

Accelerate Diagnostics, Inc
Form 10-Q
May 10, 2016

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 March 31, 2016

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)

Registrant's telephone number, including area code:
(520) 365-3100

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.

Large accelerated filer
Accelerated filer
Non-accelerated file (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

As of May 5, 2016 there were 51,218,017 shares of the registrant's common stock outstanding.

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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ACCELERATE DIAGNOSTICS, INC.
 CONDENSED CONSOLIDATED
 BALANCE SHEET
 Unaudited
 (in thousands, except per share data)

	March 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$72,033	\$120,585
Investments	44,630	11,839
Trade accounts receivable	77	77
Prepaid expenses	2,312	1,638
Other current assets	1,224	12
Total current assets	120,276	134,151
Property and equipment, net	5,218	5,016
Intellectual property, net	154	157
Total assets	\$125,648	\$139,324
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$2,673	\$2,623
Accrued liabilities	2,256	2,543
Deferred revenue and income	58	127
Capital lease obligations	—	13
Total current liabilities	4,987	5,306
Long-term deferred income	1,000	1,000
Total liabilities	5,987	6,306
Commitments and contingencies see Note 11, Commitments	—	—
Stockholders' equity:		
Common stock, \$0.001 par value;		
75,000,000 common shares authorized with 51,199,017 shares issued and outstanding on March 31, 2016 and 55,000,000 authorized with 51,191,184 shares issued and outstanding on December 31, 2015	51	51
5,000,000 preferred shares authorized and none outstanding as of March 31, 2016 and December 31, 2015	—	—
Contributed capital	245,608	243,894
Accumulated deficit	(125,989)	(110,915)
Accumulated other comprehensive (loss)	(9)	(12)
Total stockholders' equity	119,661	133,018
Total liabilities and stockholders' equity	\$125,648	\$139,324
See accompanying notes to financial statements.		

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

Unaudited

(in thousands, except per share data)

	Three Months Ended	
	March 31, 2016	March 31, 2015
Revenues:		
Product sales	\$ 143	\$—
Licensing and royalty revenues	20	14
Total revenues	163	14
Costs and expenses:		
Research and development	7,353	5,730
Sales, general and administrative	7,437	2,867
Amortization	3	2
Depreciation	542	326
Total costs and expenses	15,335	8,925
Loss from operations	(15,172)	(8,911)
Interest expense and other	—	(1)
Foreign currency exchange gain	44	—
Interest and dividend income	54	15
Total other income	98	14
Net loss	\$(15,074)	\$(8,897)
Basic and diluted net loss per share	\$(0.29)	\$(0.20)
Weighted average shares outstanding	51,196	44,650
Other comprehensive loss:		
Net loss	\$(15,074)	\$(8,897)
Net unrealized gain on available-for-sale investments	52	5
Foreign currency translation adjustment	(49)	—
Comprehensive loss	\$(15,071)	\$(8,892)

See accompanying notes to financial statements.

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

	Three Months Ended	
	March 31, 2016	March 31, 2015
Cash flows from operating activities:		
Net loss	\$(15,074)	\$(8,897)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	542	326
Amortization of intangible assets	3	2
Amortization of investment discount	37	47
Equity-based compensation	1,686	1,657
(Increase) in assets:		
Accounts receivable	—	(14)
Prepaid expense and other	(518)	(104)
Other current assets	(1,212)	(647)
Increase (decrease) in liabilities:		
Accounts payable	494	166
Accrued liabilities	906	501
Deferred revenue and income	(69)	—
Net cash used in operating activities	(13,205)	(6,963)
Cash flows from investing activities:		
Purchases of equipment	(1,681)	(1,198)
Purchase of available-for-sale securities	(36,718)	(4,503)
Sales of available-for-sale securities	500	107
Maturity of available-for-sale securities	3,400	6,355
Net cash provided by (used in) investing activities	(34,499)	761
Cash flows from financing activities:		
Exercise of warrants and options	28	66
Common stock issuance costs	(814)	—
Payments on capital lease obligations	(13)	(36)
Net cash provided by (used in) financing activities	(799)	30
Effect of exchange rate on cash	(49)	—
Decrease in cash and cash equivalents	(48,552)	(6,172)
Cash and cash equivalents, beginning of period	120,585	53,563
Cash and cash equivalents, end of period	\$72,033	\$47,391

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, 2015, as filed with the SEC on March 9, 2016.

The condensed consolidated balance sheet as of December 31, 2015 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, 2016 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.

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, certificates of deposit, and commercial paper. 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.

Inventory

The Company currently purchases and produces inventory prior to U.S. Food and Drug Administration (“FDA”) or other regulatory agency approval. We do not believe probable future economic benefit can be asserted prior to the completion of 510(k) clearance. Accordingly, the Company does not capitalize pre-launch inventory prior to the receipt of 510(k) clearance, unless the regulatory review process has progressed to a point that objective and persuasive evidence of regulatory approval is sufficiently probable, and future economic benefit can be asserted. Inventory is reported as research and development costs, or if used in marketing evaluations reported to sales, general and administrative costs on the condensed consolidated statements of operations and comprehensive loss.

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 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.

Deferred revenue represents amounts received but not yet earned under existing agreements.

Revenue from operations includes product sales, principally of ACCELERATE PHENO™ Systems formerly referred to as Accelerate ID/AST systems. 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.

Warranty

A limited warranty of less than a year is covered under selected contracts. 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 failure rates and the related estimated cost of repair. 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 sales, general and administrative 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, within the condensed consolidated statements of operations and comprehensive loss.

NOTE 2. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-10, Revenue from Contracts with Customers (Topic 606) Identifying Performance Obligations and Licensing. The amendments in this ASU do not change the core principle of the guidance described below in ASU

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2014-09 but clarify the aspects regarding the identification of performance obligations and the licensing implementation guidance. This ASU will be implemented in conjunction with ASU 2014-09.

In March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers (Topic 606) Principal versus Agent Considerations. The amendments in this ASU do not change the core principle of the guidance described below in ASU 2014-09 but clarify the implementation guidance on principal versus agent considerations. This ASU will be implemented in conjunction with ASU 2014-09.

In March 2016, the FASB issued ASU 2016-09, Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting. This guidance requires the recognition of the income tax effects of awards in the income statement when the awards vest or are settled, thus eliminating additional paid in capital pools. The guidance also allows for the employer to repurchase more of an employee's shares for tax withholding purposes without triggering liability accounting. In addition, the guidance allows for a policy election to account for forfeitures as they occur rather than on an estimated basis. The guidance is effective for us on January 1, 2017 with early adoption permitted. We are currently evaluating the impact of this guidance on our financial statements and plan to adopt on the effective date.

In February 2016, the FASB issued ASU 2016-02, Leases. 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 and the timing of adoption.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers, 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. We are carefully evaluating our existing revenue recognition practices to determine whether any 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. 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 of January 1, 2018 for us. We are permitted to adopt early but not before the original effective date of January 1, 2017. 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 are currently evaluating the transition method and the adoption date that will be elected.

NOTE 3. 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 March 31, 2016 and December 31, 2015.

	March 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 Equivalents:				
Certificates of deposit	\$441	\$ —	\$	—\$441
Money market funds	39,328	—	—	39,328
Investments:				
Certificates of deposit	4,110	—	—	4,110
US Treasury securities	14,609	—	—	14,609
US Agency securities	—	4,503	—	4,503
Corporate notes, bonds and commercial paper	—	15,322	—	15,322
Asset-backed securities	—	6,086	—	6,086
Total assets measured at fair value	\$58,488	\$ 25,911	\$	—\$84,399

	December 31, 2015 (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 Equivalents:				
Money market funds	\$5,221	\$ —	\$	—\$5,221
Investments:				
Corporate notes and bonds	—	9,332	—	9,332
Asset-backed securities	—	2,507	—	2,507
Total assets measured at fair value	\$5,221	\$ 11,839	\$	—\$17,060

Level 1 assets are priced using quoted prices in active markets for identical assets which include cash accounts, money market funds, certificates of deposit 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 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 three months ended March 31, 2016.

NOTE 4. 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 71% and 100% of the Company's cash and cash equivalents as of March 31, 2016 and December 31, 2015, respectively.

The Company extends credit to domestic and international clients in various industries. Exposure to losses on accounts receivable is principally dependent on each client's financial position. At March 31, 2016 and December 31, 2015, \$60,000 or 78% and \$50,000 or 66%, respectively, of the Company's outstanding receivable balance was with Denver Health Medical Center ("Denver Health"). See Note 7, License Agreements and Grants for more information.

For the three months ended March 31, 2016 100% of product sales was with Denver Health.

NOTE 5. INVESTMENTS

The following tables summarize the Company's available-for-sale investments at March 31, 2016 and December 31, 2015 (in thousands):

AVAILABLE-FOR-SALE INVESTMENTS

March 31, 2016
(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	\$ 6,078	\$ 8	\$ —	\$6,086
US government & agency securities	19,098	15	(1)	19,112
Corporate notes, bonds and commercial paper	15,303	22	(3)	15,322
Certificates of deposit	4,110	—	—	4,110
Total	\$ 44,589	\$ 45	\$ (4)	\$44,630

AVAILABLE-FOR-SALE INVESTMENTS

December 31, 2015
(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	\$ 2,510	\$ —	\$ (3)	\$2,507
Corporate notes and bonds	9,341	1	(10)	9,332
Total	\$ 11,851	\$ 1	\$ (13)	\$11,839

The following table summarizes the maturities of the Company's available-for-sale securities at March 31, 2016 and December 31, 2015 (in thousands):

AVAILABLE-FOR-SALE INVESTMENT MATURITIES

(in thousands)

	March 31, 2016	December 31, 2015
	Amortized Cost	Amortized Cost
	Fair Value	Fair Value

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Due in less than 1 year	\$ 14,149	\$ 14,156	\$ 11,851	\$ 11,839
Due in 1-5 years	29,435	29,467	—	—
Due in 6-10 years	1,005	1,007	—	—
Total	\$ 44,589	\$ 44,630	\$ 11,851	\$ 11,839

Proceeds from sales of marketable securities (including principal paydowns) for the three months ended

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March 31, 2016 and 2015, were \$500,000 and \$107,000 respectively. The Company determines gains and losses of marketable securities based on specific identification of the securities sold. There were no gross realized gains and losses from sales of marketable securities for the three months ended March 31, 2016 and 2015.

No other-than-temporary impairments are recorded as no investments had a fair value that remained less than its cost for more than twelve months as of March 31, 2016 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.

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment are recorded at cost and consisted of the following at March 31, 2016 and December 31, 2015 (in thousands).

PROPERTY AND EQUIPMENT

(in thousands)

	March 31, 2016	December 31, 2015
Computer equipment	\$1,989	\$1,877
Technical equipment	2,024	1,806
Facilities	3,254	1,772
Capital projects in progress	1,115	2,183
Total property and equipment	\$8,382	\$7,638
Accumulated depreciation - other	(3,164)	(2,622)
Net property and equipment	\$5,218	\$5,016

Depreciation expense (which includes amortization of capital lease assets) for the three months ended March 31, 2016 and 2015 was \$542,000 and \$326,000, respectively.

NOTE 7. LICENSE AGREEMENTS AND GRANTS

Defense Medical Research and Development Program

In May 2012, the Company and Denver Health were notified that the Defense Medical Research and Development Program (“DMRDP”) recommended \$2.0 million of funding for a proposed 35-month project. The joint proposal became the sole recipient under the Military Infectious Diseases Applied Research Award program for rapid detection of serious antibiotic-resistant infections. The project will apply the ACCELERATE PHENO™ System to wound infections and other serious infections secondary to trauma. The Company has invoiced a cumulative total of \$558,000 under this grant which is recorded as an offset to research and development expenses. The amount invoiced for the three months ended March 31, 2016 and 2015 was \$0 and \$68,000, respectively. The period of performance of this grant was extended through September 2016.

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. In June 2015, the Company executed a subaward agreement with Denver Health for the services provided as part of this grant which covered the period of February 15, 2015 through

January 31, 2016 and totaled \$689,000. The amounts invoiced for the three months ended March 31, 2016 and 2015 were \$9,000 and \$0, 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 March 31, 2016, the Company has collected all of the \$1.0 million in milestones. The full amount is recorded in long-term deferred 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 8, Deferred Revenue and Income.

Arizona R&D Refundable Tax Credit Program

The Company has applied for and met the program requirements to receive a "Certificate of Qualification" from the Arizona Commerce Authority ("Authority") which allows the Company to be eligible for a partial refund of research and development investments ("Arizona R&D Refundable Tax Credit Program"). The amounts incurred under this program are recorded as an offset to research and development expenses, and for the three months ended March 31, 2016 and 2015 were \$1.2 million and \$647,000, respectively. The refund for the 2014 tax year has been received and the amount for the 2015 tax year remains outstanding and is recorded as other current assets on the Condensed Consolidated Balance Sheets. If the amount received for this program is later determined to be incorrect or invalid, the excess may need to be repaid.

NOTE 8. 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 March 31, 2016 and December 31, 2015 follows (in thousands):

Deferred Revenue and Income
(in thousands)

	March 31, 2016	December 31, 2015
Fisher agreement	\$ 13	\$ 13
Products not yet delivered	45	114
Total current deferred revenue and income	\$ 58	\$ 127
Arizona Commerce Authority grant	\$ 1,000	\$ 1,000
Total long-term deferred income	\$ 1,000	\$ 1,000

We have received \$1.0 million in milestone payments from the Arizona Commerce Authority under the Grant Agreement described in Note 7, License Agreements and Grants. As of March 31, 2016, 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 9. EARNINGS PER SHARE

The financial statements show basic earnings (loss) per share.

The Company’s net loss for the periods presented caused the inclusion of all outstanding warrants, restricted stocks and options to purchase our Common Stock to be antidilutive. As of March 31, 2016, and December 31, 2015, there were Common Stock options, restricted stock units and warrants exercisable for 7,371,907 and 6,778,580 shares of Common Stock, respectively, which were not included in diluted loss per share as the effect was antidilutive.

NOTE 10. EMPLOYEE AND CONSULTANT EQUITY-BASED COMPENSATION

The following table summarizes option activity under all plans during the three-month period ending March 31, 2016:

Stock Option Activity

	Number of Shares	Weighted Average Exercise Price per Share
Options Outstanding January 1, 2016	6,167,170	6.91
Granted	700,161	13.02
Forfeited	(98,001)	20.65
Exercised	(8,833)	3.15
Options Outstanding March 31, 2016	6,760,497	7.34

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

Black-Scholes Assumptions for Options Granted

	Three Months Ended 3/31/2016		3/31/2015
Expected term (in years)	6.48	8.19	
Volatility	87%	89%	
Expected dividends	—	—	
Risk free interest rates	1.61%	1.78%	
Weighted average fair value	\$9.68	\$17.46	

The following table shows summary information for outstanding options, options that are exercisable (vested) and outstanding options that are either vested or expected to vest as of March 31, 2016:

Stock Option Supplemental Information

	Options Outstanding	Options Exercisable	Options Vested and Expected to Vest
Number of options	6,760,497	4,051,836	6,587,029
Weighted average remaining contractual term (in years)	7.23	6.64	7.18
Weighted average exercise price	\$ 7.34	\$ 4.93	\$ 7.16
Weighted average fair value	\$ 5.70	\$ 3.71	\$ 5.55
Aggregate intrinsic value (in thousands)	\$ 37,463	\$ 33,324	\$ 37,845

The following table summarizes restricted stock unit activity during the three-month period ending March 31, 2016:

Restricted Stock Unit (RSU) Activity

	Number of Shares	Weighted Average Grant Date Fair Value per Share
RSU's Outstanding January 1, 2016	40,250	20.91
Granted	—	—
Forfeited	—	—
Vested/released	—	—
RSU's outstanding March 31, 2016	40,250	20.91

The expense recognized on Company's Statements of Operations and Comprehensive Loss related to options is summarized below (in thousands):

Equity-Based Compensation Expenses
(in thousands)

	Three Months Ended 3/31/2016	3/31/2015
Research and development	\$202	\$ 688

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Sales, general and administrative 1,484,969
Equity-based compensation expense 1,686,657

As of March 31, 2016, unrecognized equity-based compensation cost related to unvested stock options and unvested restricted stock units was \$13.2 million and \$579,000 respectively. This is expected to be recognized over the years 2016 through 2021.

NOTE 11. COMMITMENTS

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Leases

The Company has entered into lease agreements, lease amendments, and lease extensions ("Lease Agreements") for office, laboratory and manufacturing space located in Tucson, Arizona and Europe, the last of which expires in 2018. Total rent expense, including common area charges was \$260,000 and \$115,000 for the three months ended March 31, 2016 and 2015, respectively. Future minimum lease payments under operating lease agreements are as follows (in thousands):

Operating Lease Obligations

(in thousands)

Year ending December 31:

2016	\$740
2017	173
2018	4
2019	—
Thereafter	—
Total operating lease obligations	\$917

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 \$664,000 and \$180,000 for the three months ended March 31, 2016 and 2015, 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 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 ID/AST 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 seeks 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, which motion was pending before the Court as of December 31, 2015. Subsequently, 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. Plaintiff challenges the dismissal of the amended complaint. Plaintiff's opening brief, if she does not seek additional time, is due June 6, 2016.

NOTE 12. 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.

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.

The ACCELERATE PHENO™ System, is also referred to as the "ID/AST System" or "Accelerate ID/AST System".

Forward-Looking Statements

This Quarterly Report on 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 development of the ACCELERATE PHENO™ System, the Company will obtain sufficient capital to complete the development and required clinical trials of the ACCELERATE PHENO™ System, 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 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, 2015 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 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 ID/AST 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 antibiotic. The ID/AST blood culture assay kit, which we refer to as the ACCELERATE PHENOTEST™ BC Kit, is being investigated for its ability to provide ID and AST results for patients suspected of bacteremia or fungemia, both life-threatening conditions with high morbidity and mortality risk. The Blood Culture Assay Kit is a highly multiplexed panel targeting more than 150 individual assays which have the potential to support clinicians in prescribing optimal antibiotic therapy for patients in this critical condition. The final number of assays included in the Blood Culture Assay Kit will depend on the results of our clinical trial to support marketing authorization from the FDA and FDA review of each individual assay for marketing clearance. This panel is designed to cover 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 ID/AST System and the Blood Culture Assay Kit for in vitro diagnostic use.

We anticipate commercializing the Accelerate ID/AST System in the United States, subject to the successful completion of the U.S. registration trial and submission to and clearance by the U.S. Food and Drug Administration (“FDA”) of our de novo 510(k) for the ID/AST System, which could occur as early as the third quarter of 2016.

Changes in Results of Operations: Three months ended March 31, 2016 compared to three months ended March 31, 2015

During the three months ended March 31, 2016, total revenues were \$163,000 as compared to \$14,000 during the three months ended March 31, 2015, an increase of \$149,000 or 1,064%. The increase was due to sales of ACCELERATE PHENO™ Systems (Research Use Only) in 2016. The Company does not currently capitalize pre-launch inventory and the cost of product sales is reported as research and development costs on the condensed consolidated statements of operations and comprehensive loss.

Research and development expenses for the three months ended March 31, 2016 were \$7,353,000 as compared to \$5,730,000 during the three months ended March 31, 2015, an increase of \$1,623,000 or 28%. The increase was primarily the result of increasing employee headcount, clinical trial fees, and increased purchases of laboratory and instrument engineering supplies to support research and development as well as pre-launch efforts. Research and development expenses include non-cash equity-based compensation which decreased \$486,000. We do not capitalize our inventory or internally developed instruments prior to FDA approval in accordance with U.S. GAAP and,

therefore, research and development expenses include raw materials and instruments manufactured for sales. Also included in research and development expenses are instruments manufactured for internal research and development, and trial or study use which totaled \$1,455,000 and \$1,230,000 for three months ended March 31, 2016 and 2015, respectively.

During the three months ended March 31, 2016, sales, general and administrative expenses were \$7,437,000 as compared to \$2,867,000 during the three months ended March 31, 2015, an increase of \$4,570,000 or 159%. The increase was primarily driven by salaries and related expenses as we ramp up our operations. Sales, general and administrative expenses include non-cash equity-based compensation which increased \$515,000. We do not capitalize

our internally developed instruments prior to FDA approval in accordance with U.S. GAAP and, therefore, sales, general and administrative expenses include demonstration instruments as expense totaling \$588,000 and \$69,000 for three months ended March 31, 2016 and 2015, respectively.

Depreciation for the three months ended March 31, 2016 was \$542,000 as compared to \$326,000 during the three months ended March 31, 2015, an increase of \$216,000 or 66%. The increased depreciation was the result of purchases of equipment to support the Company's Tucson facility laboratory, manufacturing and administrative space.

As a result of the above factors, loss from operations for the three months ended March 31, 2016 was \$15,172,000 as compared to the loss of \$8,911,000 during the three months ended March 31, 2015, an increase in loss from operations of \$6,261,000 or 70% which includes an increase of \$29,000 in non-cash equity-based compensation expenses. 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.

Other non-operating income during the three months ended March 31, 2016 was \$98,000 as compared to \$14,000 during the three months ended March 31, 2015, an increase of \$84,000 or 600%. This change was due to an increase in foreign currency exchange gain which includes the remeasurement of monetary assets to the U.S. dollar, and an increase in investment income.

As a result of these factors, net loss for the three months ended March 31, 2016 was \$15,074,000 as compared to a net loss of \$8,897,000 during the three months ended March 31, 2015, an increase in net loss of \$6,177,000 or 69%.

Unrealized gain on available-for-sale investments for the three months ended March 31, 2016 was \$52,000 as compared to \$5,000 during the three months ended March 31, 2015.

Foreign currency translation adjustment loss for the three months ended March 31, 2016 was \$49,000 as compared to \$0 during the three months ended March 31, 2015. The resulting comprehensive losses were \$15,071,000 and \$8,892,000 for the three months ended March 31, 2016 and 2015, respectively.

Capital Resources and Liquidity

Our primary source of liquidity has been from sales of shares of common stock. As of March 31, 2016, the Company had \$116.7 million in cash and cash equivalents and available-for-sale securities, a decrease of \$15.7 million from \$132.4 million at December 31, 2015. The primary reason for the change in these assets was the funding of operational losses.

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 11, Commitments.

As of March 31, 2016, 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 three months ended March 31, 2016 and March 31, 2015 (in thousands):

Cash Flow Summary (in thousands)

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	Three Months Ended		
	March 31, 2016	March 31, 2015	Increase (Decrease)
Net cash used in operating activities	\$(13,205)	\$(6,963)	\$ (6,242)
Net cash provided by (used in) investing activities	(34,499)	761	(35,260)
Net cash provided by (used in) financing activities	(799)	30	(829)

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The net cash used in investing activities was \$34.5 million for the three months ended March 31, 2016. Primarily comprised of available-for-sale investment purchases.

The net cash provided by investing activities was \$0.8 million for the three months ended March 31, 2015. Primarily comprised of maturing available-for-sale investments.

The net cash used in financing activities was \$0.8 million for the three months ended March 31, 2016. Primarily comprised of stock issuance costs paid in the period.

The net cash used in financing activities for the three months ended March 31, 2015 was not significant.

Our primary use of capital has been for the continued development and investment in commercialization readiness 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 March 31, 2016.

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 rates along the entire interest rate yield curve would change the fair value of our interest sensitive financial instruments by approximately \$0.4 million.

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 5, 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 March 31, 2016 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 Securities and Exchange Commission'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

There was no change in the Company's internal control over financial reporting during the period ended March 31, 2016 that materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

On March 19, 2015, a putative securities class action lawsuit was filed against 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 ID/AST 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 seeks 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, which motion was pending before the Court as of December 31, 2015. Subsequently, 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. Plaintiff challenges the dismissal of the amended complaint. Plaintiff's opening brief, if she does not seek additional time, is due June 6, 2016.

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, 2015.

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

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

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Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit No.	Description	Filing Information
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
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.

May 10, 2016 /s/ Lawrence Mehren

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

May 10, 2016 /s/ Steve Reichling

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