

Accelerate Diagnostics Reports Second Quarter 2019 Financial Results

TUCSON, Ariz., Aug. 8, 2019 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced financial results for the second quarter ended June 30, 2019.

"We achieved mixed results in the second quarter, as revenue and placements were both lighter than anticipated due to lower-than-expected capital sales in our EMEA region," commented Lawrence Mehren, President and CEO of Accelerate Diagnostics, Inc. "However, we were encouraged by our commercial progress during the quarter, highlighted by 30% sequential growth in consumable sales and by our signing of the Mayo Clinic as a key reference customer. We expect our increasingly strong customer pipeline to drive higher placements in the second half of the year, particularly in Q4, and are confident that consumable revenues will continue to ramp higher as an ever-increasing number of new customers go clinically live."

Second Quarter 2019 Highlights

- Added 55 net new commercially contracted instruments, compared to 29 in the second quarter of 2018.
- Net sales of \$1.8 million, compared to \$1.7 million in the second quarter of 2018. Instrument revenue decreased year-over-year while consumable revenue grew meaningfully over the same time period, reflecting the company's change to a reagent rental business model starting Q3 of 2018. Consumable revenue grew by over 125% as compared the second quarter of 2018 and by approximately 30% over the prior quarter.
- Gross margin was 50% for the quarter, compared to 58% in the second quarter of 2018. This decrease was the result of one-time inventory timing benefits in the prior year which did not repeat in the current year.
- Selling, general, and administrative expenses for the quarter were \$12.8 million, compared to \$15.3 million in the second quarter of 2018. This decrease was driven by lower stock-based compensation expense in the current year.
- Research and development (R&D) costs for the quarter were \$6.1 million, compared to \$6.1 million in the second quarter of 2018. R&D expense were materially unchanged due to a stable product development program.
- Net loss was \$20.8 million in the second quarter, or \$0.38 per share, which included \$2.9 million in non-cash stock-based compensation expense.
- Net cash used in the quarter was \$13.0 million, and the company ended the quarter with total cash, investments, and cash equivalents of \$137.8 million.

Year to Date 2019 Highlights

- Added 130 net new commercially contracted instruments year to date, compared to 40 for the same period from 2018.
- Net sales of \$3.6 million year to date, compared to \$2.5 million for the same period from 2018. Instrument revenue decreased while consumable revenue grew steadily reflecting the company's change to a reagent rental business model starting Q3 of 2018. Consumable revenue grew by over 125% year to date compared to the same period in the prior year.
- Gross margin was 49% year to date, compared to 51% for the same period from 2018. This decrease was in part due to one-time inventory timing benefits in the prior year that did repeat in the current year. After excluding the impacts of pre-FDA inventory previously written off to R&D, gross margin improved by 300 basis points year to date to due to higher test kit production levels.
- Selling, general, and administrative expenses were \$25.6 million year to date, compared to \$29.7 million for the same period from 2018. This decrease was driven by lower stock-based compensation expense in the current year.
- Research and development (R&D) costs were \$13.1 million year to date, compared to \$12.8 million for the same period from 2018. R&D expense remain unchanged due to a stable product development program.
- Net loss was \$42.5 million year to date, or \$0.78 per share, which included \$6.3 million in non-cash stock-based compensation expense.
- Net cash used year to date was \$28.6 million, and the company ended the quarter with total cash, investments, and cash equivalents of \$137.8 million.

Full financial results for the quarter ending June 30, 2019 will be filed on Form 10-Q through the Securities and Exchange Commission's (SEC) website at <http://www.sec.gov>.

Audio Webcast and Conference Call

The company will host a conference call at 4:30PM ET today to review its second quarter results. To participate in the conference call, dial +1.877.883.0383 and enter the conference ID: 8768870. International participants may dial +1.412.902.6506. Please dial in 10 to 15 minutes prior to the start of the conference call. A replay of the call will be available by telephone at +1.877.344.7529 (U.S.) or +1.412.317.0088 (international) using replay code 10132228 until August 29, 2019.

This conference call will also be webcast and can be accessed from the "Investors" section of the company's website at axdx.com/investors. A replay of the audio webcast will be available until August 29, 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 deadly infections. The FDA cleared system and kit fully automate the sample preparation steps to report phenotypic antibiotic susceptibility results in approximately 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 and technology, or recent publications, visit axdx.com.

Forward-Looking Statements

Certain of the statements made in this press release are forward looking, such as those, among others, about the company's projections as to when certain key business milestones may be achieved, the potential of the company's products or technology, the growth of the market, the company's estimates as to the size of its market opportunity and potential pricing, the company's competitive position and estimates of time reduction to results, and its 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, 2019, and in any other reports that the company files with the Securities and Exchange Commission. 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, except share data)

	June 30, 2019	December 31, 2018
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 87,469	\$ 66,260
Investments	50,349	100,218
Trade accounts receivable	1,911	1,860
Inventory	8,298	7,746
Prepaid expenses	1,342	980
Other current assets	805	576
Total current assets	150,174	177,640
Property and equipment, net	7,624	7,303
Right of use assets	375	—
Other non-current assets	471	322
Total assets	\$ 158,644	\$ 185,265
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,819	\$ 1,322

Accrued liabilities	3,976	4,962
Accrued interest	1,262	1,262
Deferred revenue and income	255	217
Current operating lease liability	200	—
Total current liabilities	7,512	7,763
Non-current operating lease liability	175	—
Other non-current liabilities	35	53
Convertible notes	124,917	120,074
Total liabilities	\$ 132,639	\$ 127,890
Commitments and contingencies		

Stockholders' equity:

Preferred shares, \$0.001 par value;

5,000,000 preferred shares authorized and none outstanding as of June 30, 2019 and December 31, 2018

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Common stock, \$0.001 par value;

85,000,000 common shares authorized with 54,512,492 shares issued and outstanding on June 30, 2019 and 75,000,000 common shares authorized with 54,231,876 shares issued and outstanding on December 31, 2018

55 54

Contributed capital

443,857 432,885

Treasury stock

(45,067) (45,067)

Accumulated deficit

(372,884) (330,348)

Accumulated other comprehensive income (loss)

44 (149)

Total stockholders' equity

26,005 57,375

Total liabilities and stockholders' equity

\$ 158,644 \$ 185,265

See accompanying notes to condensed consolidated financial statements.

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,	June 30,	June 30,	June 30,
	2019	2018	2019	2018
Net sales	\$ 1,806	\$ 1,692	\$ 3,557	\$ 2,493
Cost of sales	907	717	1,823	1,210
Gross profit	899	975	1,734	1,283
Costs and expenses:				
Research and development	6,149	6,060	13,083	12,842
Sales, general and administrative	12,837	15,330	25,559	29,682
Total costs and expenses	18,986	21,390	38,642	42,524
Loss from operations	(18,087)	(20,415)	(36,908)	(41,241)
Other income (expense):				
Interest expense	(3,528)	(3,205)	(6,987)	(3,363)
Foreign currency exchange (loss) gain	6	(253)	(53)	(198)
Interest income	812	774	1,653	1,075
Other expense, net	(1)	(25)	(3)	(25)
Total other expense, net	(2,711)	(2,709)	(5,390)	(2,511)
Net loss before income taxes	(20,798)	(23,124)	(42,298)	(43,752)
Provision for income taxes	(17)	(101)	(238)	(285)
Net loss	\$ (20,815)	\$ (23,225)	\$ (42,536)	\$ (44,037)
Basic and diluted net loss per share	\$ (0.38)	\$ (0.43)	\$ (0.78)	\$ (0.80)

Weighted average shares outstanding	54,476	54,003	54,407	54,821
Other comprehensive loss:				
Net loss	\$ (20,815)	\$ (23,225)	\$ (42,536)	\$ (44,037)
Net unrealized gain (loss) on available-for-sale investments	98	(2)	219	(55)
Foreign currency translation adjustment	50	(191)	(26)	(79)
Comprehensive loss	<u>\$ (20,667)</u>	<u>\$ (23,418)</u>	<u>\$ (42,343)</u>	<u>\$ (44,171)</u>

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30, 2019	June 30, 2018
Cash flows from operating activities:		
Net loss	\$ (42,536)	\$ (44,037)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,236	1,082
Amortization of investment discount	(320)	(146)
Equity-based compensation	6,278	9,011
Amortization of debt discount and issuance costs	4,843	2,273
Loss on disposal of property and equipment	407	266
(Increase) decrease in assets:		
Accounts receivable	(51)	123
Inventory	(2,217)	(4,334)
Prepaid expense and other	(588)	(697)
Increase (decrease) in liabilities:		
Accounts payable	476	206
Accrued liabilities, and other	(1,110)	661
Accrued interest	—	1,105
Deferred revenue and income	38	(935)
Deferred compensation	(18)	5
Net cash used in operating activities	<u>(33,562)</u>	<u>(35,417)</u>
Cash flows from investing activities:		
Purchases of equipment	(76)	(702)
Purchase of marketable securities	(17,601)	(91,272)
Proceeds from sales of marketable securities	13,400	3,000
Maturities of marketable securities	54,447	38,272
Net cash provided by (used in) investing activities	<u>50,170</u>	<u>(50,702)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	251	276
Proceeds from exercise of options	4,369	2,757
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	<u>4,620</u>	<u>124,472</u>
Effect of exchange rate on cash	(19)	(56)
Increase in cash and cash equivalents	21,209	38,297
Cash and cash equivalents, beginning of period	66,260	28,513
Cash and cash equivalents, end of period	<u>\$ 87,469</u>	<u>\$ 66,810</u>

See accompanying notes to condensed consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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<https://ir.axdx.com/2019-08-08-Accelerate-Diagnostics-Reports-Second-Quarter-2019-Financial-Results>