
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported) **November 6, 2018**

Accelerate Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-31822

(Commission File Number)

84-1072256

(IRS Employer Identification No.)

3950 South Country Club Road, Suite 470, Tucson, Arizona

(Address of principal executive offices)

85714

(Zip Code)

(520) 365-3100

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 6, 2018, Accelerate Diagnostics, Inc. issued a press release announcing its financial results of operations for the quarter ending September 30, 2018 and that it will host a conference call the same day to discuss such results. A copy of the press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 for Form 8-K, the information in this Item 2.02, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The following materials are filed as exhibits to this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Press Release, dated November 6, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 6, 2018

ACCELERATE DIAGNOSTICS, INC.
(Registrant)

/s/ Steve Reichling
Steve Reichling
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated November 6, 2018</u>

Accelerate Diagnostics reports Q3 2018 financial results

Revenue Placements up 40 Percent in U.S., Total Revenue up 64 Percent

TUCSON, Ariz., November 6, 2018 -- Accelerate Diagnostics, Inc. today announced financial results for the quarter ending September 30, 2018. The company reported a 40% increase in U.S. instruments placed under commercial contract, and revenue for the quarter of \$1.3 million, an increase of 64% from the prior year quarter. Worldwide, revenue-generating instruments combined with those under evaluation agreements grew to 458 instruments.

“We’re happy to report solid commercial growth this quarter, having enabled more hospitals than ever before to tailor antibiotic use specifically for individual patients much earlier,” said Lawrence Mehren, president and chief executive officer. “Despite a challenge for capital sales, we continue to drive clinical adoption through new acquisition options and a streamlined process. We believe the emerging clinical and economic outcome data, combined with strong customer advocacy, are compelling indicators of what is to come.”

During the third quarter, clinicians from the University of Arkansas for Medical Sciences presented independent clinical outcome data showing a 3-day reduction in hospital length of stay for patients with bacteremia after implementing the Accelerate Pheno™ system.¹

The company also announced it recently engaged with the U.S. Food and Drug Administration (FDA) and proposed a plan to address variability in the quantitative reference method used to compare the performance of its new test for severe bacterial pneumonia. New pre-clinical data obtained by the company in preparation of the clinical trial showed high variability in quantitative culture methods commonly used in clinical laboratories.

“We have found that the way laboratories perform cultures on lower respiratory tract specimens varies significantly across institutions, informed by local epidemiology, patient mix and treatment models,” said Dr. Romney Humphries, chief scientific officer of Accelerate Diagnostics. “This variability, however, means the results are not translatable from one site to another, and there is no true gold standard result.” Based on the need for further collaboration with the Agency, additional development, and related trial preparation, the company now expects to start the clinical trial in Q1 of 2019.

Mr. Mehren, together with Steve Reichling, chief financial officer, will host a conference call to review the financial results, commercial progress, and development updates at 4:15 p.m. Eastern Time on November 6, 2018.

Third quarter 2018 results

- Revenue-generating placements in the U.S. increased by 40%.
- Net sales of \$1.3 million for the third quarter and \$3.8 million year to date, compared to \$828 thousand and \$2.0 million for the same respective periods in the prior year.
- Gross margin realized was 49.8% for the quarter and 50.9% year to date.
- Selling, general, and administrative expenses for the quarter were \$12.2 million and \$41.8 million year to date as compared to \$11.6 million and \$33.6 million from the respective same periods in the prior year. These year-over-year increases were driven by higher personnel and customer evaluation-related costs for evaluations in the U.S. and EMEA regions.
- Research and development costs for the quarter were \$7.9 million and \$20.7 million year to date as compared to \$6.4 million and \$16.2 million from the respective same periods in the prior year. These year-over-year increases are the result of additional investments in the preparation for respiratory clinical trials and expanded scientific affairs activity.
- Net loss of \$22.1 million in the third quarter and \$66.1 million year to date, or \$0.41 and \$1.21 per share on weighted average basic shares outstanding of 54.1 million and 54.6 million shares, respectively. This net loss includes \$3.5 million in non-cash stock-based compensation expense in the third quarter and \$12.5 million year to date.
- Net cash used in the quarter was \$16.8 million and \$50 million year to date, ending the quarter with total cash, investments, and cash equivalents from all activities of \$181 million.

Full financial results for the quarter ending September 30, 2018 will be filed on Form 10-Q through the Securities and Exchange Commission’s (SEC) website at <http://www.sec.gov>.

¹ Dare R, McCain K, Lusardi K et al. Impact of Accelerate Pheno™ Rapid Blood Culture Detection System on Laboratory and Clinical Outcomes in Bacteremic Patients. Presented as an oral presentation at ID Week™ 2018.

Audio Webcast and Conference Call

Listen to an audio webcast of the call by visiting the events section of the company's investor relations website at ir.axdx.com. A replay of the audio webcast will be available until November 26, 2018.

To participate in the conference call, dial +1.877.883.0383 and enter the conference ID: 0396861

International participants may dial +1.412.902.6506. Please dial in 10-15 minutes prior to the start of the conference. A replay of the call will be available by telephone at +1.877.344.7529 (U.S.) or +1.412.317.0088 (international) using access code 10124532 until November 26, 2018.

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. (Nasdaq:AXDX), is an *in vitro* diagnostics company dedicated to providing solutions for the global challenges of antibiotic resistance and sepsis. The Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit combine several technologies aimed at reducing the time clinicians must wait to determine the most optimal antibiotic therapy for deadly infections. The FDA cleared system and kit fully automate the sample preparation steps to report phenotypic antibiotic susceptibility results in about 7 hours direct from positive blood cultures. Recent external studies indicate the solution offers results 1-2 days faster than existing methods, enabling clinicians to optimize antibiotic selection and dosage specific to the individual patient days earlier.

The "ACCELERATE DIAGNOSTICS" and "ACCELERATE PHENO" and "ACCELERATE PHENOTEST" and diamond shaped logos and marks are trademarks or registered trademarks of Accelerate Diagnostics, Inc.

For more information about the company, its products and technology, or recent publications, visit axdx.com.

Forward-Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, about our projections as to when certain key business milestones may be achieved, the potential of our products or technology, the growth of the market, our estimates as to the size of our market opportunity and potential pricing, our competitive position and estimates of time reduction to results, and our future development plans and growth strategy. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Information about the risks and uncertainties faced by Accelerate Diagnostics is contained in the section captioned "Risk Factors" in the company's most recent Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 1, 2018, and in any other reports that we file with the Securities and Exchange Commission from time to time. The company's forward-looking statements could be affected by general industry and market conditions. Except as required by federal securities laws, the company undertakes no obligation to update or revise these forward-looking statements to reflect new events, uncertainties or other contingencies.

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Source: Accelerate Diagnostics, Inc.

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
BALANCE SHEET
(in thousands, except share data)

	September 30, 2018	December 31, 2017
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 61,622	\$ 28,513
Investments	118,982	80,648
Trade accounts receivable	1,440	1,946
Inventory	9,406	8,063
Prepaid expenses	940	850
Other current assets	494	468
Total current assets	192,884	120,488
Property and equipment, net	7,412	4,890
Intellectual property, net	119	134
Other non-current assets	241	—
Total assets	<u>\$ 200,656</u>	<u>\$ 125,512</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,559	\$ 2,080
Accrued liabilities	3,518	3,636
Accrued interest	191	—
Deferred revenue and income	202	1,071
Total current liabilities	5,470	6,787
Other long term liabilities	26	21
Convertible notes	117,754	—
Total liabilities	<u>\$ 123,250</u>	<u>\$ 6,808</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred shares, \$0.001 par value; 5,000,000 preferred shares authorized and none outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value; 75,000,000 common shares authorized with 54,196,876 shares issued and outstanding on September 30, 2018 and 75,000,000 common shares authorized with 55,673,810 shares issued and outstanding on December 31, 2017	54	56
Contributed capital	430,734	360,620
Treasury Stock	(45,067)	—
Accumulated deficit	(308,156)	(241,972)
Accumulated other comprehensive loss	(159)	—
Total stockholders' equity	77,406	118,704
Total liabilities and stockholders' equity	<u>\$ 200,656</u>	<u>\$ 125,512</u>

See accompanying notes to condensed consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
Unaudited
(in thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	September 30,	September 30,	September 30,	September 30,
	2018	2017	2018	2017
Net sales	\$ 1,355	\$ 828	\$ 3,848	\$ 2,058
Cost of sales	680	191	1,889	352
Gross profit	675	637	1,959	1,706
Costs and expenses:				
Research and development	7,891	6,351	20,734	16,166
Sales, general and administrative	12,153	11,601	41,835	33,589
Total costs and expenses	20,044	17,952	62,569	49,755
Loss from operations	(19,369)	(17,315)	(60,610)	(48,049)
Other income (expense):				
Interest expense	(3,357)	—	(6,720)	—
Foreign currency exchange (loss)	(133)	(40)	(331)	(73)
Interest income	908	323	1,983	612
Other income, (expense), net	—	2	(25)	(3)
Total other income (expense), net	(2,582)	285	(5,093)	536
Net loss before income taxes	(21,951)	(17,030)	(65,703)	(47,513)
Provision for income taxes	(147)	(45)	(432)	(220)
Net loss	\$ (22,098)	\$ (17,075)	\$ (66,135)	\$ (47,733)
Basic and diluted net loss per share	\$ (0.41)	\$ (0.31)	\$ (1.21)	\$ (0.89)
Weighted average shares outstanding	54,145	55,316	54,591	53,603
Other comprehensive loss:				
Net loss	\$ (22,098)	\$ (17,075)	\$ (66,135)	\$ (47,733)
Net unrealized (loss) gain on available-for-sale investments	1	(7)	(54)	(4)
Foreign currency translation adjustment	(26)	91	(105)	295
Comprehensive loss	\$ (22,123)	\$ (16,991)	\$ (66,294)	\$ (47,442)

See accompanying notes to condensed consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONDENSED CONSOLIDATED
STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Nine Months Ended	
	September 30, 2018	September 30, 2017
Cash flows from operating activities:		
Net loss	\$ (66,135)	\$ (47,733)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,734	1,595
Amortization of intangible assets	15	9
Amortization of investment discount	(413)	298
Equity-based compensation	12,476	10,970
Amortization of debt discount and issuance costs	4,529	—
Loss on disposal of property and equipment	540	3
(Increase) decrease in assets:		
Accounts receivable	506	(1,077)
Inventory	(5,206)	(7,079)
Prepaid expense and other	55	(392)
Other current assets	(26)	(277)
Other non-current assets	(241)	—
Increase (decrease) in liabilities:		
Accounts payable	(524)	359
Accrued liabilities	(18)	780
Accrued Interest	191	—
Deferred revenue and income	(918)	46
Deferred compensation	5	—
Net cash used in operating activities	(53,430)	(42,498)
Cash flows from investing activities:		
Purchases of equipment	(842)	(2,055)
Purchases of available-for-sale securities	(115,634)	(68,423)
Sales of available-for-sale securities	3,000	9,522
Maturity of available-for-sale securities	74,496	30,049
Net cash used in investing activities	(38,980)	(30,907)
Cash flows from financing activities:		
Issuance of common stock net of issuance costs	477	83,741
Exercise of options and warrants	3,710	4,562
Proceeds from issuance of convertible note	171,500	—
Prepayment of forward stock repurchase transaction	(45,069)	—
Payment of debt issuance costs	(4,992)	—
Net cash provided by financing activities	125,596	88,303
Effect of exchange rate on cash:	(77)	289
Increase in cash and cash equivalents	33,109	15,187
Cash and cash equivalents, beginning of period	28,513	19,244
Cash and cash equivalents, end of period	\$ 61,622	\$ 34,431
Non-cash investing activities:		
Transfer of instruments from inventory to property and equipment	\$ 4,061	\$ —
Supplemental cash flow information:		
Interest paid	\$ 2,001	\$ —
Income taxes paid	\$ 435	\$ —

See accompanying notes to consolidated financial statements.