
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) February 19, 2019

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 February 19, 2019, Accelerate Diagnostics, Inc. issued a press release announcing its financial results of operations for the quarter ending December 31, 2018 and full-year 2018. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference in its entirety.

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.

Exhibit Number	Description
99.1	Press Release, dated February 19, 2019

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: February 19, 2019

ACCELERATE DIAGNOSTICS, INC.
(Registrant)

/s/ Steve Reichling
Steve Reichling
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated February 19, 2019

Accelerate Diagnostics Reports 2018 Fourth Quarter and Full-Year Financial Results

TUCSON, Ariz., February 19, 2019 -- Accelerate Diagnostics, Inc. (NASDAQ: AXDX) today announced financial results for the fourth quarter and fiscal year ended December 31, 2018.

"I am pleased to report an improvement in our commercial progress during the fourth quarter after a challenging start to 2018," said Lawrence Mehren, President and CEO of Accelerate Diagnostics, Inc. "We worked diligently over the first three quarters of the year to implement significant changes to our commercial strategy in order to improve our access to the hospital market. These efforts began to bear meaningful fruit during the fourth quarter as we added 133 new commercial contracts, including 117 in the U.S., which more than doubles our number of U.S. commercially contracted instruments. We enter 2019 with renewed confidence and belief that careful and consistent execution will enable us to capitalize on the tremendous opportunity in front of us and bring our life-saving technology to an ever-expanding number of patients around the globe."

Fourth Quarter 2018 Highlights

- Added 133 commercially contracted instruments, compared to 22 in the fourth quarter of 2017.
- Net sales of \$1.8 million, compared to \$2.1 million in the fourth quarter of 2017, a decrease attributable to lower capital sales mix as customers began adopting using reagent rental agreements, an option not available in the prior year period.
- Gross margin was 29%, which included an unfavorable 24 percentage point reduction due to increased costs arising from investments in service and manufacturing capacity ahead of production demand. Gross margin was 69% in the fourth quarter of 2017, which included a benefit of 16 percentage points due to the sale of pre-FDA manufactured instruments which had previously been written off to research and development.
- Selling, general, and administrative expenses were \$13.4 million, compared to \$11.5 million for the fourth quarter of 2017, driven by the expansion of our U.S. sales team and costs related to increased global sales and marketing activity.
- Research and development (R&D) expense was \$6.9 million, compared to \$6.1 million in the fourth quarter of 2017, due to continued investment in clinical outcomes studies and costs incurred in preparation for respiratory FDA registration and outcomes studies.
- Net loss was \$22.2 million, or \$0.41 per share, which included \$2.2 million in non-cash stock-based compensation expense.
- Net cash used was \$14.1 million.

Full Year 2018 Highlights

- Ended the year with 202 global commercially contracted instruments, compared to 78 at the end of 2017.
- Net sales of \$5.7 million, compared to \$4.2 million in 2017, driven by increased Accelerate Pheno instrument placements and the resulting sales of Accelerate PhenoTest™ BC test kits.
- Gross margin was 44%, which included an unfavorable 9 percentage point reduction due to costs arising from investments in service and manufacturing capacity ahead of production demand. Gross margin was 76% in 2017, which included a benefit of 21 percentage due to the sale of pre-FDA manufactured instruments which had previously been written off to R&D.
- Selling, general, and administrative expenses were \$55.2 million, compared to \$45.1 million in 2017, driven by expansion of the U.S. sales team and costs related to increased global sales and marketing activity.
- Research and development expenses for the year were \$27.6 million, compared to \$22.3 million in 2017, due to continued investment in clinical outcomes studies and costs incurred in preparation for respiratory FDA registration and outcomes studies.
- Net loss was \$88.3 million, or \$1.62 per share. Net loss included \$14.7 million in non-cash stock-based compensation expense.
- Net cash used was \$64.1 million. The Company ended the year with total cash, investments, and cash-equivalents from all activities of \$166.5 million.

Full financial results for the fourth quarter and full-year 2018 will be filed on Form 10-K through the Securities and Exchange Commission's (SEC) website at <http://www.sec.gov>. Investors are cautioned not to place undue reliance on these preliminary and unaudited estimates in the event of material changes.

Audio Webcast and Conference Call

The Company will host a conference call at 4:30 p.m. ET today to review its fourth quarter and full-year 2018 results.

To participate in this conference call, dial +1.877.883.0383 and enter the conference ID: 3234922. International participants may dial +1.412.902.6506. Please dial in 10-15 minutes before 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 the replay code 10128408 until May 21, 2019.

This conference call will also be webcast and can be accessed from the "Investors" section of the Company's website at ir.axdx.com. A replay of the audio webcast will be available until May 21, 2019.

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. 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 serious infections. The FDA-cleared system and kit fully automate sample preparation steps, enabling phenotypic antibiotic susceptibility results in about 7 hours directly from positive blood cultures. Recent external studies indicate the solution offers results 1 to 2 days faster than existing methods, enabling clinicians to optimize antibiotic selection and dosage specific to the individual patient's infection, 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 and the related conference call and webcast 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, Inc. 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 subsequent 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.

###

Investor Inquiries:

Laura Pierson, Accelerate Diagnostics, +1 520 365-3100, lperson@axdx.com

Media Contact:

Andrew Chasteen, Accelerate Diagnostics, +1 520 365-3100, achasteen@axdx.com

Source: Accelerate Diagnostics, Inc.

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
BALANCE SHEETS
(Unaudited)
(in thousands, except share data)

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 66,260	\$ 28,513
Investments	100,218	80,648
Trade accounts receivable	1,860	1,946
Inventory	7,746	8,063
Prepaid expenses	980	850
Other current assets	576	468
Total current assets	177,640	120,488
Property and equipment, net	7,303	4,890
Intellectual property, net	114	134
Other non-current assets	208	—
Total assets	\$ 185,265	\$ 125,512
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,322	\$ 2,080
Accrued liabilities	4,962	3,636
Accrued Interest	1,262	—
Deferred revenue and income	217	1,071
Total current liabilities	7,763	6,787
Other long term liabilities	53	21
Convertible notes	120,074	—
Total liabilities	127,890	6,808
Commitments and contingencies		
Stockholders' equity:		
Preferred shares, \$0.001 par value;		
5,000,000 preferred shares authorized and none outstanding as of December 31, 2018 and 2017	—	—
Common stock, \$0.001 par value;		
75,000,000 common shares authorized with 54,231,876 shares issued and outstanding on December 31, 2018 and		
75,000,000 authorized with 55,673,810 shares issued and outstanding on December 31, 2017	54	56
Contributed capital	432,885	360,620
Treasury stock	(45,067)	—
Accumulated deficit	(330,348)	(241,972)
Accumulated other comprehensive income (loss)	(149)	—
Total stockholders' equity	57,375	118,704
Total liabilities and stockholders' equity	\$ 185,265	\$ 125,512

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2018	2017	2016
Net sales	\$ 5,670	\$ 4,177	\$ 246
Cost of sales	3,187	1,002	—
Gross profit	2,483	3,175	246
Costs and expenses:			
Research and development	27,638	22,301	29,564
Sales, general and administrative	55,214	45,058	37,183
Total costs and expenses	82,852	67,359	66,747
Loss from operations	(80,369)	(64,184)	(66,501)
Other income (expense):			
Interest expense	(10,113)	—	—
Foreign currency exchange loss	(450)	(75)	(77)
Interest and dividend income	2,845	908	494
Other expense, net	(28)	(184)	(23)
Total other income (expense), net	(7,746)	649	394
Net loss before income taxes	(88,115)	(63,535)	(66,107)
Provision for income taxes	(211)	(493)	(267)
Net loss	\$ (88,326)	\$ (64,028)	\$ (66,374)
Basic and diluted net loss per share	\$ (1.62)	\$ (1.18)	\$ (1.29)
Weighted average shares outstanding	54,494	54,073	51,276
Other comprehensive loss:			
Net loss	\$ (88,326)	\$ (64,028)	\$ (66,374)
Net unrealized gain (loss) on available-for-sale investments	23	(117)	(64)
Foreign currency translation adjustment	(172)	321	(128)
Comprehensive loss	\$ (88,475)	\$ (63,824)	\$ (66,566)

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)
(in thousands)

	Shares	Common Stock Amount	Contributed Capital	Accumulated Deficit	Treasury stock	Accumulated Other Comprehensive	Total Stockholders' Equity
Balances, January 1, 2016	51,191	\$ 51	\$ 243,894	\$ (110,915)	\$ —	\$ (12)	\$ 133,018
Net loss	—	—	—	(66,374)	—	—	(66,374)
Exercise of options and warrants	314	1	1,496	—	—	—	1,497
Issuance of common stock under employee purchase plan	11	—	226	—	—	—	226
Short swing profits (net of costs)	—	—	866	—	—	—	866
Unrealized loss on available-for-sale securities	—	—	—	—	—	(64)	(64)
Foreign currency translation adjustment	—	—	—	—	—	(128)	(128)
Equity-based compensation	—	—	8,775	—	—	—	8,775
Balances, December 31, 2016	51,516	52	255,257	(177,289)	—	(204)	77,816
Net loss	—	—	—	(64,028)	—	—	(64,028)
Issuance of common stock	3,085	3	83,221	—	—	—	83,224
Exercise of options and warrants	1,045	1	6,605	—	—	—	6,606
Issuance of common stock under employee purchase plan	28	—	597	—	—	—	597
Unrealized loss on available-for-sale securities	—	—	—	—	—	(117)	(117)
Foreign currency translation adjustment	—	—	—	—	—	321	321
Cumulative impact of accounting change	—	—	—	(655)	—	—	(655)
Equity-based compensation	—	—	14,940	—	—	—	14,940
Balances, December 31, 2017	55,674	56	360,620	(241,972)	—	—	118,704
Net loss	—	—	—	(88,326)	—	—	(88,326)
Exercise of options and restricted stock awards issued	382	—	3,749	—	—	—	3,749
Issuance of common stock under employee purchase plan	35	—	583	—	—	—	583
Unrealized loss on available-for-sale securities	—	—	—	—	—	23	23
Foreign currency translation adjustment	—	—	—	—	—	(172)	(172)
Repurchase of common stock under Prepaid Forward contract	(1,859)	(2)	—	—	(45,067)	—	(45,069)
Issuance of convertible note	—	—	53,283	—	—	—	53,283
Cumulative impact of accounting change	—	—	—	(50)	—	—	(50)
Equity-based compensation	—	—	14,650	—	—	—	14,650
Balances, December 31, 2018	54,232	\$ 54	\$ 432,885	\$ (330,348)	\$ (45,067)	\$ (149)	\$ 57,375

See accompanying notes to consolidated financial statements.

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

	Years Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	\$ (88,326)	\$ (64,028)	\$ (66,374)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,561	2,196	2,351
Amortization of investment discount	(621)	326	374
Equity-based compensation	14,650	13,933	8,775
Amortization of debt discount and issuance costs	6,849	—	—
Realized gain on available-for-sale securities	—	—	(6)
Loss on disposal of property and equipment	678	240	23
(Increase) decrease in assets:			
Accounts receivable	86	(1,912)	43
Inventory	(4,451)	(7,759)	—
Prepaid expense and other assets	(250)	(459)	1,121
Increase (decrease) in liabilities:			
Accounts payable	(748)	1,064	(1,242)
Accrued liabilities	1,426	596	1,619
Accrued interest	1,262	—	—
Deferred revenue and income	(904)	36	(92)
Deferred compensation	32	21	—
Net cash used in operating activities	(67,756)	(55,746)	(53,408)
Cash flows from investing activities:			
Purchases of equipment	(998)	(2,966)	(2,409)
Purchase of marketable securities	(120,556)	(82,333)	(74,075)
Proceeds from sales of marketable securities	3,000	11,522	9,716
Maturities of marketable securities	98,416	48,049	17,200
Net cash used in investing activities	(20,138)	(25,728)	(49,568)
Cash flows from financing activities:			
Proceeds from exercise of warrants and options	3,749	6,606	1,497
Common stock issuance cost	—	—	(814)
Proceeds from issuance of common stocks and warrants	583	83,821	226
Recovery of related party short-swing profits	—	—	866
Payments on capital lease obligations	—	—	(13)
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	125,771	90,427	1,762
Effect of exchange rate on cash	(130)	316	(127)
Increase (decrease) in cash and cash equivalents	37,747	9,269	(101,341)
Cash and cash equivalents, beginning of period	28,513	19,244	120,585
Cash and cash equivalents, end of period	<u>\$ 66,260</u>	<u>\$ 28,513</u>	<u>\$ 19,244</u>

See accompanying notes to consolidated financial statements.