Accelerate Diagnostics, Inc
Form 10-Q
November 09, 2016

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

þ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended September 30, 2016

o 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 of incorporation or organization)	(I.R.S. Employer Identification No.)

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. þ Yes o 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). þ Yes o 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	o
Accelerated filer	þ
Non-accelerated file	o (Do not check if a smaller reporting company)
Smaller reporting company	o

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

As of November 7, 2016 there were 51,436,947 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
(in thousands, except share data)

	Unaudited September 30, 2016	Audited December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,731	$ 120,585
Investments	61,422	11,839
Trade accounts receivable	159	77
Prepaid expenses	1,267	1,638
Other current assets	102	12
Total current assets	91,681	134,151
Property and equipment, net	4,802	5,016
Intellectual property, net	149	157
Total assets	$ 96,632	$ 139,324
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,400	$ 2,623
Accrued liabilities	2,005	2,543
Deferred revenue and income	44	127
Capital lease obligations	—	13
Total current liabilities	4,449	5,306
Long-term deferred income	1,000	1,000
Total liabilities	$ 5,449	$ 6,306
Commitments and contingencies see Note 12, Commitments	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 75,000,000 common shares authorized with 51,404,551 shares issued and outstanding on September 30, 2016 and 55,000,000 authorized with 51,191,184 shares issued and outstanding on December 31, 2015	51	51
Preferred shares, $0.001 par value; 5,000,000 preferred shares authorized and none outstanding as of September 30, 2016 and December 31, 2015	—	—
Contributed capital	252,295	243,894
Accumulated deficit	(161,154)	(110,915)
Accumulated other comprehensive gain (loss)	(9)	(12)
Total stockholders' equity	91,183	133,018
Total liabilities and stockholders' equity	$ 96,632	$ 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		Nine Months Ended	
	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Revenues:				
Product sales	$2	$76	$145	$76
Licensing and royalty revenues	22	16	62	49
Total revenues	24	92	207	125
Costs and expenses:				
Research and development	7,531	6,499	22,948	19,356
Sales, general and administrative	9,308	4,332	25,983	11,953
Amortization	3	3	8	8
Depreciation	598	465	1,745	1,194
Total costs and expenses	17,440	11,299	50,684	32,511
Loss from operations	(17,416)	(11,207)	(50,477)	(32,386)
Interest expense and other	—	(1)	—	(3)
Foreign currency exchange gain (loss)	(42)	1	(115)	1
Interest and dividend income	159	21	353	53
Total other income	117	21	238	51
Net loss	$(17,299)	$(11,186)	$(50,239)	$(32,335)
Basic and diluted net loss per share	$(0.34)	$(0.25)	$(0.98)	$(0.72)
Weighted average shares outstanding	51,239	44,727	51,216	44,685
Other comprehensive loss:				
Net loss	$(17,299)	$(11,186)	$(50,239)	$(32,335)
Net unrealized (loss) gain on available-for-sale investments	(70)	(1)	11	(4)
Foreign currency translation adjustment	(8)	(2)	(8)	(2)
Comprehensive loss	$(17,377)	$(11,189)	$(50,236)	$(32,341)

See accompanying notes to financial statements.

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

	Nine Months Ended	
	September 30, 2016	September 30, 2015
Cash flows from operating activities:		
Net loss	$(50,239)	$(32,335)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,745	1,194
Amortization of intangible assets	8	8
Amortization of investment discount	251	147
Equity-based compensation	6,591	5,995
Realized (gain) on sale of investments	(6)	—
(Increase) decrease in assets:		
Accounts receivable	(82)	(664)
Prepaid expense and other	525	(642)
Other current assets	(90)	—
Increase (decrease) in liabilities:		
Accounts payable	103	(329)
Accrued liabilities	670	1,400
Deferred revenue and income	(83)	(14)
Net cash used in operating activities	(40,607)	(25,240)
Cash flows from investing activities:		
Purchases of equipment	(2,301)	(2,594)
Purchases of available-for-sale securities	(73,585)	(12,418)
Sales of available-for-sale securities	8,716	141
Maturity of available-for-sale securities	14,955	11,307
Net cash used in investing activities	(52,215)	(3,564)
Cash flows from financing activities:		
Issuance of common stocks	80	—
Exercise of options and warrants	864	542
Common stock issuance costs	(814)	—
Payments on capital lease obligations	(13)	(110)
Recovery of related party short-swing profits	866	—
Net cash provided by financing activities	983	432
Effect of exchange rate on cash	(15)	—
Decrease in cash and cash equivalents	(91,854)	(28,372)
Cash and cash equivalents, beginning of period	120,585	53,563
Cash and cash equivalents, end of period	$28,731	$25,191

See accompanying notes to financial statements.

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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. During the nine months ended September 30, 2016 new entities were formed based in Europe.

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, 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 de novo request being granted by the U.S. FDA. Accordingly, the Company does not capitalize pre-launch inventory prior to receipt of marketing authorization, 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. Costs associated with the Company's purchase of inventory are either reported as research and development costs, or if the inventory is used in marketing evaluations, as 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 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 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 or loss, within the condensed consolidated statements of operations and comprehensive loss.

NOTE 2. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 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 (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 and the timing of adoption.

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. 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. 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 are currently evaluating the transition method and the adoption date that will be elected. We will implement ASU 2014-09 and all relevant subsequently issued ASU's on Topic 606 concurrently.

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 September 30, 2016 and December 31, 2015.

	September 30, 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	$28,731	$ —	$ —	$28,731
Investments:				
Certificates of deposit	7,011	—	—	7,011
US Treasury securities	8,580	—	—	8,580
US Agency securities	—	4,507	—	4,507
Asset-backed securities	—	6,566	—	6,566
Corporate notes and bonds	—	34,758	—	34,758
Total investments	15,591	45,831	—	61,422
Total assets measured at fair value	$44,322	$ 45,831	$ —	$90,153

	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 and cash equivalents	$120,585	$ —	$ —	$120,585
Investments:				
Asset-backed securities	—	2,507	—	2,507
Corporate notes and bonds	—	9,332	—	9,332
Total investments	—	11,839	—	11,839
Total assets measured at fair value	$120,585	$ 11,839	$ —	$132,424

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 nine months ended September 30, 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 70% and 100% of the Company’s cash and cash equivalents as of September 30, 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 September 30, 2016 and December 31, 2015, $147,000 or 93% and $50,000 or 66%, respectively, of the Company’s outstanding receivable balance was with one grantor. See Note 7, License Agreements and Grants for more information.

One customer accounted for 100% of product sales for the three months ended September 30, 2016, while two customers accounted for 100% of product sales for the nine months ended September 30, 2016. 100% product sales for the three and nine months ended September 30, 2015 was with a third customer.

NOTE 5. INVESTMENTS

The following tables summarize the Company’s available-for-sale investments at September 30, 2016 and December 31, 2015:

AVAILABLE-FOR-SALE INVESTMENTS
September 30, 2016
(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Certificates of deposit	$ 7,011	$ —	$ —	$7,011
US Treasury securities	8,569	11	—	8,580
US Agency securities	4,510	—	(3)	4,507
Asset-backed securities	6,554	12	—	6,566
Corporate notes and bonds	34,780	8	(30)	34,758
Total	$ 61,424	$ 31	$ (33)	$61,422

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 September 30, 2016 and December 31, 2015:

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AVAILABLE-FOR-SALE INVESTMENT MATURITIES
(in thousands)

	September 30, 2016		December 31, 2015	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in less than 1 year	$41,018	$41,019	$11,851	$11,839
Due in 1-5 years	20,406	20,403	—	—
Total	$61,424	$61,422	$11,851	$11,839

Proceeds from sales of marketable securities (including principal paydowns), for the three months ended September 30, 2016 and 2015 were $7,716,000 and $0, respectively, and for the nine months ended September 30, 2016 and 2015 were $8,716,000 and $141,000, respectively. The Company determines gains and losses of marketable securities based on specific identification of the securities sold. There were $6,000 realized gains from sales of marketable securities for the three and nine months ended September 30, 2016, and no gross realized gains or losses from sales of marketable securities for the three and nine months ended September 30, 2015. The gross proceeds associated with the realized gains for the three and nine months ended September 30, 2016 were $7,204,000. The balance of unrealized gains reclassified out of accumulated other comprehensive income for the three and nine months ended September 30, 2016 was $16,000. No balances were reclassified out of accumulated other comprehensive income for the three and nine months ended September 30, 2015.

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 September 30, 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.

Additional information regarding the fair value of our financial instruments is included in Note 3, Fair Value of Financial Instruments.

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment are recorded at cost and consisted of the following at September 30, 2016 and December 31, 2015.

PROPERTY AND EQUIPMENT
(in thousands)

	September 30, 2016	December 31, 2015
Computer equipment	$ 2,303	$ 1,877
Technical equipment	2,358	1,806
Facilities	3,528	1,772
Capital projects in progress	980	2,183
Total property and equipment	$ 9,169	$ 7,638
Accumulated depreciation - other	(4,367)	(2,622)
Net property and equipment	$ 4,802	$ 5,016

Depreciation expense (which includes amortization of capital lease assets) for the three months ended September 30, 2016 and 2015 was $598,000 and $465,000, respectively, and for the nine months ended September 30, 2016 and 2015 was $1,745,000 and $1,194,000, 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 $612,000 under this grant which is recorded as an offset to research and development expenses. The amounts invoiced for the three months ended September 30, 2016 and 2015 were $10,000 and $43,000, respectively, and for the nine months ended September 30, 2016 and 2015 was $54,000 were $179,000, respectively. The period of performance for this grant was complete as of September 30, 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 carbepenem-resistant Enterobacteriaceae directly from whole blood. The Company completed the first subaward agreement with Denver Health for services provided as part of this grant on January 31, 2016. A second subward was obtained which continued the period of performance through January 31, 2017. The cumulative award amount under these subawards is $818,000. The amounts invoiced for the three months ended September 30, 2016 and 2015 were $8,000 and $467,000, respectively, and for the nine months ended September 30, 2016 and 2015 were $67,000 and $467,000, respectively. Amounts invoiced under this grant are recorded as an offset to research and development expenses.

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 September 30, 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 nine months ended September 30, 2016 and 2015 were $1.2 million and $647,000, respectively, and no amounts were incurred for the

three months ended September 30, 2016 and 2015. The refund for the 2014 and 2015 tax years is collected. 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 September 30, 2016 and December 31, 2015 follows:

Deferred Revenue and Income
(in thousands)

	September 30, 2016	December 31, 2015
Fisher agreement	$ —	$ 13
Products not yet delivered	44	114
Total current deferred revenue and income	$ 44	$ 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 September 30, 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. 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, 2015, as filed with the SEC on March 9, 2016. As of December 31, 2015 there were 571,160 shares unexercised. During the three and nine months ended September 30, 2016, warrants to purchase 143,344 shares were exercised at an exercise price of $2.00 per share, leaving 427,816 shares unexercised at September 30, 2016. Proceeds from the exercise of such warrants totaling $287,000 are recorded as common stock and contributed capital in the Condensed Consolidated Balance Sheet included in Part I, Item 1. Financial Statements of this report.

NOTE 10. 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 stocks and options to purchase our common stock to be antidilutive. As of September 30, 2016, and December 31, 2015, there were common stock options, restricted stock units and warrants exercisable for 7,439,375 and 6,778,580 shares of common stock, respectively, which were not included in diluted loss per share as the effect was antidilutive.

NOTE 11. EMPLOYEE AND CONSULTANT EQUITY-BASED COMPENSATION

The following table summarizes option activity under all plans during the nine-month period ending September 30, 2016:

Stock Option Activity

	Number of Shares	Weighted Average Exercise Price per Share
Options outstanding January 1, 2016	6,167,170	6.91
Granted	998,600	13.82
Forfeited	(125,008)	19.90
Exercised	(66,764)	8.64
Expired	(2,689)	15.85
Options Outstanding September 30, 2016	6,971,309	7.64

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	
	September 30, 2016	September 30, 2015
Expected term (in years)	6.46	6.37
Volatility	89%	91%
Expected dividends	—	—
Risk free interest rates	1.30%	1.79%

Weighted average fair value	$15.40	$15.94

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 September 30, 2016:

Stock Option Supplemental Information

	Options Outstanding	Options Exercisable	Options Vested and Expected to Vest
Number of options	6,971,309	4,451,559	6,837,977
Weighted average remaining contractual term (in years)	6.84	6.14	6.80
Weighted average exercise price	$ 7.64	$ 4.94	$7.50
Weighted average fair value	$ 5.90	$ 3.72	$5.79
Aggregate intrinsic value (in thousands)	$ 136,748	$ 99,339	$135,135

The following table summarizes restricted stock unit activity during the nine-month period ending September 30, 2016:

Restricted Stock Unit (RSU) Activity

	Number of Shares	Weighted Average Grant Date Fair Value per Share
RSUs Outstanding January 1, 2016	40,250	20.91
Granted	—	—
Forfeited	—	—
Vested/released	—	—
RSUs outstanding September 30, 2016	40,250	20.91

The expense recognized on Company’s Statements of Operations and Comprehensive Loss related to options is summarized below:

Equity-Based Compensation Expenses
(in thousands)

	Three Months Ended		Six Months Ended	
	9/30/2016	9/30/2015	9/30/2016	9/30/2015
Research and development	$504	$ 406	$1,168	$ 1,842
Sales, general and administrative	2,166	1,404	5,423	4,153
Equity-based compensation expense	$2,670	$ 1,810	$6,591	$ 5,995

As of September 30, 2016, unrecognized equity-based compensation cost related to unvested stock options and unvested restricted stock units was $12.0 million and $409,000 respectively. This is expected to be recognized over the years 2016 through 2021.

NOTE 12. COMMITMENTS

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 $286,000 and $208,000 for the three months ended September 30, 2016 and 2015, respectively, and for the nine months ended September 30, 2016 and 2015 was $826,000 and $490,000, respectively. Future minimum lease payments under operating lease agreements are as follows:

Operating Lease Obligations (in thousands)	
Year ending December 31:	
2016	$249
2017	998
2018	79
2019	—
Thereafter	—
Total operating lease obligations	$1,326

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 $354,000 and $665,000 for the three months ended September 30, 2016 and 2015, respectively, and $1,778,000 and $1,023,000 for the nine months ended September 30, 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 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 pending.

NOTE 13. 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 14. 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.

The Accelerate Pheno™ system, is also generically referred to herein 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 th 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 Accelerate PhenoTest™ BC Kit is a highly multiplexed panel targeting 140 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 Accelerate PhenoTest™ BC Kit will depend on the results of FDA's 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 Pheno™ system and the Accelerate PhenoTest™ BC Kit for in vitro diagnostic use. On July 11, 2016 Accelerate submitted to the FDA a De Novo request for pre market authorization of its Accelerate Pheno™ system and Accelerate PhenoTest™ BC Kit based on a clinical study representing over 1,800 samples across 13 sites. We anticipate commercializing the Accelerate Pheno™ system in the United States, subject to clearance by the U.S. Food and Drug Administration ("FDA"). We expect to have a decision no later than the first quarter of 2017, or as early as the fourth quarter of 2016.

Changes in Results of Operations: three months ended September 30, 2016 compared to three months ended September 30, 2015

During the three months ended September 30, 2016, total revenues were $24,000 as compared to $92,000 during the three months ended September 30, 2015, a decrease of $68,000 or 74%. The decrease was due to sales of Accelerate Pheno™ systems (Research Use Only) during the three months ended September 30, 2015. 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 September 30, 2016 were $7,531,000 as compared to $6,499,000 during the three months ended September 30, 2015, an increase of $1,032,000 or 16%. 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 for the three months ended September 30, 2016

and 2015 of $504,000 and $406,000, respectively, which increased $98,000. We do not capitalize our inventory prior to FDA approval in accordance with U.S. GAAP, accordingly instruments and consumables charged to research and development were $795,000 and $235,000 for three months ended September 30, 2016 and 2015, respectively.

During the three months ended September 30, 2016, sales, general and administrative expenses were $9,308,000 as compared to $4,332,000 during the three months ended September 30, 2015, an increase of $4,976,000 or 115%. The increase was primarily driven by salaries and related expenses as we ramp up our sales and marketing operations globally. Sales, general and administrative expenses include non-cash equity-based compensation for the

three months ended September 30, 2016 and 2015 of $2,166,000 and $1,404,000, respectively, which increased $762,000. We do not capitalize our internally developed instruments prior to FDA approval in accordance with U.S. GAAP at which time we believe the costs will be recoverable and, therefore, sales, general and administrative expenses include performance verification program and demonstration instruments as expense totaling $1,181,000 and $31,000 for the three months ended September 30, 2016 and 2015, respectively.

Depreciation for the three months ended September 30, 2016 was $598,000 as compared to $465,000 during the three months ended September 30, 2015, an increase of $133,000 or 29%. The increased depreciation was the result of purchases of equipment and leasehold improvements 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 September 30, 2016 was $17,416,000 as compared to the loss of $11,207,000 during the three months ended September 30, 2015, an increase in loss from operations of $6,209,000 or 55%. Loss from operations include non-cash equity-based compensation for the three months ended September 30, 2016 and 2015 of $2,670,000 and $1,810,000, respectively, which increased $860,000. 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 September 30, 2016 was $117,000 as compared to $21,000 during the three months ended September 30, 2015, an increase of $96,000 or 457%. This change was due to an increase in investment income.

As a result of these factors, net loss for the three months ended September 30, 2016 was $17,299,000 as compared to a net loss of $11,186,000 during the three months ended September 30, 2015, an increase in net loss of $6,113,000 or 55%.

Unrealized loss on available-for-sale investments for the three months ended September 30, 2016 was $70,000 as compared to $1,000 during the three months ended September 30, 2015.

Foreign currency translation adjustment loss for the three months ended September 30, 2016 was $8,000 as compared to $2,000 during the three months ended September 30, 2015.

The resulting comprehensive losses were $17,377,000 and $11,189,000 for the three months ended September 30, 2016 and 2015, respectively.

Changes in Results of Operations: nine months ended September 30, 2016 compared to nine months ended September 30, 2015

During the nine months ended September 30, 2016, total revenues were $207,000 as compared to $125,000 during the nine months ended September 30, 2015, an increase of 82,000 or 66%. The increase was due to sales of Accelerate Pheno™ systems (Research Use Only) during the nine months ended September 30, 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 nine months ended September 30, 2016 were $22,948,000 as compared to $19,356,000 during the nine months ended September 30, 2015, an increase of $3,592,000 or 19%. 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 for the nine months ended September 30, 2016 and 2015 of $1,168,000 and $1,842,000, respectively, which decreased $674,000. We do not capitalize our inventory prior to FDA approval in accordance with U.S. GAAP, accordingly instruments and consumables charged to research and development were $3,897,000 and $2,446,000 for nine months ended September 30, 2016 and 2015, respectively.

During the nine months ended September 30, 2016, sales, general and administrative expenses were $25,983,000 as compared to $11,953,000 during the nine months ended September 30, 2015, an increase of $14,030,000 or 117%. The increase was primarily driven by salaries and related expenses as we ramp up our sales

and marketing operations globally. Sales, general and administrative expenses include non-cash equity-based compensation for the nine months ended September 30, 2016 and 2015 of $5,423,000 and $4,153,000, respectively, which increased $1,270,000. We do not capitalize our internally developed instruments prior to FDA approval in accordance with U.S. GAAP at which time we believe the costs will be recoverable and, therefore, sales, general and administrative expenses include performance verification program and demonstration instruments as expense totaling $2,517,000 and $360,000 for nine months ended September 30, 2016 and 2015, respectively.

Depreciation for the nine months ended September 30, 2016 was $1,745,000 as compared to $1,194,000 during the nine months ended September 30, 2015, an increase of $551,000 or 46%. The increased depreciation was the result of purchases of equipment and leasehold improvements to support the Company's Tucson facility laboratory, manufacturing and administrative space.

As a result of the above factors, loss from operations for the nine months ended September 30, 2016 was $50,477,000 as compared to the loss of $32,386,000 during the nine months ended September 30, 2015, an increase in loss from operations of $18,091,000 or 56%. Loss from operations include non-cash equity-based compensation for the nine months ended September 30, 2016 and 2015 of $6,591,000 and $5,995,000, respectively, which increased $596,000. 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 nine months ended September 30, 2016 was $238,000 as compared to $51,000 during the nine months ended September 30, 2015, an increase of $187,000 or 367%. This change was due to an increase in investment income.

As a result of these factors, net loss for the nine months ended September 30, 2016 was $50,239,000 as compared to a net loss of $32,335,000 during the nine months ended September 30, 2015, an increase in net loss of $17,904,000 or 55%.

Unrealized gain on available-for-sale investments for the nine months ended September 30, 2016 was $11,000 as compared to an unrealized loss of $4,000 during the nine months ended September 30, 2015.

Foreign currency translation adjustment loss for the nine months ended September 30, 2016 was $8,000 as compared to $2,000 during the nine months ended September 30, 2015.

The resulting comprehensive losses were $50,236,000 and $32,341,000 for the nine months ended September 30, 2016 and 2015, respectively.

Capital Resources and Liquidity

Our primary source of liquidity has been from sales of shares of common stock. As of September 30, 2016, the Company had $90.2 million in cash and cash equivalents and available-for-sale securities, a decrease of $42.3 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 12, Commitments.

As of September 30, 2016, management believes that current cash balances will be more than sufficient to fund our capital and liquidity needs for the next twelve months.

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The following summarizes selected items in the Company's consolidated statements of cash flows for the nine months ended September 30, 2016 and September 30, 2015:

Cash Flow Summary
(in thousands)

	Nine Months Ended		
	September 30, 2016	September 30, 2015	Increase (Decrease)
Net cash used in operating activities	$(40,607)	$(25,240)	$(15,367)
Net cash used in investing activities	(52,215)	(3,564)	(48,651)
Net cash provided by financing activities	983	432	551

The net cash used in operating activities was $40.6 million and $25.2 million for the nine months ended September 30, 2016 and 2015, respectively, and was primarily comprised of the net loss from the statements of operations and comprehensive loss.

The net cash used in investing activities was $52.2 million and $3.6 million for the nine months ended September 30, 2016 and 2015, respectively, and was primarily comprised of purchases of available-for-sale investments, offset by the maturity of other available-for-sale investments during such periods.

The net cash provided by financing activities was $983,000 for the nine months ended September 30, 2016. This is primarily comprised of proceeds received from the recovery of related party short swing profits and exercised options and warrants; which were partially offset by stock issuance costs paid in the period for the prior year issuance of common stock. The net cash provided by financing activities was $432,000 for the nine months ended September 30, 2015 and was primarily comprised of exercised options.

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 September 30, 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 $477,000.

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 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 September 30, 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 September 30, 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 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 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 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 pending.

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.

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.

November 9, 2016 /s/ Lawrence Mehren
Lawrence Mehren
President and Chief Executive Officer
(Principal Executive Officer)

November 9, 2016 /s/ Steve Reichling
Steve Reichling
Chief Financial Officer
(Principal Financial and Accounting Officer)