

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 ..

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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 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, <u>2015</u>	December 31, <u>2014</u>
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	45	45
44,657,329 (as of March 31, 2015) and 44,639,829 (as of December 31, 2014) shares issued and outstanding	—	—

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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,
	<u>2015</u>	<u>2014</u>
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.

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

(in thousands)

	Three-month period ended	
	March 31,	March 31,
	<u>2015</u>	<u>2014</u>
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	Significant Other Observable Inputs	Significant Unobservable Inputs	
	(Level 1)	(Level 2)	(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, <u>2015</u>	December 31, <u>2014</u>
Computer equipment	\$1,655	\$ 1,020
Manufacturing and laboratory equipment	1,957	1,625