ACCELERATE DIAGNOSTICS, INC

FORM 8-K
(Current report filing)

Filed 01/10/18 for the Period Ending 01/10/18

Address	3950 S. COUNTRY CLUB ROAD #470 BUILDING 3-307 TUCSON, AZ, 85714
Telephone	303-863-8088
CIK	0000727207
Symbol	AXDX
SIC Code	3826 - Laboratory Analytical Instruments
Industry	Advanced Medical Equipment & Technology
Sector	Healthcare
Fiscal Year	12/31

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) **January 10, 2018**

Accelerate Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-31822	**84-1072256**
(Commission File Number)	(IRS Employer Identification No.)

3950 South Country Club, Suite 470, Tucson, Arizona	**85714**
(Address of principal executive offices)	(Zip Code)

(520) 365-3100
(Registrant's telephone number, including area code)

(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 January 10, 2018, Accelerate Diagnostics, Inc. (the "Company") issued a press release (the "Press Release") announcing certain preliminary financial results for the quarter ending December 31, 2017. 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 the related information contained in 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 8.01. Other Events.

In addition to the disclosure described above under Item 2.02 of this Current Report on Form 8-K, the Press Release also announced the Company's declaration of conformity to the European *In Vitro* Diagnostic Directive 98/79/EC and CE mark of its latest assay for the Accelerate Pheno™ system targeting severe bacterial pneumonia infections. A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated herein by reference in its entirety.

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 January 10, 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.

ACCELERATE DIAGNOSTICS, INC.
(Registrant)

Date: January 10, 2018

/s/ Steve Reichling
Steve Reichling
Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release, dated January 10, 2018

Exhibit 99.1

Accelerate Diagnostics achieves CE-IVD milestone for severe bacterial pneumonia assay, doubles revenue for 2017 in Q4

TUCSON, Ariz., Jan 10, 2018 – Accelerate Diagnostics, Inc. announced today its declaration of conformity to the European *In Vitro* Diagnostic Directive 98/79/EC and CE mark of its latest assay for the Accelerate Pheno™ system targeting severe bacterial pneumonia infections. During the related study, results for the severe pneumonia assay were available about 57 hours faster than the standard of care.

In addition, the company announced preliminary revenue for the fourth quarter of 2017 of $2.1 million, a 52 times increase over the fourth quarter of 2016. Preliminary revenue for the full year of 2017 is estimated at $4.2 million, a 16 times increase over the prior year. Instruments under agreement increased by 42 in the fourth quarter bringing the total of instruments under customer agreement to 337.

Financial results for the full year and quarter ending December 31, 2017 will be filed 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 estimates in the event of material changes.

About Accelerate Diagnostics, Inc.

Accelerate Diagnostics, Inc. (Nasdaq:AXDX), is an *in vitro* diagnostics company dedicated to providing solutions for the global challenge of antibiotic resistance and healthcare-associated infections. The company recently obtained FDA marketing authorization for antimicrobial susceptibility testing direct from positive blood culture samples using its Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit. The system and kit leverage proprietary molecular identification methods and morphokinetic cellular analysis (MCA) to provide minimum inhibitory concentrations for a range of applicable antibiotics. The fully-automated system is designed to eliminate the lengthy culture and sample preparation steps required prior to antimicrobial susceptibility testing. Recent market studies suggest the solution offers results 1-2 days faster than conventional methods, enabling clinicians to optimize antibiotic selection, dosage, and infusion strategy specific to the individual patient and their infection.

For more information about the company, its products or technology, visit http://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, such as the ongoing commercial launch, demand, and 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 February 28, 2017, 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.