

Accelerate Diagnostics, Inc
Form 10-Q
August 07, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended June 30, 2017

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

Commission file number: 001-31822

ACCELERATE DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

84-1072256

(State or other jurisdiction

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

of incorporation or organization)

3950 South Country Club, Suite 470

Tucson, Arizona

85714

(Address of principal executive offices)(Zip Code)

(520) 365-3100

(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," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Emerging growth company

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

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

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

As of August 1, 2017 there were 55,298,222 shares of the registrant's common stock outstanding.

1

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

<u>Item 1. Financial Statements</u>	<u>3</u>
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>21</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>25</u>
<u>Item 4. Controls and Procedures</u>	<u>26</u>

Part II - OTHER INFORMATION

<u>Item 1. Legal Proceedings</u>	<u>26</u>
<u>Item 1A. Risk Factors</u>	<u>26</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>27</u>
<u>Item 3. Defaults Upon Senior Securities</u>	<u>27</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>27</u>
<u>Item 5. Other Information</u>	<u>27</u>
<u>Item 6. Exhibits</u>	<u>27</u>

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ACCELERATE DIAGNOSTICS, INC.
 CONDENSED CONSOLIDATED
 BALANCE SHEET
 Unaudited
 (in thousands)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$62,609	\$19,244
Investments	72,609	58,519
Trade accounts receivable	682	34
Inventory	5,720	—
Prepaid expenses	1,157	468
Other current assets	496	183
Total current assets	143,273	78,448
Property and equipment, net	4,844	4,258
Intellectual property, net	140	146
Total assets	\$148,257	\$82,852
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$1,534	\$992
Accrued liabilities	3,611	3,009
Deferred revenue and income	1,078	35
Total current liabilities	6,223	4,036
Long-term deferred income	—	1,000
Total liabilities	\$6,223	\$5,036
Commitments and contingencies see Note 16, Commitments		
Stockholders' equity:		
Common stock, \$0.001 par value;		
75,000,000 common shares authorized with 55,291,222 shares issued and outstanding on June 30, 2017 and 75,000,000 authorized with 51,516,309 shares issued and outstanding on December 31, 2016	55	52
Preferred shares, \$0.001 par value;		
5,000,000 preferred shares authorized and none outstanding as of June 30, 2017 and December 31, 2016	—	—
Contributed capital	350,577	255,257
Accumulated deficit	(208,601)	(177,289)
Accumulated other comprehensive (loss)	3	(204)
Total stockholders' equity	142,034	77,816
Total liabilities and stockholders' equity	\$148,257	\$82,852

See accompanying notes to financial statements.

3

ACCELERATE DIAGNOSTICS, INC.
 CONDENSED CONSOLIDATED
 STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Unaudited

(in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Net sales	\$699	\$20	\$1,230	\$183
Cost of sales	135	—	161	—
Gross Profit	564	20	1,069	183
Costs and expenses:				
Research and development	5,527	8,425	9,815	16,100
Sales, general and administrative	11,460	9,484	21,988	17,144
Total costs and expenses	16,987	17,909	31,803	33,244
Loss from operations	(16,423)	(17,889)	(30,734)	(33,061)
Interest expense and other	(5)	—	(5)	—
Foreign currency exchange loss	(7)	(117)	(33)	(73)
Interest and dividend income	153	140	290	194
Total other income	141	23	252	121
Net loss before income taxes	(16,282)	(17,866)	(30,482)	(32,940)
Provision from income taxes	(175)	—	(175)	—
Net loss	\$(16,457)	\$(17,866)	\$(30,657)	\$(32,940)
Basic and diluted net loss per share	\$(0.31)	\$(0.35)	\$(0.58)	\$(0.64)
Weighted average shares outstanding	53,568	51,213	52,732	51,205
Other comprehensive loss:				
Net loss	\$(16,457)	\$(17,866)	\$(30,657)	\$(32,940)
Net unrealized gain on available-for-sale investments	3	29	3	81
Foreign currency translation adjustment	204	49	204	—
Comprehensive loss	\$(16,250)	\$(17,788)	\$(30,450)	\$(32,859)

See accompanying notes to financial statements.

ACCELERATE DIAGNOSTICS, INC.
 CONDENSED CONSOLIDATED
 STATEMENT OF CASH FLOWS
 Unaudited
 (in thousands)

	Six Months Ended	
	June 30, 2017	June 30, 2016
Cash flows from operating activities:		
Net loss	\$(30,657)	\$(32,940)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,045	1,147
Amortization of intangible assets	6	5
Amortization of investment discount	219	123
Equity-based compensation	7,450	3,921
Loss on disposal of property & equipment	5	—
(Increase) decrease in assets:		
Accounts receivable	(648)(92
Inventory	(5,537)—
Prepaid expense and other	(624)272
Other current assets	(313)(1,220
Increase (decrease) in liabilities:		
Accounts payable	528	(394
Accrued liabilities	392	1,175
Deferred revenue and income	43	(84
Net cash used in operating activities	(28,091)(28,087
Cash flows from investing activities:		
Purchases of equipment	(1,643)(2,084
Purchases of available-for-sale securities	(39,342)(63,534
Sales of available-for-sale securities	6,522	1,000
Maturity of available-for-sale securities	18,449	9,380
Net cash used in investing activities	(16,014)(55,238
Cash flows from financing activities:		
Issuance of common stock net issuance costs	83,854	—
Exercise of options and warrants	3,418	95
Common stock issuance costs	—	(814
Payments on capital lease obligations	—	(13
Recovery of related party short-swing profits	—	991
Net cash provided by financing activities	87,272	259
Effect of exchange rate on cash:	198	—
Increase (decrease) in cash and cash equivalents	43,365	(83,066
Cash and cash equivalents, beginning of period	19,244	120,585
Cash and cash equivalents, end of period	\$62,609	\$37,519

See accompanying notes to financial statements.

ACCELERATE DIAGNOSTICS, INC.

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Unaudited

NOTE 1. ORGANIZATION AND NATURE OF BUSINESS; BASIS OF PRESENTATION; PRINCIPLES OF CONSOLIDATION; SIGNIFICANT ACCOUNTING POLICIES

Accelerate Diagnostics, Inc. (“we” or “us” or “our” or “Accelerate” or “the Company”) is an in vitro diagnostics company dedicated to providing solutions which improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“U.S. GAAP”) and applicable rules and regulations of the United States Securities and Exchange Commission (“SEC”) regarding interim financial reporting. Certain information and note disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Therefore, these condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, as filed with the SEC on February 28, 2017.

The condensed consolidated balance sheet as of December 31, 2016 included herein was derived from the audited financial statements as of that date, but does not include all disclosures such as notes required by U.S. GAAP.

The accompanying unaudited condensed consolidated financial statements reflect all normal recurring adjustments necessary to present fairly the financial position, results of operations, and cash flows for the interim periods presented, but are not necessarily indicative of the results of operations to be anticipated for the entire year ending December 31, 2017, or any future period.

All amounts are rounded to the nearest thousand dollars unless otherwise indicated.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries after elimination of intercompany transactions and balances.

Cash and Cash Equivalents

All highly liquid investments with an original maturity of three months or less at time of purchase are considered to be cash equivalents. Cash and cash equivalents include overnight repurchase agreement accounts and other investments. As part of our cash management process, excess operating cash is invested in overnight repurchase agreements with our bank. Repurchase agreements and other investments classified as cash and cash equivalents are not deposits and

are not insured by the U.S. Government, the FDIC or any other government agency and involve investment risk including possible loss of principal. We believe however, that the market risk arising from holding these financial instruments is minimal.

Investments

The Company invests excess funds in various investments which are primarily held in the custody of major financial institutions. Investments consist of debt securities in U.S. government and agency securities, corporate debt securities and certificates of deposit. Management classifies its investments as available-for-sale investments and

records these investments in the condensed consolidated balance sheet at fair value. The Company considers all available-for-sale securities, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs. Unrealized gains or losses for available-for-sale securities are included in accumulated other comprehensive income or loss, a component of stockholders' equity. The Company classifies its investments as current based on the nature of the investments and their availability for use in current operations.

The Company assesses whether an other-than-temporary impairment loss has occurred due to declines in fair value or other market conditions when an investment's fair value remains less than its cost for more than twelve months. This assessment includes a determination of whether the investment is expected to recover in value and whether the Company has the intent and ability to hold the investment until the anticipated recovery in value occurs. When an investment is identified as having an other-than-temporary impairment loss, we adjust the cost basis of the investment down to fair value resulting in a realized loss. The new cost basis is not changed for subsequent recoveries in fair value and temporary future increases or decreases in fair value are included in other comprehensive income.

Reclassification

Certain prior year amounts have been reclassified for consistency with the current year presentation and had no effect on our net income, stockholders' equity or cash flows. In the current period presentation and the revised prior period presentation, depreciation and amortization expenses are reported as a component of the individual costs and expenses as part of the condensed consolidated statements of operations and comprehensive loss. The amount of depreciation and amortization expenses now reported as a component of research and development costs for the three months ended June 30, 2017 and 2016 were \$404,000 and \$362,000, respectively, and for the six months ended June 30, 2017 and 2016 were \$784,000 and \$683,000, respectively. The amount of depreciation and amortization expenses now reported as a component of sales, general and administrative costs for the three months ended June 30, 2017 and 2016 were \$138,000 and \$245,000, respectively, and for the six months ended June 30, 2017 and 2016 were \$267,000 and \$468,000, respectively.

In the current and revised prior period presentation, product sales and licensing and royalty revenues are reported as net sales as part of the condensed consolidated statements of operations and comprehensive loss. The amounts that have been reclassified had no effect on our net income, stockholders' equity or cash flows.

Inventory

Inventory is stated at the lesser of cost or net realizable value, with cost determined on the first-in-first-out method. The allocation of production overhead to inventory costs is based on normal production capacity. Abnormal amounts of idle facility expense and spoilage are expensed as incurred, and not included in overhead subject to capitalization. The Company maintains provisions for excess and obsolete inventory based on management's estimates of forecasted demand and, where applicable, product expiration. The Company adopted Accounting Standards Update ("ASU") 2015-11, Simplifying the Measurement of Inventory (Topic 310) Inventory on January 1, 2017. This ASU simplifies the subsequent measurement of inventory by using only the lower of cost or net realizable value. The adoption did not have an effect on the Company's consolidated financial statements.

Property and Equipment

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and expenditures for major improvements are capitalized. Gains and losses from retirement or replacement are included in costs and expenses. Depreciation of property and equipment is computed using the straight-line method over the estimated useful life of the assets, ranging from greater than one year to seven years. Leasehold improvements are depreciated over the remaining life of the lease or the life of the asset, whichever is less.

Property and equipment includes diagnostic instruments used for sales demonstrations and instruments under rental agreements. The Company retains title to the instruments under these arrangements.

Revenue

The Company recognizes revenue in accordance with ASC 605, Revenue Recognition, when persuasive evidence of an arrangement exists, the price is fixed or determinable, collection is reasonably assured and delivery of products has occurred or services have been rendered. Additional considerations include whether the applicable fee arrangement contains future delivery or performance obligations that should be divided into separate accounting

7

units, whether the arrangement requires the Company to retain risks consistent with a collaborative arrangement, and/or whether any of the fees are contingent on the achievement of future milestones.

Product revenue is derived from the sale or rental of our instruments and sales of related consumable products. When an instrument is sold, revenue is generally recognized upon installation of the unit consistent with contract terms, which do not include a right of return. When a consumable product is sold, revenue is generally recognized upon shipment.

We also provide instruments to customers under bundled rental agreements. Under these agreements, we install the instrument in the customer's facility and provide service. The customer agrees to purchase consumable products at a stated price over the term of the agreement which is typically less than seven years. Contracts sometimes have renewal clauses but such clauses do not provide for a bargain renewal option or penalize the customer if they do not renew. The instrument remains the Company's property throughout the term of the agreement and there is no transfer of title upon expiration. Revenue is recognized as consumable products are shipped or delivered, depending on contract terms.

For multiple element arrangements, the total consideration for an arrangement is allocated among the separate elements in the arrangement based on a selling price hierarchy. The selling price hierarchy for a deliverable is based on: (1) vendor specific objective evidence ("VSOE"), if available; (2) third party evidence of selling price if VSOE is not available; or (3) an estimated selling price, if neither VSOE nor third party evidence is available. Estimated selling price is our best estimate of the selling price of an element in a transaction. The Company limits the amount of revenue recognized for delivered elements to the amount that is not contingent on the future delivery of products or services or other future performance obligations.

Leases

The Company accounts for leases in accordance with ASC 840, Leases, which requires leases to be classified as either operating or capital leases. In general, the Company classifies leases as capital leases when there is either a transfer of ownership at the end of the lease term, the lease contains a bargain purchase option, the lease term is seventy-five percent or more of the estimated economic life of the leased property or the minimum lease payments are ninety percent or more of the fair value at lease inception. Other leases are classified as operating leases.

Operating lease rent is recorded as an operating expense monthly. For capital leases, both an asset and liability are recorded at the inception of the lease based on the present value of lease payments. The asset is included with property and equipment on the condensed consolidated balance sheet and amortization is recorded on a straight-line basis over the term of the lease reported as a component of the individual costs and expenses as part of the condensed consolidated statements of operations and comprehensive loss. For the liability, the amount due within the next year is recorded as capital lease obligations and the amount due in more than a year is recorded as long-term capital lease obligation on the condensed consolidated balance sheet. Interest expense is recorded based on the implicit or explicit interest rate used in the lease and is included as non-operating interest expense on the condensed consolidated statements of operations and comprehensive loss.

Equity-Based Compensation

The Company awards stock options and other equity-based instruments to its employees, directors and consultants. Compensation cost related to equity-based instruments is based on the fair value of the instrument on the grant date, and is recognized over the requisite service period on a straight-line basis over the vesting period for each tranche (an accelerated attribution method). For unvested consultant grants, the assumptions are updated at the end of each reporting period until the grant is vested. The Company estimates the fair value of stock option awards, including

modifications of stock option awards, using the Black-Scholes option pricing model. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield.

• **Volatility:** The expected volatility is based on the historical volatility of the Company's stock price over the most recent period commensurate with the expected term of the stock option award.

Expected term: The estimated expected term for employee awards is based on the calculation published by the SEC in **SAB110** for use when there is not a sufficient history of employee exercise patterns. For consultant awards, the estimated expected term is the same as the life of the award.

Risk-free interest rate: The risk-free interest rate is based on published U.S. Treasury rates for a term commensurate with the expected term.

Dividend yield: The dividend yield is estimated as zero as the Company has not paid dividends in the past and does not have any plans to pay any dividends in the foreseeable future.

The Company implemented ASU 2016-09, Compensation-Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting on January 1, 2017. Pursuant to this guidance, we made a policy election to account for forfeitures as they occur rather than on an estimated basis. For periods prior to the adoption of this ASU, the Company estimated the forfeiture rate of unvested awards based on the forfeitures in the previous twelve-month period. The rate was calculated separately for awards to the board of directors/executives and all other awards. Further information regarding this change is included in Note 14, Employee Equity-Based Compensation.

The Company also has an employee stock purchase program whereby eligible employees can elect payroll deductions that are subsequently used to purchase common stock at a discounted price. There is no compensation recorded for this program as (i) the purchase discount does not exceed the issuance costs that would have been incurred to raise a significant amount of capital by a public offering, (ii) substantially all employees that meet limited employment qualifications may participate on an equitable basis, and (iii) the plan does not incorporate option features that would require compensation to be recorded.

See Note 14, Employee Equity-Based Compensation for further information.

Cost of Sales

Cost of sales consists of raw materials, depreciation, direct labor and stock-based compensation expense, manufacturing overhead, facility costs and warranty costs.

Warranty

Instruments are typically sold with a 1 year limited warranty, while kits and accessories are typically sold with a 60 day limited warranty. Accordingly, a provision for the estimated cost of the limited warranty repair is recorded at the time revenue is recognized. Our estimated warranty provision is based on our estimate of future repair events and the related estimated cost of repairs. The Company periodically assesses the adequacy of the warranty reserve and adjusts the amount as necessary. The expense incurred for these provisions is included in cost of sales on the condensed consolidated statements of operations and comprehensive loss.

Shipping and Handling

Shipping and handling costs billed to customers are included as a component of revenue. The corresponding expense incurred with third party carriers is included as a component of sales, general and administrative costs on the condensed consolidated statements of operations and comprehensive loss.

Foreign Currency Translation and Foreign Currency Transactions

The Company follows ASC 830, Foreign Currency Matters, which provides guidance on foreign currency transactions and translation of financial statements. Adjustments resulting from translating foreign functional currency financial statements into U.S. dollars are included in the foreign currency translation adjustment, within the condensed consolidated statements of operations and comprehensive loss.

The Company has assets and liabilities, primarily receivables and payables, which are denominated in currencies other than their functional currency. These balance sheet items are subject to re-measurement, the impact of which is recorded in foreign currency exchange gain or loss, within the condensed consolidated statements of operations and comprehensive loss.

9

NOTE 2. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2017, the Financial Accounting Standards Board (“FASB”) issued ASU 2017-09, Compensation—Stock Compensation (Topic 718) Scope of Modification Accounting. This amendment clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending December 31, 2018 and interim periods within that annual period. Early adoption is permitted. We are currently assessing the impact this will have on our consolidated financial statements and the timing of adoption.

In March 2017, the FASB issued ASU 2017-08, Receivable-Nonrefundable Fees and Other Costs (Topic 310-20) Premium Amortization on Purchased Callable Debt Securities. This amendment shortens the amortization period for certain callable debt securities held at a premium. Specifically, the amendment requires premiums to be amortized to the earliest call date. The amendments do not require an accounting change for securities held at a discount; the discount continues to be amortized to maturity. The guidance is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. If an entity early adopts in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The amendments should be applied on a modified retrospective basis, with a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. We are currently assessing the impact this will have on our consolidated financial statements and the timing of adoption.

In October 2016, the FASB issued ASU 2016-16, Income Taxes (Topic 740) Intra-Entity Transfers of Assets Other Than Inventory. The update amends accounting guidance for intra-entity transfers of assets other than inventory to require the recognition of income tax consequences when the transfer occurs. The update is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2017, with early adoption permitted. A modified retrospective approach should be applied. We are currently assessing the impact this will have on our consolidated financial statements and the timing of adoption.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments, which amends the guidance on measuring credit losses on financial assets (including trade accounts receivable and available for sale debt securities) held at amortized cost. Currently, an “incurred loss” methodology is used for recognizing credit losses, which delays recognition until it is probable a loss has been incurred. The amendment requires assets valued at amortized cost to be presented at the net amount expected to be collected using an allowance for credit losses. Reversal of credit losses on available-for-sale debt securities will be recorded in the current period net income. The amendment will be effective for us on January 1, 2020, with early adoption permitted. We do not anticipate this guidance will have a significant impact on our financial statements and plan to adopt on the effective date.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This replaces the existing standards relating to leases for both lessees and lessors. For lessees, the new standard requires most leases to be recorded on the balance sheet with expenses recognized much like the existing standard. For lessors, the new standard modifies the classification criteria and accounting for sales-type and direct financing leases and eliminates leveraged leases. For both lessees and lessors, the standard eliminates real estate-specific provisions, changes some of the presentation and disclosure requirements, and changes sale and leaseback criteria. The ASU is required for us on January 1, 2019, with early adoption permitted. We are currently assessing the impact this will have on our consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The standard's core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers Deferral of the Effective Date, which deferred the effective date resulting in a new effective date for us of January 1, 2018. Early adoption is permitted. FASB has issued several other ASU's which provide further guidance on Topic 606 and have the same effective date. The standard allows for either "full retrospective" adoption, meaning the standard is applied to all of the periods presented, or "modified retrospective" adoption, meaning the standard is applied only to the most current period presented in the financial statements. We will implement ASU 2014-09 and all relevant subsequently issued ASU's

on Topic 606 concurrently on January 1, 2018, and are currently evaluating the transition method. We are carefully evaluating our existing revenue recognition practices to determine the extent to which our contracts in the scope of the guidance will be affected by the new requirements. The effects may include identifying performance obligations in existing arrangements, determining the transaction price and allocating the transaction price to each separate performance obligation. We will also establish practices to determine when a performance obligation has been satisfied, and recognize revenue in accordance with the new requirements. Given limited revenues have been recognized to date, we have not yet determined the effect of the standard.

NOTE 3. FDA CLEARANCE

On February 23, 2017, the U.S. Food and Drug Administration (“FDA”) granted Accelerate’s de novo request to market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit for identification and antibiotic susceptibility testing of pathogens directly from positive blood culture samples.

Due to various factors, the Company manufactured inventory in advance of regulatory approval (pre-launch inventory).

On January 1, 2017, the regulatory review process had progressed to a point that objective and persuasive evidence of approval was sufficiently probable, and a future economic benefit existed. On January 1, 2017, the Company started capitalizing pre-launch inventory. Additional information regarding inventory is included in Item 1, Note 7, Inventory.

Prior to January 1, 2017, all pre-launch inventory was not capitalized, because a future economic benefit could not be asserted. Costs associated with the Company’s purchase of inventory were reported as research and development costs, or if the inventory was used in marketing evaluations, as sales, general and administrative costs on the consolidated statements of operations and comprehensive loss.

NOTE 4. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables represent the financial instruments measured at fair value on a recurring basis on the financial statements of the Company and the valuation approach applied to each class of financial instruments at June 30, 2017, and December 31, 2016.

	June 30, 2017 (in thousands)			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents				
Money market funds	\$46,987	\$ —	\$ —	—\$46,987
Commercial paper	—	5,386	—	5,386
Total cash and cash equivalents	46,987	5,386	—	52,373
Investments:				
Certificates of deposit	—	12,410	—	12,410
US Treasury securities	7,025	—	—	7,025
US Agency securities	—	4,499	—	4,499
Commercial paper	—	5,141	—	5,141
Asset-backed securities	—	5,026	—	5,026
Corporate notes and bonds	—	38,508	—	38,508
Total investments	7,025	65,584	—	72,609
Total assets measured at fair value	\$54,012	\$ 70,970	\$ —	—\$124,982

	December 31, 2016 (in thousands)			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Money market funds	\$ 10,970	\$ —	\$ —	—\$10,970
Investments:				

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Certificates of deposit	—	7,257	—	7,257
US Treasury securities	8,544	—	—	8,544
US Agency securities	—	4,501	—	4,501
Asset-backed securities	—	5,557	—	5,557
Corporate notes and bonds	—	32,660	—	32,660
Total investments	8,544	49,975	—	58,519
Total assets measured at fair value	\$ 19,514	\$ 49,975	\$	—\$ 69,489

Money market funds are included in cash and cash equivalents on the condensed consolidated balance sheet.

Level 1 assets are priced using quoted prices in active markets for identical assets which include money market funds and U.S. Treasury securities as these specific assets are liquid.

Level 2 available-for-sale securities are priced using quoted market prices for similar instruments or nonbinding

12

market prices that are corroborated by observable market data. The Company uses inputs such as actual trade data, benchmark yields, broker/dealer quotes, and other similar data, which are obtained from quoted market prices, independent pricing vendors, or other sources, to determine the ultimate fair value of these assets and liabilities. The Company uses such pricing data as the primary input to make its assessments and determinations as to the ultimate valuation of its investment portfolio and has not made, during the periods presented, any material adjustments to such inputs. There were no transfers between levels during the six months ended June 30, 2017.

NOTE 5. CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, investments and accounts receivable, including receivables from major customers.

The Company's main financial institution for banking operations held 70% and 57% of the Company's cash and cash equivalents as of June 30, 2017, and December 31, 2016, respectively.

NOTE 6. INVESTMENTS

The following tables summarize the Company's available-for-sale investments at June 30, 2017, and December 31, 2016:

AVAILABLE-FOR-SALE INVESTMENTS

June 30, 2017

(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	\$ 12,410	\$ —	—\$ —	\$12,410
US Treasury securities	7,041	—	(16) 7,025
US Agency securities	4,516	—	(17) 4,499
Commercial paper	5,141	—	—	5,141
Asset-backed securities	5,027	—	(1) 5,026
Corporate notes and bonds	38,547	—	(39) 38,508
Total	\$ 72,682	\$ —	—\$ (73) \$72,609

AVAILABLE-FOR-SALE INVESTMENTS

December 31, 2016

(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	\$ 7,257	\$ —	\$ —	\$7,257
US Treasury securities	8,553	1	(10) 8,544
US Agency securities	4,514	—	(13) 4,501
Asset-backed securities	5,554	3	—	5,557
Corporate notes and bonds	32,717	3	(60) 32,660
Total	\$ 58,595	\$ 7	\$ (83) \$58,519

The following table summarizes the maturities of the Company's available-for-sale securities at June 30, 2017, and December 31, 2016:

AVAILABLE-FOR-SALE INVESTMENT

MATURITIES

(in thousands)

	June 30, 2017		December 31, 2016	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in less than 1 year	\$57,292	\$57,246	\$45,391	\$45,344
Due in 1-5 years	15,390	15,363	13,204	13,175
Total	\$72,682	\$72,609	\$58,595	\$58,519

Proceeds from sales of marketable securities (including principal paydowns), for the three months ended June 30, 2017 and 2016 were \$6.5 million and \$500,000, respectively, and for the for the six months ended June 30, 2017 and 2016 were \$6.5 million and \$1.0 million, respectively. The Company determines gains and losses of marketable securities based on specific identification of the securities sold. There were no gross realized gains or losses from sales of marketable securities for the three and six months ended June 30, 2017 and 2016.

No other-than-temporary impairments are recorded as no material investment had a fair value that remained less than its cost for more than twelve months as of June 30, 2017, and there have been no other indicators of impairment. The Company does not intend to sell investments and it is more likely than not that we will not be required to sell investments before recovering the amortized cost.

Additional information regarding the fair value of our financial instruments is included in Note 4, Fair Value of Financial Instruments.

NOTE 7. INVENTORY

Inventory is stated at the lesser of cost or net realizable value, with cost determined on the first-in-first-out method. The allocation of production overhead to inventory costs is based on normal production capacity. Abnormal amounts of idle facility expense and spoilage are expensed as incurred, and not included in overhead subject to capitalization. The Company maintains provisions for excess and obsolete inventory based on management's estimates of forecasted demand and, where applicable, product expiration. The components of inventories were as follows (in thousands):

	June 30, 2017	December 31, 2016
Raw materials	\$2,768	\$ —
Work in process	372	—
Finished goods	2,580	—
Inventory, net	\$5,720	\$ —

NOTE 8. PROPERTY AND EQUIPMENT

Property and equipment are recorded at cost and consisted of the following at June 30, 2017, and December 31, 2016.

PROPERTY AND EQUIPMENT

(in thousands)

	June 30, 2017	December 31, 2016
Computer equipment	\$2,834	\$ 2,270
Technical equipment	3,080	2,427
Facilities	3,506	3,387
Instruments	885	—
Capital projects in progress	415	1,010
Total property and equipment	\$10,720	\$ 9,094
Accumulated depreciation - other	(5,876)	(4,836)
Net property and equipment	\$4,844	\$ 4,258

Depreciation expense (which includes amortization of capital lease assets) for the three months ended June 30, 2017 and 2016 was \$540,000 and \$605,000, respectively, and for the six months ended June 30, 2017 and 2016 was \$1.0 million and \$1.1 million, respectively.

NOTE 9. LICENSE AGREEMENTS AND GRANTS

National Institute of Health Grant

In February 2015, the National Institute of Health awarded Denver Health and the Company a five-year, \$5.0 million grant to develop a fast and reliable identification and categorical susceptibility test carbapenem-resistant Enterobacteriaceae directly from whole blood. The cumulative sub-award amount is \$818,000, under which the Company has invoiced a total of \$560,000, which is recorded as an offset to research and development expenses. The amounts invoiced for the three months ended June 30, 2017 and 2016 were \$0 and \$50,000, respectively, and for the six months ended June 30, 2017 and 2016 were \$3,000 and \$59,000, respectively.

Arizona Commerce Authority

In August 2012, the Company entered into a Grant Agreement (the “Grant Agreement”) with the Arizona Commerce Authority, an agency of the State of Arizona (the “Authority”), pursuant to which the Authority provided certain state and county sponsored incentives for the Company to relocate its corporate headquarters to, and expand its business within, the State of Arizona (the “Project”). Pursuant to the Grant Agreement, the Authority agreed to provide a total grant in the amount of \$1.0 million (the “Grant”) for the use by the Company in the advancement of the Project. The Grant is payable out of an escrow account in four installments, upon the achievement of the following milestones:

• Milestone 1 – Relocation of Company’s operations and corporate headquarters to Arizona and creation of 15 Qualified Jobs (as defined below).

• Milestone 2 – Creation of 30 Qualified Jobs (including Qualified Jobs under Milestone 1).

• Milestone 3 – Creation of 40 Qualified Jobs (including Qualified Jobs under Milestones 1 and 2).

•

Milestone 4 – Creation of 65 Qualified Jobs (including Qualified Jobs under Milestones 1, 2 and 3) and capital investment of at least \$4.5 million.

For purposes of the Grant Agreement, a “Qualified Job” is a job that is permanent, full-time, new to Arizona, and for which the Company pays average (across all Qualified Jobs identified by the Company in its discretion) annual wages of at least \$63,000 and offers health insurance benefits and pays at least 65% of the premiums associated with

such benefits. The amount of each installment payment will be determined in accordance with a formula specified in the Grant Agreement. The Grant Agreement also contains other customary provisions, including representations, warranties and covenants of both parties. As of June 30, 2017, the Company has collected all of the \$1.0 million in milestones. The full amount is recorded in current deferred revenue and income until the economic development provisions of the grant have been satisfied in full, as there are “claw-back” provisions which would require repayment of certain amounts received if employment levels are not sustained during the term of the arrangement. Once the “claw-back” provisions expire in January 2018, we will recognize the grant as an offset to expense. Further details are included in Note 10, Deferred Revenue and Income.

Arizona R&D Refundable Tax Credit Program

The Company received a “Certificate of Qualification” from the Authority, which allowed the Company a partial refund of research and development investments. The amounts incurred under this program are recorded as an offset to research and development expenses, and for the six months ended June 30, 2017 and 2016 were \$0 and \$1.2 million, respectively, and no amounts were incurred for three months ended June 30, 2017 and 2016, respectively. If the amount received for this program is later determined to be incorrect or invalid, the excess may need to be repaid.

NOTE 10. DEFERRED REVENUE AND INCOME

Deferred revenue consists of amounts received for products or services not yet delivered or earned. Deferred income consists of amounts received for commitments not yet fulfilled. If we anticipate that the revenue or income will not be earned within the following twelve months, the amount is reported as long-term deferred income. A summary of the balances as of June 30, 2017, and December 31, 2016, follows:

Deferred Revenue and Income

(in thousands)

	June 30, 2017	December 31, 2016
Products and services not yet delivered	\$78	\$ 35
Arizona Commerce Authority grant	1,000	—
Total current deferred revenue and income	\$1,078	\$ 35
Arizona Commerce Authority grant	—	1,000
Total long-term deferred income	\$—	\$ 1,000

We have received \$1.0 million in milestone payments from the Authority under the Grant Agreement described in Note 9, License Agreements and Grants. As of June 30, 2017, no such payments have been recognized in income, and we do not anticipate recognizing such payments as income until the “claw-back” provisions under the Grant Agreement expire in January 2018.

NOTE 11. STOCK PURCHASE

In April 2012, we entered into a Securities Purchase Agreement with Abeja Ventures, LLC pursuant to which the Company agreed, among other things, to issue a warrant to purchase shares of the Company's common stock. Further details of this agreement are included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, as filed with the SEC on February 28, 2017. As of December 31, 2016, there were warrants to purchase 415,871 shares unexercised. During the three and six months ended June 30, 2017, warrants to purchase 370,307 shares were exercised at an exercise price of \$2.00 per share. Proceeds from the exercise of such warrants totaling, \$741,000 are recorded as common stock and contributed capital in the condensed consolidated balance sheet. The remaining warrants to purchase 45,564 shares expired unexercised on June 26, 2017.

NOTE 12. PUBLIC OFFERING

On May 9, 2017, the Company published a prospectus supplement underwritten by J.P. Morgan Securities LLC, William Blair & Company, L.L.C., Piper Jaffray & Co. and BTIG, LLC ("Underwriters") offering 2.8 million shares of common stock with an option for the Underwriters to purchase up to 413,000 additional shares of common stock for a total of 3.2 million shares. The public offering price was \$28.850 per share and underwriting discounts and commissions were \$1.731 per share for net proceeds of \$27.119 per share.

The public offering was finalized and 2.8 million shares of common stock were delivered to the purchasers on or around May 15, 2017. The Underwriters partially exercised their option to purchase an additional 335,000 shares, with the sale closing on June 14, 2017, and the option as to the remaining shares expired June 15, 2017. Proceeds from the sales totaled \$89.0 million less underwriting discounts, commissions and other costs of \$5.8 million for net proceeds of \$83.2 million. The net proceeds will be used for general corporate purposes and to fund our commercialization efforts. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, technologies, product candidates or other intellectual property, although we have no present commitments or agreements to do so. Accordingly, we will retain broad discretion over the use of these proceeds.

NOTE 13. EARNINGS PER SHARE

The financial statements show basic and diluted loss per share.

The Company's net loss for the periods presented caused the inclusion of all outstanding warrants, restricted stock and options to purchase our common stock to be antidilutive. As of June 30, 2017, and December 31, 2016, there were common stock options, restricted stock units and warrants exercisable for 7,530,193 and 7,313,245 shares of common stock, respectively, which were not included in diluted loss per share as the effect was antidilutive.

NOTE 14. EMPLOYEE EQUITY-BASED COMPENSATION

The following table summarizes option activity under all plans during the six-month period ending June 30, 2017:

Stock Option Activity

	Number of Shares	Weighted Average Exercise Price per Share
Options outstanding December 31, 2016	6,857,124	7.72
Granted	1,054,561	24.54

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Forfeited	(117,338)	22.15
Exercised	(288,303)	9.29
Expired	(1)	18.07
Options Outstanding June 30, 2017	7,506,043	9.80

The table below summarizes the resulting weighted average inputs used to calculate the estimated fair value of options awarded during the periods shown below:

17

Black-Scholes Assumptions for Options
Granted

	Three Months Ended		
	June 30, 2017	June 30, 2016	
Expected term (in years)	6.12	6.20	
Volatility	75	% 85	%
Expected dividends	—	—	
Risk free interest rates	2.02	% 1.45	%
Weighted average fair value	\$ 16.80	\$ 9.66	

The following table shows summary information for outstanding options and options that are exercisable (vested) as of June 30, 2017:

Stock Option Supplemental Information

	Options Outstanding	Options Exercisable
Number of options	7,506,043	5,070,585
Weighted average remaining contractual term (in years)	6.56	5.60
Weighted average exercise price	\$ 9.80	\$ 5.73
Weighted average fair value	\$ 7.28	\$ 4.33
Aggregate intrinsic value (in thousands)	\$ 131,115	\$ 109,601

The following table summarizes restricted stock unit activity during the six-month period ending June 30, 2017:

Restricted Stock Unit (RSU) Activity

	Number of Shares	Weighted Average Grant Date Fair Value per Share
RSUs Outstanding December 31, 2016	40,250	20.91
Granted	—	—
Forfeited	—	—
Vested/released	(16,100)	20.91
RSUs outstanding June 30, 2017	24,150	20.91

The expense recognized on the Company's condensed consolidated statements of operations and comprehensive loss related to options is summarized below:

Equity-Based Compensation Expenses
(in thousands)

Three Months Ended		Six Months Ended	
June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Cost of sales	\$22	\$—	\$22	\$—
Research and development	1,166	462	1,892	664
Sales, general and administrative	3,047	1,773	5,536	3,257
Equity-based compensation expense	\$4,235	\$ 2,235	\$7,450	\$ 3,921

18

As of June 30, 2017, \$183,000 and \$27,000 of equity-based compensation expense was a component of capitalized inventory and property and equipment respectively.

As of June 30, 2017, unrecognized equity-based compensation cost related to unvested stock options and unvested restricted stock units was \$19.4 million and \$258,000 respectively. This is expected to be recognized over the years 2017 through 2022.

As discussed in Note 1, we implemented ASU 2016-09, Compensation-Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting on January 1, 2017. Pursuant to this guidance, we made a policy election to account for forfeitures as they occur rather than on an estimated basis and, therefore, equity based compensation expense for the three and six months ended June 30, 2017 has been calculated based on actual forfeitures in our condensed consolidated statements of operations and comprehensive loss, rather than our previous approach which was net of estimated forfeitures. Share-based compensation expense for the three and six months ended June 30, 2016 is recorded net of estimated forfeitures, which were based on historical forfeitures and adjusted to reflect changes in facts and circumstances, if any. This change was accounted for using the modified retrospective transition method. This election resulted in a cumulative-effect adjustment which increased our accumulated deficit and additional paid-in capital by \$655,000 for all outstanding awards as of January 1, 2017. We believe this election simplifies several aspects of the accounting for share-based payment transactions.

This new guidance requires that we record excess tax benefits and tax deficiencies related to the settlement of employee stock-based compensation to the income tax expense line item on our condensed consolidated statements of operations and comprehensive loss. The new guidance also states that previously unrecognized excess tax benefits should be recognized on a modified retrospective basis as of the beginning of the annual period of adoption. At January 1, 2017, we recorded approximately \$1.5 million of additional deferred tax assets, which are fully offset by a valuation allowance. Accordingly, the adoption of ASU 2016-09 did not result in an adjustment to retained earnings for the cumulative effect of the tax benefit of the stock compensation.

The new guidance also requires excess tax benefits to be classified as an operating activity in the statement of cash flows rather than as a financing activity. Additionally, ASU 2016-09 requires that the minimum tax withholding paid on behalf of employees for share-based awards be classified as a financing activity in the statement of cash flows. Adoption of ASU 2016-09 did not result in any adjustments to prior period disclosures on the condensed consolidated statement of cash flows.

NOTE 15. INCOME TAXES

For the six months ended June 30, 2017, the Company recorded a provision for income taxes of \$175,000, which primarily related to a profitable foreign jurisdiction without any net operating loss carryforwards. The Company's tax expense for the six months ended June 30, 2017 differs from the tax expense computed by applying the U.S. statutory tax rate to its year-to-date pre-tax loss of \$30.5 million as no tax benefits were recorded for tax losses generated in the U.S. and other foreign jurisdictions. At June 30, 2017, the Company had deferred tax assets primarily related to U.S. federal and state tax loss carryforwards. The Company provided a full valuation allowance against its deferred tax assets as future realization of such assets is not more likely than not to occur.

At June 30, 2017, the Company had gross unrecognized tax benefits of \$1.1 million. The Company is not currently under examination by taxing authorities and does not believe the amount of unrecognized tax benefits will significantly increase or decrease over the next 12 months.

NOTE 16. COMMITMENTS

Leases

The Company has entered into lease agreements, lease amendments, and lease extensions the last of which expires in 2022. Total rent expense, including common area charges was \$309,000 and \$280,000 for the three months ended June 30, 2017 and 2016, respectively, and for the six months ended June 30, 2017 and 2016 was \$625,000 and \$540,000, respectively. Future minimum lease payments under operating lease agreements are as follows:

Operating Lease Obligations

(in thousands)

Year ending December 31:

2017	\$514
2018	179
2019	96
2020	55
2021	23
Thereafter	2
Total operating lease obligations	\$869

Clinical Trial Agreements

The Company has entered into master agreements with clinical trial sites in which we typically pay a set amount for start-up costs and then pay for work performed. These agreements typically indemnify the clinical trial sites from any and all losses arising from third party claims as a result of the Company's negligence, willful misconduct or misrepresentation. The Company incurred clinical trial expense of \$18,000 and \$760,000 for the three months ended June 30, 2017 and 2016, respectively, and \$27,000 and \$1.4 million for the six months ended June 30, 2017 and 2016, respectively. The expense incurred as part of the clinical trial is included in research and development on the condensed consolidated statements of operations and comprehensive loss.

Legal Matters

On March 19, 2015, a putative securities class action lawsuit was filed against Accelerate Diagnostics, Inc., Lawrence Mehren, and Steve Reichling, Rapp v. Accelerate Diagnostics, Inc., et al., U.S. District Court, District of Arizona, 2:2015-cv-00504. The complaint alleges that we violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, by making false or misleading statements about our Accelerate Pheno™ system, formerly called the BACcel System. Plaintiff purports to bring the action on behalf of a class of persons who purchased or otherwise acquired our stock between March 7, 2014, and February 17, 2015. On June 9, 2015, Julia Chang was appointed Lead Plaintiff of the purported class. On June 23, 2015, Plaintiff filed an amended complaint alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5, by making false or misleading statements or omissions about our ID/AST System and by allegedly employing schemes to defraud. Plaintiff sought certification of the action as a class action, compensatory damages for the class in an unspecified amount, legal fees and costs, and such other relief as the court may order. Defendants moved to dismiss the amended complaint on July 21, 2015. The Court granted the motion and dismissed the case with prejudice on January 28, 2016. On February 26, 2016, Plaintiff filed a notice of appeal with the United States Court of Appeals for the Ninth Circuit, which challenges the dismissal of the amended complaint. Chang v. Accelerate Diagnostics, Inc., et al., No. 2:15-CV-00504-SPL (9th Cir. filed Feb. 26, 2016). The appeal has been fully briefed and is scheduled for argument in September 2017.

NOTE 17. SEGMENTS

The Company operates as one operating segment. Operating segments are defined as components of an enterprise for which separate financial information is evaluated regularly by the chief operating decision maker, who is the chief executive officer, in deciding how to allocate resources and assessing performance. The Company's business operates in one operating segment because the Company's chief operating decision maker evaluates the Company's financial information and resources and assesses the performance of these resources on a consolidated basis. Since the Company operates in one operating segment, all required financial segment information can be found in the consolidated financial statements.

NOTE 18. RELATED PARTY TRANSACTIONS

In June 2016, the Company recorded a net amount of \$866,000 related to the recovery of short-swing profits under Section 16(b) of the Securities Exchange Act of 1934, as amended. The Company recognized these related party proceeds as an increase to contributed capital on the condensed consolidated balance sheet.

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

Introductory Note

Except as otherwise indicated by the context, references in this Quarterly Report on Form 10-Q (this "Form 10-Q") to the "Company," "Accelerate," "we," "us" or "our" are references to the combined business of Accelerate Diagnostics, Inc.

Forward-Looking Statements

This Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Company intends that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements, which can be identified by the use of words such as "may," "will," "expect," "anticipate," "estimate," or "continue," or variations thereon or comparable terminology, include the plans and objectives of management for future operations, including plans and objectives relating to the products and future economic performance of the Company. In addition, all statements other than statements of historical facts that address activities, events, or developments the Company expects, believes, or anticipates will or may occur in the future, and other such matters, are forward-looking statements.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. These forward-looking statements are based on assumptions that the Company will retain key management personnel, the Company will be successful in the commercialization of the Accelerate Pheno™ system, the Company will obtain sufficient capital to commercialize the Accelerate Pheno™ system and continue development of complementary products, the Company will be able to protect its intellectual property, the Company's ability to respond to technological change, that the Company will accurately anticipate market demand for the Company's products and that there will be no material adverse change in the Company's operations or business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of the Company. Although the Company believes that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate and, therefore, there can be no assurance that the results contemplated in forward-looking statements will be realized. We

undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") summarizes the significant factors affecting our results of operations, liquidity, capital resources and

21

contractual obligations. The following discussion and analysis should be read in conjunction with the Company's unaudited condensed consolidated financial statements and related notes included elsewhere herein. Certain information contained in the discussion and analysis set forth below and 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. The Company's future operating results may be affected by various trends and factors which are beyond the Company's control. These include, among other factors, general public perception of issues and solutions, and other uncertain business conditions that may affect the Company's business. The Company cautions the reader that a number of important factors discussed herein, and in other reports filed with the SEC including but not limited to the risks in the section entitled "Risk Factors" in its Annual Report on Form 10-K for the period ended December 31, 2016, could affect the Company's actual results and cause actual results to differ materially from those discussed in forward-looking statements.

Our MD&A is composed of the following sections: Overview, Changes in Results of Operations, Capital Resources and Liquidity and Off-Balance Sheet Arrangements. All amounts have been rounded to the nearest thousand unless otherwise indicated.

Overview

Accelerate Diagnostics, Inc. is an in vitro diagnostics company dedicated to providing solutions that improve patient outcomes and lower healthcare costs through the rapid diagnosis of serious infections. Microbiology laboratories are in need of new tools to address what the U.S. Centers for Disease Control and Prevention calls one of the most serious healthcare threats of our time, antibiotic resistance. A significant contributing factor to the rise of resistance is the overuse and misuse of antibiotics, which is exacerbated by a lack of timely diagnostic results. The delay of these results is often due to the reliance by microbiology laboratories on traditional culture-based tests that often take two to three days to complete. Our technology platform is built to address these challenges by delivering significantly faster and accurate testing of infectious pathogens in various patient sample types.

Since 2004, we have focused our efforts on research into and the development of an innovative rapid diagnostic platform, the Accelerate Pheno™ system, intended for the rapid diagnosis of infectious pathogens. Our goal is to reduce the failure rate of initial antibiotic drug therapy by shortening lab turnaround time to hours rather than the two to three days now required to deliver identification and susceptibility results.

The Accelerate Pheno™ system utilizes genotypic technology to identify, or "ID," infectious pathogens and phenotypic technology to conduct antibiotic susceptibility testing, or "AST," which determines whether live bacterial or fungal cells are resistant or susceptible to a particular antimicrobial agent. The Accelerate PhenoTest™ BC Kit, provides ID and AST results for patients suspected of bacteremia or fungemia, both life-threatening conditions with high morbidity and mortality risk. The Accelerate PhenoTest™ BC Kit is a highly multiplexed panel targeting over 80% of the routine and significant pathogens causing blood stream infections and over 90% of the antibiotics useful in treating those pathogens.

On June 30, 2015, we declared our conformity to the European In Vitro Diagnostic Directive 98/79 EC and applied a CE Mark to the Accelerate Pheno™ system and the Accelerate PhenoTest™ BC Kit for in vitro diagnostic use. On February 23, 2017, the FDA granted our de novo request to market our Accelerate Pheno™ system and Accelerate PhenoTest™ BC Kit in the United States. The Accelerate PhenoTest™ BC kit includes 140 assays for both identification and susceptibility testing, of which 116 were cleared by the FDA and 24 assays are available in an RUO only mode of the software.

Changes in Results of Operations: Three and six months ended June 30, 2017 compared to three and six months ended June 30, 2016

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Three Months Ended				Six Months Ended						
June 30,				June 30,						
(in thousands)				(in thousands)						
2017	2016	\$	%	2017	2016	\$	%			
		Change	Change			Change	Change			
Net sales	\$699	\$20	\$679	3,395	%	\$1,230	\$183	\$1,047	572	%

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

For the three and six months ended June 30, 2017, total revenues increased due to sales of Accelerate Pheno™ systems and Accelerate PhenoTest™ BC kits.

	Three Months Ended June 30, (in thousands)				Six Months Ended June 30, (in thousands)			
	2017	2016	\$ Change	% Change	2017	2016	\$ Change	% Change
Cost of sales	\$ 135	\$ —	\$ 135	100 %	\$ 161	\$ —	\$ 161	100 %
Gross Profit	\$ 564	\$ 20	\$ 544	2,720 %	\$ 1,069	\$ 183	\$ 886	484 %

For the three and six months ended June 30, 2017, cost of sales and gross profit increased as a result of the Company capitalizing inventory in connection with the FDA granting Accelerate's de novo request to market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit.

Inventory without a cost basis was sold to customers during the three and six months ended June 30, 2017. This inventory was comprised of pre-launch inventory previously not capitalized, and expensed in a previous period. Cost of sales associated with this inventory during the three and six months ended June 30, 2017, would have been an additional \$228,000 and \$407,000, respectively.

	Three Months Ended June 30, (in thousands)				Six Months Ended June 30, (in thousands)			
	2017	2016	\$ Change	% Change	2017	2016	\$ Change	% Change
Research and development	\$ 5,527	\$ 8,425	\$(2,898)	(34) %	\$ 9,815	\$ 16,100	\$(6,285)	(39) %

Research and development expenses for the three and six months ended June 30, 2017, decreased as compared to the same periods in the prior year as a result of clinical trial expenses not recurring in the current periods. Additionally, on January 1, 2017, the regulatory review process had progressed to a point that objective and persuasive evidence of approval was sufficiently probable, and a future economic benefit existed for the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit. As a result, the Company started capitalizing pre-launch inventory for the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit on January 1, 2017. Prior to January 1, 2017, all pre-launch inventory was not capitalized, because a future economic benefit couldn't be asserted.

Pre-launch inventory not capitalized in accordance with U.S. GAAP, which included instruments and consumables charged to research and development were \$76,000 and \$1.6 million for the three months ended June 30, 2017 and 2016, respectively, and \$151,000 and \$3.1 million for the six months ended June 30, 2017 and 2016, respectively.

Research and development expenses include non-cash equity-based compensation of \$1.2 million and \$462,000 for the three months ended June 30, 2017 and 2016, respectively, and \$1.9 million and \$664,000 for the six months ended June 30, 2017 and 2016, respectively. The increase in non-cash equity-based compensation was primarily driven by an increase in the number of employees and stock option grants.

	Three Months Ended June 30, (in thousands)				Six Months Ended June 30, (in thousands)			
	2017	2016	\$ Change	% Change	2017	2016	\$ Change	% Change

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Sales, general and administrative \$11,460 \$9,484 \$1,976 21 % \$21,988 \$17,144 \$4,844 28 %

Sales, general and administrative expenses for the three and six months ended June 30, 2017, increased due to an increase in salaries and related expenses as we ramp up our sales and marketing operations globally.

23

Pre-launch inventory not capitalized in accordance with U.S. GAAP, which included instruments and consumables charged to sales, general and administrative expenses were \$12,000 and \$748,000 for the three months ended June 30, 2017 and 2016, respectively, and \$29,000 and \$1.3 million for the six months ended June 30, 2017 and 2016, respectively.

Sales, general and administrative expenses include non-cash equity-based compensation of \$3.0 million and \$1.8 million for the three months ended June 30, 2017 and 2016, respectively, and \$5.5 million and \$3.3 million for the six months ended June 30, 2017 and 2016, respectively. The increase in non-cash equity-based compensation was primarily driven by an increase in the number of employees and stock option grants.

Three Months Ended June 30, (in thousands)				Six Months Ended June 30, (in thousands)			
2017	2016	\$ Change	% Change	2017	2016	\$ Change	% Change
Loss from operations	\$(16,423)	\$(17,889)	\$ 1,466 (8)%	\$(30,734)	\$(33,061)	\$ 2,327 (7)%	

For the three and six months end June 30, 2017, loss from operations decreased as a result of the Company capitalizing inventory in connection with the FDA granting Accelerate's de novo request to market the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit.

Loss from operations include non-cash equity-based compensation of \$4.2 million and \$2.2 million for the three months ended June 30, 2017 and 2016, respectively, and \$7.5 million and \$3.9 million for the six months ended June 30, 2017 and 2016, respectively. This loss and further losses are anticipated and was the result of our continued investments in research and development, expanded laboratory and operational space, increased employee headcount and other factors as we develop and commercialize the Company's products.

Three Months Ended June 30, (in thousands)				Six Months Ended June 30, (in thousands)			
2017	2016	\$ Change	% Change	2017	2016	\$ Change	% Change
Total other income	\$ 141	\$ 23	\$ 118 513 %	\$ 252	\$ 121	\$ 131 108 %	

Other non-operating income during the three and six months ended June 30, 2017, increased due to an increase in interest and dividends, which were offset by other components of other income.

Three Months Ended June 30, (in thousands)				Six Months Ended June 30, (in thousands)			
2017	2016	\$ Change	% Change	2017	2016	\$ Change	% Change
Provision from income taxes	\$(175)	\$	-(175) 100 %	\$(175)	\$	-(175) 100 %	

Due to net losses incurred, we have only recorded tax provisions related to tax liabilities generated by our foreign subsidiaries.

Capital Resources and Liquidity

Our primary source of liquidity has been from sales of shares of common stock. As of June 30, 2017, the Company had \$135.2 million in cash and cash equivalents and available-for-sale securities, an increase of \$57.5 million from \$77.8 million at December 31, 2016. The primary reason for the change in these assets was a public offering that occurred during the six months ended June 30, 2017.

The Company is subject to a Lease Agreement with Pima County of Arizona. The future minimum lease payments under the Lease Agreement are included in Item 1, Note 16, Commitments.

As of June 30, 2017, management believes that current cash balances will be more than sufficient to fund our capital and liquidity needs for the next twelve months.

The following summarizes selected items in the Company's consolidated statements of cash flows for the six months ended June 30, 2017, and 2016:

Cash Flow Summary
(in thousands)

	Six Months Ended		
	June 30, 2017	June 30, 2016	Increase (Decrease)
Net cash used in operating activities	\$(28,091)	\$(28,087)	\$ (4)
Net cash used in investing activities	(16,014)	(55,238)	39,224
Net cash provided by financing activities	87,272	259	87,013

The net cash used in operating activities was \$28.1 million and \$28.1 million for the six months ended June 30, 2017, and 2016, respectively. These losses are the result of our continued investments in research and development, expanded laboratory and operational space, increased employee headcount and other factors as we develop and prepare to commercialize the Company's products.

The net cash used in investing activities was \$16.0 million for the six months ended June 30, 2017, and is primarily comprised of purchases of available-for-sales securities, offset by sales and maturities of available-for-sale securities. Net cash used in investing activities was \$55.2 million for the six months ended June 30, 2016, and is primarily comprised of purchases of available-for-sale investments, offset by sales and maturities of available-for-sale investments.

The net cash provided by financing activities was \$87.3 million for the six months ended June 30, 2017, and is primarily comprised of proceeds from a public offering. The net cash provided by financing activities was \$259,000 for the six months ended June 30, 2016, and was primarily comprised of the recovery of short swing profits from related parties, offset by common stock issuance cost.

Our primary use of capital has been for development and commercialization of the Accelerate Pheno™ system. We believe our capital requirements will continue to be met with our existing cash balance and those provided under grants, exercises of warrants and stock options and/or additional issuance of equity or debt securities. However, if capital requirements vary materially from those currently planned, we may require additional capital sooner than expected. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to us, if at all. Additional issuances of equity or convertible debt securities will result in dilution to our current common stockholders.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of June 30, 2017.

Item 3. Quantitative and Qualitative Disclosures

Interest Rate Risk

Our investment portfolio is exposed to market risk from changes in interest rates. The fair market value of fixed rate securities may be adversely impacted by fluctuations in interest rates while income earned on floating rate securities may decline as a result of decreases in interest rates. We have historically maintained a relatively short average maturity for our investment portfolio, and we believe a hypothetical 100 basis point adverse move in interest

25

rates along the entire interest rate yield curve would change the fair value of our interest-sensitive financial instruments by approximately \$521,000.

Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We attempt to ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. 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 securities that management believes to be of high credit quality. Further information regarding our investments is included in Item 1, Note 6, Investments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of the Company's management, the Company's Principal Executive Officer and Principal Financial Officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of June 30, 2017, to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

During the six months ended June 30, 2017, in connection with the Company's preparations to commercialize the Accelerate Pheno™ system and Accelerate PhenoTest™ BC Kit the Company implemented additional internal controls related to revenue recognition and inventory.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On March 19, 2015, a putative securities class action lawsuit was filed against Accelerate Diagnostics, Inc., Lawrence Mehren, and Steve Reichling, Rapp v. Accelerate Diagnostics, Inc., et al., U.S. District Court, District of Arizona, 2:2015-cv-00504. The complaint alleges that we violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5, by making false or misleading statements about our Accelerate Pheno™ system, formerly called the BACcel System. Plaintiff purports to bring the action on behalf of a class of persons who purchased or otherwise acquired our stock between March 7, 2014, and February 17, 2015. On June 9, 2015, Julia Chang was appointed Lead Plaintiff of the purported class. On June 23, 2015, Plaintiff filed an amended complaint alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5, by making false or misleading statements or omissions about our ID/AST System and by allegedly employing schemes to defraud. Plaintiff sought certification of the action as a class action, compensatory damages for the class in an unspecified amount, legal fees and costs, and such other relief as the court may order. Defendants moved to dismiss the amended complaint on July 21, 2015. The Court granted the motion and dismissed the case with prejudice on January 28, 2016. On February 26, 2016, Plaintiff filed a notice of appeal with the United States Court of Appeals for the Ninth Circuit, which challenges the dismissal of the amended complaint. Chang v. Accelerate Diagnostics, Inc., et al., No. 2:15-CV-00504-SPL (9th Cir. filed Feb. 26, 2016). The appeal has been fully briefed and is scheduled for argument in September 2017.

Item 1A. Risk Factors

There have been no material changes to the risk factors that were disclosed in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

26

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description	Filing Information
3.1.1	Certificate of Amendment to Certificate of Incorporation of Registrant	Incorporated by reference to Exhibit A to the Registrant's Definitive Information Statement on Schedule 14C filed on July 12, 2013
3.1.2	Certificate of Amendment to Certificate of Incorporation of Registrant	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on March 15, 2016
3.2	Bylaws of Registrant	Incorporated by reference to Exhibit 3.2 filed with the Registrant's Annual Report on Form 10-K for the fiscal year ended July 31, 2012
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2		Filed herewith

Edgar Filing: Accelerate Diagnostics, Inc - Form 10-Q

Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32 Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 Filed herewith

101** XBRL Instance Document

101** XBRL Taxonomy Extension Schema Document

101** XBRL Taxonomy Calculation Linkbase Document

101** XBRL Taxonomy Extension Definition Linkbase Document

101** XBRL Taxonomy Label Linkbase Document

101** XBRL Taxonomy Presentation Linkbase Document

** Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data

files fail to comply with the submission requirements. Users of this data are advised that, pursuant to Rule 406T, these interactive data files are deemed not filed and otherwise are not subject to liability.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACCELERATE DIAGNOSTICS, INC.

August 7, 2017 /s/ Lawrence Mehren

Lawrence Mehren
President and Chief Executive Officer
(Principal Executive Officer)

August 7, 2017 /s/ Steve Reichling

Steve Reichling
Chief Financial Officer
(Principal Financial and Accounting Officer)