Accelerate Diagnostics reports Q2 2018 financial results

TUCSON, Ariz., Aug. 6, 2018 /PRNewswire/ -- 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 guarter 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-overyear 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 <u>ir.axdx.com</u>. 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.

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 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.

ACCELERATE DIAGNOSTICS, INC. CONDENSED CONSOLIDATED BALANCE SHEET

(in thousands)

	June 30, 2018 Unaudited	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$66,810	
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	
Total current assets	212,608	•
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	
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 54

issued and outstanding on December 31, 2017

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)

Net sales	Three Mo June 30, 2018 \$1,692	nths Ended June 30, 2017 \$699		hs Ended June 30, 2017 \$1,230
Cost of sales	717	135	1,210	161
Gross profit	975	564	1,283	1,069
Costs and expenses: Research and development Sales, general and administrative Total costs and expenses	6,060	5,527	12,842	9,815
	15,330	11,460	29,682	21,988
	21,390	16,987	42,524	31,803
Loss from operations	(20,415)	(16,423)	(41,241)	(30,734)
Other income (expense): Interest expense Foreign currency exchange (loss) Interest income Other expense, net Total other income (expense), net	(3,205) (253) 774 (25) (2,709)		(3,363) (198) 1,075 (25) (2,511)	— (33) 290 (5) 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 Net unrealized (loss) gain on available-for-sale investments Foreign currency translation adjustment Comprehensive loss	\$(23,225)	\$(16,457)	\$(44,037)	\$(30,657)
	(2)	3	(55)	3
	(191)	204	(79)	204
	\$(23,418)	\$(16,250)	\$(44,171)	\$(30,450)

ACCELERATE DIAGNOSTICS, INC. CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS Unaudited

(in thousands)

	June 30, 2018	
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

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SOURCE Accelerate Diagnostics

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Six Months Ended

Accelerate Diagnostics reports Q2 2018 financial results (51 KB)

Additional assets available online: Additional assets available online:

https://ir.axdx.com/accelerate-diagnostics-reports-q2-2018-financial-results