

Accelerate Diagnostics, Inc
Form 10-Q
November 02, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

or

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

For the transition period from ___ to ___

Commission File Number: 001-31822

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. 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

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

(§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 filer (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of October 26, 2015, there were 44,738,956 shares of the registrant’s common stock outstanding.

TABLE OF CONTENTS

| | |
|---|----|
| PART I – FINANCIAL INFORMATION | 3 |
| Item 1. Financial Statements | 3 |
| Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations | 17 |
| Item 3. Quantitative and Qualitative Disclosures About Market Risk | 23 |
| Item 4. Controls and Procedures | 23 |
| PART II – OTHER INFORMATION | 23 |
| Item 1. Legal Proceedings | 23 |
| Item 1A. Risk Factors | 23 |
| Item 2. Unregistered Sales of Equity Securities and Use of Proceeds | 24 |
| Item 3. Defaults Upon Senior Securities | 24 |
| Item 4. Mine Safety Disclosures | 24 |
| Item 5. Other Information | 24 |
| Item 6. Exhibits | 24 |

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

ACCELERATE DIAGNOSTICS, INC.**CONDENSED CONSOLIDATED****BALANCE SHEETS****Unaudited**

(in thousands, except share data)

| | September 30, <u>2015</u> | December 31, <u>2014</u> |
|--|--|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 25,191 | \$ 53,563 |
| Investments | 13,840 | 13,115 |
| Trade accounts receivable | 742 | 78 |
| Prepaid expenses and other | 1,147 | 342 |
| Total current assets | 40,920 | 67,098 |
| Property and equipment, net | 3,676 | 2,536 |
| Intellectual property, net | 159 | 167 |
| Total assets | \$ 44,755 | \$ 69,801 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,552 | \$ 2,129 |
| Accrued liabilities | 1,953 | 494 |
| Deferred income | 13 | 13 |
| Capital lease obligations | 50 | 147 |
| Total current liabilities | 3,568 | 2,783 |
| Long-term deferred income | 1,000 | 1,014 |
| Long-term capital lease obligation | ----- | 13 |
| Total liabilities | 4,568 | 3,810 |
| Commitments and contingencies (see note 12) | ----- | ----- |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value; | | |
| 55,000,000 common shares authorized | | |
| 44,738,956 (as of September 30, 2015) and 44,639,829 (as of December 31, 2014) shares issued and outstanding | 45 | 45 |
| 5,000,000 preferred shares authorized and none outstanding as of September 30, 2015 and December 31, 2014 | ----- | ----- |

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

| | | |
|--|-----------|-----------|
| Contributed capital | 137,893 | 131,356 |
| Accumulated deficit | (97,752) | (65,417) |
| Accumulated other comprehensive income | 1 | 7 |
| Total stockholders' equity | 40,187 | 65,991 |
| Total liabilities and stockholders' equity | \$44,755 | \$69,801 |

See accompanying notes to consolidated financial statements.

3

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

(in thousands, except per share data)

| | Three-month period ended September 30, | | Nine-month period ended September 30, | |
|---|---|-------------|--|-------------|
| | 2015 | 2014 | 2015 | 2014 |
| Revenues: | | | | |
| Licensing and royalty revenues | \$ 16 | \$ 16 | \$ 49 | \$ 43 |
| Product sales | 76 | ----- | 76 | ----- |
| Total revenues | 92 | 16 | 125 | 43 |
| Costs and expenses: | | | | |
| Research and development | 6,499 | 5,949 | 20,003 | 14,074 |
| Sales, general and administrative | 4,332 | 2,625 | 11,953 | 8,116 |
| Amortization | 3 | 18 | 8 | 56 |
| Depreciation | 465 | 251 | 1,194 | 536 |
| Total costs and expenses | 11,299 | 8,843 | 33,158 | 22,782 |
| Loss from operations | (11,207) | (8,827) | (33,033) | (22,739) |
| Interest expense | (1) | (2) | (2) | (5) |
| Interest and dividend income | 22 | 15 | 53 | 49 |
| Total other income | 21 | 13 | 51 | 44 |
| Net loss before income taxes | (11,186) | (8,814) | (32,982) | (22,695) |
| Benefit from income taxes | ----- | ----- | 647 | 527 |
| Net loss | \$(11,186) | \$(8,814) | \$(32,335) | \$(22,168) |
| Basic and diluted net loss per share | \$(0.25) | \$(0.20) | \$(0.72) | \$(0.51) |
| Weighted average shares outstanding | 44,727 | 44,583 | 44,685 | 43,293 |
| Other comprehensive loss: | | | | |
| Net loss | \$(11,186) | \$(8,814) | \$(32,335) | \$(22,168) |
| Net unrealized loss on available-for-sale investments | (3) | (17) | (6) | (11) |
| Comprehensive loss | \$(11,189) | \$(8,831) | \$(32,341) | \$(22,179) |

See accompanying notes to consolidated financial statements.

4

ACCELERATE DIAGNOSTICS, INC.**CONDENSED CONSOLIDATED****STATEMENT OF CASH FLOWS****Unaudited**

(in thousands)

| | Nine-month period ended September 30, September 30, | |
|---|--|--------------------|
| | <u>2015</u> | <u>2014</u> |
| Net loss | \$(32,335) | \$(22,168) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 1,194 | 536 |
| Amortization of intangible assets | 8 | 56 |
| Amortization on investment instruments | 147 | 229 |
| Equity-based compensation | 5,995 | 7,334 |
| Increase in assets: | | |
| Accounts receivable | (664) | (65) |
| Prepaid expense and other | (642) | (547) |
| (Decrease) increase in liabilities: | | |
| Accounts payable | (329) | 528 |
| Accrued liabilities | 1,400 | 125 |
| Deferred income | <u>(14)</u> | <u>(22)</u> |
| Net cash used in operating activities | (25,240) | (13,994) |
| Purchases of equipment | (2,594) | (1,357) |
| Purchase of available-for-sale securities | (12,418) | (6,614) |
| Sales of available-for-sale securities | 141 | 246 |
| Maturity of available-for-sale securities | <u>11,307</u> | <u>4,007</u> |
| Net cash used in investing activities | (3,564) | (3,718) |
| Issuance of common stock | ----- | 44,875 |
| Exercise of options | 542 | 730 |
| Payments on capital lease obligations | <u>(110)</u> | <u>(71)</u> |
| Net cash provided by financing activities | <u>432</u> | <u>45,534</u> |
| (Decrease) increase in cash and cash equivalents | (28,372) | 27,822 |
| Cash and cash equivalents, beginning of period | <u>53,563</u> | <u>30,029</u> |
| Cash and cash equivalents, end of period | <u>\$25,191</u> | <u>\$57,851</u> |

See accompanying notes to consolidated 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. Microbiology laboratories are in need of new tools to address what the U.S. Centers for Disease Control and Prevention (“CDC”) calls one of the most serious healthcare threats of our time, antibiotic resistance. A significant contributor 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 of 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 and deliver fast and accurate testing of infectious pathogens in various patient sample types.

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, 2014, as filed with the SEC on February 26, 2015.

The condensed consolidated balance sheet as of December 31, 2014 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, 2015 or any future period.

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

Use of Estimates

The preparation of condensed consolidated 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 condensed consolidated financial statements and the reported

amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

6

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.

NOTE 2. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In July 2015, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2015-11, *Simplifying the Measurement of Inventory*. The new standard requires entities that measure inventory using first-in, first-out or average cost inventory to report inventory at the lower of cost and net realizable value. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The ASU will become effective for us on January 1, 2016. We do not expect the adoption of ASU 2015-11 to have a significant impact on our condensed consolidated financial statements.

In April 2015, the FASB issued ASU 2015-05, *Intangibles-Goodwill and Other – Internal-Use Software; Customer’s Accounting for Fees Paid in a Cloud Computing Arrangement*. Prior to this ASU, U.S. GAAP did not include explicit guidance about a customer’s accounting for fees paid in a cloud computing arrangement. Examples of cloud computing arrangements include software as a service, platform as a service, infrastructure as a service, and other similar hosting arrangements. This ASU provides guidance to customers about whether a cloud computing arrangement includes a software license, in which case the customer should account for such license consistent with the acquisitions of other software licenses. If the cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The ASU does not change the accounting for service contracts. The new standard is effective for us on January 1, 2016 with early adoption permitted. We do not expect the adoption of ASU 2015-05 to have a significant impact on our condensed consolidated financial statements.

In January 2015, the FASB issued ASU 2015-01, *Income Statement - Extraordinary and Unusual Items*. The new standard eliminates from U.S. GAAP the concept of extraordinary items. Prior to the adoption of this standard, extraordinary items have been segregated from the results of ordinary operations and shown separately in the income statement, net of tax, after income from continuing operations. The new standard eliminates such segregation as well as the requirements to disclose applicable income taxes and either present or disclose earnings-per-share data applicable to the extraordinary item. The new standard is effective for us on January 1, 2016 with early adoption permitted. We do not expect the adoption of ASU 2015-01 to have a significant impact on our condensed consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern*. The new standard requires management of public and private companies to evaluate whether there is substantial doubt about the entity’s ability to continue as a going concern and, if so, disclose that fact. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. The new standard is effective for us on January 1, 2016 with early adoption permitted. We do not expect the adoption of ASU 2014-15 to have a significant impact on our condensed consolidated financial statements.

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 July 2015, the FASB 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 September 30, 2015 and December 31, 2014.

FINANCIAL INSTRUMENTS MEASURED AT FAIR VALUE

September 30, 2015

(in thousands)

| | Quoted Prices in Active Markets for Identical Assets | Significant Other Observable Inputs | Significant Unobservable Inputs | Total |
|--|---|--|--|--------------|
| | <u>(Level 1)</u> | <u>(Level 2)</u> | <u>(Level 3)</u> | |
| Assets: | | | | |
| Money market funds (cash equivalents) | \$3,214 | \$— | \$— | \$3,214 |
| Corporate notes and bonds | — | 11,324 | — | 11,324 |
| Asset-backed securities | — | 2,516 | — | 2,516 |
| Total assets measured at fair value | \$3,214 | \$13,840 | \$— | \$17,054 |

FINANCIAL INSTRUMENTS MEASURED AT FAIR VALUE

December 31, 2014

(in thousands)

| | Quoted Prices in Active Markets for Identical Assets | Significant Other Observable Inputs | Significant Unobservable Inputs | Total |
|--|---|--|--|--------------|
| | <u>(Level 1)</u> | <u>(Level 2)</u> | <u>(Level 3)</u> | |
| Assets: | | | | |
| Money market funds (cash equivalents) | \$13,127 | \$— | \$— | \$13,127 |
| Corporate notes and bonds | — | 12,974 | — | 12,974 |
| Asset-backed securities | — | 141 | — | 141 |
| Total assets measured at fair value | \$13,127 | \$13,115 | \$— | \$26,242 |

8

Level 1 assets are priced using quoted prices in active markets for identical assets which include cash accounts and money market funds 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-month period ended September 30, 2015.

Additional information regarding our investments is included in Note 5, Investments.

NOTE 4: CONCENTRATION OF CREDIT RISK

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

The Company's main financial institution for banking operations held 99% and 83% of the Company's cash and cash equivalents as of September 30, 2015 and December 31, 2014, 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, 2015 and December 31, 2014, 87% and 98%, 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.

NOTE 5. INVESTMENTS

The following tables summarize the Company's available-for-sale investments at September 30, 2015 and December 31, 2014 (in thousands):

**AVAILABLE-FOR-SALE
INVESTMENTS**

September 30, 2015

(in thousands)

| | Gross | Gross | |
|------------------|-------------------|-------------------|-------------------|
| Amortized | Unrealized | Unrealized | |
| Cost | Gains | Losses | Fair Value |

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

| | | | | |
|---------------------------|----------|-----|------|------------|
| Asset-backed securities | \$2,515 | \$1 | \$— | \$2,516 |
| Corporate notes and bonds | 11,324 | 7 | (7 |) 11,324 |
| Total | \$13,839 | \$8 | \$(7 |) \$13,840 |

December 31, 2014

(in thousands)

| | Amortized | Gross | Gross | |
|---------------------------|------------------|---------------------|----------------------|--------------------------|
| | Cost | Unrealized | Unrealized | <u>Fair Value</u> |
| | | <u>Gains</u> | <u>Losses</u> | |
| Asset-backed securities | \$141 | \$— | \$— | \$141 |
| Corporate notes and bonds | 12,967 | 10 | (3 |) 12,974 |
| Total | \$13,108 | \$10 | \$(3 |) \$13,115 |

The following table summarizes the maturities of the Company's available-for-sale securities at September 30, 2015 and December 31, 2014 (in thousands):

AVAILABLE-FOR-SALE INVESTMENT MATURITIES

(in thousands)

| | September 30, 2015 | | December 31, 2014 | |
|-------------------------|-----------------------|--------------|-------------------|--------------|
| | Amortized | Fair | Amortized | Fair |
| | Cost | Value | Cost | Value |
| Due in less than 1 year | \$12,334 | \$12,335 | \$10,586 | \$10,585 |
| Due in 1-3 years | 1,505 | 1,505 | 2,522 | 2,530 |
| Total | \$13,839 | \$13,840 | \$13,108 | \$13,115 |

Proceeds from sales of marketable securities (including principal paydowns) for the three-month periods ended September 30, 2015 and 2014 was \$0 and \$125,000, respectively, and for the nine-month periods ended September 30, 2015 and 2014 was \$141,000 and \$246,000, respectively. The Company determines gains and losses of marketable securities based on specific identification of the securities sold. There were no material gross realized gains or losses from sales of marketable securities for the three-month or nine-month periods ended September 30, 2015 and 2014.

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 September 30, 2015 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 Statements.

NOTE 6. PROPERTY AND EQUIPMENT

Property and equipment are recorded at cost and consisted of the following at September 30, 2015 and December 31, 2014 (in thousands):

Property and Equipment

(in thousands)

| | September | December |
|--|------------------|-----------------|
| | 30, | 31, |
| | 2015 | 2014 |
| Computer equipment | \$ 1,894 | \$ 1,020 |
| Technical equipment | 2,033 | 1,625 |
| Facilities | 1,790 | 842 |
| Capital lease – leasehold improvements | 266 | 266 |
| Capital projects in progress | 331 | 227 |

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

| | | |
|--|----------|----------|
| Total property and equipment | \$ 6,314 | \$ 3,980 |
| Accumulated amortization – capital lease | (233) | (133) |
| Accumulated depreciation – other | (2,405) | (1,311) |
| Net property and equipment | \$ 3,676 | \$ 2,536 |

10

Depreciation expense, which includes amortization of capital lease assets, for the three-month periods ended September 30, 2015 and 2014 was \$465,000 and \$251,000, respectively, and for the nine-month periods ended September 30, 2015 and 2014 was \$1,194,000 and \$536,000, respectively.

NOTE 7. LICENSE AGREEMENTS AND GRANTS

Schott Jenaer Glas GmbH

The Company signed a licensing agreement for microarraying slides using OptiChem coatings with Schott Jenaer Glas GmbH (“SCHOTT”) in November 2004. In November 2014, the agreement was amended and extended with an expiration date that coincides with the expiration of the underlying patents. Royalties are 5% of SCHOTT’s net product sales. Revenue is recognized as SCHOTT’s net product sales are reported to the Company.

NanoString Technologies

In October 2007, the Company entered into an exclusive seven-year license with NanoString Technologies, Inc. (“NanoString”). The license grants NanoString the right to apply OptiChem coatings to NanoString’s proprietary molecular detection products.

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 \$2,000,000 of funding for a project which ended in August 2015. 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 applied the Accelerate ID/AST 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-month periods ended September 30, 2015 and 2014 was \$43,000 and \$50,000 respectively, and for the nine-month periods ended September 30, 2015 and 2014 was \$179,000 and \$150,000, respectively.

National Institute of Health Grant

In February 2015, we were notified that the National Institute of Health awarded a five year, \$5,000,000 grant to Denver Health and ourselves to develop a fast and reliable identification and categorical susceptibility test carbapenem-resistant Enterobacteriaceae directly from whole blood. In June 2015, we executed a subaward agreement with Denver Health for the services we will provide as part of this grant which covers the period of February 15, 2015 through January 31, 2016 and totals \$689,000. The amount invoiced for the three-month and nine-month periods ended September 30, 2015 and 2014 was \$467,000 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 \$1,000,000 (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 \$4,520,000.

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 December 31, 2014, the Company had collected all of the \$1,000,000 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 other non-operating income. Further details are included in Note 8, Deferred Income.

NOTE 8. DEFERRED INCOME

Deferred income consists of amounts received for commitments not yet fulfilled. If we anticipate that the 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, 2015 and December 31, 2014 follows (in thousands):

Deferred Income

(in thousands)

| | September 30, <u>2015</u> | December 31, <u>2014</u> |
|---|--|--------------------------------|
| Fisher agreement | \$ 13 | \$ 13 |
| Total current deferred income | \$ 13 | \$ 13 |
| Arizona Commerce Authority Grant (see Note 7) | \$ 1,000 | \$ 1,000 |
| Fisher agreement | — | 14 |
| Total long-term deferred income | \$ 1,000 | \$ 1,014 |

Deferred income includes a \$40,000 payment received from Fisher Scientific in July 2013, none of which was recognized in the three-month periods ended September 30, 2015 and 2014, and \$14,000 and \$13,000 were recognized in the nine-month periods ending September 30, 2015 and 2014, respectively. We anticipate earning the remaining \$13,000 in May 2016.

Through December 31, 2014, we received \$1,000,000 in milestone payments from the Arizona Commerce Authority under the Grant Agreement described in Note 7, License Agreements and Grants. As of September 30, 2015, 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 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, 2015 and December 31, 2014, there were Common Stock options, restricted stocks and warrants exercisable for 6,676,081 and 6,174,886 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 nine-month period ended September 30, 2015.

Stock Option Activity

| | Number of | Weighted |
|--|---------------|------------------|
| | <u>Shares</u> | Average |
| | | Exercise Price |
| | | <u>per Share</u> |
| Options Outstanding December 31, 2014 | 5,628,726 | \$5.20 |
| Granted | 589,577 | 21.46 |
| Forfeited | (54,505) | 11.71 |
| Exercised | (99,127) | 5.46 |
| Options Outstanding September 30, 2015 | 6,064,671 | 6.71 |

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

Black-Scholes Assumptions for Options Granted
 Three-month period
 ended
September
30, **September**
30,

| | <u>2015</u> | | <u>2014</u> | |
|-----------------------------|--------------------|---|--------------------|---|
| Expected term (in years) | 6.37 | | 6.46 | |
| Volatility | 91 | % | 94 | % |
| Expected dividends | \$— | | \$— | |
| Risk free interest rates | 1.79 | % | 2.11 | % |
| Weighted average fair value | \$15.94 | | \$ 13.92 | |

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, 2015:

Stock Option Supplemental Information

| | Options Outstanding | Options Exercisable | Options Vested and Expected to Vest |
|--|--------------------------------|--------------------------------|--|
| Number of options | 6,064,671 | 3,411,338 | 5,983,442 |
| Weighted average remaining contractual term (in years) | 7.36 | 6.96 | 7.35 |
| Weighted average exercise price | \$6.71 | \$4.21 | \$6.60 |
| Weighted average fair value | \$5.25 | \$3.14 | \$5.16 |
| Aggregate intrinsic value (in thousands) | \$49,844 | \$39,820 | \$50,048 |

The following table summarizes equity-based compensation expense recognized in the condensed consolidated statements of operations for the periods indicated (in thousands):

Equity-Based Compensation Expense

(in thousands)

| | Three-month period ended September 30, | | Nine-month period ended September 30, | |
|--|---|-------------|--|-------------|
| | 2015 | 2014 | 2015 | 2014 |
| Research and development | \$425 | \$ 1,113 | \$1,860 | \$ 3,225 |
| Sales, general and administrative | 1,385 | 1,290 | 4,135 | 4,109 |
| Total stock-based compensation expense | \$1,810 | \$ 2,403 | \$5,995 | \$ 7,334 |

The following table summarizes restricted stock activity during the nine-month period ended September 30, 2015, none of which are vested as of September 30, 2015:

Restricted Stock Activity

| | Number of <u>Shares</u> | Weighted Average Grant Date Fair Value <u>per Share</u> |
|---|----------------------------|--|
| Restricted Stocks Outstanding December 31, 2014 | — | \$— |
| Granted | 40,250 | 20.91 |

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

| | | |
|--|--------|---------|
| Forfeited | — | — |
| Vested/released | — | — |
| Restricted Stocks Outstanding September 30, 2015 | 40,250 | \$20.91 |

As of September 30, 2015, unrecognized equity-based compensation cost related to unvested stock options and restricted stock was \$11.2 million and \$787,000, respectively.

14

NOTE 11. INCOME TAXES

The Arizona Commerce Authority (“Authority”) notified us that we meet the program requirements to receive a “Certificate of Qualification” and, therefore, are eligible for a refund of research and development investments amounting to a maximum of \$647,000 and \$527,000 for tax years 2014 and 2013, respectively. The “Certificate of Qualification” does not obligate the Arizona Department of Revenue to issue either refund. Furthermore, the calculation of the actual refund due will be based on actual qualifying expenses and income tax liability for the corresponding tax year and if qualifying expenses decrease or income tax liability increases, the refund amount may be less than the maximum amounts. If the amount received for the tax credit is later determined to be incorrect or invalid, the excess may be treated as a tax deficiency. We have recorded the refund amounts of \$647,000 and \$527,000 as a non-operating benefit from income taxes in the nine-month periods ending September 30, 2015 and 2014, respectively, and the refunds were deposited in June 2015 and May 2014, respectively.

NOTE 12. COMMITMENTS, CONTINGENCIES AND LEGAL MATTERS**Operating & Capital Lease Obligations**

In August 2012, the company entered into a Lease Agreement (“Lease”) with Pima County, a political subdivision of the State of Arizona which has been subsequently amended, the details of which are included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the SEC on February 26, 2015. In May 2015, we exercised the option to extend the term of the lease for an additional one-year period, resulting in a new expiration date in January 2017.

In July 2015, the Company entered into another Lease Agreement with Pima County, pursuant to which the Company leased approximately 6,207 square feet of space located in Tucson, Arizona for a period of two years, which may be extended by the Company for an additional year. The 6,207 square feet consists of approximately 3,827 square feet of existing space (“Existing Premises”) and approximately 2,380 square feet of new construction by the Company (“Expansion Premises”). The Company agreed to pay rent equal to \$9.24 per square foot per year for the Existing Premises and \$5.00 per square foot per year for the Expansion Premises for a combined total rent of approximately \$47,000 per year. The Company will also pay for constructions costs and other expenses to get both spaces to a usable condition. Rent will commence and actual usable square footage will be calculated upon the completion of construction and notice of substantial completion.

Total rent expense for the Tucson facility, including common area charges for the three-month periods ending September 30, 2015 and 2014 was \$208,000 and \$85,000, respectively, and for the nine-month periods ending September 30, 2015 and 2014 was \$490,000 and \$198,000, respectively. Future minimum lease payments are as follows (in thousands):

Operating Lease Obligations

(in thousands)

| | |
|--------------------------|--------|
| Year ending December 31: | |
| Remaining in 2015 | \$ 186 |
| 2016 | 931 |
| 2017 | 114 |
| 2018 | — |
| 2019 | — |

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

| | |
|-----------------------------------|---------|
| Thereafter | — |
| Total operating lease obligations | \$1,231 |

The future minimum lease payments under our capital lease arrangement together with the present value of the net minimum lease payments as of September 30, 2015 are as follows:

Capital Lease Obligations

| | |
|--------------------------------------|------|
| (in thousands) | |
| Year ending December 31: | |
| Remaining in 2015 | \$38 |
| 2016 | 13 |
| 2017 | — |
| 2018 | — |
| 2019 | — |
| Total minimum lease payments | \$51 |
| Less amount representing interest | (1) |
| Present value minimum lease payments | \$50 |

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 losses associated with their participation in the clinical trial. We incurred \$665,000 and \$0 for these arrangements during the three-month periods ending September 30, 2015 and 2014, respectively, and \$1,023,000 and \$0 for these arrangements during the nine-month periods ending September 30, 2015 and 2014, respectively which are included in research and development expenses 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 us, 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 is pending before the Court. We believe the case is without merit and intend to defend it vigorously. However, an adverse result could have a material adverse effect upon our financial condition or results of operations.

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.

16

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

Introductory Note

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

Forward-Looking Statements

This 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 Company's 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 ID/AST system, the Company will obtain sufficient capital to complete the development and required clinical trials of the Accelerate ID/AST 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, 2014 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. (“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. Microbiology laboratories are in need of new tools to address what the U.S. Centers for Disease Control and Prevention (“CDC”) calls one of the most serious healthcare threats of our time, antibiotic resistance. A significant contributor 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 of 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 ID/AST System™ (the “ID/AST System” or “Accelerate ID/AST 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 (“ID”) infectious pathogens and phenotypic technology to conduct antibiotic susceptibility testing (“AST”), which determines whether live bacterial or fungal cells are resistant or susceptible to a particular antibiotic. Development of this system and the first test kit for positive blood culture samples is substantially complete. On June 30, 2015, the company declared its conformity to the European *In Vitro* Diagnostic Directive 98/79 EC and CE Mark of the Accelerate ID/AST system and IS/AST Blood Culture Assay for *in vitro* diagnostic use. The Company anticipates commercializing the FDA approved product in the first half of 2016 following the successful completion of the U.S. registration trial. Achieving this milestone will depend on our ability to achieve the goals specified in our detailed project plan according to the deadlines included in such plan.

We plan to introduce additional test kits for use on the Accelerate ID/AST System enabling the system’s use with other sample types. In addition, we plan to invest in the development of additional instruments, tests, and other solutions.

Changes in Results of Operations: Three-month period ended September 30, 2015 compared to three-month period ended September 30, 2014

During the three-month period ended September 30, 2015, total revenues were \$92,000 as compared to \$16,000 during the three-month period ended September 30, 2014, an increase of \$76,000 or 475% due to the sale of an ID/AST system.

Research and development expenses for the three-month period ended September 30, 2015 were \$6,499,000 as compared to \$5,949,000 during the three-month period ended September 30, 2014, an increase of \$550,000 or 9%. The increase was primarily the result of pilot 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-month periods ended September 30, 2015 and 2014 of \$425,000 and \$1,113,000, respectively. We do not capitalize our internally developed instruments prior to FDA approval in accordance with U.S. GAAP and, therefore, research and development expenses include instruments manufactured for sales, internal research and development, and trial or study use as expenses for the three-month periods ended September 30, 2015 and 2014 totaling \$235,000 and \$0, respectively.

During the three-month period ended September 30, 2015, sales, general and administrative expenses were \$4,332,000 as compared to \$2,625,000 during the three-month period ended September 30, 2014, an increase of \$1,707,000 or 65%. 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 for the three-month periods ended September 30, 2015 and 2014 of \$1,385,000 and \$1,290,000, respectively. 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 expenses for the three-month periods ended September 30, 2015 and 2014 totaling \$31,000 and \$0, respectively.

During the three-month period ended September 30, 2015, amortization was \$3,000 as compared to \$18,000 during the three-month period ended September 30, 2014, a decrease of \$15,000 or 83%. This decrease is the result of patents that became fully amortized during the previous year.

Depreciation for the three-month period ended September 30, 2015 was \$465,000 as compared to \$251,000 during the three-month period ended September 30, 2014, an increase of \$214,000 or 85%. The increased depreciation was the result of purchases of equipment for the Company's Tucson facility laboratory, manufacturing and administrative space.

As a result of the above factors, loss from operations for the three-month period ended September 30, 2015 was \$11,207,000 as compared to the loss of \$8,827,000 during the three-month period ended September 30, 2014, an increase in loss from operations of \$2,380,000 or 27%. The loss includes non-cash equity-based compensation expenses for the three-month periods ended September 30, 2015 and 2014 of \$1,810,000 and \$2,403,000, respectively. This loss and further losses are anticipated and was the result of our continued investments in research and development, expanded laboratory and operational space, increased employee headcount and other factors as we develop and prepare to commercialize the Company's products.

Other non-operating income during the three-month period ended September 30, 2015 was \$21,000 as compared to \$13,000 during the three-month period ended September 30, 2014, an increase of \$8,000 or 62%. This change was due to increased interest and dividend income on our invested funds which decreased slightly between the two periods.

As a result of these factors, net loss for three-month period ended September 30, 2015 was \$11,186,000 as compared to a net loss of \$8,814,000 during the three-month period ended September 30, 2014, an increase in net loss of \$2,372,000 or 27%.

Unrealized loss on available-for-sale investments for the three-month period ended September 30, 2015 was \$3,000 as compared to a loss of \$17,000 during the three-month period ended September 30, 2014. The resulting comprehensive losses were \$11,189,000 and \$8,831,000 for the three-month periods ended September 30, 2015 and 2014, respectively.

Changes in Results of Operations: Nine-month period ended September 30, 2015 compared to nine-month period ended September 30, 2014

During the nine-month period ended September 30, 2015, total revenues were \$125,000 as compared to \$43,000 during the nine-month period ended September 30, 2014, an increase of \$82,000 or 191% due to increased revenues associated with license agreements and the sale of an instrument.

Research and development expenses for the nine-month period ended September 30, 2015 were \$20,003,000 as compared to \$14,074,000 during the nine-month period ended September 30, 2014, an increase of \$5,929,000 or 42%. The increase was primarily the result of increasing employee headcount, pilot 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-month periods ended September 30, 2015 and 2014 of \$1,860,000 and \$3,225,000, respectively. We do not capitalize our internally developed instruments prior to FDA approval in accordance with U.S. GAAP and, therefore, research and development expenses include instruments manufactured for sales, internal research and development, and trial or study use as expenses for the nine-month periods ended September 30, 2015 and 2014 totaling \$2,446,000 and \$0, respectively.

During the nine-month period ended September 30, 2015, sales, general and administrative expenses were \$11,953,000 as compared to \$8,116,000 during the nine-month period ended September 30, 2014, an increase of \$3,837,000 or 47%. 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 for the six-months periods ended September 30, 2015 and 2014 of \$4,135,000 and \$4,109,000, respectively. 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 expenses for the nine-month periods ended September 30, 2015 and 2014 totaling \$360,000 and \$0, respectively.

During the nine-month period ended September 30, 2015, amortization was \$8,000 as compared to \$56,000 during the nine-month period ended September 30, 2014, a decrease of \$48,000 or 86%. This decrease is the result of patents that became fully amortized during the previous year.

Depreciation for the nine-month period ended September 30, 2015, was \$1,194,000 as compared to \$536,000 during the nine-month period ended September 30, 2014, an increase of \$658,000 or 123%. The increased depreciation was the result of purchases of equipment for the Company's Tucson facility laboratory, manufacturing and administrative space.

As a result of the above factors, loss from operations for the nine-month period ended September 30, 2015 was \$33,033,000 as compared to the loss of \$22,739,000 during the nine-month period ended September 30, 2014, an increase in loss from operations of \$10,294,000 or 45%. The loss includes non-cash equity-based compensation expenses for the nine-month periods ended September 30, 2015 and 2014 of \$5,995,000 and \$7,334,000, respectively. This loss and further losses are anticipated and was the result of our continued investments in research and development, expanded laboratory and operational space, increased employee headcount and other factors as we develop and prepare to commercialize the Company's products.

Other non-operating income during the nine-month period ended September 30, 2015 was \$51,000 as compared to \$44,000 during the nine-month period ended September 30, 2014, an increase of \$7,000 or 16%. This change was due to increased interest and dividend income on our invested balances which decreased between the two periods.

Income tax benefit during the nine-month period ended September 30, 2015 was \$647,000 as compared to \$527,000 during the nine-month period ended September 30, 2014, an increase of \$120,000 or 23%. This is due to an increase in our elected partial refund of research and development tax credits.

As a result of these factors, net loss for nine-month period ended September 30, 2015 was \$32,335,000 as compared to a net loss of \$22,168,000 during the nine-month period ended September 30, 2014, an increase in net loss of \$10,167,000 or 46%.

Unrealized loss on available-for-sale investments for the nine-month period ended September 30, 2015 was \$6,000 as compared to a loss of \$11,000 during the nine-month period ended September 30, 2014. The resulting comprehensive losses were \$32,341,000 and \$22,179,000 for the nine-month periods ended September 30, 2015 and 2014, respectively.

Capital Resources and Liquidity

Our primary use of capital has been for the continued development and commercialization of the Accelerate ID/AST system. Our primary source of liquidity has been from sales of shares of common stock. As of September 30, 2015, the Company had \$39.0 million in cash and cash equivalents and available-for-sale securities, a decrease of \$27.7 million from \$66.7 million at December 31, 2014. The primary reason for the change in these assets was the funding of operational losses and purchase of capital equipment.

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, Contingencies and Legal Matters.

We believe our existing cash balances, together with capital provided under grants or raised through exercises of warrants and stock options, and/or additional issuances of equity or debt securities will be sufficient to meet our ongoing capital requirements. However, if our capital requirements vary materially from those currently planned or anticipated, 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. Issuances of additional shares of our common stock or preferred stock (or convertible debt securities), whether in connection with a rights offering, follow-on offering or otherwise, would dilute existing stockholders and may adversely affect the market price of our common stock.

The following summarizes selected items in the Company's condensed consolidated statements of cash flows for the nine-month periods ended September 30, 2015 and the year ended December 31, 2014 (in thousands):

Cash Flow Summary

(in thousands)

| | September 30, | December 31, |
|---|----------------------|---------------------|
| | <u>2015</u> | <u>2014</u> |
| Net cash used in operating activities | \$(25,240 |) \$(18,785 |
| Net cash used in investing activities | (3,564 |) (3,372 |
| Net cash provided by financing activities | 432 | 45,691 |

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of September 30, 2015.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The Company's interest income is sensitive to fluctuations in the general level of U.S. interest rates. As such, changes in U.S. interest rates affect the interest earned on the Company's cash and cash equivalents and investments.

Our exposure to market risk is limited to our cash and cash equivalents, all of which have original maturities of less than three months and available-for-sale investments some of which have maturities under a year and some of which have maturities of more than a year. 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. We currently do not hedge interest rate exposure. 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, 2015 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 three-month period ended September 30, 2015 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 us, 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 is

pending before the Court. We believe the case is without merit and intend to defend it vigorously. However, an adverse result could have a material adverse effect upon our financial condition or results of operations.

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, 2014.

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 2, 2015 /s/ Lawrence Mehren
Lawrence Mehren

President and Chief Executive Officer
(Principal Executive Officer)

November 2, 2015 /s/ Steve Reichling
Steve Reichling

Chief Financial Officer
(Principal Financial and Accounting Officer)