

Accelerate Diagnostics Reports Third Quarter 2020 Financial Results

TUCSON, Ariz., Nov. 5, 2020 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced financial results for the third quarter ended September 30, 2020.

"We achieved solid revenue growth in the third quarter, driven by continued steady utilization within our installed base of live Pheno instruments, an improving go-live cadence, and a large capital deal in the U.S.," commented Jack Phillips, President and CEO of Accelerate Diagnostics, Inc. "While COVID-related delays in the go-live process have begun to moderate, our ability to contract new customers continues to be affected by the pandemic. However, we are beginning to see an improvement in customer engagement as our recent product approvals and upcoming product releases are beginning to stimulate new interest in Accelerate Diagnostics. I am very pleased with the efforts put forth by everyone on the Accelerate team during the quarter, as we have continued to make meaningful operational and financial progress in the face of an unprecedented macro-environment."

Third Quarter 2020 Highlights

- Added 5 contracted instruments in the quarter and brought 22 instruments live in the U.S.
- Ended the third quarter with 223 U.S. live revenue-generating instruments, with another 192 U.S. contracted Pheno instruments not yet live.
- Net sales of \$3.6 million, compared to \$2.3 million in the third quarter of 2019, or 57% growth.
- Gross margin was 36% for the quarter, compared to 51% in the third quarter of 2019. This decrease was the result of pandemic-related effects on manufacturing and dilution from the large capital deal in the quarter.
- Selling, general, and administrative expenses for the quarter were \$11.5 million, compared to \$12.7 million in the third 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 \$5.0 million, compared to \$6.1 million in the third quarter of 2019. This decrease was the result of increased efficiencies and lower external study spend.
- Net loss was \$18.8 million in the third quarter, or \$0.33 per share, which included \$4.7 million in non-cash stock-based compensation expense.
- Net cash used in the quarter was \$11.2 million, and the company ended the quarter with total cash, investments, and cash equivalents of \$77.5 million.
- Received 510k approval for a new suite of product enhancements to the Accelerate Pheno® system, which improve performance and expand Pheno's antimicrobial susceptibility testing (AST) menu for bloodstream infections.
- Received FDA Emergency Use Authorization for the MS Fast fully automated chemiluminescence immunoassay analyzer and SARS-CoV-2 tests for the detection of IgG and IgM.

Year to Date 2020 Highlights

- Net sales were \$8.1 million year-to-date as compared to \$5.8 million from the same period in the prior year, or 40% growth.
- Gross margin was 41% year-to-date, compared to 50% from the same period in the prior year. This decrease was the result of pandemic related effects on supply chain and dilution from the large capital deal in the quarter.
- Selling, general, and administrative expenses were \$35.7 million year-to-date, compared to \$38.3 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 \$16.2 million year-to-date, compared to \$19.1 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 \$59.3 million year-to-date, or \$1.07 per share, which included \$12.3 million in non-cash stock-based compensation expense.
- Net cash used was \$31.0 million year-to-date, and the company ended the quarter with total cash, investments, and cash equivalents of \$77.5 million.

Full financial results for the quarter ending September 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 third quarter results. To listen to the 2020 third quarter financial results call by phone, dial +1.877.883.0383 and enter the conference ID: 0113821. 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 the replay code 10148610 until November 26, 2020.

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 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 COVID-related delays in the go-live process moderating, and improvement in customer engagement beginning to stimulate new interest in our company and 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)

	September 30, 2020	December 31, 2019
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 27,029	\$ 61,014
Investments	50,463	47,437
Trade accounts receivable	2,610	3,222
Inventory	9,459	8,059
Prepaid expenses	961	955
Other current assets	1,517	1,165
Total current assets	92,039	121,852
Property and equipment, net	7,104	7,905
Right of use assets	3,402	3,917
Other non-current assets	1,674	750
Total assets	\$ 104,219	\$ 134,424
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,372	\$ 2,351
Accrued liabilities	3,176	3,828
Accrued interest	191	1,262

Deferred revenue	338	271
Current portion of long-term debt	511	—
Current operating lease liability	482	450
Total current liabilities	7,070	8,162
Non-current operating lease liability	3,231	3,579
Other non-current liabilities	259	19
Long-term debt	5,028	—
Convertible notes	138,299	130,043
Total liabilities	\$ 153,887	\$ 141,803

Commitments and contingencies

Stockholders' deficit:

Preferred shares, \$0.001 par value;

5,000,000 preferred shares authorized and none outstanding as of September 30, 2020 and December 31, 2019

— —

Common stock, \$0.001 par value;

85,000,000 common shares authorized with 57,027,429 shares issued and outstanding on September 30, 2020 and 85,000,000 common shares authorized with 54,708,792 shares issued and outstanding on December 31, 2019

57 55

Contributed capital

469,302 452,344

Treasury stock

(45,067) (45,067)

Accumulated deficit

(474,054) (414,653)

Accumulated other comprehensive income (loss)

94 (58)

Total stockholders' deficit

(49,668) (7,379)

Total liabilities and stockholders' deficit

\$ 104,219 \$ 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)

	Three Months Ended		Nine Months Ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Net sales	\$ 3,588	\$ 2,271	\$ 8,056	\$ 5,827
Cost of sales	2,287	1,117	4,745	2,940
Gross profit	1,301	1,154	3,311	2,887
Costs and expenses:				
Research and development	5,001	6,064	16,191	19,145
Sales, general and administrative	11,465	12,743	35,738	38,302
Total costs and expenses	16,466	18,807	51,929	57,447
Loss from operations	(15,165)	(17,653)	(48,618)	(54,560)
Other income (expense):				
Interest expense	(3,955)	(3,598)	(11,540)	(10,585)
Foreign currency exchange gain (loss)	229	(89)	191	(142)
Interest income	149	676	753	2,329
Other income (expense), net	(15)	(9)	(82)	(12)
Total other expense, net	(3,592)	(3,020)	(10,678)	(8,410)
Net loss before income taxes	(18,757)	(20,673)	(59,296)	(62,970)
Provision for income taxes	—	239	—	—

Net loss	\$ (18,757)	\$ (20,434)	\$ (59,296)	\$ (62,970)
Basic and diluted net loss per share	\$ (0.33)	\$ (0.37)	\$ (1.07)	\$ (1.16)
Weighted average shares outstanding	56,560	54,553	55,617	54,456
Other comprehensive loss:				
Net loss	\$ (18,757)	\$ (20,434)	\$ (59,296)	\$ (62,970)
Net unrealized gain (loss) on debt securities available-for-sale	(117)	10	62	229
Foreign currency translation adjustment	71	(113)	90	(139)
Comprehensive loss	\$ (18,803)	\$ (20,537)	\$ (59,144)	\$ (62,880)

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended	
	September 30, 2020	September 30, 2019
Cash flows from operating activities:		
Net loss	\$ (59,296)	\$ (62,970)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,270	1,862
Amortization of investment discount	43	(400)
Equity-based compensation	12,291	9,409
Amortization of debt discount and issuance costs	8,256	7,370
Realized loss on sale of investments	3	—
Loss on disposal of property and equipment	546	577
Contributions to deferred compensation plan	(248)	—
(Increase) decrease in assets:		
Accounts receivable	532	(782)
Inventory and instruments in property and equipment	(1,734)	(3,286)
Prepaid expense and other	(1,267)	(319)
Increase (decrease) in liabilities:		
Accounts payable	76	788
Accrued liabilities, and other	(759)	(2,115)
Accrued interest	(1,071)	(1,071)
Deferred revenue and income	67	33
Deferred compensation	240	(25)
Net cash used in operating activities	(40,051)	(50,929)
Cash flows from investing activities:		
Purchases of equipment	(1,364)	(148)
Purchase of marketable securities	(44,589)	(20,710)
Proceeds from sales of marketable securities	—	13,400
Maturities of marketable securities	41,707	78,922
Net cash (used in) provided by investing activities	(4,246)	71,464
Cash flows from financing activities:		
Proceeds from issuance of common stock	296	1,363
Proceeds from exercise of options	4,458	4,879
Proceeds from debt	5,552	—
Payment of debt	(13)	—
Net cash provided by financing activities	10,293	6,242

Effect of exchange rate on cash	19	(99)
(Decrease) increase in cash and cash equivalents	(33,985)	26,678
Cash and cash equivalents, beginning of period	61,014	66,260
Cash and cash equivalents, end of period	<u>\$ 27,029</u>	<u>\$ 92,938</u>

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended	
	September 30, 2020	September 30, 2019
Non-cash investing activities:		
Net transfer of instruments from inventory to property and equipment	\$ 1,284	\$ 3,225
Supplemental cash flow information:		
Interest paid	\$ 4,288	\$ 4,288
Income taxes paid, net of refunds	\$ 46	\$ 54

See accompanying notes to condensed consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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<https://ir.axdx.com/2020-11-05-Accelerate-Diagnostics-Reports-Third-Quarter-2020-Financial-Results>