of service included in the purchase price and offer additional years of service for a fee. If our service and support costs increase, our business and operations may be adversely affected.

We may be unable to consistently manufacture our instruments and consumable kits, including SMRT Cells, to the specifications required by our customers or in quantities necessary to meet demand at an acceptable cost.

In order to successfully derive revenue from our products, we need to supply our customers with products that meet the specifications, quality requirements and expectations of our customers. Our customers have previously experienced variability in the performance of our instruments and SMRT Cells. 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 those products and specifications developed pursuant to the Roche Agreement. There is also no assurance that we will be able to increase manufacturing yields and decrease costs. Furthermore, we may not be able to increase manufacturing to meet anticipated demand. An inability to manufacture products that consistently meet specifications, in necessary quantities and at commercially acceptable costs, will have a negative material impact on our business.

Rapidly changing technology in life sciences could make the products we are developing obsolete unless we continue to develop and commercialize new and improved products and pursue new market opportunities.

Our industry is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry standards. Our future success will depend 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 market opportunities. These new market opportunities may be outside the scope of our proven expertise or in areas where the market demand is unproven, and new products and services developed

by us may not gain market acceptance. Our inability to develop and introduce new products and to gain market acceptance of new products could harm our future operating results. Unanticipated difficulties or delays in replacing existing products with new products or in commercializing improved or new products in sufficient quantities to meet customer demand could diminish future demand for our products and harm our future operating results.

A significant portion of our potential 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 instrument sales represent significant capital purchases for our customers. Our potential customers include academic and government institutions, genome centers, medical research institutions, pharmaceutical, agricultural, biotechnology 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, particularly in light of the recent United States federal government shutdown, the spending priorities among various types of research equipment and policies regarding capital expenditures during economically uncertain periods. Any decrease in capital spending or change in spending priorities of our customers and potential customers could significantly reduce the demand for our products. Any delay or reduction in purchases by potential customers or our inability to forecast fluctuations in demand could harm our future operating results.

We may be unable to successfully increase sales of our products.

Our ability to achieve profitability depends on our ability to attract customers for our products, and we may be unable to effectively market our products. To perform sales, marketing, distribution and customer support functions successfully, we face a number of risks, including:

- our ability to attract, retain and manage the sales, marketing and service personnel necessary to expand market acceptance for our technologies;
- 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 globally or in certain regions of the world. There is no guarantee, when we enter into such arrangements, that we will be successful in attracting desirable sales and distribution partners; there is also no guarantee that we will be able to enter into such arrangements on terms favorable to us. If our sales and marketing efforts, or those of any of our third-party sales and distribution partners, are not successful, our technologies and products may not gain market acceptance, which could materially impact our business operations.

We rely on other companies for the manufacture of certain components and sub-assemblies and intend to outsource additional sub-assemblies in the future. 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 precision manufacturing. The nature of the 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. If we are required to purchase these components from an alternative source, it could take several months or longer to qualify the alternative sources. If we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our products in a timely fashion or in sufficient quantities or under acceptable terms. Additionally, for some of those components that are currently purchased from a sole or single source supplier, we have not yet arranged for alternative suppliers.

The operations of our third-party manufacturing partners and suppliers could be disrupted by conditions unrelated to our business or operations or beyond our control. 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. Our current manufacturing process is characterized by long lead times between the ordering and delivery of our products. If we are unable to reduce our manufacturing costs and establish and maintain reliable high volume manufacturing suppliers as we scale our operations, our business could be materially harmed.

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 third parties is unable to deliver our products, the delivery and acceptance 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.

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, engineering and other personnel, our ability to develop our products could be harmed, and we may be unable to achieve our goals.

Our future 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 future technological and product innovations, and we will need to hire additional qualified personnel. Our industry, particularly in the San Francisco Bay Area, is characterized by high demand and intense competition for talent, and the turnover rate can 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. Our employees could leave our company with little or no prior notice and would be free to work for a competitor. 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. The loss of any of these individuals or any inability to attract or retain qualified personnel, including scientists, engineers and others, could prevent us from pursuing collaborations and adversely affect our product development and introductions, business growth prospects, results of operations and financial condition.

We have raised, and intend to raise, additional financing to fund our existing operations. Equity and debt securities we issue may have rights senior to common stockholders.

We have raised, and intend to raise, additional funds through public or private debt or equity financing. Additional funds may not be available on terms acceptable to us or at all, particularly in light of restrictions under our debt agreement. We have incurred and may further incur additional debt. Debt holders have rights senior to common stockholders to make claims on our assets and the terms of our existing debt agreement restrict certain activities, including our ability to pay dividends on our common stock. We intend to raise additional funds beyond the transactions completed to date, which will result in additional dilution to our stockholders.

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.

Some of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in new product development and manufacturing capabilities and more established distribution channels to deliver products to customers than we do. These competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. In light of these advantages, even if our technology is more effective than the products or service offerings of our competitors, current or potential customers might accept competitive products and services in lieu of purchasing our products. Increased competition may result in pricing pressures, which could harm our sales, profitability or market share. Our failure to compete effectively could materially and adversely affect our business, financial condition or results of operations.

Our products 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 technology are complex and may develop or contain undetected defects or errors. We cannot provide assurance that material performance problems will not arise. Despite testing, defects or errors may arise in our products, which could result in a failure to achieve increased market acceptance, diversion of development resources, injury to our reputation and increased warranty, service and maintenance costs. We ship our PacBio RS II instruments with one year of service included in the purchase price with an option to purchase one or more additional years of service. We also provide a warranty for our consumables, but claims must be made within 30 days from the shelf life date or “use by” date. The warranty is limited to replacing, or at our option, giving credit for, any consumable with defects in material or workmanship. Defects or errors in our products might also discourage customers from purchasing our products. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating margins. In addition, such defects or errors could lead to the filing of product liability claims against us or against third parties who 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 assets 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 serious adverse effect on our business, financial condition and results of operations.

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 third parties will develop tools that will be useful with our products or be viewed as useful by our customers or potential customers. A lack of additional available complementary sample preparation and informatics tools may impede the adoption of our products and may adversely impact our business.

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

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 adversely affected. International operations entail a variety of risks, including challenges in staffing and managing foreign operations, tariffs and other trade barriers, unexpected changes in legislative or regulatory requirements of foreign countries into which we sell our products, difficulties in obtaining export licenses or in overcoming other trade barriers and restrictions resulting in delivery delays and significant taxes or other burdens of complying with a variety of foreign laws. In conducting our international operations, we will be subject to U.S. laws relating to our international activities, as well as foreign laws relating to our activities in other countries. Failure to comply with these laws may subject us to financial and other penalties in the U.S. and foreign countries that could impact our operations or financial condition.

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 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. Our costs of materials from international suppliers may increase if in order to continue doing business with us they raise their prices 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.

Ethical, legal, privacy and social concerns 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 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. Such concerns or governmental restrictions could limit the use of our products, which could have a material adverse effect on our business, financial condition and results of operations.

Our products could in the future be subject to regulation by the U.S. Food and Drug Administration or other domestic and international regulatory agencies, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business and results of operations.

Our products are not currently subject to U.S. Food and Drug Administration, or FDA, clearance or approval since they are not intended for use in the diagnosis or treatment of disease. However, in the future, certain of our products or related applications could be subject to FDA regulation, or the FDA's regulatory jurisdiction could be expanded to include our products. Even where a product is exempted from FDA clearance or approval, the FDA may impose restrictions as to the types of customers to which we can market and sell our products or to which our partners can market and sell our products. Such regulation and restrictions may materially and adversely affect our business, financial condition and results of operations.

Many countries have laws and regulations that could affect our products. The number and scope of these requirements are increasing. Unlike many of our competitors, this is an area where we do not have expertise. We, or our other third-party sales and distribution partners, as applicable, 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.

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.

Our facilities in California are located near known 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 the San Francisco Bay Area are located near known 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.

We are subject to existing and potential additional governmental regulation 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 existing and potential additional 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. The failure to satisfy export control criteria or to obtain necessary clearances could delay or prevent shipment of products, which could adversely affect our revenue and profitability. Moreover, the life sciences industry, which is expected 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 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 could increase the cost of operating our business.

Regulations related to conflict minerals may 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, or the Dodd-Frank Act, that require us to conduct diligence, and report whether or not our products contain conflict minerals. The implementation of these new 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 instruments contain minerals not determined to be conflict free or if we are unable to alter our processes or sources of supply to avoid such materials. Reputational harm could adversely affect our business, financial condition or results of operations.

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 re-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. generally accepted accounting principles. 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 were required to perform an evaluation of our internal control over financial reporting. While we performed this evaluation and concluded that our internal control over financial reporting was operating effectively as of December 31, 2013 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 ability to use net operating losses to offset future taxable income may be subject to substantial limitations.

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, or NOLs, to offset future taxable income. We believe that we have had one or more ownership changes, as a result of which our existing NOLs are currently subject to limitation. Future changes in our stock ownership could result in additional ownership changes under Section 382. We may not be able to utilize a material portion of our NOLs, even if we attain profitability.

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 competitors 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;
- our patents or the patents of our licensors may not be of sufficient scope 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;
- we 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 among countries. 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 patents that may be granted to us, 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 we fail to meet our obligations under these licenses, these third parties could terminate the licenses. 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 could subject us to claims of intellectual property infringement. 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 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 assure you that we will be able to obtain such licenses or expanded rights on reasonable terms or at all. In addition, we have limited rights to participate in the prosecution and enforcement of the patents and patent applications that we have licensed. 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 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, consultants and certain academic collaborators to enter into confidentiality and assignment of inventions agreements, and by requiring our third-party manufacturing partners to enter into confidentiality agreements. There can be no assurance, however, that such measures 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 third parties asserting prior invention by others or invalidity on various grounds, through proceedings, such as interferences, reexamination or opposition proceedings. Addressing these challenges to our intellectual property has previously 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, as a result of these challenges, our patents or pending patent applications may be determined to be unpatentable to us, invalidated or unenforceable in whole or in part. Accordingly, adverse rulings from the relevant patent offices in these proceedings may negatively impact the scope of our intellectual property protection for our products and technology and may adversely affect 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 action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government and U.S. government funding must be disclosed in any resulting patent applications. In addition, our rights in such inventions are subject to government license rights and foreign manufacturing restrictions.

We may become 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 may have from time to time taken, and may in the future take, actions that we believe violate our patent rights. Legal actions to enforce these patent rights can be expensive and may involve the diversion of significant management time and resources. Our enforcement actions may not be successful, could give rise to legal claims against us and could result in some of our intellectual property rights being determined to be invalid or not enforceable.

We 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 belonging 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. 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. Patent litigation between competitors in our industry is common. Additionally, we have certain obligations to many of our customers 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, 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 to indemnify 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 that we 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 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 our having to pay substantial damage awards or be prevented from selling some or all of our products, which could 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 our 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 and otherwise adversely

affect our business.

Risks Related to Owning Our Common Stock

The price of our common stock has been, 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 bookings, financial condition and operating results;
- announcements of technological innovations by us or our competitors;
- announcements by 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 or capital commitments;

- 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 and 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;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; and
- general economic and market conditions.

Stock markets in general and the market for companies in our industry in particular have experienced price and volume fluctuations that 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 recent 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.

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

Our PacBio RS II instrument has lengthy sales and purchase order cycles because it is a major capital item and generally requires the approval of our customers' senior management. This may contribute to substantial fluctuations in our quarterly operating results, particularly during the 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 operating results have resulted in decreases in our stock price. Such fluctuations also mean that investors may not be able to rely upon our operating results in any particular period as an indication of future performance.

If securities or industry analysts publish negative reports about our business, our share price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our shares or change their opinion of our shares, our share price would likely decline. If one or more of these analysts cease coverage of our

company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Future sales of our common stock could cause our share price to fall.

We filed a shelf registration statement on Form S-3 with the SEC pursuant to which we may, from time to time, sell up to an aggregate of \$150 million of our common stock, warrants or debt securities. We subsequently established “at-the-market” offerings pursuant to which we may offer and sell shares of our common stock. We are not obligated to make or continue to make any sales of shares of our common stock under the “at-the-market” offerings. The sale of securities under the registration statement, including pursuant to the “at-the-market” offerings, has resulted and will result in dilution of our stockholders and could cause our share price to fall.

In addition, the holders of a significant number of shares of our common stock are entitled to rights with respect to registration of such shares under the Securities Act pursuant to an investor rights agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired. Such holders have waived their registration rights with respect to the sale of shares of our common stock pursuant to the sales agreement relating to the “at-the-market” offerings through May 2015. We have also filed a registration statement on Form S-8 under the Securities Act to register shares for issuance under our 2004 Equity Incentive Plan, 2005 Stock Plan, 2010 Equity Incentive Plan, ESPP and 2010 Outside Director Equity Incentive Plan. Each of our 2010 Equity Incentive Plan, ESPP and 2010 Outside Director Equity Incentive Plan provides for automatic increases in the shares reserved for issuance under the plan which could result in additional dilution to our stockholders. Additionally, warrants to purchase 5,500,000 shares of our common stock issued in connection with our debt agreement could result in additional dilution to our stockholders.

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

Our existing significant stockholders, executive officers, directors and their affiliates beneficially own a significant number of our outstanding shares of common stock. As a result, these stockholders will 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 certificate of incorporation and bylaws, as amended and restated, 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 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 Chairman of the Board, the Chief Executive Officer or the President;
- establish an advance notice procedure 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 development agreement with Roche may deter or reduce the number of potential acquirers thus reducing or placing negative pressure on our stock price.

The Roche Agreement could make an acquisition of our company, which may be beneficial to our stockholders, less likely, whether or not we realize the expected benefits from the Roche Agreement. For example, the exclusive rights and licenses granted to Roche pursuant to the Roche Agreement, or our development, manufacturing and supply obligations pursuant to the Roche Agreement, may make an acquisition of our company less appealing to third parties that compete with Roche.

Our large number of authorized but unissued shares of common stock may potentially dilute your 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 cash dividends on our common stock and do not intend to pay any cash 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Default Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable

Item 6. Exhibits

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed (other than exhibits 32.1 and 32.2) as part of this Quarterly Report on Form 10-Q and such Exhibit Index is incorporated herein by reference.

31

Signatures

Pursuant to the requirements of the Securities 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: By: /s/ SUSAN K. BARNES
November
5, 2014

Susan K. Barnes
Executive Vice President

And

Chief Financial Officer

Date: By: /s/ BRIAN B. DOW
November
5, 2014

Brian B. Dow
Vice President

And

Principal Accounting Officer

Exhibit Index

Exhibit

Number Exhibit Description

- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1* Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
- 32.2* Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).

- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

*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

