November 2, 2017

Accelerate Diagnostics reports Q3 2017 financial results

TUCSON, Ariz., Nov. 02, 2017 (GLOBE NEWSWIRE) -- Accelerate Diagnostics, Inc. today announced preliminary financial results for the quarter ending September 30, 2017. The company further reported signed agreements for 295 instruments year to date; contracts for customer evaluations total 239 instruments while revenue generating placements grew to 56 across the U.S., European, and Middle East regions.

Net sales for the third quarter 2017 was $828,000 compared to $24,000 in the third quarter of 2016. The increase was driven by sales of the Accelerate Pheno™ system and Accelerate PhenoTest™ BC kit.

"Eight months into our launch, we are meeting or exceeding the majority of our expected commercial metrics and funnel assumptions," said Lawrence Mehren, President and CEO. "While we would prefer the rate of conversions to be faster, we believe the number of qualified prospects and evaluation contracts, conversion win rate, pricing, and other measures confirm the value of the company and its products."

The company also reported achieving several milestones across a number of development initiatives during the quarter, highlighting the completion of the assay development phase for its upcoming kit targeting severe pneumonia. Development is also complete for two new key antibiotics for European customers that will be added to the Accelerate PhenoTest™ BC kit and submitted for CE Mark near year end. In addition, the company announced plans to develop new kits aimed at sample types for complicated urinary tract infections and intra-abdominal infections.

"Complicated urinary tract infections are a great target for us," said Dr. Romney Humphries, Chief Science Officer for Accelerate. "Often these organisms are multi-drug resistant, cost an estimated $14 billion in the United States, and may lead to urosepsis, a potentially fatal condition."

Intra-abdominal infections also represent a high-acuity target for the fast, phenotypic, and fully automated antimicrobial susceptibility results offered by the company's system, Humphries said, noting that these infections often keep patients in the hospital for a week or longer when associated with highly drug-resistant organisms which can cause typical empiric therapy to fail.

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 4:15 p.m. Eastern Time on November 2, 2017.

Preliminary third quarter 2017 results

- Net sales of $828,000 compared to $24,000 in the third quarter of 2016
- Gross margin realized was 77% including inventory previously recorded as research and development (R&D) expense
- Selling, general, and administrative expenses of $11.6 million, compared to $9.6 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 third quarter of $6.4 million, compared to $7.9 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 $17 million, or $0.31 per share on weighted average basic shares of 55.3 million shares outstanding, which includes $3.5 million in non-cash stock-based compensation expense
- Net cash used in the quarter was $13.9 million, ending the quarter with total cash, and cash-equivalents from all activities of $121.3 million

Full financial results for the quarter ending September 30, 2017 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 November 7th. Investors are cautioned not to place undue reliance on these preliminary 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 November 16, 2017.

To participate in the conference call, dial +1.877.883.0383 and enter the conference ID: 3435682.

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 10112771 until November 16, 2017.

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 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.
CONDENSED CONSOLIDATED
BALANCE SHEET
Unaudited
(in thousands)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,431	$ 19,244
Investments	86,889	58,519
Trade accounts receivable	1,111	34
Inventory	7,341	—
Prepaid expenses	1,048	468
Other current assets	460	183
Total current assets	131,280	78,448
Property and equipment, net	4,690	4,258
Intellectual property, net	137	146
Total assets	$ 136,107	$ 82,852
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$ 1,369	$ 992
Accrued liabilities	3,733	3,009
Deferred revenue and income	1,081	35
Total current liabilities	6,183	4,036
Long-term deferred income	—	1,000
Total liabilities	$ 6,183	$ 5,036
Stockholders' equity:		
Common stock, $0.001 par value;		
75,000,000 common shares authorized with 55,397,563 shares issued and outstanding on September 30, 2017 and 75,000,000 authorized with 51,516,309 shares issued and outstanding on December 31, 2016	55	52
Preferred shares, $0.001 par value;		
5,000,000 preferred shares authorized and none outstanding as of September 30, 2017 and December 31, 2016	—	—
Contributed capital	355,458	255,257
Accumulated deficit	(225,676)	(177,289)
Accumulated other comprehensive (loss)	87	(204)
Total stockholders' equity	129,924	77,816
Total liabilities and stockholders' equity	$ 136,107	$ 82,852

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

	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Net sales	$ 828	$ 24	$ 2,058	$ 207
Cost of sales	191	—	352	—
Gross Profit	637	24	1,706	207
Costs and expenses:				
Research and development	6,351	7,874	16,166	23,974
Sales, general and administrative	11,601	9,566	33,589	26,710
Total costs and expenses	17,952	17,440	49,755	50,684
Loss from operations	(17,315)	(17,416)	(48,049)	(50,477)
Interest expense and other	2	—	(3)	—
Foreign currency exchange loss	(40)	(42)	(73)	(115)
Interest and dividend income	323	159	612	353
Total other income	285	117	536	238
Net loss before income taxes	(17,030)	(17,299)	(47,513)	(50,239)
Provision from income taxes	(45)	—	(220)	—
Net loss	$ (17,075)	$ (17,299)	$ (47,733)	$ (50,239)
Basic and diluted net loss per share	$ (0.31)	$ (0.34)	$ (0.89)	$ (0.98)
Weighted average shares outstanding	55,316	51,239	53,603	51,216
Other comprehensive loss:				
Net loss	$ (17,075)	$ (17,299)	$ (47,733)	$ (52,239)

Net unrealized gain on available-for-sale investments	(7)	(70)	(4)	11
Foreign currency translation adjustment	91	(8)	295	(8)
Comprehensive loss	$ (16,991)	$ (17,377)	$ (47,442)	$ (50,236)

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

	Nine Months Ended	
	September 30, 2017	**September 30, 2016**
Cash flows from operating activities:		
Net loss	$ (47,733)	$ (50,239)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,595	1,745
Amortization of intangible assets	9	8
Amortization of investment discount	298	251
Equity-based compensation	10,970	6,591
Realized (gain) on sale of investments	—	(6)
Loss on disposal of property & equipment	3	—
(Increase) decrease in assets:		
Accounts receivable	(1,077)	(82)
Inventory	(7,079)	—
Prepaid expense and other	(392)	525
Other current assets	(277)	(90)
Increase (decrease) in liabilities:		
Accounts payable	359	103
Accrued liabilities	780	670
Deferred revenue and income	46	(83)
Net cash used in operating activities	(42,498)	(40,607)
Cash flows from investing activities:		
Purchases of equipment	(2,055)	(2,301)
Purchases of available-for-sale securities	(68,423)	(73,585)
Sales of available-for-sale securities	9,522	8,716
Maturity of available-for-sale securities	30,049	14,955
Net cash used in investing activities	(30,907)	(52,215)
Cash flows from financing activities:		
Issuance of common stock net issuance costs	83,741	80
Exercise of options and warrants	4,562	864
Common stock issuance costs	—	(814)
Payments on capital lease obligations	—	(13)
Recovery of related party short-swing profits	—	866
Net cash provided by financing activities	88,303	983
Effect of exchange rate on cash:	289	(15)
Increase (decrease) in cash and cash equivalents	15,187	(91,854)
Cash and cash equivalents, beginning of period	19,244	120,585
Cash and cash equivalents, end of period	$ 34,431	$ 28,731

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