

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

TUCSON, Ariz., Feb. 19, 2019 /PRNewswire/ -- 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.

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

| | | |
|---|-------------------|-------------------|
| Contributed capital | 54 | 56 |
| Treasury stock | 432,885 | 360,620 |
| Accumulated deficit | (45,067) | — |
| Accumulated other comprehensive income (loss) | (330,348) | (241,972) |
| Total stockholders' equity | (149) | — |
| Total liabilities and stockholders' equity | 57,375 | 118,704 |
| | <u>\$ 185,265</u> | <u>\$ 125,512</u> |

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 Income (Loss) | 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 | \$ 66,260 | \$ 28,513 | \$ 19,244 |

See accompanying notes to consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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<https://ir.axdx.com/2019-02-19-Accelerate-Diagnostics-Reports-2018-Fourth-Quarter-and-Full-Year-Financial-Results>