

Accelerate Diagnostics Reports Third Quarter 2023 Results

TUCSON, Ariz., Nov. 9, 2023 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced financial results for the third quarter ended September 30, 2023.

"During the quarter we made significant advances with our Wave program," commented Jack Phillips, Chief Executive Officer of Accelerate Diagnostics, Inc. "We are getting results well within current standard of care methods to provide same-shift patient results, which gives us confidence our innovative technology will provide same-shift clinical impact."

Third Quarter 2023 Operating Highlights:

- Wave Beta modules are operational in our lab delivering on our key product requirements: goal of time-to-result of less than 4.5 hours on average, high through-put sample processing, random access for continuous sample loading and platform scalability.
- Added six contracted Pheno instruments during the quarter, ending the quarter with 339 U.S. clinically live Pheno revenue-generating instruments and another 70 U.S. contracted Pheno instruments in the process of being implemented.
- Secured more than twenty existing U.S. Pheno customers to multi-year contract extensions for rapid positive blood culture susceptibility testing during the quarter.

Third Quarter 2023 Financial Highlights:

- Net sales for the third quarter ended September 30, 2023 were \$3.3 million, compared to \$3.0 million in the third quarter of the prior year, a 10% increase. This increase was primarily driven by capital equipment sales in the quarter.
- Gross margin was approximately 3% for the quarter, compared to 21% in the third quarter of the prior year. This decrease was driven primarily by a non-cash write-down of \$1.2 million of excess inventory.
- Selling, general, and administrative (SG&A) costs for the quarter were \$7.8 million, compared to \$8.3 million for the same quarter of the prior year. This decrease was the result of lower employee-related expenses.
- Research and development (R&D) costs for the quarter were \$7.0 million, compared to \$7.3 million from the same quarter of the prior year. This decrease was driven by a reduction in third-party spend related to the development of our next generation AST platform.
- Net income was \$0.9 million in the third quarter, resulting in basic and diluted earnings per share of \$0.06. Our positive net income was driven by a fair-value adjustment of the derivative liability related to our convertible notes.
- Net cash used in the quarter excluding financing activities was \$9.6 million and the Company ended the quarter with total cash, investments and cash equivalents \$21.2 million.

Year-to-date 2023 Financial Highlights:

- Net sales were \$9.0 million year-to-date, compared to \$9.8 million from the same period of the prior year, or an 8% decrease driven by lower capital instrument sales in 2023 compared to the prior year.
- Gross margin was approximately 20% for the quarter, reflecting the non-cash write-down of \$1.2 million of excess inventory recorded during the period, compared to 25% in the third quarter of the prior year.
- Selling, general, and administrative (SG&A) costs year-to-date were \$25.4 million, compared to \$30.4 million for the same period of the prior year.
- Research and development (R&D) costs were \$19.8 million year to date, compared to \$20.9 million from the same period of the prior year.
- Net cash used excluding financing activities was \$38.4 million.

Full financial results for the quarter ending September 30, 2023 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 2023 third quarter financial results on Thursday, November 9, 2023, at 4:30 p.m. Eastern Time, call by phone, +1.877.883.0383 and enter Elite Entry Number: 9121489. 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 6290760 until November 30, 2023.

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 November 30, 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 loss from operations 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)	
	2023	2022	2023	2022
Sales, General and Administrative	\$ 7,761	\$ 8,255	\$ 25,432	\$ 30,422
Non-cash equity-based compensation as a component of sales, general and administrative	1,488	911	2,647	6,557
Sales, general and administrative less non-cash equity-based compensation	\$ 6,273	\$ 7,344	\$ 22,785	\$ 23,865
	Three Months Ended September 30, (in thousands)		Nine Months Ended September 30, (in thousands)	
	2023	2022	2023	2022
Research and Development	\$ 6,996	\$ 7,285	\$ 19,783	\$ 20,885
Non-cash equity-based compensation as a component of research and development	269	151	1,130	1,052
Research and development less non-cash equity-based compensation	\$ 6,727	\$ 7,134	\$ 18,653	\$ 19,833
	Three Months Ended September 30, (in thousands)		Nine Months Ended September 30, (in thousands)	
	2023	2022	2023	2022
Loss from operations	\$ (14,650)	\$ (14,961)	\$ (43,298)	\$ (48,845)
Non-cash equity-based compensation as a component of loss from operations	1,815	1,229	4,023	8,179
Loss from operations less non-cash equity-based compensation	\$ (12,835)	\$ (13,732)	\$ (39,275)	\$ (40,666)

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 and the related conference call are forward-looking or may have forward-looking implications, such as, among others: the company's future development plans and growth strategy, including plans and objectives relating to its future operations, products and performance; projections as to when certain key business milestones may be achieved; expectations regarding the potential or benefits of the company's products and technologies; projections of future demand for the company's products; the company's continued investment in new product development to both enhance its existing products and bring new ones to market; the company's expectations relating to current supply chain impacts and inflationary pressures; the company's expectations regarding its commercial partnerships, such as with Becton, Dickinson and Company, including anticipated benefits from such collaboration; the company's expectations and plans relating to regulatory approvals; and the company's liquidity and capital requirements. Actual results or developments may differ materially from those projected or implied in these forward-looking statements due to significant risks and uncertainties, including, but not limited to: volatility throughout the global economy and the related impacts to the businesses of the company's suppliers and customers, such as customer demand fluctuations, supply chain constraints and inflationary pressures, as well as difficulties in resolving the company's continuing financial condition and ability to obtain additional capital to meet its financial obligations. Other important factors that could cause the company's actual results to differ materially from those in its forward-looking statements include those discussed in the company's filings with the Securities and Exchange Commission (the "SEC"), including in the "Risk Factors" sections of the company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings with the SEC. 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.

	September 30, 2023	December 31, 2022
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$20,162	\$34,905
Investments	989	10,656
Trade accounts receivable, net	2,666	2,416
Inventory	3,553	5,194
Prepaid expenses	1,435	818
Other current assets	3,638	2,025
Total current assets	32,443	56,014
Property and equipment, net	2,609	3,478
Finance lease assets, net	1,807	2,422
Operating lease right of use assets, net	1,352	1,859
Other non-current assets	1,113	1,242
Total assets	\$39,324	\$65,015
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$4,812	\$4,501
Accrued liabilities	3,437	2,682
Accrued interest	1,186	472
Deferred revenue	596	547
Current portion of convertible notes	726	56,413
Finance lease, current	468	1,113
Operating lease, current	963	829
Derivative liability	25,598	—
Total current liabilities	37,786	66,557
Finance lease, non-current	270	782
Operating lease, non-current	816	1,545
Deferred income, non-current	1,090	—
Other non-current liabilities	1,068	874
Accrued interest related-party	—	663
Long-term debt related-party	—	16,858
Convertible notes, non-current	33,327	—
Total liabilities	\$74,357	\$87,279
Stockholders' deficit:		
Preferred shares, \$0.001 par value; 5,000,000 preferred shares authorized with no shares issued and outstanding on September 30, 2023 and 5,000,000 preferred shares authorized with 3,954,546 shares issued and outstanding on December 31, 2022	—	4
Common stock, \$0.001 par value; 450,000,000 common shares authorized with 14,504,695 shares issued and outstanding on September 30, 2023 and 200,000,000 common shares authorized with 9,747,755 shares issued and outstanding on December 31, 2022	14	10
Contributed capital	666,239	630,428
Treasury stock	(45,067)	(45,067)
Accumulated deficit	(655,859)	(607,239)
Accumulated other comprehensive loss	(360)	(400)
Total stockholders' deficit	(35,033)	(22,264)
Total liabilities and stockholders' deficit	\$39,324	\$65,015

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, 2023	September 30, 2022	September 30, 2023	September 30, 2022
Net sales	\$3,299	\$2,960	\$9,032	\$9,780

Cost of sales:				
Cost of sales	2,008	2,381	5,931	7,318
Inventory write-down	1,184	—	1,184	—
Total cost of sales	3,192	2,381	7,115	7,318
Gross profit	107	579	1,917	2,462
Costs and expenses:				
Research and development	6,996	7,285	19,783	20,885
Sales, general and administrative	7,761	8,255	25,432	30,422
Total costs and expenses	14,757	15,540	45,215	51,307
Loss from operations	(14,650)	(14,961)	(43,298)	(48,845)
Other income (expense):				
Interest expense	(2,205)	(203)	(3,798)	(1,833)
Interest expense related-party	—	(495)	(1,817)	(495)
Gain (loss) on extinguishment of debt	51	—	(6,499)	3,565
(Loss) on extinguishment of debt related party	—	—	(6,755)	—
Gain on fair value adjustment	18,056	—	13,026	—
Foreign currency exchange gain	(428)	(261)	(170)	(221)
Interest income	246	73	921	151
Other (expense) income, net	(29)	(49)	56	(206)
Total other income (expense), net	15,691	(935)	(5,036)	961
Net income (loss) before income taxes	1,041	(15,896)	(48,334)	(47,884)
Provision for income taxes	(131)	—	(286)	—
Net income (loss)	\$910	\$(15,896)	\$(48,620)	\$(47,884)
Basic net income (loss) per share	\$0.06	\$(1.83)	\$(4.13)	\$(6.21)
Basic weighted average shares outstanding	14,433	8,701	11,777	7,705
Dilutive net income (loss) per share	\$0.06	\$(1.83)	\$(4.13)	\$(6.21)
Dilutive weighted average shares outstanding	14,553	8,701	11,777	7,705
Other comprehensive loss:				
Net income (loss)	\$910	\$(15,896)	\$(48,620)	\$(47,884)
Net unrealized gain (loss) on debt securities available-for-sale	—	48	28	(84)
Foreign currency translation adjustment	293	139	12	(101)
Comprehensive income (loss)	\$1,203	\$(15,709)	\$(48,580)	\$(48,069)

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, September 30,
2023 2022

Cash flows from operating activities:

Net loss	\$(48,620)	\$(47,884)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,434	2,207
Amortization of investment discount	—	94
Equity-based compensation	4,023	8,179
Amortization of debt discount and issuance costs	2,060	386
Amortization of debt discount related-party	1,033	275
Loss on disposal of property and equipment	134	74
Unrealized (gain) loss on equity investments	(61)	206
Loss (gain) on extinguishment of debt	6,499	(3,565)
Loss on extinguishment of debt with related party	6,755	—
Gain on fair value adjustments	(13,026)	—
Inventory write-down	1,184	—

(Increase) decrease in assets:		
Contributions to deferred compensation plan	—	(174)
Accounts receivable	(250)	(73)
Inventory	298	(245)
Prepaid expense and other	956	(491)
Increase (decrease) in liabilities:		
Accounts payable	218	1,221
Accrued liabilities and other	67	1,153
Accrued interest	1,738	(785)
Accrued interest to related-party	784	220
Deferred revenue and income	1,139	73
Deferred compensation	194	(49)
Net cash used in operating activities	(32,441)	(39,178)

Cash flows from investing activities:

Purchases of equipment	(925)	(446)
Purchase of marketable securities	—	(27,506)
Maturities of marketable securities	9,695	34,527
Net cash provided by investing activities	8,770	6,575

Cash flows from financing activities:

Proceeds from issuance of common stock to related party	4,000	—
Proceeds from issuance of common stock	—	32,872
Payments on finance leases	(1,357)	(1,109)
Proceeds from exercise of options	—	7
Proceeds from issuance of common stock under employee purchase plan	—	184
Proceeds from issuance of 5.00% Notes	10,000	—
Transaction costs related to debt and equity issuances	(3,731)	(192)
Payment of debt	—	(6)
Net cash provided by financing activities	8,912	31,756

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

	Nine Months Ended	
	September 30, September 30,	
	2023	2022
Effect of exchange rate on cash	16	(64)
Decrease in cash and cash equivalents	(14,743)	(911)
Cash and cash equivalents, beginning of period	34,905	39,898
Cash and cash equivalents, end of period	\$20,162	\$38,987
Non-cash investing activities:		
Net transfer of instruments from inventory to property and equipment	\$343	\$(78)
Non-cash financing activities:		
Extinguishment of 2.50% Notes through issuance of common stock	\$—	\$10,180
Capital contribution from the exchange of secured note and accrued interest through the issuance of common stock with related party	\$25,363	\$29,847
Exchange of 2.50% Notes and accrued interest for 5.00% Notes	\$56,893	\$—
Debt premium on issuance of 5.00% Notes	\$6,023	\$—
Derivative liability	\$38,160	\$—
2.50% Notes extinguished in connection with exchange transaction	\$—	\$49,624
Fair value of new note issued in connection with the exchange transaction	\$—	\$16,024
Fair value of common stock warrant issued in connection with the exchange transaction	\$—	\$3,753
Extinguishment of 5.00% Notes through issuance of common stock	\$330	\$—
Extinguishment of derivative liability in connection with extinguishment of 5.00% Notes	\$380	\$—
Issuance of common stock in connection with extinguishment of 5.00% Notes	\$658	\$—
Supplemental cash flow information:		
Interest paid	\$—	\$2,214

See accompanying notes to condensed consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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<https://ir.axdx.com/2023-11-09-Accelerate-Diagnostics-Reports-Third-Quarter-2023-Results>