

Accelerate Diagnostics, Inc  
Form 10-Q  
May 10, 2013

**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 March 31, 2013

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**

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 May 1, 2013, there were 38,842,209 shares of the registrant's common stock outstanding.

**INDEX**

**PART I**

Item 1	Financial Statements	4
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3	Quantitative and qualitative Disclosures about Market Risk	16
Item 4	Controls and Procedures	16

**PART II**

Item 1	Legal Proceedings	16
Item 1A	Risk Factors	16
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	17
Item 3	Defaults Upon Senior Securities	17
Item 4	Mine Safety Disclosures	17
Item 5	Other Information	17
Item 6	Exhibits	17

**PART I—FINANCIAL INFORMATION****Item 1. Financial Statements.**ACCELERATE DIAGNOSTICS, INC.  
CONDENSED BALANCE SHEETS  
MARCH 31, 2013 AND DECEMBER 31, 2012

## ASSETS

	<b><u>March 31,</u></b> <b><u>2013</u></b>	<b><u>December 31,</u></b> <b><u>2012</u></b>
	<b><u>(Unaudited)</u></b>	
Current assets:		
Cash and cash equivalents	\$29,256,692	\$12,068,747
Trade accounts receivable	793,500	763,899
Prepaid expenses and other (Note 5)	92,132	16,379
Total current assets	\$30,142,324	\$12,849,025
Property and equipment, net (Note 6)	776,852	147,811
Intellectual property, net (Note 7)	309,869	319,280
Total Assets	\$31,229,045	\$13,316,116

## LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$28,979	\$299,650
Accrued compensation and other liabilities	1,036,566	870,384
Deferred revenue (Note 8)	70,498	78,034
Total current liabilities	\$1,136,043	\$1,248,068
Long-term liabilities	—	—
Total liabilities	\$1,136,043	\$1,248,068
Shareholders' equity (Note 9):		
Common stock, \$0.001 par value;		
45,000,000 shares authorized; 38,832,209 (2013) and 25,331,939 (2012)	38,832	25,332
shares issued and outstanding		
Contributed capital	51,805,215	31,244,462
Accumulated deficit	(21,751,045)	(19,201,746)
Total shareholders' equity	30,093,002	12,068,048
Total liabilities and shareholders' equity	\$31,229,045	\$13,316,116

See accompanying notes to financial statements.

ACCELERATE DIAGNOSTICS, INC.  
 CONDENSED STATEMENT OF OPERATIONS  
 FOR THE THREE MONTHS ENDED MARCH 31, 2013 AND 2012  
 (Unaudited)

Revenues (Note 8):	2013	2012
OptiChem revenue	\$ 15,678	\$ 9,197
Total revenues	\$ 15,678	\$ 9,197
Costs and expenses:		
Research and development	\$ 1,881,980	\$ 98,183
General and administrative	629,018	162,263
Amortization (Note 7)	19,054	64,261
Marketing and sales	—	1,141
Depreciation	36,386	515
Total costs and expenses	\$ 2,566,438	\$ 326,363
Income (Loss) from operations	(\$2,550,760 )	(\$317,166 )
Other (expense) income:		
Interest and dividend income	1,461	2,052
Unrealized holding gain (loss) on investments	—	15,612
Total other income	\$ 1,461	\$ 17,664
Net income(loss)	(\$2,549,299 )	(\$299,502 )
Net income (loss) per share: Basic and diluted net income(loss) per share	(\$0.09 )	(\$0.03 )
Weighted average shares outstanding	29,133,781	11,103,367

See accompanying notes to financial statements.

ACCELERATE DIAGNOSTICS, INC.  
 CONDENSED STATEMENTS OF CASH FLOWS  
 FOR THE THREE MONTH PERIODS ENDED MARCH 31, 2013 AND 2012

Cash flows from operating activities:	2013	2012
Net loss	(\$2,549,299 )	(\$299,502 )
Adjustments to reconcile net (loss) to net cash (used in) operating activities:		
Depreciation	36,386	515
Amortization	19,054	64,261
Fair value of stock options granted for services	436,893	36,130
(Increase) decrease in assets:		
Accounts receivable	(29,601 )	(2,060 )
Inventory	—	—
Prepaid expense and other	(75,754 )	(924 )
Increase (decrease) in liabilities:		
Accounts payable	(270,671 )	18,682
Accrued liabilities	166,182	267
Deferred revenue	(7,536 )	(8,328 )
Deferred compensation	—	(17,380 )
Net cash (used in) operating activities	(\$2,274,346 )	(\$208,339 )
Cash flows from investing activities:		
Purchases of equipment and patent costs	(\$675,069 )	(\$22,311 )
Contribution to Deferred Compensation Trust	—	—
Net cash (used in) investing activities	(\$675,069 )	(\$22,311 )
Cash flows from financing activities:		
Exercise of Warrants and Options	20,137,360	—
Net cash provided by financing activities	\$ 20,137,360	\$ —
Increase (decrease) in cash and cash equivalents	17,187,945	(230,650)
Cash and cash equivalents, beginning of quarter	12,068,747	587,556
Cash and cash equivalents, end of quarter	\$ 29,256,692	\$ 356,906

See accompanying notes to financial statements.



**ACCELERATE DIAGNOSTICS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**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 BACce™ platform utilizes a proprietary culture-free process with both genomic and phenotypic detection technologies that decrease time to result while maintaining high sensitivity and specificity.

The financial statements included herein have been prepared by Accelerate without audit, pursuant to the rules and regulations of the United States Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures normally included in the financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted as allowed by such rules and regulations. The Company believes that the disclosures are adequate to make the information presented not misleading. These financial statements should be read in conjunction with our audited financial statements dated July 31, 2012, which were included in our Annual Report on Form 10-K as filed with the SEC on October 26, 2012, and our audited financial statements dated December 31, 2012, which were included in our Transition Report on Form 10-K as filed with the SEC on March 20, 2013.

Management believes that the accompanying unaudited financial statements are prepared in conformity with generally accepted accounting principles, which require the use of management estimates, and contain all adjustments (including normal recurring adjustments) necessary to present fairly the operations and cash flows for the periods presented. The results of operations for the three months ended March 31, 2013 may not be indicative of the results of operations for the fiscal year ended December 31, 2013.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those

estimates.

It is management's opinion that all adjustments necessary for a fair statement of the results for the interim periods have been made, and all such adjustments are of a normal recurring nature. These financial statements should be read in conjunction with the company's transition report on form 10-K dated December 31, 2012, and its most recent annual report dated July 31, 2012.

### **Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents 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, 2013 and December 31, 2012, the Company's uninsured cash balance was approximately \$29,006,692 and \$12,004,575, 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, 2013, 95% of the outstanding receivable balance was with one company, Nanosphere, for the final milestone payment under our license arrangement with them. The Company believes this receivable to be collectible and as such it has not been reserved but does represent a concentration of credit risk with one customer. The Company performs ongoing credit evaluations of its clients' financial condition.

### **Estimated Fair Value of Financial Instruments**

The carrying amounts of cash and cash equivalents, investments and other long-term liabilities approximates fair value at that respective period's balance sheet date.

The carrying value of all other financial instruments potentially subject to valuation risk, principally consisting of accounts receivable and accounts payable, also approximates fair value.

The following methods and assumptions were used to estimate the fair value of financial instruments:

Cash and Cash Equivalents – Generally, cash held by the Company is invested in US Treasury securities. The carrying amount approximates fair value. Investments - The carrying amount is based on quoted market prices plus cash. Long-Term Receivables - discounted future cash flows. Other Long-Term Liabilities - The carrying amount approximates fair value.

### **Cash and Cash Equivalents**

All highly liquid investments with an original maturity of three months or less at time of purchase are considered to be cash equivalents. Cash and cash equivalents include overnight repurchase agreement accounts. As part of our cash management process, excess operating cash is invested in overnight repurchase agreements with our bank. Repurchase agreements are not deposits and are not insured by the U.S. Government, the FDIC or any other government agency and involve investment risk including possible loss of principal. We believe however, that the market risk arising from holding these financial instruments is minimal.

## **Inventory**

As of March 31, 2013 and December 31, 2012 the company held no inventory.

## **Property and Equipment**

Property and equipment are recorded at cost. Maintenance and repairs are charged to expense as incurred and expenditures for major improvements are capitalized. Gains and losses from retirement or replacement are included in costs and expenses. Depreciation of property and equipment is computed using the straight-line method over the estimated useful life of the assets, ranging from three to seven years.

## **Research and Development**

Research and development costs charged to operations for the three-month periods ended March 31, 2013 and 2012 were \$1,881,980 and \$98,183, respectively.

## **Intellectual Property**

Intellectual property is amortized over the period the asset is expected to contribute directly or indirectly to the Company's future cash flows. The Company evaluates the remaining useful life of each intellectual property that is being amortized each reporting period to determine whether events and circumstances warrant a revision to the remaining period of amortization. Included in intellectual property are patents and technology. Intellectual properties are currently being amortized over their estimated useful lives of 20 years.

### **Long-lived Assets**

Long-lived assets and certain identifiable intangibles to be held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company continuously evaluates the recoverability of its long-lived assets based on estimated future cash flows from and the estimated fair value of such long-lived assets, and provides for impairment if such undiscounted cash flows or the estimated fair value are insufficient to recover the carrying amount of the long-lived asset. See Note 7 below.

### **Revenue Recognition**

We recognize revenue in accordance with ASC 605, "Revenue Recognition," when persuasive evidence of an arrangement exists, the price is fixed or determinable, collection is reasonably assured and delivery of products has occurred or services have been rendered.

### **OptiChem Revenues**

Revenue is recognized upon the receipt of royalty payments from our licenses.

### **Sales Returns and Allowances**

Allowances on accounts receivable and notes receivable are recorded when circumstances indicate collection is doubtful for particular accounts receivable. Receivables are written off if reasonable collection efforts prove unsuccessful. The Company provides for sales returns and allowances on a specific account basis.

### **Deferred Revenue**

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

## **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 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.

## **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 shareholders by the weighted average number of common shares outstanding for the period.

The Company's net loss for the periods presented cause the inclusion of potential Common Stock instruments outstanding to be antidilutive. For the period ended March 31, 2013 and the fiscal year ended December 31, 2012, there were Common Stock options and warrants exercisable for 5,350,660 (571,160 warrants and 4,779,500 options) and 18,431,930 (14,071,430 warrants and 4,360,500 options) shares of Common Stock, respectively, which were not included in diluted loss per share as the effect was antidilutive.

### **Equity Based Compensation**

The Company awards stock options and other equity-based instruments to its employees, directors and consultants. Compensation cost related to equity based awards is based on the fair value of the instrument on the grant date, and is recognized over the requisite service period. The Company estimates the fair value of stock option awards, including modifications of stock option awards, using the Black-Scholes option pricing model. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield. The Company's expected volatility is based on the historical volatility of the Company's stock price over the most recent period commensurate with the expected term of the stock option award. The estimated expected option life is based on historical employee exercise patterns and other factors useful in estimating the expected holding behavior of our option holders. The Company has not paid dividends in the past and does not have any plans to pay any dividends in the future. See Note 9 for further information.

### **Comprehensive Income (loss)**

The Company follows ASC 220, "Reporting Comprehensive Income," which establishes standards for reporting and displaying comprehensive income (loss) and its components (revenues, expenses, gains and losses) in a full set of general-purpose financial statements. The Company has no other items that would be included in comprehensive income (loss).

### **NOTE 3. RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS**

There have been no new accounting pronouncements issued but not yet adopted that are expected to materially affect the Company's financial condition or results of operations.

### **NOTE 4. INVENTORY**

The Company as of March 31, 2013 and December 31, 2012 did not hold any inventory.

#### **NOTE 5. PREPAID EXPENSES AND OTHER CURRENT ASSETS**

Prepaid expenses and other current assets as of March 31, 2013 and December 31, 2012 totaled \$92,132 and \$16,379, respectively.

#### **NOTE 6. PROPERTY AND EQUIPMENT**

Property and equipment are recorded at cost and consisted of the following as of March 31, 2013 and December 31, 2012.

	<b>3/31/2013</b>	<b>12/31/2012</b>
Computer equipment	\$299,449	\$89,109
Laboratory and scientific equipment	559,526	323,151
Furniture and fixtures	36,988	36,988
Leasehold improvements	258,453	39,741
Total property and equipment	1,154,416	488,989
Accumulated depreciation	(377,564 )	(341,178 )
Net property and equipment	\$776,852	\$147,811

Depreciation expense for the three-month periods ended March 31, 2013 and 2012 was \$36,386 and \$515, respectively.





**NOTE 7. INTELLECTUAL PROPERTY**

Intellectual property consisted of the following at the dates indicated:

	<b>3/31/2013</b>	<b>12/31/2012</b>
OptiChem Technologies	\$ 192,954	\$ 192,954
Patents	221,476	211,833
Trademarks	—	—
	414,430	404,787
Accumulated amortization	(104,561 )	(85,507 )
Net intellectual property	\$ 309,869	\$ 319,280

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 March 31, 2013 and 2012 was \$19,054 and \$64,261, 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.

During the former fiscal year ended July 31, 2012, management determined that certain capitalized intellectual property amounts carried on our balance sheet were no longer recoverable or abandoned its plan to pursue marketability and accordingly reduced the amortized book values by \$1,996,583 and recognized the loss in its reported loss from operations. Also, during the former first quarter ended October 31, 2012, management determined that certain capitalized patent amounts carried on our balance sheet are no longer recoverable or abandoned its plan to pursue marketability and accordingly reduced the amortized book values by \$333,487 and recognized the loss in its reported loss from operations.

**NOTE 8. LICENSE AGREEMENTS AND GRANTS**

The Company signed a licensing agreement for microarraying slides using OptiChem coatings with Schott Jenaer Glas GmbH ("SCHOTT") on November 4, 2004. Since this time, SCHOTT and the Company have extended this license. On August 15, 2011, Schott Technical Glass Solutions GmbH renewed and expanded its licenses for OptiChem microarray slide products, designated as Schott Nexterion Slide H and Slide HS. The terms remain substantially the same as in previous agreements, with the expansion to include microarray slide products intended for use in medical

diagnostic devices. Previous agreements excluded medical applications. This expansion makes SCHOTT the second company that intends to use OptiChem coatings on medical devices.

The new agreement extends the non-exclusive license through November 24, 2014. SCHOTT paid the Company \$150,000 comprised of a one-time license fee (\$50,000) and non-refundable prepaid royalties (\$100,000). Royalties consist of 5% of SCHOTT's net product sales. For medical applications, SCHOTT agrees to refer individual customers directly to the Company for licensing if annual purchases by a customer exceed 20,000 units.

On October 5, 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.

On July 9, 2010 the Company entered into a non-exclusive license to Nanosphere, Inc. The license grants to Nanosphere the right to apply OptiChem coatings to Nanosphere's proprietary analytical products. The products may also include FDA-regulated diagnostics devices. Pursuant to the license agreement, Nanosphere paid the Company a non-refundable first-year fee of \$150,000 plus a \$15,000 technology transfer fee. On each anniversary of the agreement date, the license calls for Nanosphere to pay to the Company the amounts of \$350,000 in 2011; \$600,000 in 2012, and \$750,000 in 2013 in order to complete the payments for rights under the remaining patent life. Pursuant to the Company's revenue recognition policies and generally accepted accounting principles, all of the amounts due from Nanosphere were recognized as OptiChem revenue during the fiscal year ended July 31, 2010.

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 \$750,000. 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 BACcel rapid diagnostic system to wound infections and other serious infections secondary to trauma.

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.

**NOTE 9. EMPLOYEE STOCK BASED COMPENSATION**

On March 31, 2013, there were Common Stock options outstanding at exercise prices ranging from \$0.73 to \$5.24 per share with expiration dates between July 31, 2013 and March 5, 2023. For the three months ended March 31, 2013 and 2012, stock options and warrants exercisable into 5,350,660 and 885,000 shares of Common Stock, respectively, were not included in the computation of diluted earnings per share because their effect was antidilutive.

For the quarters ended March 31, 2013 and 2012, the Company accounted for the compensation cost related to awards of stock options and other equity-based instruments to its employees, directors and consultants based on the fair value of the instrument on the grant date, and recognized this cost over the requisite service period. During the quarter ended March 31, 2013, the Company issued options to purchase at total of 429,000 common shares at exercise prices between \$4.21 and \$5.24 per share.

The fair value of options granted under the stock option agreements and stock-based compensation plans discussed above is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants for the three months ended March 31, 2013: no dividend yield; risk free interest rate of 1.17% to 1.28%; expected life of 6.6 years; and expected volatility of 96% to 98%. The weighted average remaining contractual life of options outstanding at March 31, 2013 and 2012 was 8.49 and 2.4 years, respectively.

As of March 31, 2013, unrecognized share-based compensation cost related to unvested stock options was \$4,401,256. For the three-month periods ended March 31, 2013 and 2012, the Company recognized \$436,893 and \$36,130, respectively, in stock-based compensation costs related to the issuance of stock options to employees.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Result of Operations.**

### **Forward Looking Information**

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 BACcel™ system, the Company will obtain sufficient capital to complete the development of the BACcel™ 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 discussion should be read in conjunction with the Company's unaudited condensed financial statements and related notes included elsewhere herein. 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 Securities and Exchange Commission including but not limited to the risks in the section entitled "Risk Factors" are in its Form 10-K for the transition period ended December 31, 2012, could affect the Company's actual results and cause actual results to differ materially from those discussed in forward-looking statements.

## Overview

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

On June 26, 2012, we closed upon the sale to Abeja at a purchase price of \$1.03 per share for an aggregate purchase price of \$14,420,000 of 14,000,000 shares of the Company's Common Stock, a warrant to purchase 7,000,000 shares of the Company's Common Stock at an exercise price of \$1.03 per share and another warrant to purchase 7,000,000 shares of the Company's Common Stock at an exercise price of \$2.00 per share (collectively the "Investment").

Since 2004, we have focused our efforts on the development of an innovative rapid diagnostic platform, the BACcel™ system, intended for rapid diagnosis in life-threatening bacterial infections. Our goal is to reduce the failure rate of initial therapy by shortening the lab turnaround time to less than eight hours, rather than the 2-3 days now required. Rapid testing would provide guidance in time to influence initial therapy.

The BACcel™ system applies our proprietary technology to eliminate time-consuming bacterial culturing, thus eliminating the major source of delay with current testing methods. Our system includes a fixed instrument and proprietary single-use (disposable) test cassettes. Each cassette tests a single patient specimen and is then discarded.

BACcel™ uses long-accepted bacteriological testing principles, but applies our proprietary technology to adapt them to analyze live bacteria extracted directly from a patient specimen. The instrumentation uses automated digital microscopy to measure the responses of extracted live bacterial cells to various test conditions. Our system analyzes thousands of these individual cells to arrive at organism identification and antibiotic resistance characteristics.

Based on internal lab data, we believe that the BACcel™ system will identify the organisms present in a patient's specimen and count the number of organisms of each type in less than one hour after receiving a specimen. We believe that the BACcel™ system will then additionally report antibiotic resistance for each type of organism within a total of 4-6 hours after receiving a specimen. The clinical purpose of reporting antibiotic resistance is to narrow the drug choices available for therapy and rule out antibiotic classes that are most likely to fail. Quantitative identification in less than one hour enables first-dose therapy guidance that can improve the efficacy of antimicrobial treatment. In addition, de-escalation before the second dose helps to prolong the effectiveness of broad-spectrum antibiotics when lower-cost and older narrow-spectrum agents can provide at least equivalent activity (drug "stewardship").



**Changes in Results of Operations: Three months ended March 31, 2013 compared to three months ended March 31, 2012**

During the three months ended March 31, 2013, total revenues were \$15,678 as compared to \$9,197 during the three month period ended March 31, 2012, an increase of \$6,481 or 70.4%. The increase was due to fluctuations in partner sales volumes on which royalties were due the Company.

Research and development expenses for the three months ended March 31, 2013 were \$1,881,980 as compared to \$98,183 during the three months ended March 31, 2012, an increase of \$1,783,797 or 1,816.8%. The increase is primarily the result of increasing employee headcount in instrument and bio assays, whose salaries and wages comprised \$813,910 of the increase. The remainder of the increase was related to the purchase of laboratory and instrument engineering supplies to support accelerated R&D efforts.

During the three months ended March 31, 2013, general and administrative expenses were \$629,018 as compared to \$162,263 during the three-month period ended March 31, 2012, an increase of \$466,755 or 287.6%. The increase was primarily the result of increases in wages and related expenses, non-cash stock option expense and expenses for professional service

During the three months ended March 31, 2013, amortization was \$19,054 as compared to \$64,261 during the three-month period ended March 31, 2012, a decrease of \$45,207 resulting from the write-off of intangible assets during the prior eight months including \$1,996,583 written off during the period ended July 31, 2012 and an additional \$333,487 written off during the period ended October 31, 2012. Management determined that these capitalized intellectual property amounts carried on our balance sheet were no longer recoverable and abandoned its plan to pursue marketability.

Marketing and sales expenses for the three months ended March 31, 2013 were \$0 as compared to \$1,141 during the three months ended March 31, 2012. The decrease was driven by the timing of external services utilized.

Depreciation for the three months ended March 31, 2013 was \$36,386 as compared to \$515 during the three months ended March 31, 2012, an increase of \$35,871 or 6,965.2%. The increased depreciation was the result of purchases of equipment to up-fit the new Tucson facility laboratories.

As a result of the above factors, loss from operations for the three months ended March 31, 2013 was \$2,550,760 as compared to the net loss of \$317,166 during the three months ended March 31, 2012, an increase in net loss of \$2,233,594.

Other non-operating income/(loss) during the three months ended March 31, 2013 was \$1,461 as compared to \$17,664 during the three months ended March 31, 2012 a decrease of \$16,203 or 91.7%. The decrease was driven by unrealized gain recognized on the Rabbi Trust investment balance during the three month period ended March 31, 2012 which was liquidated and transferred as of December 31, 2012 and such did not recur in the current period.

As a result of these factors, net loss for the three months ended March 31, 2013 was \$2,549,299 as compared to a net loss of \$299,502 during the three months ended March 31, 2012, an increase in net loss of \$2,249,797.

### **Capital Resources and Liquidity**

During the three months ended March 31, 2013, we did not generate positive cash flows from operating activities.

Our primary sources of liquidity have been from sales of shares of our Common Stock and revenues from operations. As of March 31, 2013, the Company had \$29,256,692 in cash and cash equivalents, an increase of \$17,187,945 from

\$12,068,747 at December 31, 2012. The primary reason for the change in cash and cash equivalents was the exercise of the majority of Abeja Ventures, LLC's ("Abeja") outstanding warrants. On March 6, 2013, Abeja exercised in full its warrant to purchase 7,000,000 shares of the Company's 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 the Company's 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 \$20,067,680 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.

The Company has now closed its Denver location and fully relocated to Tucson, Arizona where it is subject to a Lease Agreement with Pima County of Arizona. The future minimum lease payments under the Lease Agreement are \$105,346, \$140,461, \$140,461, and \$35,115 for 2013, 2014, 2015, and 2016, respectively. The Company has contractual obligations to a former director and officer of the Company in the amount of \$822,000 during the fiscal year ending December 31, 2013.

As of March 31, 2013, management believes that current cash balances will be more than sufficient to fund our capital and liquidity needs for the next fiscal year.

The following summarizes the Company's capital resources at March 31, 2013 compared with December 31, 2012:

	March 31, 2013	December 31, 2012
Cash and cash equivalents	\$29,256,692	\$12,068,747
Accounts receivable (short term)	793,500	\$763,899
Current assets	30,142,324	\$12,849,025
Total assets	31,229,045	\$13,316,116
Current liabilities	1,136,043	\$1,248,068
Working Capital	29,006,281	\$11,600,957
Net cash (used)/provided by operating activities	\$(2,274,346)	\$(2,136,153)
Net cash (used in)/provided by investing activities	\$(675,069)	\$(153,348)
Net cash (used) provided by financing activities	20,137,360	\$100,000

Our primary use of capital has been for the research and development of the BACcel™ system. We believe our capital requirements will continue to be met with our existing cash balance, revenues provided by licensors 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.

### **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, cash equivalents, and short-term investments.

### **Item 4. Controls and Procedures.**

An evaluation was conducted under the supervision and with the participation of the Company's Management, including the Company's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of the

design and operation of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based on that evaluation, the CEO and the CFO concluded that as of March 31, 2013, the Company's disclosure controls and procedures were effective as of such date to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. The CEO and the CFO also confirmed that there was no change in the Company's internal control over financial reporting during the quarter ended March 31, 2013.

## **PART II—OTHER INFORMATION**

### **Item 1. Legal Proceedings.**

Not Applicable.

### **Item 1A. Risk Factors.**

There have been no material changes to the risk factors that were disclosed in the Company's Transition Report on Form 10-K for the transition period ended December 31, 2012.

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

Not Applicable.

### **Item 3. Defaults Upon Senior Securities.**

Not applicable.

### **Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

- 31.1 Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32\* Certificate of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 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.

May 10, 2013 By: /s/ Lawrence Mehren

(Date Signed) Lawrence Mehren, President and Chief Executive Officer

/s/ Steve Reichling

Steve Reichling, Chief Financial Officer and Chief Accounting Officer