

Accelerate Diagnostics Reports Third Quarter 2022 Financial Results

TUCSON, Ariz., Nov. 14, 2022 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced financial results for the third quarter for the period ended September 30, 2022.

"Our third quarter results were generally in line with my expectations," commented Jack Phillips, Chief Executive Officer of Accelerate Diagnostics, Inc. "While I was pleased with the significant progress we made in readying for commercialization with BD and on development of our next generation AST platform, the FDA's challenge of Arc's regulatory status was an unexpected set-back. Despite this news, BD remains committed to our long-term commercial partnership."

Third Quarter 2022 Highlights

- Added 6 contracted instruments and brought 9 instruments live in the U.S. in the quarter.
- Ended the second quarter with 323 U.S. clinically live and revenue-generating instruments, with another 81 U.S. contracted instruments in the process of being implemented and not yet revenue-generating.
- Net sales were \$3.0 million, compared to \$3.1 million in the third quarter of the prior year, or a 3% decrease. This decrease was driven by the timing of capital equipment sales, while recurring revenues grew by 14% compared to the same period in the prior year.
- Gross margin was 26% for the quarter, compared to 32% in the second quarter of the prior year. The decline in gross margins resulted from inflation to manufacturing costs and other factors.
- Selling, general, and administrative (SG&A) costs for the quarter were \$8.3 million, compared to \$10.8 million from the same quarter of the prior year. SG&A costs for the quarter excluding non-cash stock-based compensation were \$7.3 million, compared to \$7.5 million from the same quarter of the prior year. SG&A was relatively unchanged over these periods.
- Research and development (R&D) costs for the quarter were \$7.3 million, compared to \$4.7 million from the same quarter of the prior year. R&D costs excluding non-cash stock-based compensation expense for the quarter were \$7.1 million, compared to \$4.4 million from the quarter of the prior year. This increase was the result of investment in our next generation AST platform.
- Net loss was \$15.7 million in the second quarter, resulting in \$0.18 net loss per share. Net loss excluding non-cash stock-based compensation expense for the second quarter was \$14.5 million.
- Net cash used in the quarter excluding financing was \$14.3 million.

Year-to-date 2022 Highlights

- Net sales were \$9.8 million year-to-date, compared to \$8.4 million from the same period of the prior year, or a 16% increase. Growth was driven by increases in both capital and recurring revenues.
- Gross margin was 27% year-to-date, compared to 35% from the same period of the prior year. The decline in gross margins resulted from ongoing pandemic-related impacts to manufacturing costs and other factors.
- Selling, general, and administrative (SG&A) costs year-to-date were \$30.4 million, compared to \$37.7 million from the same period of the prior year. SG&A costs excluding non-cash stock-based compensation were \$23.9 million year to date, compared to \$23.3 million from the same period of the prior year.
- Research and development (R&D) costs were \$20.9 million year to date, compared to \$17.3 million from the same period of the prior year. R&D costs excluding non-cash stock-based compensation expense were \$19.8 million year to date, compared to \$13.0 million from the same period of the prior year. This increase was the result of investment in our next generation AST platform.
- Net loss was \$47.7 million year to date, resulting in \$0.62 net loss per share. Net loss excluding non-cash stock-based compensation expense was \$39.5 million.
- Net cash used excluding financing was \$41.1 million
- Ended the quarter with total cash, investments, and cash equivalents of \$55.4 million.

Full financial results for the quarter ending September 30, 2022 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

To listen to the 2022 third quarter financial results, call by phone, +1.877.883.0383 and enter Elite Entry Number: 5844198. 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 7894082 until December 5, 2022.

This conference call will also be webcast and can be accessed from the company's website at ir.axdx.com. A replay of the audio webcast will be available until February 14, 2023.

Use of Non-GAAP Financial Measures

This press release contains certain financial measures that are not recognized measures under accounting principles generally accepted in the United States of America ("GAAP"), which include SG&A, R&D, and Net income (loss) amounts excluding stock-based compensation expenses.

Our management and board of directors use expenses excluding the cost of stock-based compensation to understand and evaluate our operating performance and trends, to prepare and approve our annual budget and to develop short-term and long-term operating and financing plans. Accordingly, we believe that expenses excluding the cost of stock-based compensation provides useful information for investors in understanding and evaluating our operating results in the same manner as our management and our board of directors. Expenses excluding the cost of stock-based compensation is a non-GAAP financial measure and should be considered in addition to, not as superior to, or as a substitute for, SG&A expenses, R&D expenses, and net income (loss) reported in accordance with GAAP. The following tables present a reconciliation of SG&A expenses, R&D expenses and net income (loss) excluding stock-based compensation to comparable GAAP measures for the periods indicated:

	Three Months Ended September 30, (in thousands)		Nine Months Ended September 30, (in thousands)	
	2022	2021	2022	2021
Sales, General and Administrative	\$ 8,255	\$ 10,806	\$ 30,422	\$ 37,744
Non-cash equity-based compensation as a component of sales, general and administrative	911	3,281	6,557	14,461
Sales, general and administrative less non-cash equity-based compensation	\$ 7,344	\$ 7,525	\$ 23,865	\$ 23,283

	Three Months Ended September 30, (in thousands)		Nine Months Ended September 30, (in thousands)	
	2022	2021	2022	2021
Research and Development	\$ 7,285	\$ 4,712	\$ 20,885	\$ 17,341
Non-cash equity-based compensation as a component of research and development	151	266	1,052	4,340
Research and development less non-cash equity-based compensation	\$ 7,134	\$ 4,446	\$ 19,833	\$ 13,001

	Three Months Ended September 30, (in thousands)		Nine Months Ended September 30, (in thousands)	
	2022	2021	2022	2021
Loss from operations	\$ (14,770)	\$ (14,532)	\$ (48,654)	\$ (52,148)
Non-cash equity-based compensation as a component of loss from operations	1,229	3,629	8,179	19,058
Loss from operations less non-cash equity-based compensation	\$ (13,541)	\$ (10,903)	\$ (40,475)	\$ (33,090)

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 or may have forward looking implications, such as, among others, Mr. Phillip's statements regarding BD commercialization preparations, development of our next generation AST platform, and BD's commitment to our long-term commercial partnership. 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 14, 2022, 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 SHEETS

(in thousands, except share data)

	September 30, 2022	December 31, 2021
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$38,987	\$39,898
Investments	16,407	23,720
Trade accounts receivable, net	2,393	2,320
Inventory	5,392	5,067
Prepaid expenses	1,119	768
Other current assets	1,974	1,558
Total current assets	66,272	73,331
Property and equipment, net	3,621	5,389
Finance lease assets, net	2,319	—
Operating lease right of use assets, net	2,012	2,510
Other non-current assets	1,623	1,817
Total assets	\$75,847	\$83,047
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$2,819	\$1,983
Accrued liabilities	4,300	2,853
Accrued interest	118	909
Deferred revenue	524	451
Current portion of long-term debt	80	80
Finance lease, current	953	—
Operating lease, current	774	669
Total current liabilities	9,568	6,945
Finance lease, non-current	698	—
Operating lease, non-current	1,775	2,381
Other non-current liabilities	759	808

Accrued interest related-party	220	—
Long-term debt related-party	16,299	—
Convertible notes	56,325	107,984
Total liabilities	\$85,644	\$118,118
Stockholders' deficit:		
Preferred shares, \$0.001 par value; 5,000,000 preferred shares authorized and 3,954,546 outstanding as of September 30, 2022 and December 31, 2021	4	4
Common stock, \$0.001 par value; 200,000,000 common shares authorized with 97,240,983 shares issued and outstanding on September 30, 2022 and 100,000,000 common shares authorized with 67,649,018 shares issued and outstanding on December 31, 2021	97	68
Contributed capital	627,853	580,652
Treasury stock	(45,067)	(45,067)
Accumulated deficit	(592,439)	(570,668)
Accumulated other comprehensive loss	(245)	(60)
Total stockholders' deficit	(9,797)	(35,071)
Total liabilities and stockholders' deficit	\$75,847	\$83,047

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 September 30, 2022	September 30, 2021	Nine Months Ended September 30, 2022	September 30, 2021
Net sales	\$2,960	\$3,122	\$9,780	\$8,439
Cost of sales	2,190	2,136	7,127	5,502
Gross profit	770	986	2,653	2,937
Costs and expenses:				
Research and development	7,285	4,712	20,885	17,341
Sales, general and administrative	8,255	10,806	30,422	37,744
Total costs and expenses	15,540	15,518	51,307	55,085
Loss from operations	(14,770)	(14,532)	(48,654)	(52,148)
Other (expense) income:				
Interest expense	(203)	(4,211)	(1,833)	(12,477)
Interest expense related-party	(495)	—	(495)	—
Gain on extinguishment of debt	—	9,840	3,565	9,840
Foreign currency exchange loss	(261)	(78)	(221)	(238)
Interest income	73	—	151	55
Other (expense) income, net	(49)	(5)	(206)	69
Total other (expense) income, net	(935)	5,546	961	(2,751)
Net loss before income taxes	(15,705)	(8,986)	(47,693)	(54,899)
Provision for income taxes	—	—	—	—
Net loss	\$(15,705)	\$(8,986)	\$(47,693)	\$(54,899)
Basic and diluted net loss per share	\$(0.18)	\$(0.15)	\$(0.62)	\$(0.91)
Weighted average shares outstanding	87,011	61,146	77,049	60,250
Other comprehensive loss:				
Net loss	\$(15,705)	\$(8,986)	\$(47,693)	\$(54,899)

Net unrealized gain (loss) on debt securities available-for-sale	48	(3)	(84)	(21)
Foreign currency translation adjustment	139	(27)	(101)	(87)

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, 2022	September 30, 2021
Cash flows from operating activities:		
Net loss	\$(47,693)	\$(54,899)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,207	1,875
Amortization of investment discount	94	153
Equity-based compensation	8,179	19,058
Amortization of debt discount and issuance costs	386	9,250
Amortization of debt discount related-party	275	—
Loss (gain) on disposal of property and equipment	74	(202)
Unrealized loss on equity investments	206	—
Gain on extinguishment of debt	(3,565)	(9,840)
(Increase) decrease in assets:		
Contributions to deferred compensation plan	(174)	(343)
Accounts receivable	(73)	(719)
Inventory	(245)	(527)
Prepaid expense and other	(491)	860
Increase (decrease) in liabilities:		
Accounts payable	1,221	1,017
Accrued liabilities	962	(436)
Accrued interest	(785)	(1,059)
Deferred revenue and income	73	93
Deferred compensation	(49)	343
Net cash used in operating activities	(39,398)	(35,376)
Cash flows from investing activities:		
Purchases of equipment	(446)	(202)
Purchase of marketable securities	(27,506)	(22,345)
Maturities of marketable securities	34,527	33,601
Net cash provided by investing activities	6,575	11,054
Cash flows from financing activities:		
Proceeds from issuance of common stock	32,872	22,640
Payments on finance leases	(1,109)	—
Proceeds from exercise of options	7	1,456
Proceeds from issuance of common stocks under employee purchase plan	184	245
Transaction costs related to debt exchange	(192)	—
Payment of debt	(6)	(6)
Accrued interest from related-party	220	—
Net cash provided by financing activities	31,976	24,335

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, 2022	September 30, 2021
Effect of exchange rate on cash	(64)	(69)
Decrease in cash and cash equivalents	(911)	(56)
Cash and cash equivalents, beginning of period	39,898	35,781
Cash and cash equivalents, end of period	\$38,987	\$35,725
Non-cash investing activities:		
Net transfer of instruments (to) from inventory to property and equipment	\$(78)	\$500
Non-cash financing activities:		
Extinguishment of convertible senior notes through issuance of common stock	\$10,180	\$—
Convertible notes due from related-party extinguished in connection with the exchange transaction, net of deferred issuance costs	\$49,624	\$—
Fair value of new note from related-party issued in connection with the exchange transaction	\$16,024	\$—
Fair value of common stock warrant issued to related-party in connection with exchange transaction	\$3,753	\$—
Capital contribution from related-party in connection with the exchange transaction	\$29,847	\$—
Supplemental cash flow information:		
Interest paid	\$2,214	\$2,144

See accompanying notes to condensed consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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<https://ir.axdx.com/2022-11-14-Accelerate-Diagnostics-Reports-Third-Quarter-2022-Financial-Results>