Accelerate Diagnostics Reports Second Quarter 2020 Financial Results & Announces New Product Offering

TUCSON, Ariz., Aug. 6, 2020 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced financial results for the second guarter ended June 30, 2020.

"While the progress of new contracts and go-lives continued to be slowed by the effects of the pandemic, utilization within our existing base of live Pheno instruments continued to prove durable during the second quarter," commented Jack Phillips, President and CEO of Accelerate Diagnostics, Inc. "Despite these external disruptions, our internal R&D teams have made considerable progress, enabling today's announcement of several new products as part of our enhanced portfolio strategy. These include the immediate launch of an AST-only test kit and the imminent launch of a new workflow instrument, the PhenoPrep, the first application of which is enabling automated rapid MALDI identification results. We also entered into an exclusive supply and collaboration arrangement with Ascend Diagnostics to commercialize a complementary desktop MALDI instrument. We are excited about these new additions to our product portfolio and believe they will help position Accelerate for sustained success and more rapid adoption of our technology as the market continues to recover from the unprecedented impacts of COVID-19."

Second Quarter 2020 Highlights

- Added 6 new contracted instruments in the quarter and brought 6 instruments live, including 4 in the U.S.
- Ended the second quarter with 201 U.S. live revenue-generating instruments, with another 213 U.S. contracted Pheno instruments not yet live.
- Net sales of \$2.1 million, compared to \$1.8 million in the second quarter of 2019, or 17% growth.
- Gross margin was 45.0% for the quarter, compared to 50% in the second quarter of 2019. This decrease was the result of lower absorption of labor and overhead costs in the current quarter.
- Selling, general, and administrative expenses for the quarter were \$11.3 million, compared to \$12.8 million in the second quarter of 2019. This decrease was driven by pandemic-related reductions in sales and marketing spend related to travel and trade shows.
- Research and development (R&D) costs for the quarter were \$5.3 million, compared to \$6.1 million in the second quarter of 2019. This decrease was the result of increased efficiencies and lower external study spend.
- Net loss was \$19.2 million in the second quarter, or \$0.35 per share, which included \$3.4 million in non-cash stock-based compensation expense.
- Net cash used in the quarter was \$8.1 million, and the company ended the quarter with total cash, investments, and cash equivalents of \$88.7 million.
- Launched PhenoAST Test, an AST-only test kit, and announced the upcoming launch of PhenoPrep instrument in Q1 2021
- Entered into exclusive supply and collaboration agreement with Ascend Diagnostics to commercialize a desktop MALDI system.
- Recently submitted final FDA Emergency Use Authorization review items and data for the MS Fast fullyautomated chemiluminescence immunoassay analyzer and SARS-CoV-2 tests for the detection of IgG and IgM.

Year to Date 2020 Highlights

- Net sales were \$4.4 million year-to-date as compared to \$3.6 million from the same period in the prior year, or 22% growth.
- Gross margin was 45.0% year-to-date, compared to 49% from the same period in the prior year. This decrease was the result of lower absorption of labor and overhead costs in the first half of 2020.
- Selling, general, and administrative expenses were \$24.3 million year-to-date, compared to \$25.6 million from the same period in the prior year. This decrease was driven by pandemic-related reductions in sales and marketing spend related to travel and trade shows.
- Research and development (R&D) costs were \$11.2 million year-to-date, compared to \$13.1 million from the same period in the prior year. This decrease was the result of increased efficiencies and lower external study spend.
- Net loss was \$40.5 million year-to-date, or \$0.74 per share, which included \$7.6 million in non-cash stock-based compensation expense.
- Net cash used was \$24.5 million year-to-date, and the company ended the quarter with total cash,

investments, and cash equivalents of \$88.7 million.

Full financial results for the quarter ending June 30, 2020 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: 6487727. 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 10145894 until August 27, 2020.

This conference call will also be webcast and can be accessed from the "Investors" section of the company's website at axxx.com/investors. A replay of the audio webcast will be available until November 7, 2020.

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, among others, Mr. Phillips statements about adapting our business to maximize our commercial execution in the near term and our longer-term initiative to strengthen our commercial foundation and expand our portfolio of products. 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 27, 2020, 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, 2020			December 31, 2019		
ASSETS	Unaudited					
Current assets: Cash and cash equivalents Investments Trade accounts receivable Inventory Prepaid expenses Other current assets Total current assets Property and equipment, net	\$	47,368 41,326 2,592 8,723 1,400 1,099 102,508 8,004	\$	61,014 47,437 3,222 8,059 955 1,165 121,852 7,905		
Right of use assets		3,569		3,917		

Other non-current assets		734		750
Total assets	\$	114,815	\$	134,424
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	2,702	\$	2,351
Accrued liabilities	Ψ	3,346	Ψ	3,828
Accrued interest		1,262		1,262
Deferred revenue		232		271
Current portion of long-term debt		2,129		_
Current operating lease liability		447		450
Total current liabilities		10,118		8,162
Non-current operating lease liability		3,366		3,579
Other non-current liabilities		190		19
Long-term debt		2,662		_
Convertible notes		135,469		130,043
Total liabilities	\$	151,805	\$	141,803
Commitments and contingencies				
Stockholders' deficit: Preferred shares, \$0.001 par value; 5,000,000 preferred shares authorized and none outstanding as of June 30, 2020 and December 31, 2019		_		_
Common stock, \$0.001 par value; 85,000,000 common shares authorized with 56,249,482 shares issued and outstanding on June 30, 2020 and 85,000,000 common shares authorized				
with 54,708,792 shares issued and outstanding on December 31, 2019		56		55
Contributed capital		463,178		452,344
Treasury stock		(45,067)		(45,067)
Accumulated deficit		(455,297)		(414,653)
Accumulated other comprehensive income (loss)		140		(58)
Total stockholders' deficit		(36,990)		(7,379)
Total liabilities and stockholders' deficit	\$	114,815	\$	134,424

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)

		onths Ended		iths Ended
	June 30, June 30, 2020 2019		June 30, 2020	June 30, 2019
Net sales	\$ 2,125	\$ 1,806	\$ 4,468	\$ 3,557
Cost of sales	1,171	907	2,459	1,823
Gross profit	954	899	2,009	1,734
Costs and expenses:				
Research and development	5,347	6,149	11,189	13,083
Sales, general and administrative	11,332	12,837	24,275	25,559
Total costs and expenses	16,679	18,986	35,464	38,642
Loss from operations	(15,725)	(18,087)	(33,455)	(36,908)
Other income (expense):				
Interest expense	(3,835)	(3,528)	(7,584)	(6,987)
Foreign currency exchange gain (loss)	91	6	(37)	(53)

Interest income Other income (expense), net	²²⁴	8 <u>12</u> (1)	6 04)	1,653
Total other expense, net	(3,505)	(2,711)	 (7,084)	(5,390)
Net loss before income taxes Provision for income taxes	(19,230) —	(20,798) (17)	(40,539) —	(42,298) (238)
Net loss	\$ (19,230)	\$ (20,815)	\$ (40,539)	\$ (42,536)
Basic and diluted net loss per share Weighted average shares outstanding	\$ (0.35) 55,445	\$ (0.38) 54,476	\$ (0.74) 55,139	\$ (0.78) 54,407
Other comprehensive loss: Net loss Net unrealized gain (loss) on debt	\$ (19,230)	\$ (20,815)	\$ (40,539)	\$ (42,536)
securities available-for-sale	(44) 34	98 50	179 19	219 (26)
Foreign currency translation adjustment Comprehensive loss	\$ (19,240)	\$ (20,667)	\$ (40,341)	\$ (42,343)

See accompanying notes to condensed consolidated financial statements.

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

(in thousands)

	Six Mon June 30, 2020	ths Ended June 30, 2019
Cash flows from operating activities:		
Net loss	\$ (40,539)	\$ (42,536)
Adjustments to reconcile net loss to net cash used in operating		
activities:		
Depreciation and amortization	1,571	1,236
Amortization of investment discount	13	(320)
Equity-based compensation	7,615	6,278
Amortization of debt discount and issuance costs	5,426	4,843
Realized loss on sale of investments	3	_
Loss on disposal of property and equipment	527	407
Contributions to deferred compensation plan	(160)	_
(Increase) decrease in assets:		
Accounts receivable	550	(51)
Inventory	(1,979)	(2,217)
Prepaid expense and other	(363)	(588)
Increase (decrease) in liabilities:		
Accounts payable	390	476
Accrued liabilities, and other	(581)	(1,110)
Deferred revenue and income	(39)	38
Deferred compensation	171	(18)
Net cash used in operating activities	(27,395)	(33,562)
Cash flows from investing activities:		
Purchases of equipment	(643)	(76)
Purchase of marketable securities	(21,509)	(17,601)
Proceeds from sales of marketable securities	_	13,400
Maturities of marketable securities	27,844	54,447
Net cash provided by investing activities	5,692	50,170
Cash flows from financing activities:		
Proceeds from issuance of common stock	216	251
Proceeds from exercise of options	3,031	4,369
Proceeds from debt	4,791	_

Net cash provided by financing activities	8,038	4,620
Effect of exchange rate on cash	19	(19)
(Decrease) increase in cash and cash equivalents Cash and cash equivalents, beginning of period	(13,646) 61,014	21,209 66,260
Cash and cash equivalents, end of period	\$ 47,368	\$ 87,469

See accompanying notes to condensed consolidated financial statements.

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

(in thousands)

	Six Months Ended				
	J	une 30, 2020	Jı	June 30, 2019	
Non-cash investing activities:					
Transfer of instruments from inventory to property and equipment	\$	1,288	\$	1,715	
Supplemental cash flow information:					
Interest paid	\$	2,144	\$	2,144	
Income taxes paid, net of refunds	\$	26	\$	9	

See accompanying notes to condensed consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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