**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) **August 6, 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 August 6, 2018, Accelerate Diagnostics, Inc. issued a press release announcing its financial results of operations for the quarter ending June 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 August 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.

ACCELERATE DIAGNOSTICS, INC.
(Registrant)

Date: August 6, 2018

/s/ Steve Reichling
Steve Reichling
Chief Financial Officer

**EXHIBIT INDEX**

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release, dated August 6, 2018 |

**Exhibit 99.1**

**Accelerate Diagnostics reports Q2 2018 financial results**

*Revenue up 142 Percent, Global install base up 25 Percent*

TUCSON, Ariz., August 6, 2018 – Accelerate Diagnostics, Inc. today announced financial results for the quarter ending June 30, 2018. The company posted revenue of $1.7 million, up 142% from the prior year quarter, and reported a record number of new agreements signed in the quarter bringing the global total to 430 instruments. Contracts for customer evaluations total 312 instruments while commercial placements grew to 118 across the U.S., European, and Middle East regions.

“We’re excited to report a record number of new customer agreements this quarter,” said Lawrence Mehren, President and CEO. “While not yet fully translated into revenue, this sales momentum, strong customer advocacy, and upcoming clinical outcome data are quite encouraging.”

In addition, the company reported securing new agreements with prominent group purchasing organizations during the quarter. The agreements, covering approximately 1,400 hospitals, add additional value to member hospitals and aim to streamline the adoption process.

The company also announced progress on the development of its severe bacterial pneumonia kit including alignment with the U.S. Food and Drug Administration (FDA) on a shorter and less complex, 510(k) regulatory pathway, and clinical trial for the test. The expected start of the U.S. clinical trial is on or before our Q3 conference call.

Mr. Mehren, together with Steve Reichling, the company’s 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 August 6, 2018.

**Second quarter 2018 results**

- Global install base increased by 25% during the quarter
- Net sales of $1.7 million for the second quarter and $2.5 million year to date, compared to $699 thousand and $1.2 million, for the same respective periods in the prior year
- Gross margin realized was 58% for the quarter and 52% year to date
- Selling, general, and administrative expenses for the quarter were $15.3M and $29.7M year to date as compared to $11.5M and $22.0M from the respective same periods in the prior year. These year-over-year increases were driven by higher personnel and customer evaluation related costs in the US and EU
- Research and development costs for the quarter were $6.1M and $12.9M year to date as compared to $5.5M and $9.8M 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 $23.2 million in the second quarter and $44.0 million year to date, or $0.43 and $0.80 per share on weighted average basic shares of 54.0 million and 54.8 million shares outstanding, respectively. This net loss includes $3.4 million in non-cash stock-based compensation expense in the second quarter and $9.0 million year to date.
- Net cash used in the quarter was $17.1 million, ending the quarter with total cash, investments, and cash-equivalents from all activities of $197.4 million

Full financial results for the quarter ending June 30, 2018 will be filed on Form 10-Q through the Securities and Exchange Commission’s (SEC) website at http://www.sec.gov. The company anticipates filing on August 7, 2018. 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**

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 August 27, 2018.

To participate in the conference call, dial +1.877.883.0383 and enter the conference ID: 6994802

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 10120739 until August 27, 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 sepsis, antibiotic resistance and healthcare-associated infections. Every 3-4 seconds someone dies from sepsis. In the United States, sepsis remains a leading cause of death, taking more lives than HIV, breast cancer, and prostate cancer combined. Bacteria are the most common cause of the serious infections that lead to sepsis, and continue to develop resistance to antibiotics. These antibiotic resistant bacteria further complicate the treatment approach for physicians who already wait days for lab results to determine which antibiotics are likely to be effective against the infection.

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 these infections. The FDA cleared system and kit fully automate the sample preparation steps to report phenotypic antibiotic susceptibility results within 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.



For more information about the company, its products or technology, 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)

| | June 30, 2018 | December 31, 2017 |
|---|---|---|
| | Unaudited | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 66,810 | $ 28,513 |
| Investments | 130,594 | 80,648 |
| Trade accounts receivable | 1,823 | 1,946 |
| Inventory | 11,317 | 8,063 |
| Prepaid expenses | 1,421 | 850 |
| Other current assets | 643 | 468 |
| Total current assets | 212,608 | 120,488 |
| Property and equipment, net | 5,443 | 4,890 |
| Intellectual property, net | 124 | 134 |
| Other non-current assets | 78 | — |
| Total assets | $ 218,253 | $ 125,512 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,355 | $ 2,080 |
| Accrued liabilities | 5,302 | 3,636 |
| Deferred revenue and income | 185 | 1,071 |
| Total current liabilities | 7,842 | 6,787 |
| Other long term liabilities | 26 | 21 |
| Convertible notes | 115,499 | — |
| Total liabilities | $ 123,367 | $ 6,808 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred shares, $0.001 par value; 5,000,000 preferred shares authorized and none outstanding as of June 30, 2018 and December 31, 2017 | — | — |
| Common stock, $0.001 par value; 75,000,000 common shares authorized with 54,090,575 shares issued and outstanding on June 30, 2018 and 75,000,000 authorized with 55,673,810 shares issued and outstanding on December 31, 2017 | 54 | 56 |
| Contributed capital | 426,091 | 360,620 |
| Treasury Stock | (45,067) | — |
| Accumulated deficit | (286,058) | (241,972) |
| Accumulated other comprehensive loss | (134) | — |
| Total stockholders' equity | 94,886 | 118,704 |
| Total liabilities and stockholders' equity | $ 218,253 | $ 125,512 |

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

| | Three Months Ended | | Six Months Ended | |
|---|---|---|---|---|
| | June 30, 2018 | June 30, 2017 | June 30, 2018 | June 30, 2017 |
| **Net sales** | $ 1,692 | $ 699 | $ 2,493 | $ 1,230 |
| **Cost of sales** | 717 | 135 | 1,210 | 161 |
| Gross profit | 975 | 564 | 1,283 | 1,069 |
| **Costs and expenses:** | | | | |
| Research and development | 6,060 | 5,527 | 12,842 | 9,815 |
| Sales, general and administrative | 15,330 | 11,460 | 29,682 | 21,988 |
| Total costs and expenses | 21,390 | 16,987 | 42,524 | 31,803 |
| Loss from operations | (20,415) | (16,423) | (41,241) | (30,734) |
| **Other income (expense):** | | | | |
| Interest expense | (3,205) | — | (3,363) | — |
| Foreign currency exchange (loss) | (253) | (7) | (198) | (33) |
| Interest income | 774 | 153 | 1,075 | 290 |
| Other expense, net | (25) | (5) | (25) | (5) |
| Total other income (expense), net | (2,709) | 141 | (2,511) | 252 |
| Net loss before income taxes | (23,124) | (16,282) | (43,752) | (30,482) |
| Provision for income taxes | (101) | (175) | (285) | (175) |
| Net loss | $ (23,225) | $ (16,457) | $ (44,037) | $ (30,657) |
| Basic and diluted net loss per share | $ (0.43) | $ (0.31) | $ (0.80) | $ (0.58) |
| Weighted average shares outstanding | 54,003 | 53,568 | 54,821 | 52,732 |
| **Other comprehensive loss:** | | | | |
| Net loss | $ (23,225) | $ (16,457) | $ (44,037) | $ (30,657) |
| Net unrealized (loss) gain on available-for-sale investments | (2) | 3 | (55) | 3 |
| Foreign currency translation adjustment | (191) | 204 | (79) | 204 |
| Comprehensive loss | $ (23,418) | $ (16,250) | $ (44,171) | $ (30,450) |

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

| | Six Months Ended | |
|---|---|---|
| | **June 30, 2018** | **June 30, 2017** |
| **Cash flows from operating activities:** | | |
| Net loss | $ (44,037) | $ (30,657) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 1,072 | 1,045 |
| Amortization of intangible assets | 10 | 6 |
| Amortization of investment discount | (146) | 219 |
| Equity-based compensation | 9,011 | 7,450 |
| Amortization of debt discount and issuance costs | 2,273 | — |
| Loss on disposal of property and equipment | 266 | 5 |
| (Increase) decrease in assets: | | |
| Accounts receivable | 123 | (648) |
| Inventory | (3,138) | (5,537) |
| Prepaid expense and other | (444) | (624) |
| Other current assets | (175) | (313) |
| Other non-current assets | (78) | — |
| Increase (decrease) in liabilities: | | |
| Accounts payable | 206 | 528 |
| Accrued liabilities | 661 | 392 |
| Accrued Interest | 1,105 | — |
| Deferred revenue and income | (935) | 43 |
| Deferred compensation | 5 | — |
| Net cash used in operating activities | (34,221) | (28,091) |
| **Cash flows from investing activities:** | | |
| Purchases of equipment | (1,898) | (1,643) |
| Purchases of available-for-sale securities | (91,272) | (39,342) |
| Sales of available-for-sale securities | 3,000 | 6,522 |
| Maturity of available-for-sale securities | 38,272 | 18,449 |
| Net cash used in investing activities | (51,898) | (16,014) |
| **Cash flows from financing activities:** | | |
| Issuance of common stock net of issuance costs | 276 | 83,854 |
| Exercise of options and warrants | 2,757 | 3,418 |
| Proceeds from issuance of convertible note | 171,499 | — |
| Prepayment of forward stock repurchase transaction | (45,069) | — |
| Payment of debt issuance costs | (4,991) | — |
| Net cash provided by financing activities | 124,472 | 87,272 |
| Effect of exchange rate on cash: | (56) | 198 |
| Increase in cash and cash equivalents | 38,297 | 43,365 |
| Cash and cash equivalents, beginning of period | 28,513 | 19,244 |
| Cash and cash equivalents, end of period | $ 66,810 | $ 62,609 |