Accelerate Diagnostics reports Q4 and Full-Year Financial Results for 2017

TUCSON, Ariz., Feb. 15, 2018 (GLOBE NEWSWIRE) -- Accelerate Diagnostics, Inc. today announced preliminary full-year 2017 financial results including the quarter ending December 31, 2017. The company reported revenue for Q4 of $2.1 million, doubling revenue for the year, and signed agreements for 337 instruments. Contracts for customer evaluations covered 259 instruments while revenue placements totaled 78 across the U.S., European, and Middle East regions.

Net sales were $4.2 million for the year compared to $246,000 for the prior year, 2016. The increase was driven by sales of the company's solution for sepsis intervention and antimicrobial stewardship, the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit. The U.S. Food and Drug Administration (FDA) reviewed and permitted marketing of the system and kit in late February 2017.

"We were optimistic going into our launch year, and by most measures it was a success," said Lawrence Mehren, President and CEO. "Now, with the recent data showing significant reductions in sepsis mortality from our first clinical customer, we've reached an important point where other hospitals, and the government, have started to notice. This is good news and we believe points to an exciting year ahead. A huge thanks to the entire team and especially our customers."

With its initial diagnostic for antimicrobial stewardship and sepsis intervention underway, the company recently announced initiatives focused on 2018 revenue and its respiratory test, the Accelerate PhenoTest™ svBP kit, targeting severe pneumonia. Clinical trials for this new kit are expected to begin in Q2 or Q3 of 2018, followed by a submission for review by the FDA.

President and Chief Executive Officer, Lawrence Mehren, and Chief Financial Officer, Steve Reichling, will host a conference call to review the financial results, commercial progress, and development updates at 4:30 p.m. Eastern Time on February 15, 2018.

Fourth Quarter 2017

- Net sales of $2.1 million, a 54 times increase compared to the fourth quarter of 2016
- Gross margin realized was 69% including inventory previously recorded as research and development (R&D) expense
- Selling, general, and administrative expenses of $11.5 million, compared to $10.5 million in the prior year period, driven by higher personnel and customer evaluation-related costs across the U.S. and Europe
- R&D expenses for the fourth quarter of $6.1 million, compared to $5.6 million in the same quarter of 2016 due to clinical trial and pre-launch inventory costs incurred in the prior year period which did not repeat
- Net loss of $15.1 million, or $0.27 per share on weighted average basic shares of 55.4 million shares outstanding, which contained $2.9 million in non-cash stock-based compensation expense
- Net cash used in the quarter was $12.1 million

Full Year 2017

- Net sales of $4.2 million, a 17 times increase compared to the prior 2016 year
- Gross margin realized was 76% including inventory previously recorded as research and development (R&D) expense
- Selling, general, and administrative expenses of $45.1 million, compared to $37.2 million in the prior year period, driven by higher personnel and customer evaluation-related costs across the U.S. and Europe
- R&D expenses for the year of $22.3 million, compared to $29.5 million in 2016 due to clinical trial and pre-launch inventory costs incurred in the prior year period which did not repeat
- Net loss of $62.9 million, or $1.16 per share on weighted average basic shares of 54 million shares outstanding, which contained $13.9 millionin non-cash stock-based compensation expense
- Net cash used in the year was $51.8 million, ending the quarter with total cash, and cash-equivalents from all activities of $109.1 million

2018 Outlook

The following forward-looking statements reflect estimates based on information as of February 15, 2018 and are subject to uncertainty. Additional information is available under the heading: Forward-Looking Statements.

Full year 2018 revenue is expected to be between $21 to $30 million, with heavy weighting on the second half of the year. Pricing for the BC kit is expected to hold as it did in 2017, above $200 per kit with potential to increase slightly with demand. Capital mix is targeted above 50%.

Complete and audited financial results for the year and quarter ending December 31, 2017 will be filed on Form 10-K through the Securities and Exchange Commission's (SEC) website at http://www.sec.gov. The company anticipates filing on February 28th. 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 March 9, 2018.

To participate in the conference call, dial +1.877.883.0383 and enter the conference ID: 9292688.

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 10115445 until March 9, 2018.

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.

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 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.

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

	December	**December**

	31, 2017	31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,513	$ 19,244
Investments	80,648	58,519
Trade accounts receivable	1,946	34
Inventory	8,063	—
Prepaid expenses	850	468
Other current assets	467	183
Total current assets	120,487	78,448
Property and equipment, net	4,890	4,258
Intellectual property, net	134	146
Other non-current assets	1,216	—
Total assets	$ 126,727	$ 82,852
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,080	$ 992
Accrued liabilities	3,636	3,009
Deferred revenue and income	1,070	35
Total current liabilities	6,183	4,036
Long-term deferred income	—	1,000
Other long-term liabilities	21	—
Total liabilities	$ 6,807	$ 5,036
Stockholders' equity:		
Common stock, $0.001 par value;		
75,000,000 common shares authorized with 55,673,810 shares issued and outstanding on December 31, 2017 and 75,000,000 authorized with 51,516,309 shares issued and outstanding on December 31, 2016	56	52
Preferred shares, $0.001 par value;		
5,000,000 preferred shares authorized and none outstanding as of December 31, 2017 and December 31, 2016	—	—
Contributed capital	360,620	255,257
Accumulated deficit	(240,825)	(177,289)
Accumulated other comprehensive (loss)	69	(204)
Total stockholders' equity	119,920	77,816
Total liabilities and stockholders' equity	$ 126,727	$ 82,852

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

	Years Ended December 31,		
	2017	**2016**	**2015**
Net Sales	4,177	246	147
Cost of Sales	1,002	—	—

Gross Profit	3,175	246	147
Costs and expenses:			
Research and development	22,300	29,564	27,142
Sales, general and administrative	45,057	37,183	18,554
Total costs and expenses	67,357	66,747	45,696
Loss from operations	(64,182)	(66,501)	(45,549)
Interest expense	—	—	(4)
Foreign currency exchange loss	(75)	(77)	(19)
Interest and dividend income	908	494	74
Other expense, net	(184)	(23)	—
Total other income	649	394	51
Net loss before income taxes	(63,533)	(66,107)	(45,498)
Income tax benefit (expense)	651	(267)	—
Net loss	$ (62,882)	$ (66,374)	$ (45,498)
Basic and diluted net loss per share	$ (1.16)	$ (1.29)	$ (1.01)
Weighted average shares outstanding	54,073	51,276	44,998
Other comprehensive loss:			
Net loss	$ (62,882)	$ (66,374)	$ (45,498)
Net unrealized loss on available-for-sale investments	(118)	(64)	(20)
Foreign currency translation adjustment	391	(128)	1
Comprehensive loss	$ (62,609)	$ (66,566)	$ (45,517)

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Source: Accelerate Diagnostics, Inc.

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(27 KB)

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