Accelerate Diagnostics, Inc
Form 10-Q
May 07, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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 x 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 x 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 x
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 x

As of April 21, 2015, there were 44,657,329 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)

	Unaudited March 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$47,391	$53,563
Investments	11,061	13,115
Trade accounts receivable	92	78
Prepaid expenses	473	342
Other current assets	647	—
Total current assets	59,664	67,098
Property and equipment, net	3,508	2,536
Intellectual property, net	165	167
Total assets	$63,337	$69,801
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$2,364	$2,129
Accrued liabilities	1,000	494
Deferred income	13	13
Capital lease obligations	124	147
Total current liabilities	3,501	2,783
Long-term deferred income	1,014	1,014
Long-term capital lease obligation	—	13
Total liabilities	4,515	3,810
Commitments and contingencies (see note 12)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 55,000,000 common shares authorized 44,657,329 (as of March 31, 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 March 31, 2015 and December 31, 2014		
Contributed capital	133,079	131,356
Accumulated deficit	(74,314)	(65,417)
Accumulated other comprehensive income	12	7
Total stockholders' equity	58,822	65,991
Total liabilities and stockholders' equity	$63,337	$69,801

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 ended	
	March 31,	March 31,
	2015	2014
Revenues:		
Licensing and royalty revenues	$14	$14
Total revenues	14	14
Costs and expenses:		
Research and development	6,377	3,564
Sales, general and administrative	2,867	2,044
Amortization	2	19
Depreciation	326	134
Total costs and expenses	9,572	5,761
Loss from operations	(9,558)	(5,747)
Interest expense	(1)	—
Interest and dividend income	15	18
Total other income	14	18
Net loss before income taxes	(9,544)	(5,729)
Benefit from income taxes	647	527
Net loss	$(8,897)	$(5,202)
Basic and diluted net loss per share	(0.20)	(0.12)
Weighted average shares outstanding	44,650	41,895
Other comprehensive loss:		
Net loss	$(8,897)	$(5,202)
Net unrealized gain on available-for-sale investments	5	4
Comprehensive loss	$(8,892)	$(5,198)

See accompanying notes to consolidated financial statements.

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ACCELERATE DIAGNOSTICS, INC.

CONDENSED CONSOLIDATED

STATEMENT OF CASH FLOWS

Unaudited

(in thousands)

	Three-month period ended	
	March 31,	**March 31,**
	2015	**2014**
Net loss	$(8,897)	$(5,202)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	326	134
Amortization of intangible assets	2	19
Amortization on investment instruments	47	58
Equity-based compensation	1,657	1,760
(Increase) decrease in assets:		
Accounts receivable	(14)	(16)
Prepaid expense and other	(104)	(791)
Other current assets	(647)	—
Increase (decrease) in liabilities:		
Accounts payable	166	125
Accrued liabilities	501	244
Deferred income	—	(4)
Net cash used in operating activities	(6,963)	(3,673)
Purchases of equipment	(1,198)	(424)
Purchase of available-for-sale securities	(4,503)	(514)
Sales of available-for-sale securities	107	—
Maturity of available-for-sale securities	6,355	—
Net cash provided (used) in investing activities	761	(938)
Exercise of warrants and options	66	730
Rights offering costs incurred	—	(6)
Payments on capital lease obligations	(36)	—
Net cash provided by financing activities	30	724
Decrease in cash and cash equivalents	(6,172)	(3,887)
Cash and cash equivalents, beginning of period	53,563	30,029
Cash and cash equivalents, end of period	$47,391	$26,142

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

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.

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.

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. There were no intercompany transactions for the three-month periods ending March 31, 2015 and March 31, 2014.

NOTE 2. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In January 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 are 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 the ASU 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 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 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.

NOTE 3. FAIR VALUE OF FINANCIAL INSTRUMENTS

The following tables represent the financial instruments measured at fair value on a recurring basis on the financial statements of the Company and the valuation approach applied to each class of financial instruments at March 31, 2015 and December 31, 2014.

FINANCIAL INSTRUMENTS MEASURED AT FAIR VALUE

March 31, 2015

(in thousands)

	Quoted Prices in Active Markets for Identical Assets	**Significant Other Observable Inputs**	**Significant Unobservable Inputs**
	(Level 1)	**(Level 2)**	**(Level 3)**

				Total
Assets:				
Money market funds (cash equivalents)	$15,201	$—	$—	$15,201
Corporate notes and bonds	—	11,027	—	11,027
Asset-backed securities	—	34	—	34
Total assets measured at fair value	$15,201	$11,061	$—	$26,262

FINANCIAL INSTRUMENTS MEASURED AT FAIR VALUE

December 31, 2014

(in thousands)

	Quoted Prices in Active Markets for Identical Assets (Level 1)	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Total**
Assets:				
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

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 three-month period ended March 31, 2015.

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 periodically maintains cash balances at a commercial bank in excess of the Federal Deposit Insurance Corporation insurance limit of $250,000. At March 31, 2015 and December 31, 2014, the Company’s uninsured cash balance was approximately $48.2 million and $53.6 million, respectively.

The Company grants credit to domestic and international clients in various industries. Exposure to losses on accounts receivable is principally dependent on each client's financial position. At March 31, 2015 and December 31, 2014, 99% and 98%, respectively, of the outstanding receivable balance was with Denver Health and the Department of Defense related to the Defense Medical Research and Development Program. 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 March 31, 2015 and December 31, 2014 (in thousands):

AVAILABLE-FOR-SALE INVESTMENTS

March 31, 2015

(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Asset-backed securities	$ 34	$ —	$ —	$ 34
Corporate notes and bonds	11,016	14	(3)	11,027
Total	$ 11,050	$ 14	$ (3)	$ 11,061

December 31, 2014

(in thousands)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
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 March 31, 2015 and December 31, 2014 (in thousands):

AVAILABLE-FOR-SALE INVESTMENT MATURITIES

(in thousands)

	March 31, 2015		December 31, 2014	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Due in less than 1 year	$9,023	$9,025	$10,586	$10,585
Due in 1-3 years	2,027	2,036	2,522	2,530
Total	$11,050	$11,061	$13,108	$13,115

Proceeds from sales of marketable securities (including principal paydowns) for the three-month periods ended March 31, 2015 and 2014, were $107,000 and $0 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 and losses from sales of marketable securities for the three-month periods ended March 31, 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 March 31, 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.

NOTE 6. PROPERTY AND EQUIPMENT

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

Property and Equipment

(in thousands)

	March 31, 2015	December 31, 2014
Computer equipment	$1,655	$ 1,020
Manufacturing and laboratory equipment	1,957	1,625
Furniture and fixtures	212	212
Leasehold improvements	634	630
Capital lease – leasehold improvements	266	266
Capital projects in progress	554	227
Total property and equipment	$5,278	$ 3,980
Accumulated amortization – capital lease	(167)	(133)
Accumulated depreciation – other	(1,603)	(1,311)
Net property and equipment	$3,508	$ 2,536

Depreciation expense, which includes amortization of capital lease assets, for the three-month periods ended March 31, 2015 and 2014 was $326,000 and $134,000, respectively.

NOTE 7. LICENSE AGREEMENTS AND GRANTS

Schott Janaer 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 Medical Center (“Denver Health”) were notified that the Defense Medical Research and Development Program (“DMRDP”) recommended $2,000,000 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 Accelerate

ID/AST system to wound infections and other serious infections secondary to trauma. The Company has invoiced a cumulative total of $447,000 under this grant which is recorded as an offset to research and development expenses. The amount invoiced for the three-month periods ended March 31, 2015 and 2014 was $68,000 and $40,000, respectively.

Arizona Commerce Authority

In August 2012, the Company entered into a Grant Agreement (the "Grant Agreement") with the Arizona Commerce Authority, an agency of the State of Arizona (the "Authority"), pursuant to which the Authority provided certain state and county sponsored incentives for the Company to relocate its corporate headquarters to, and expand its business within, the State of Arizona (the "Project"). Pursuant to the Grant Agreement, the Authority agreed to provide a total grant in the amount of $1,000,000 (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.

National Institute of Health

In February 2015, we were notified that the National Institute of Health awarded a five year, $5,000,000 grant to Denver Health Medical Center and ourselves to develop a fast and reliable identification and categorical susceptibility test carbepenem-resistant Enterobacteriaceae directly from whole blood. We are still working out the final contractual agreement with Denver Health Medical Center.

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 March 31, 2015 and December 31, 2014 follows (in thousands):

Deferred Income

(in thousands)

	March 31, 2015	December 31, 2014
Fisher agreement	$13	$ 13
Total current deferred income	$13	$ 13
Arizona Commerce Authority Grant (see Note 7)	$1,000	$ 1,000
Fisher agreement	14	14
Total long-term deferred income	$1,014	$ 1,014

Deferred income includes a $40,000 payment received from Fisher Scientific in July 2013, of which $13,000 was recognized as an offset against research and development expenses in the year ended December 31, 2014. We anticipate earning $13,000 of the remaining amount in the next twelve months and the final $14,000 in future years.

Through December 31, 2014, $1,000,000 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. EARNINGS PER SHARE

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

The Company’s net loss for the periods presented caused the inclusion of all outstanding warrants, restricted stocks and options to purchase our Common Stock to be antidilutive. As of March 31, 2015 and December 31, 2014, there were Common Stock options, restricted stocks and warrants exercisable for 6,473,788 and 6,174,886 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-month period ended March 31, 2014 have been revised for the effects of the April, 2014 rights offering.

NOTE 10. EMPLOYEE AND CONSULTANT EQUITY-BASED COMPENSATION

The following table summarizes option activity under all plans during the three-month period ended March 31, 2015.

Stock Option Activity

	Number of Shares	Weighted Average Exercise Price

		per Share
Options Outstanding December 31, 2014	5,603,726	$5.21
Granted	288,652	20.75
Forfeited	(12,500)	16.70
Exercised	(17,500)	3.74
Expired	—	—
Options Outstanding March 31, 2015	5,862,378	$5.95

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 Months Ended March 31,	
	2015	2014
Expected term (in years)	8.19	6.01
Volatility	89 %	97 %
Expected dividends	—	—
Risk free interest rates	1.78 %	1.84 %
Weighted average fair value	$17.46	$11.46

The following table shows summary information for outstanding options, options that are exercisable (vested) and outstanding options that are either vested or expected to vest as of March 31, 2015:

Stock Option Supplemental Information

	Options Outstanding	**Options Exercisable**	**Options Vested and Expected to Vest**
Number of options	5,862,378	2,936,170	5,832,057
Weighted average remaining contractual term (in years)	7.78	7.49	7.78
Weighted average exercise price	$5.95	$4.02	$5.92
Weighted average fair value	$4.68	$2.97	$4.65
Aggregate intrinsic value (in thousands)	$96,961	$54,256	$96,643

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 Months Ended March 31,	
	2015	2014
Research and development	$688	$824
Sales, general and administrative	969	936
Total stock-based compensation expense	$1,657	$1,760

The following table summarizes restricted stock activity during the three-month period ended March 31, 2015, none of which are vested as of March 31, 2015:

Restricted Stock Activity

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Restricted Stocks Outstanding December 31, 2014	—	$—
Granted	40,250	20.91
Forfeited	—	—
Vested/released	—	—
Restricted Stocks Outstanding March 31, 2015	40,250	$20.91

As of March 31, 2015, unrecognized equity-based compensation cost related to unvested stock options and restricted stock was $11.3 million and $894,000, respectively.

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 three-month periods ending March 31, 2015 and 2014, respectively. The refund for the 2013 tax year has been received and the amount for the 2014 tax year remains outstanding and is recorded as other current assets on the Condensed Consolidated Balance Sheets.

NOTE 12. COMMITMENTS, CONTINGENCIES AND LEGAL MATTERS

Operating & Capital Lease Obligations

Total rent expense for the Tucson facility, including common area charges for the three-month periods ending March 31, 2015 and 2014 was $115,000 and $49,000, respectively. Future minimum lease payments are as follows (in thousands):

	Operating Lease Obligations
(in thousands)	
Year ending December 31:	
2015	$633
2016	60
2017	—
2018	—
2019	—
Thereafter	—
Total operating lease obligations	$693

The future minimum lease payments under our capital lease arrangement together with the present value of the net minimum lease payments as of March 31, 2015 are as follows:

	Capital Lease Obligations
(in thousands)	
Year ending December 31:	
2015	$113
2016	13
2017	—
2018	—
2019	—
Total minimum lease payments	$126
Less amount representing interest	(2)
Present value minimum lease payments	$124

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. We incurred $180,000 and $0 for these arrangements during the three-month periods ending March 31, 2015 and 2014 respectively.

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. 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. 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.

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 th plans and objectives of management for future operations, including plans and objectives relating to the products and future economic performance of the Company. In addition, all statements other than statements of historical facts that address activities, events, or developments the Company expects, believes, or anticipates will or may occur in the future, and other such matters, are forward-looking statements.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. These forward-looking statements are based on assumptions that the Company will retain key management personnel, the Company will be successful in the development of the Accelerate 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 approximately five 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. Accordingly, we plan to initiate a U.S. clinical trial to support U.S. Food and Drug Administration ("FDA") marketing approval in the first half of 2015, and following the successful completion of this trial, we plan to commercialize the FDA approved system. Achieving each of these milestones 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 to realize our mission of establishing global market leadership in clinical microbiology.

Changes in Results of Operations: Three-month period ended March 31, 2015 compared to three-month period ended March 31, 2014

During the three-month period ended March 31, 2015, total revenues were $14,000 which were essentially unchanged from our revenues during the three-month period ended March 31, 2014.

Research and development expenses for the three-month period ended March 31, 2015 were $6,377,000 as compared to $3,564,000 during the three-month period ended March 31, 2014, an increase of $2,813,000 or 79%. The increase was primarily the result of increasing employee headcount, and increased purchases of laboratory and instrument engineering supplies to support research and development as well as pre-launch efforts. Research and development expenses include non-cash equity-based compensation for the three-months periods ended March 31, 2015 and 2014 of $688,000 and $824,000, respectively.

During the three-month period ended March 31, 2015, sales, general and administrative expenses were $2,867,000 as compared to $2,044,000 during the three-month period ended March 31, 2014, an increase of $823,000 or 40%. The increase is 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-months periods ended March 31, 2015 and 2014 of $969,000 and $936,000, respectively.

During the three-month period ended March 31, 2015, amortization was $2,000 as compared to $19,000 during the three-month period ended March 31, 2014, a decrease of $17,000 or 89%. This decrease is the result of patents that became fully amortized during the previous year.

Depreciation for the three-month period ended March 31, 2015, was $326,000 as compared to $134,000 during the three-month period ended March 31, 2014, an increase of $192,000 or 143%. 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 March 31, 2015 was $9,558,000 as compared to the loss of $5,747,000 during the three-month period ended March 31, 2014, an increase in loss from operations of $3,811,000 or 66%. The loss includes non-cash equity-based compensation expenses for the three-month periods ended March 31, 2015 and 2014 of $1,657,000 and $1,760,000, 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 March 31, 2015 was $14,000 as compared to $18,000 during the three-month period ended March 31, 2014, a decrease of $4,000 or 22%. This change was due to decreased interest and dividend income on our cash balances and investments which decreased between the two periods.

Income tax benefit during the three-month period ended March 31, 2015 was $647,000 as compared to $527,000 during the three-month period ended March 31, 2014. 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 three-month period ended March 31, 2015 was $8,897,000 as compared to a net loss of $5,202,000 during the three-month period ended March 31, 2014, an increase in net loss of $3,695,000 or 71%.

Unrealized gain on available-for-sale investments for the three-month period ended March 31, 2015 was $5,000 as compared to a gain of $4,000 during the three-month period ended March 31, 2014. The resulting comprehensive losses were $8,892,000 and $5,198,000 for the three-month periods ended March 31, 2015 and 2014, respectively.

Capital Resources and Liquidity

Our primary source of liquidity has been from sales of shares of common stock. As of March 31, 2015, the Company had $58.5 million in cash and cash equivalents and available-for-sale securities, a decrease of $8.2 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.

As of March 31, 2015, 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 condensed consolidated statements of cash flows for the three-month periods ended March 31, 2015 and the year ended December 31, 2014 (in thousands):

Cash Flow Summary
(in thousands)

	March 31, 2015	**December 31, 2014**
Net cash used in operating activities	$ (6,963)	$ (18,785)
Net cash provided (used) in investing activities	761	(3,372)
Net cash provided by financing activities	30	45,691

Our primary use of capital has been for the continued development and commercialization of the Accelerate ID/AST system. We believe our capital requirements will continue to be met with our existing cash balance and those provided under grants, exercises of warrants and stock options and/or, additional issuance of equity or debt securities. 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 March 31, 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.

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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 March 31, 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 March 31, 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. 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. 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	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.

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SIGNATURES

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

ACCELERATE DIAGNOSTICS, INC.

May 7, 2015 /s/ Lawrence Mehren
Lawrence Mehren

President and Chief Executive Officer
(Principal Executive Officer)

May 7, 2015 /s/ Steve Reichling
Steve Reichling

Chief Financial Officer
(Principal Financial and Accounting Officer)