

Accelerate Diagnostics, Inc  
Form 10-Q  
November 04, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2014  
or

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

For the transition period from \_\_\_ to \_\_\_

Commission File Number: 001-31822

**ACCELERATE DIAGNOSTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction  
of incorporation or organization)

**84-1072256**

(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**

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

|   |                           |
|---|---------------------------|
| Large accelerated filer   | Accelerated filer         |
| Non-accelerated 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 27, 2014, there were 44,609,829 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 SHEETS**

(in thousands, except share data)

|  | <b>September<br/>30,<br/><u>2014</u></b> | <b>December<br/>31,<br/><u>2013</u></b> |
|--|--|---|
|  | (Unaudited)                              |   |
| Current assets:  |  |   |
| Cash and cash equivalents  | \$57,851                                 | \$30,029                                |
| Investments  | 14,081                                   | 11,960                                  |
| Trade accounts receivable  | 89                                       | 24                                      |
| Prepaid expenses and other   | 677                                      | 130                                     |
| Total current assets   | 72,698                                   | 42,143                                  |
| Property and equipment, net  | 2,270                                    | 1,047                                   |
| Intellectual property, net   | 185                                      | 241                                     |
| Total Assets   | \$75,153                                 | \$43,431                                |
| Current liabilities:   |  |   |
| Accounts payable   | \$1,102                                  | \$540                                   |
| Accrued liabilities  | 741                                      | 515                                     |
| Deferred revenue and income  | 74                                       | 82                                      |
| Capital lease obligation   | 146                                      | —                                       |
| Total current liabilities  | 2,063                                    | 1,137                                   |
| Long-term deferred income  | 763                                      | 777                                     |
| Long-term capital lease obligation   | 50                                       | —                                       |
| Total liabilities  | 2,876                                    | 1,914                                   |
| Stockholders' equity:  |  |   |
| Common stock, \$0.001 par value;<br>55,000,000 common shares authorized<br>44,583,092 (as of September 30, 2014) and 41,649,521 (as of<br>December 31, 2013) shares issued and outstanding | 45                                       | 42                                      |
| 5,000,000 preferred shares authorized and none outstanding as of<br>September 30, 2014 and December 31, 2013   | —  | —                                       |
| Contributed capital  | 128,873                                  | 75,937                                  |
| Accumulated deficit  | (56,652                                  | ) (34,484 )                             |
| Accumulated other comprehensive income   | 11                                       | 22                                      |
| Total stockholders' equity   | 72,277                                   | 41,517                                  |
| Total liabilities and stockholders' equity   | \$75,153                                 | \$43,431                                |

See accompanying notes to consolidated financial statements.

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

**Unaudited**

(in thousands, except per share data)

|  | Three-month period<br>ended<br><b>September<br/>30,</b> |             | Nine-month period<br>ended<br><b>September<br/>30,</b> |             |
|--|---|-------------|--|-------------|
|  | <b>2014</b>   | <b>2013</b> | <b>2014</b>  | <b>2013</b> |
| Revenues:  |   |             |  |             |
| Licensing and royalty revenues                               | \$ 16   | \$ 13       | \$ 43  | \$ 36       |
| Total revenues   | 16  | 13          | 43   | 36          |
| Costs and expenses:  |   |             |  |             |
| Research and development                                     | 5,949   | 2,655       | 14,074   | 6,996       |
| Sales, general and administrative                            | 2,625   | 1,052       | 8,116  | 2,916       |
| Amortization   | 18  | 19          | 56   | 58          |
| Depreciation   | 251   | 84          | 536  | 191         |
| Total costs and expenses                                     | 8,843   | 3,810       | 22,782   | 10,161      |
| Loss from operations   | (8,827 )  | (3,797 )    | (22,739 )  | (10,125 )   |
| Other expense  | (2 )  | (9 )        | (5 )   | (10 )       |
| Interest and dividend income                                 | 15  | 9           | 49   | 13          |
| Total other income   | 13  | 0           | 44   | 3           |
| Net loss before income taxes                                 | (8,814 )  | (3,797 )    | (22,695 )  | (10,122 )   |
| Benefit from income taxes                                    | —   | —           | 527  | —           |
| Net Loss   | \$(8,814 )  | \$(3,797 )  | \$(22,168 )  | \$(10,122 ) |
| Net loss per share: Basic and diluted net loss per share     | \$(0.20 )   | \$(0.10 )   | \$(0.51 )  | \$(0.28 )   |
| Weighted average shares outstanding                          | 44,583  | 39,876      | 43,293   | 36,083      |
| Comprehensive loss:  |   |             |  |             |
| Net loss   | \$(8,814 )  | \$(3,797 )  | \$(22,168 )  | \$(10,122 ) |
| Net unrealized (loss) gain on available-for-sale investments | (17 )   | 11          | (11 )  | 10          |
| Comprehensive loss   | \$(8,831 )  | \$(3,786 )  | \$(22,179 )  | \$(10,112 ) |

See accompanying notes to consolidated financial statement



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

**Unaudited**

(in thousands)

|   | Nine-month period<br>ended |                    |
|---|----------------------------|--------------------|
|   | <b>September</b>           | <b>September</b>   |
|   | <b>30,</b>                 | <b>30,</b>         |
|   | <b><u>2014</u></b>         | <b><u>2013</u></b> |
| Cash flows from operating activities:                                       |                            |                    |
| Net loss  | \$(22,168)                 | \$(10,122 )        |
| Adjustments to reconcile net loss to net cash used in operating activities: |                            |                    |
| Depreciation  | 536                        | 191                |
| Amortization of intangible assets   | 56                         | 58                 |
| Amortization of investment discount   | 229                        | —                  |
| Stock-based compensation  | 7,334                      | 2,612              |
| Impairment of intangibles   | —                          | 9                  |
| (Increase) decrease in assets:  |                            |                    |
| Accounts receivable   | (65 )                      | 658                |
| Prepaid expense and other   | (547 )                     | (99 )              |
| Increase (decrease) in liabilities:   |                            |                    |
| Accounts payable  | 528                        | (293 )             |
| Accrued liabilities   | 125                        | (549 )             |
| Deferred revenue and income   | (22 )                      | 533                |
| Net cash used in operating activities                                       | (13,994)                   | (7,002 )           |
| Cash flows from investing activities:                                       |                            |                    |
| Purchases of equipment  | (1,357 )                   | (1,090 )           |
| Purchase of available-for-sale securities                                   | (6,614 )                   | (10,949 )          |
| Sales of available-for sale securities                                      | 246                        | —                  |
| Maturity of available-for-sale securities                                   | 4,007                      | —                  |
| Net cash used in investing activities                                       | (3,718 )                   | (12,039 )          |
| Cash flows from financing activities:                                       |                            |                    |
| Issuance of common stock and warrants                                       | 44,875                     | 19,911             |
| Exercise of warrants and options  | 730                        | 20,514             |
| Payments on capital lease obligations                                       | (71 )                      | —                  |
| Net cash provided by financing activities                                   | 45,534                     | 40,425             |
| Increase in cash and cash equivalents                                       | 27,822                     | 21,384             |
| Cash and cash equivalents, beginning of period                              | 30,029                     | 12,069             |
| Cash and cash equivalents, end of period                                    | \$57,851                   | \$ 33,453          |



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**

Accelerate Diagnostics, Inc. (“Accelerate” or the “Company”) is a Delaware corporation focused on developing and commercializing innovative instrumentation for the rapid identification and antibiotic susceptibility testing of infectious pathogens. The Company’s ID/AST instrument utilizes a proprietary culture-free process with both genomic and phenotypic detection technologies that decrease time to result while maintaining high sensitivity and specificity.

**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, 2013, as filed with the SEC on March 7, 2014 and subsequently amended by the Annual Report on Form 10-K/A (Amendment No. 1) that we filed with the SEC on March 28, 2014.

The condensed consolidated balance sheet as of December 31, 2013 included herein was derived from the audited financial statements as of that date, but does not include all disclosures including 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, 2014 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.

## **NOTE 2. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS**

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-15, *Presentation of Financial Statements – Going Concern*. The new standard required 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 annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early adoption is permitted. We do not expect the adoption of the ASU to have a significant impact on our 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. The new standard is effective for us on January 1, 2017. Early adoption is not permitted. 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 that will be elected.

In July 2013, the FASB issued ASU 2013-11, which requires a reporting entity to present an unrecognized tax benefit as a liability in the financial statements separate from deferred tax assets if a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date to settle taxes that would result from the disallowance of the tax position or if a reporting entity does not intend to use the deferred tax asset for such purpose. The amendments in ASU 2013-11 are effective for fiscal years, and interim periods within those years, beginning on or after December 15, 2013. The adoption of ASU 2013-11 did not have a material impact on the Company's consolidated financial statements.

In March 2013, the FASB issued ASU 2013-04, which provides guidance on the recognition, measurement, and disclosure of obligations resulting from joint and several liability arrangements for which the total amount of the obligation is fixed at the reporting date. The update requires an entity to measure obligations resulting from joint and several liability obligations for which the total amount of the obligation within the scope of the update is fixed at the reporting date, as the sum of the amount the reporting entity agreed to pay on the basis of its arrangements among its co-obligors and any additional amount the reporting entity expects to pay on behalf of its co-obligors. The update also requires an entity to disclose the nature and amount of the obligation as well as other information about those obligations. The amendments in ASU 2013-04 are effective for fiscal years and interim periods within those years, beginning on or after December 15, 2013 and must be applied retrospectively. The adoption of ASU 2013-04 did not have a material impact on the Company's consolidated financial position, results of operations, or cash flows.

### **NOTE 3. FAIR VALUE OF FINANCIAL INSTRUMENTS**

The carrying amounts of financial instruments such as cash equivalents, restricted cash, accounts receivable, prepaid expenses, other current assets, accounts payable, accrued expenses, and other current liabilities approximate the related fair values due to the short-term maturities of these instruments. The Company may invest its excess cash into financial instruments that are readily convertible into cash, such as marketable securities, money market funds and certificates of deposit with original maturities of three months or less at the date of purchase. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. The Company has established guidelines to maintain safety and liquidity for our financial instruments, and the cost of securities sold is based on the specific identification method.

*ASC Topic 820, Fair Value Measurements and Disclosures* has redefined fair value and required the Company to establish a framework for measuring fair value and expand disclosures about fair value measurements. The framework requires the valuation of assets and liabilities subject to fair value measurements using a three tiered approach and fair value measurement be classified and disclosed in one of the following three categories:

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Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability;

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e. supported by little or no market activity).

The following tables represent the financial instruments measured at fair value on a recurring basis on the consolidated financial statements of the Company subject to *ASC Topic 820, Fair Value Measurements and Disclosure*, and the valuation approach applied to each class of financial instruments at September 30, 2014 and December 31, 2013 (in thousands):

### September 30, 2014

(in thousands)

|  | Quoted Prices in Active<br>Markets for Identical<br>Assets (Level 1) | Significant Other<br>Observable Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) | Total     |
|--|--|---|--|-----------|
| <b>Assets:</b>                           |  |   |  |           |
| Money market funds<br>(cash equivalents) | \$ 11,913  | \$ —  | \$ —   | \$ 11,913 |
| Corporate notes and<br>bonds             | —  | 13,827  | —  | 13,827    |
| Asset-backed<br>securities               | —  | 254   | —  | 254       |
| Total assets measured<br>at fair value   | \$ 11,913  | \$ 14,081   | \$ —   | \$ 25,994 |

### December 31, 2013

(in thousands)

|  | Quoted Prices in Active<br>Markets for Identical<br>Assets (Level 1) | Significant Other<br>Observable Inputs<br>(Level 2) | Significant<br>Unobservable<br>Inputs<br>(Level 3) | Total     |
|--|--|---|--|-----------|
| <b>Assets:</b>                           |  |   |  |           |
| Money market funds<br>(cash equivalents) | \$ 27,096  | \$ —  | \$ —   | \$ 27,096 |
| Corporate notes and<br>bonds             | —  | 11,460  | —  | 11,460    |
| Asset-backed<br>securities               | —  | 500   | —  | 500       |
|  | \$ 27,096  | \$ 11,960   | \$ —   | \$ 39,056 |

Total assets measured  
at fair value

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 significant transfers between levels during the nine-month period ended September 30, 2014.

#### NOTE 4. INVESTMENTS

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

|                           | <b>Amortized<br/>Cost</b> | <b>Gross<br/>Unrealized<br/>Gains</b> | <b>Gross<br/>Unrealized<br/>Losses</b> | <b>Fair Value</b> |
|---------------------------|---------------------------|---------------------------------------|--|-------------------|
| Asset-backed securities   | \$254                     | \$—                                   | \$—                                    | \$254             |
| Corporate notes and bonds | 13,816                    | 15                                    | (4 )                                   | 13,827            |
| Total                     | \$14,070                  | \$15                                  | \$(4 )                                 | \$14,081          |

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

|                         | <b>Amortized<br/>Cost</b> | <b>Fair Value</b> |
|-------------------------|---------------------------|-------------------|
| Due in less than 1 year | \$11,036                  | \$11,034          |
| Due in 1-3 years        | 3,034                     | 3,047             |
| Total                   | \$14,070                  | \$14,081          |





**NOTE 5. PROPERTY AND EQUIPMENT**

Property and equipment are recorded at cost and consisted of the following at September 30, 2014 and December 31, 2013 (in thousands):

| <b>Property and Equipment</b><br>(in thousands) | <b>September December</b> |             |
|---|---------------------------|-------------|
|   | <b>30,</b>                | <b>31,</b>  |
|   | <b>2014</b>               | <b>2013</b> |
| Computer equipment                              | \$ 897                    | \$ 567      |
| Laboratory and scientific equipment             | 1,300                     | 791         |
| Furniture and fixtures                          | 206                       | 37          |
| Manufacturing equipment                         | 89                        | —           |
| Leasehold improvements                          | 620                       | 279         |
| Capital lease – leasehold improvements          | 266                       | —           |
| Capital projects in progress                    | 55                        | —           |
| Total property and equipment                    | \$ 3,433                  | \$ 1,674    |
| Accumulated amortization – capital lease        | (100 )                    | —           |
| Accumulated depreciation – other                | (1,063 )                  | (627 )      |
| Net property and equipment                      | \$ 2,270                  | \$ 1,047    |

Depreciation expense, which includes amortization of capital lease assets, for the three-month periods ended September 30, 2014 and 2013 was \$251,000 and \$84,000 respectively, and for the nine-month periods ended September 30, 2014 and 2013, was \$536,000 and \$191,000, respectively.

**NOTE 6. INTELLECTUAL PROPERTY**

Intellectual property consisted of the following at the dates indicated (in thousands):

| <b>Intellectual Property</b><br>(in thousands) | <b>September December</b> |            |
|--|---------------------------|------------|
|  | <b>30,</b>                | <b>31,</b> |

|                           | <b>2014</b> | <b>2013</b> |
|---------------------------|-------------|-------------|
| Technologies              | \$ 193      | \$ 193      |
| Patents                   | 210         | 210         |
| Subtotal                  | \$ 403      | \$ 403      |
| Accumulated amortization  | (218 )      | (162 )      |
| Net intellectual property | \$ 185      | \$ 241      |

Future amortization expense for the intangible assets is estimated as follows (in thousands):

| <b>Intangible Assets Future<br/>Amortization<br/>Years Ending December 31<br/>(in thousands)</b> |       |
|--|-------|
| Remaining in 2014  | \$7   |
| 2015   | 8     |
| 2016   | 8     |
| 2017   | 8     |
| 2018   | 8     |
| Thereafter   | 146   |
| Total future amortization  | \$185 |

Intellectual properties are recorded at cost and are being amortized on a straight-line basis over their estimated useful lives of 20 years or the patent application life specific to each capitalized patent. Amortization expense for the three-month periods ended September 30, 2014 and 2013 was \$18,000 and \$19,000, respectively, and for the nine-month periods ended September 30, 2014 and 2013 was \$56,000 and \$58,000, respectively. The Company routinely evaluates the recoverability of its long-lived assets based upon estimated future cash flows from and estimated fair value of such long-lived assets. If in management's judgment, the anticipated undiscounted cash flows or estimated fair value are insufficient to recover the carrying amount of the long-lived asset, the Company will determine the amount of the impairment and the value of the asset will be written down. Impairment of intangible assets for the three- and nine-month periods ending September 30, 2014 and 2013 was \$0 and \$9,200, respectively.

## NOTE 7. LICENSE AGREEMENTS AND GRANTS

In May 2012, the Company and Denver Health were notified that the Defense Medical Research and Development Program (“DMRDP”) recommended \$2 million of funding for a proposed 35-month project of which the Company estimates it will receive direct monies for internal research and development of \$650,000. 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 Company’s ID/AST instrument to wound infections and other serious infections secondary to trauma. The Company has invoiced a cumulative total of \$308,000 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, 2014 and 2013 was \$50,000 and \$50,000, respectively, and for the nine-month periods ended September 30, 2014 and 2013 was \$150,000 and \$104,000, respectively.

On August 22, 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 will provide 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 September 30, 2014 the Company has collected \$750,000 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, we will recognize the grant as other non-operating income. Further details are included in Note 8, Deferred Revenue and Income.

**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, 2014 and December 31, 2013 follows (in thousands):

**Deferred Revenue and Income**

(in thousands)

|   | <b>September<br/>30,<br/>2014</b> | <b>December<br/>31,<br/>2013</b> |
|---|-----------------------------------|----------------------------------|
| Prepaid royalties                             | \$ 61                             | \$ 69                            |
| Fisher agreement                              | 13                                | 13                               |
| Total current deferred revenue and income     | \$ 74                             | \$ 82                            |
| Arizona Commerce Authority Grant (see Note 7) | \$ 750                            | \$ 750                           |
| Fisher agreement                              | 13                                | 27                               |
| Total long-term deferred income               | \$ 763                            | \$ 777                           |

Deferred revenue includes prepaid royalty fees. In September 2011, \$100,000 of prepaid royalty fees was received of which \$2,000 and \$3,000 were recognized during the three-month periods ended September 30, 2014 and 2013, respectively, and \$8,000 and \$15,000 were recognized during the nine-month periods ended September 30, 2014 and 2013, respectively. Recognized amounts are reflected as licensing and royalty revenue.

Deferred income includes a \$40,000 payment received from Fisher Scientific in July 2013, of which \$13,000 and \$0 has been recognized as an offset against research and development expenses in the three-month and nine-month periods ended September 30, 2014 and 2013, respectively. We anticipate earning \$13,000 of the remaining amount in the next twelve months and the final \$13,000 in future years.

Through September 30, 2014, \$750,000 in milestone payments from the Arizona Commerce Authority were received of which none has been recognized in income and we do not anticipate earning any of it in the next fiscal year. Further details regarding the Arizona Commerce Authority agreement are included in Note 7, License Agreements and Grants.

## **NOTE 9. STOCK PURCHASE**

On April 20, 2012, we entered into a Securities Purchase Agreement with Abeja Ventures, LLC (“Abeja”), pursuant to which the Company agreed to sell and issue to Abeja at a purchase price of \$1.03 per share for an aggregate purchase price of \$14,420,000; (i) 14,000,000 shares of the Company’s common stock (“Common Stock”); (ii) a warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$1.03 per share (the “\$1.03 Warrant”); and (iii) another warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$2.00 per share (the “\$2.00 Warrant”), with each warrant exercisable prior to the fifth anniversary of the closing of the transactions contemplated by the Securities Purchase Agreement (collectively, the “Investment”). The purchase of Common Stock and warrants pursuant to the Investment, which was consummated on June 26, 2012, qualified for equity treatment under U.S. GAAP. The respective values of the warrants and Common Stock were calculated using their relative fair values and both are classified under Contributed Capital. The value therefore recorded for the warrants was \$5,896,000 and for the Common Stock was \$8,524,000.

Both warrants were exercisable until June 26, 2017, which was the fifth anniversary of the date on which the warrants were issued. Other significant terms and conditions of the warrants are as follows:

he warrants provide for partial exercises, but they do not provide for a “cashless” exercise feature (i.e., they may only be exercised for cash);

the warrants do not contain anti-dilution provisions that would trigger exercise price or other adjustments as a result of subsequent issuances of the Company’s equity securities, but they do contain customary provisions for equitable adjustments in connection with stock dividends, stock splits or reclassifications of Common Stock;

following certain types of fundamental transactions involving the Company (e.g., a transaction resulting in a change in control of the Company), the holder of the warrants would continue to be entitled to exercise the warrants in exchange for the equity securities or alternate consideration receivable by a holder of Common Stock as a result of the fundamental transaction; and

the holder of the warrants is entitled to certain demand and piggy-back registration rights, including for shelf registrations, with respect to the shares of Common Stock issuable upon its exercise of the warrants.

On March 6, 2013, Abeja exercised in full its warrant to purchase 7,000,000 shares of Common Stock at an exercise price of \$1.03 per share. On the same date, Abeja also exercised the 92% of its warrant to purchase an additional 7,000,000 shares of Common Stock at an exercise price of \$2.00 per share (Abeja exercised such warrant for 6,428,840 shares, leaving 571,160 shares unexercised). The Company received aggregate funds of \$20,068,000 in connection with such exercises. Shares issued by the Company in connection with the warrant exercises were issued directly to the members of Abeja on a pro rata basis in accordance with their membership interests and written exercise instructions provided to the Company by Abeja. Immediately after giving effect to the warrant exercises, Abeja also distributed in kind to its members (on a pro rata basis in accordance with their membership interests) the remaining shares of Common Stock held by that entity.

#### **NOTE 10. RIGHTS OFFERING**

On April 7, 2014, the Company commenced a rights offering to raise \$45 million to fund continued operations, clinical trials, and product commercialization efforts. Under the terms of the rights offering, the Company distributed, at no charge to the holders of its Common Stock as of 5:00 p.m., New York City time, on March 14, 2014, which was established as the record date for the rights offering, 0.063921 non-transferable subscription rights for each share of Common Stock owned on the record date. Each whole subscription right allowed the holder to subscribe to purchase one share of Common Stock at a subscription price of \$16.80 per share. In the aggregate, the Company intended to issue 2,678,571 shares of Common Stock in connection with the rights offering. The purpose of the rights offering was to raise equity capital in a cost-effective manner that gives all of the Company's existing stockholders the opportunity to participate on a pro rata basis.

In connection with the rights offering, the Company received standby commitments from the Jack W. Schuler Living Trust and the Schuler Family Foundation. The standby purchasers agreed to purchase any and all shares of Common Stock that were not subscribed for by stockholders in connection with the rights offering. On May 1, 2014, the Company entered into an Assignment and Assumption Agreement with the standby purchasers, Oracle Institutional Partners, L.P. and Oracle Partners, L.P., pursuant to which each standby purchaser assigned and transferred its respective rights, responsibilities, liabilities and obligations under the Standby Purchase Agreement to purchase 297,619 shares of Common Stock not subscribed for by the Company's stockholders in connection with the rights offering to (i) Oracle Institutional Partners, L.P., with respect to 119,047 shares of such Common Stock, and (ii) Oracle Partners, L.P., with respect to the remaining 178,572 shares of such Common Stock.

The rights offering period expired at 5:00 p.m., New York City time, on April 28, 2014, and the transactions contemplated by the rights offering and the Standby Purchase Agreement described above (including the Company's issuance of an aggregate of 2,678,571 shares of its Common Stock to the rights offering participants and standby purchasers) were completed on May 19, 2014. The Company received gross proceeds of \$45,000,000 before costs associated with the transactions which totaled \$126,000.

Because the exercise price of the rights offering of \$16.80 was less than the fair value of the Company's shares of Common Stock at the expiration of the offering, there is a bonus element that is treated similar to a stock dividend. The weighted average shares outstanding, as well as the basic and diluted loss per share for the three-month and nine-month periods ended September 30, 2013 have been revised for those effects.

#### **NOTE 11. EARNINGS PER SHARE**

The Company follows *ASC 260, Earnings Per Share*, which requires companies to present basic earnings per share and diluted earnings per share. Basic earnings (loss) per share includes no dilution and is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding for the period.

The Company's net loss for the periods presented caused the inclusion of certain outstanding warrants and options to purchase our Common Stock to be antidilutive. As of September 30, 2014 and December 31, 2013, there were Common Stock options and warrants exercisable for 6,171,593 (571,160 warrants and 5,600,433 options) and 5,731,246 (571,160 warrants and 5,160,086 options) shares of Common Stock, respectively, which were not included in diluted loss per share as the effect was antidilutive.

Weighted average shares outstanding for the three and nine-month periods ended September 30, 2013 have been revised for the effects of the rights offering (See Note 10, Rights Offering).

**NOTE 12. EMPLOYEE STOCK-BASED COMPENSATION**

At the Company's 2014 Annual Meeting of Stockholders held on May 29, 2014, stockholders approved an amendment to the Company's 2012 Omnibus Equity Incentive Plan increasing the number of shares of Common Stock reserved and available for grant thereunder by 4,000,000 to 9,500,000 shares.



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

|  | <b>Stock-Based Compensation Expense</b> |           |                   |          |
|--|---|-----------|-------------------|----------|
|  | (in thousands)                          |           |                   |          |
|  | Three-month period                      |           | Nine-month period |          |
|  | ended                                   |           | ended             |          |
| September                              | <b>September</b>                        | September | <b>September</b>  |          |
| 30,                                    | <b>30,</b>                              | 30,       | <b>30,</b>        |          |
| 2014                                   | <b>2013</b>                             | 2014      | <b>2013</b>       |          |
| Research and development               | \$ 1,113                                | \$ 468    | \$ 3,225          | \$ 1,145 |
| Sales, general and administrative      | 1,290                                   | 540       | 4,109             | 1,467    |
| Total stock-based compensation expense | \$ 2,403                                | \$ 1,008  | \$ 7,334          | \$ 2,612 |

The following table summarizes option activity under all plans during the nine-month period that ended on September 30, 2014:

| Stock Option Activity                  | Number of Shares | Weighted Average Exercise Price |
|--|------------------|---------------------------------|
|  |                  | per Share                       |
| Options Outstanding December 31, 2013  | 5,160,086        | \$3.45                          |
| Granted                                | 709,025          | \$15.78                         |
| Cancelled                              | (13,678          | ) \$13.06                       |
| Exercised                              | (255,000         | ) \$2.86                        |
| Expired                                | —                | —                               |
| Options Outstanding September 30, 2014 | 5,600,433        | \$5.01                          |

The following table summarizes relevant information for options outstanding and options exercisable at September 30, 2014:

| Stock Option Supplemental Information                  | Options Outstanding | Options Exercisable |
|--|---------------------|---------------------|
| Number of options                                      | 5,600,433           | 1,756,885           |
| Weighted average remaining contractual term (in years) | 8.15                | 7.72                |
| Weighted average exercise price                        | \$5.01              | \$2.26              |
| Weighted average fair value                            | \$3.85              | \$1.52              |

|  |          |          |
|--|----------|----------|
| Aggregate intrinsic value (in thousands) | \$92,000 | \$34,000 |
|--|----------|----------|

As of September 30, 2014, unrecognized share-based compensation cost related to unvested stock options was \$8,982,000.

**NOTE 13. INCOME TAXES**

Deferred tax assets and liabilities are recorded for the estimated future tax effects of temporary differences between the tax basis of assets and liabilities and amounts reported in the accompanying balance sheets. The change in deferred tax assets and liabilities for the period represents the deferred tax provision or benefit for the period. Effects of changes in enacted tax laws in deferred tax assets and liabilities are reflected as an adjustment to the tax provision or benefit in the period of enactment.

The Company follows the provisions of *ASC 740, Income Taxes*, to account for any uncertainty in income taxes with respect to the accounting for all tax positions taken (or expected to be taken) on any income tax return. This guidance applies to all open tax periods in all tax jurisdictions in which the Company is required to file an income tax return. Under U.S. GAAP, in order to recognize an uncertain tax benefit the taxpayer must be more likely than not of sustaining the position, and the measurement of the benefit is calculated as the largest amount that is more than 50% likely to be realized upon resolution of the benefit. The Company determined that no uncertain tax positions have been taken or are expected to be taken that could have a material effect on the Company's income tax liabilities. Interest and penalties, if any, would be recorded to general and administrative expenses.

On January 8, 2014, we were notified by the Arizona Commerce Authority ("Authority") that we meet the program requirements to receive a "Certificate of Qualification" and, therefore, are eligible for a partial refund of research and development investments. Our research and development tax credit for 2013 is \$703,000 which made us eligible to claim a partial refund of 75% or \$527,000. We claimed this partial refund and, by doing so, irrevocably forfeited the remaining 25% tax credit amount along with any additional tax credits that might become available if our qualifying expenses increase or income tax liability decreases. The \$527,000 refund has been received and is recorded as a non-operating benefit from income taxes. If the amount received for this tax credit is later determined to be incorrect or invalid, the excess may be treated as a tax deficiency.

#### **NOTE 14. COMMITMENTS**

##### **Operating & Capital Lease Obligations**

On August 20, 2012, the Company entered into a Lease Agreement ("Lease") with Pima County, a political subdivision of the State of Arizona ("Landlord"), pursuant to which the Company will lease approximately 15,096 square feet of office space located in Tucson, Arizona for a period of three years (the "Initial Term"), which may be extended by the Company for up to three additional one-year periods (each a "Renewal Term"). The Lease also provides that the Company has the option, with six months prior notice to Landlord, to lease either or both of two additional areas with an aggregate size of approximately 7,920 square feet.

Pursuant to the Lease, the Company agreed to: (i) pay rent equal to \$9.25 per usable square foot per year (approximately \$140,000 per year) during the Initial Term and \$19.80 per usable square foot per year (approximately \$298,900 per year) during any Renewal Term; (ii) relocate its corporate offices to the Tucson area and begin operations within 30 days of the date that the tenant improvements are substantially completed (the "Commencement Date"); and (iii) within 18 months of the Commencement Date, employ at least 30 individuals with a median salary of at least \$70,000, which median salary must be maintained throughout the term of the Lease. If the Company fails to satisfy the condition described in clause (iii) of the preceding sentence, the rental rate under the Lease will be

increased by a percentage that is twice the percentage by which the Company's annual payroll has fallen short of the specified goal (subject to a cap equal to \$19.80 per usable square foot per year). The Lease also provides that Landlord will pay for tenant improvements (up to a cap of \$1,400,000) as well as certain repairs, utilities and insurance. As of February 1, 2013, we relocated our headquarters into the above described leased space in Tucson, Arizona.

On October 15, 2013, the Company executed the First Amendment to the Lease with Pima County to exercise its option and to expand its lease premises by 4,551 square feet whereby Pima County provided tenant improvements. After the completion of tenant improvements, the Company occupied this additional space in January, 2014. Pursuant to the First Amendment, the Company agreed to (i) pay rent equal to \$9.25 per square foot per year (approximately \$42,000 per year) and (ii) repay tenant improvements over the remaining lease term. These tenant improvements are treated as a capital lease whereby both an asset and a liability have been recorded and periodic interest and depreciation will be recorded to amortize the value of this asset and the liability over the remaining lease term. Further details regarding this capital lease are included in Note 5, Property and Equipment.

The future minimum lease payments under the capital lease together with the present value of the net minimum lease payments as of September 30, 2014 are as follows:

**Capital Lease Obligations**

(in thousands)

|                                      |       |
|--------------------------------------|-------|
| Year ending December 31:             |       |
| Remaining in 2014                    | \$38  |
| 2015                                 | 151   |
| 2016                                 | 13    |
| 2017                                 | —     |
| 2018                                 | —     |
| Total minimum lease payments         | \$202 |
| Less amount representing interest    | (6 )  |
| Present value minimum lease payments | \$196 |

In April 2014, the Company entered into a Second Amendment to the Lease with Pima County, pursuant to which the Company exercised its option to build-out and occupy 3,594 square feet and an additional 4,163 square feet not contemplated in the Lease for manufacturing and other operational requirements. Pursuant to the Second Amendment, the Company also agreed to: (i) pay rent equal to \$9.25 per usable square foot per year for the 3,594 option space and \$17.63 per usable square foot per year for the additional 4,163 square feet during the Initial Term; (ii) pay rent of \$19.80 per usable square foot per year for the 3,594 option space and \$17.63 per usable square foot per year for the additional 4,163 square feet during any Renewal Term; (iii) restore the 3,594 option space and the 4,163 additional space to a reasonable office typical tenant space at the end of the Lease; and (iii) adhere to all other terms of the Lease. The Company estimates that the costs for restoration at the end of the Lease as described in (ii) of the Second Amendment are immaterial and, therefore, no accrual has been recorded.

Total rent expense for the Tucson facility, including common area charges, for three-month periods ending September 30, 2014 and 2013 was approximately \$85,000 and \$30,000, respectively, and for the nine-month periods ending September 30, 2014 and 2013 was approximately \$198,000 and \$123,000 respectively. Future minimum lease payments under this agreement are as follows (in thousands):

**Operating Lease Obligations**

(in thousands)

|                          |      |
|--------------------------|------|
| Year ending December 31: |      |
| Remaining in 2014        | \$72 |
| 2015                     | 289  |
| 2016                     | 24   |

|                                   |       |
|-----------------------------------|-------|
| 2017                              | —     |
| 2018                              | —     |
| Thereafter                        | —     |
| Total operating lease obligations | \$385 |

## 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 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 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 ID/AST instrument, the Company will obtain sufficient capital to complete the development and required clinical trials of the ID/AST instrument, 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, 2013, as amended, 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.

## **Overview**

Accelerate Diagnostics, Inc. ("we" or "the Company") is focused on developing and commercializing innovative instrumentation for the rapid identification and antibiotic susceptibility testing of infectious pathogens. The Company's ID/AST instrument utilizes a proprietary culture-free process with both genomic and phenotypic detection technologies that decrease time to result while maintaining high sensitivity and specificity.

Every six minutes, another American dies from a hospital-acquired infection (HAI). The U.S. Centers for Disease Control and Prevention (“CDC”) estimates that almost 100,000 HAI fatalities occur annually that are attributable to bacterial infections acquired in a US healthcare facility. HAI occurs when a patient enters the hospital for some reason other than an infectious disease, then contracts infection more than two days after admission. Despite intensive efforts to improve prevention and care, mortality has remained the same for more than ten years.

Yet, in theory, none of these patients should die. An effective antibiotic exists for almost every HAI. Although bacterial strains exist that may resist any particular drug, strains that resist all antibiotics remain rare.

Lab delay is a major culprit leading to the high HAI mortality rate. Medical experts believe that inadequate initial therapy substantially elevates the risk of severe morbidity and mortality in critically ill patients. For critically ill patients, the physician must start adequate antibiotics within 2-4 hours of symptom onset. But lab cultures typically take 2-3 days to assess their antibiotic susceptibility. The physician has no choice but to start therapy without knowing the organism or its drug susceptibility. Most often, the physician must choose a combination of two or three broad-spectrum antibiotics, based on the patient’s history, clinical indicators, and the hospital’s recent history of antibiotic effectiveness in similar infections. Unfortunately, widespread and increasingly complex multiple antibiotic resistance typically causes such “empiric therapy” to prove inadequate in 20% to 40% of cases.



Switching to adequate therapy as soon as the next day fails to improve outcomes. Once an infection passes a critical point, antibiotics have little to no impact on its condition.

Popular news media have reported widely about methicillin-resistant *Staphylococcus aureus* (“MRSA”) as a multi-resistant “superbug.” Organizations such as the CDC and the Infectious Diseases Society of America have also identified other multi-drug resistant organisms as presenting even greater threats. They include *Pseudomonas*, *Acinetobacter*, and *Klebsiella*. In the hospital intensive care unit (“ICU”), “Staph” infections (including MRSA) typically cause approximately 30% of fatal HAIs. This increase in multi-drug resistant organisms creates an opportunity for the Company by driving demand for rapid susceptibility.

We believe that the development of new classes of antibiotics has significantly declined. Improved prevention and infection control have limited potential. In the meantime, bacteria continue to evolve and develop additional drug resistance. Bacteria have become so well adapted to the hospital that even the best preventive efforts do not eradicate them. Hospitals that lead in best preventive practices still suffer from endemic hospital-adapted strains that continue to cause high rates of attributable morbidity and mortality. Such examples suggest that each passing year sees a reduction in the number of cases that can be treated successfully with any particular drug.

We believe that dramatically speeding up laboratory diagnostics will help to improve the success rate for initial therapy for HAIs.

**Changes in Results of Operations: Three-month period ended September 30, 2014 compared to three-month period ended September 30, 2013**

During the three-month period ended September 30, 2014, total revenues were \$16,000, as compared to \$13,000 during the three-month period ended September 30, 2013, an increase of \$3,000 or 23%. The increase was due to fluctuations in partner sales volumes on which royalties were due the Company.

Research and development expenses for the three-month period ended September 30, 2014 were \$5,949,000, as compared to \$2,655,000 during the three-month period ended September 30, 2013, an increase of \$3,294,000 or 124%. The increase was primarily the result of increasing employee headcount, increased non-cash stock based compensation expenses of \$645,000 and increased purchases of laboratory and instrument engineering supplies to support research and development as well as pre-launch efforts.

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During the three-month period ended September 30, 2014, sales, general and administrative expenses were \$2,625,000, as compared to \$1,052,000 during the three-month period ended September 30, 2013, an increase of \$1,573,000 or 150%. The increase was primarily driven by salaries and related expenses as we ramp up our operations and includes an increase in non-cash stock based compensation expenses of \$750,000.

During the three-month period ended September 30, 2014, amortization was \$18,000, as compared to \$19,000 during the three-month period ended September 30, 2013, a decrease of \$1,000 or 5%.

Depreciation for the three-month period ended September 30, 2014 was \$251,000, as compared to \$84,000 during the three-month period ended September 30, 2013, an increase of \$167,000 or 199%. The increased depreciation was the result of purchases of equipment to up-fit the Company's new Tucson facility laboratory and administrative space.

As a result of the above factors, loss from operations for the three-month period ended September 30, 2014 was \$8,827,000, as compared to a loss of \$3,797,000 for the three-month period ended September 30, 2013, an increase in loss from operations of \$5,030,000 or 132%. 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, 2014 was \$13,000, as compared to \$0 during the three-month period ended September 30, 2013, an increase of \$13,000. This change was due to increased interest and dividend income on our cash balances and investments, which increased year-over-year.

As a result of these factors, net loss for the three-month period ended September 30, 2014 was \$8,814,000, as compared to a net loss of \$3,797,000 during the three-month period ended September 30, 2013, an increase in net loss of \$5,017,000 or 132%.

Unrealized loss on available-for-sale investments for the three-month period ended September 30, 2014 was \$17,000, as compared to an unrealized gain of \$11,000 during the three-month period ended September 30, 2013. The resulting comprehensive losses were \$8,831,000 and \$3,786,000 for the three-month periods ending September 30, 2014 and 2013, respectively.

**Changes in Results of Operations: Nine-month period ended September 30, 2014 compared to nine-month period ended September 30, 2013**

During the nine-month period ended September 30, 2014, total revenues were \$43,000, as compared to \$36,000 during the nine-month period ended September 30, 2013, an increase of \$7,000 or 19%. The increase was due to fluctuations in partner sales volumes on which royalties were due the Company.

Research and development expenses for the nine-month period ended September 30, 2014 were \$14,074,000, as compared to \$6,996,000 during the nine-month period ended September 30, 2013, an increase of \$7,078,000 or 101%. The increase was primarily the result of increasing employee headcount, an increase in non-cash stock based compensation expense of \$2,080,000 and increased purchases of laboratory and instrument engineering supplies to support research and development as well as pre-launch efforts.

During the nine-month period ended September 30, 2014, sales, general and administrative expenses were \$8,116,000, as compared to \$2,916,000 during the nine-month period ended September 30, 2013, an increase of \$5,200,000 or 178%. The increase was primarily driven by salaries and related expenses as we ramp up our operations and includes an increase in non-cash stock based compensation expenses of \$2,642,000.

During the nine-month period ended September 30, 2014, amortization was \$56,000 as compared to \$58,000 during the nine-month period ended September 30, 2013, a decrease of \$2,000 or 3%.

Depreciation for the nine-month period ended September 30, 2014 was \$536,000, as compared to \$191,000 during the nine-month period ended September 30, 2013, an increase of \$345,000 or 181%. The increased depreciation was the result of purchases of equipment to up-fit the Company's new Tucson facility laboratory and administrative space.

As a result of the above factors, loss from operations for the nine-month period ended September 30, 2014 was \$22,739,000, as compared to a loss of \$10,125,000 for the nine-month period ended September 30, 2013, an increase

in loss from operations of \$12,614,000 or 125%. This loss was 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, 2014 was \$44,000, as compared to \$3,000 during the nine-month period ended September 30, 2013, an increase of \$41,000 or 1367%. This change was due to increased interest and dividend income on our cash balances and investments, which increased year-over-year.

As a result of these factors, net loss before income taxes for the nine-month period ended September 30, 2014 was \$22,695,000, as compared to a net loss of \$10,122,000 during the nine-month period ended September 30, 2013, an increase in net loss of \$12,573,000 or 124%.

Benefit from income taxes for the nine-month period ended September 30, 2014 was \$527,000, as compared to \$0 during the nine-month period ended September 30, 2013. This is due to becoming eligible for and electing a partial refund of research and development tax credits as described above in Item 1, Note 13 Income Taxes. The resulting net losses were \$22,168,000 and \$10,122,000 for the nine-month periods ending September 30, 2014 and 2013, respectively.

Unrealized loss on available-for-sale investments for the nine-month period ended September 30, 2014 was \$11,000, as compared to a \$10,000 gain on available-for-sale investments during the nine-month period ended September 30, 2013. The resulting comprehensive losses were \$22,179,000 and \$10,112,000 for the nine-month periods ending September 30, 2014 and 2013, respectively.

### **Capital Resources and Liquidity**

During the nine-month period ended September 30, 2014, we did not generate positive cash flows from operating activities.

Our primary source of liquidity has been from sales of shares of common stock. As of September 30, 2014, the Company had \$71.9 million in cash and cash equivalents and available-for-sale securities, an increase of \$29.9 million from \$42 million at December 31, 2013. The primary reason for the change in these assets was the Company's successful completion of the rights offering described in Item 1, Note 10, Rights Offering.

As discussed in Item 1, Note 10 Rights Offering, on April 7, 2014, the Company commenced a rights offering to raise \$45 million which resulted in gross proceeds of \$45 million before expenses upon completion in May, 2014. The purpose of the rights offering was to raise equity capital in a cost-effective manner that gives all of the Company's existing stockholders the opportunity to participate on a pro rata basis. The net proceeds of the offering will be used for working capital and specifically to fund continued operations, clinical trials, and product commercialization efforts.

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 14 Commitments.

As of September 30, 2014, management believes that current cash balances will be more than sufficient to fund our capital and liquidity needs for the next twelve months.

The following summarizes selected items in the Company's unaudited condensed consolidated statements of cash flows for the nine-month period ended September 30, 2014 and fiscal year ended December 31, 2013 (in thousands):

**Cash Flow Summary**  
(in thousands)

|   | September<br>30, | December<br>31, |
|---|------------------|-----------------|
|   | <u>2014</u>      | <u>2013</u>     |
| Net cash used in operating activities     | 13,994           | 9,749           |
| Net cash used in investing activities     | 3,718            | 13,171          |
| Net cash provided by financing activities | 45,534           | 40,880          |

Our primary use of capital has been for the continued development and commercialization of the ID/AST instrument. 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. Further, 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, 2014.

## **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, short-term investments, which have an average maturity of less than one year and available for sale investments which have a maturity of more than one 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 4, Investments, to the footnotes to the financial statements included in this Quarterly Report on Form 10-Q.

## **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, 2014 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified

in the SEC's rules and forms and (ii) accumulated and communicated to the Company's management, including its Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

### **Changes in Internal Control Over Financial Reporting**

During the third quarter of 2013, the Company began an implementation of a new enterprise resource planning (ERP) information technology system. This implementation is planned in phases to correspond with the needs of the Company. The first phase, which involved transitioning the purchasing, accounts payable and general ledger functions to the new ERP was completed in January, 2014. The second phase, which involved implementation of manufacturing functions in the new ERP, was completed August, 2014. Further phases are planned to correspond with other business milestones. During each phase of the implementation, an appropriate level of training of employees, testing of the system and monitoring of the financial results recorded in the system is conducted.

Besides as noted above, there was no change in the Company's internal control over financial reporting during the quarterly period ended September 30, 2014 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**

We are not currently a party to any material legal proceedings.

### **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, as amended, for the fiscal year ended December 31, 2013.

### **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**

| <b><u>Exhibit No.</u></b> | <b><u>Description</u></b>  | <b><u>Filing Information</u></b> |
|---------------------------|--|----------------------------------|
| 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                        | Certificate 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

\* Furnished

\*\* 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 4, 2014 /s/ *Lawrence Mehren*  
Lawrence Mehren

President and Chief Executive Officer  
(Principal Executive Officer)

November 4, 2014 /s/ *Steve Reichling*  
Steve Reichling

Chief Financial Officer  
(Principal Financial and Accounting Officer)