Accelerate Diagnostics Reports Fourth Quarter and Full-Year 2023 Financial Results

TUCSON, Ariz., March 28, 2024 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced financial results for the fourth quarter and year ended December 31, 2023.

"In 2023, we made significant progress with the development of our next-generation rapid Antibiotic Susceptibility Testing system, Accelerate Wave™. We continue to advance this important development program and believe that we remain on plan to begin our clinical trials in the second quarter of 2024," commented Jack Phillips, President and CEO of Accelerate Diagnostics, Inc. "In addition, we continue to expand and secure our Accelerate Pheno® customer base, with an upgrade path to Wave adoption. Based on consistent customer feedback, Accelerate Wave is anticipated to set the new standard for rapid, same-shift, susceptibility testing," Mr. Phillips continued.

2023 Fourth Quarter Results

- Notable Wave program achievements during the quarter included:
    - Completed Wave system integration.
    - Significantly advanced antibiotic susceptibility testing (AST) performance of gram-negative positive blood culture menu for approximately 200 bug-drug combinations and running approximately 5,000 unique strains of gram-negative organisms with average time-to-results below 4.5 hours.
- Completed extensive reviews with U.S. and EMEA customers to validate Wave's product specifications and menu roll-out strategy. Approximately 90% of customers have expressed interest in adopting Accelerate Wave for both rapid positive blood culture and isolated colony testing given unique perceived benefits compared to existing and emerging automated susceptibility platforms.
- In the United States, added six new contracted Pheno instruments during the quarter, ending the quarter with 340 clinically live Pheno revenue-generating instruments and another 71 contracted Pheno instruments in the process of being implemented.
- Executed a collaboration and quality agreement with Bruker Corporation for the Accelerate Arc™ system, made significant progress towards completing U.S. clinical trials and anticipate submission to the U.S. Food and Drug Administration (FDA) during the first quarter of 2024.
- Net sales for the quarter were $3.0 million, compared to $3.0 million for the same quarter of the prior year. Sales for the quarter included a decrease in instrument sales of 11% over the same quarter of the prior year driven by the timing and number of contracts in the funnel, while revenues from consumable products increased by 9% compared to the same period in the prior year.
- Gross margin was approximately 21% for the quarter, compared to approximately 28% for the same quarter of the prior year. The decline in gross margins resulted from inflation in manufacturing related costs and other factors.
- Selling, general, and administrative (SG&A) costs for the quarter were $5.8 million, compared to $8.8 million for the same quarter of the prior year. The decline in SG&A costs is a result of lower employee-related expenses. SG&A costs include non-cash stock-based compensation of $1.0 million and $2.0 million, respectively, for the same periods.
- Research and development (R&D) costs for the quarter were $5.6 million, compared to $6.0 million for the same quarter of the prior year. The decline in R&D costs is a result of lower employee-related expenses as well as lower third-party development costs for our next generation susceptibility instrument Accelerate Wave. R&D costs include non-cash stock-based compensation of $0.3 million and $0.4 million, respectively, for the same periods.
- Net loss was $13.0 million for the quarter, resulting in $0.89 net loss per share.
- Cash used in the fourth quarter was $7.9 million. This reflects a continued reduction in operating cash use over the prior quarters of 2023, following cost cutting measures implemented throughout the year.

2023 Full Year Results

- Secured approximately 65% of current U.S. Pheno customers to multi-year contracts for rapid susceptibility testing, reflecting customers' commitment to Accelerate rapid AST technology and interest in Wave.
- Net Sales were $12.1 million for the year, compared to $12.8 million in the prior year. While year-over-year revenues for consumable products increased by approximately 5%, overall annual revenue was down year-over-year due to a challenging capital sales environment in all our sales regions.
- Gross margin was approximately 21% for the year, compared to approximately 26% for the prior year. The overall decline in gross margin primarily resulted from a $1.2 million inventory write-down of excess inventory during the third quarter of 2023. Gross margin for the year, excluding inventory write-down and non-cash equity-based compensation was approximately 33%.
- Selling, general, and administrative (SG&A) costs were $31.2 million for the year, compared to $39.2 million for the prior year. The decline in SG&A costs is a result of lower employee-related expenses during the year. SG&A costs include non-cash stock-based compensation of $3.7 million and $8.5 million, respectively, for the same periods.
- Research and development (R&D) costs were $25.4 million for the year, compared to $26.9 million for the prior year. The decline in R&D costs is a result of lower employee-related expenses as well as lower third-party development for our next-generation rapid AST system, Accelerate Wave. R&D costs include non-cash stock-based compensation of $1.4 million and $1.4 million, respectively, for the same periods.
- GAAP net loss was $61.6 million for the year, resulting in $4.94 net loss per share.
- Cash used for the year was $46.3 million, which includes approximately $8 million of debt restructuring related expenses.
- Ended the year with total cash, investments, and cash equivalents of $13.2 million.

Full financial results for the year ended December 31, 2023 will be filed on Form 10-K through the Securities and Exchange Commission's (SEC) website at http://www.sec.gov.

Audio Webcast and Conference Call

Management will host a conference call on Thursday, March 28, 2024, at 4:30 p.m. Eastern Time to review 2023 fourth quarter and full year results.

To listen to the 2023 fourth quarter and full year results, call by phone, +1.877.883.0383 and enter Elite Entry Number: 7172610.

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 7585609 until April 18, 2024.

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 for 30 days.

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 operating income (loss) amounts excluding stock-based compensation expenses.

Our management and board of directors use expenses excluding the cost of stock-based compensation and certain impairment transactions 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 and certain impairment transactions 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 and certain impairment transactions 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 operating income (loss) reported in accordance with GAAP. The following tables present a reconciliation of Cost of sales, SG&A expenses, R&D expenses and operating income (loss) excluding stock-based compensation and certain impairment transactions to comparable GAAP measures for the periods indicated:

	Three Months Ended December 31, (in thousands)		Twelve Months Ended December 31, (in thousands)	
	2023	**2022**	**2023**	**2022**
Cost of sales	$ 2,394	$ 2,381	$ 9,509	$ 9,449
Inventory impairment charges included in cost of sales	-	-	1,184	-
Non-cash equity-based compensation as a component of cost of sales	53	95	300	665
Cost of sales less impairment charges and non-cash equity-based compensation	$ 2,341	$ 2,286	$ 8,025	$ 8,784

	Three Months Ended December 31, (in thousands)		Twelve Months Ended December 31, (in thousands)	
	2023	**2022**	**2023**	**2022**
Sales, General and Administrative	$ 5,792	$ 8,772	$ 31,225	$ 39,193
Non-cash equity-based compensation as a component of sales, general and administrative	1,045	1,984	3,691	8,541
Sales, general and administrative less non-cash equity-based compensation	$ 4,747	$ 6,788	$ 27,534	$ 30,652

	Three Months Ended December 31, (in thousands)		Twelve Months Ended December 31, (in thousands)	
	2023	**2022**	**2023**	**2024**
Research and Development	$ 5,570	$ 6,030	$ 25,353	$ 26,915
Non-cash equity-based compensation as a component of research and development	266	367	1,396	1,419
Research and development less non-cash equity-based compensation	$ 5,304	$ 5,663	$ 23,957	$ 25,496

	Three Months Ended December 31, (in thousands)		Twelve Months Ended December 31, (in thousands)	
	2023	**2022**	**2023**	**2022**
Loss from operations	$ (10,729)	$ (13,961)	$ (54,028)	$ (62,805)
Non-cash equity-based compensation as a component of loss from operations	1,364	2,446	5,387	10,625
Loss from operations less non-cash equity-based compensation	$ (9,365)	$ (11,515)	$ (48,641)	$ (52,180)

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 "ACCELERATE ARC" and "ACCELERATE WAVE" 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 within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the company intends that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements, which can be identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "estimate," or "continue," or variations thereon or comparable terminology, include but are not limited to, statements about: 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, including the company's belief that it remains on plan to begin its clinical trials for the Accelerate Wave system in the second quarter of 2024; expectations regarding the potential or benefits of the company's products and technologies, including the company's anticipation that the Accelerate Wave system will set the new standard for rapid, same-shift, susceptibility testing; projections of future demand for the company's products, including the Accelerate Wave system; 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 Bruker Corporation, including anticipated benefits from such collaboration; the company's intentions and plans relating to regulatory approvals, including the company's anticipated submission to the FDA during the first quarter of 2024 for the Accelerate Arc system; the company's liquidity and capital requirements; and the company's belief that cost cutting measures implemented throughout 2023 will continue to drive cash burn reductions into 2024. 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, whether due to customer demand fluctuations, supply chain constraints and inflationary pressures or otherwise; difficulties in resolving the company's continuing financial condition and ability to obtain additional capital to meet its financial obligations; the company's ability to obtain any regulatory approvals; and less than expected operating and financial benefits resulting from cost cutting measures. 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. These forward-looking statements are also based on certain additional assumptions, including, but not limited to, that the company will retain key management personnel; the company will be successful in the commercialization of its products; the company will obtain sufficient capital to commercialize its products and continue development of complementary products; the company will be successful in obtaining marketing authorization for its products from the FDA and other regulatory agencies and governing bodies; the company will be able to protect its intellectual property; the company's ability to respond effectively to technological change; the company's ability to accurately anticipate market demand for its products; and that there will be no material adverse change in the company's operations or business and general market and industry 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. Forward-looking statements speak only as of the date they are made and should not be relied upon as representing the company's plans and expectations as of any subsequent date.

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
BALANCE SHEETS
(in thousands, except share data)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,138	$ 34,905
Investments	1,081	10,656
Trade accounts receivable, net	2,622	2,416
Inventory	3,310	5,194
Prepaid expenses	380	818
Purchase obligation put option asset	3,419	—
Other current assets	1,516	2,025
Total current assets	24,466	56,014
Property and equipment, net	2,389	3,478
Finance lease assets, net	1,518	2,422
Operating lease right of use assets, net	1,177	1,859
Other non-current assets	1,816	1,242
Total assets	$ 31,366	$ 65,015
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 4,796	$ 4,501
Accrued liabilities	3,243	2,682
Accrued interest	164	472
Deferred revenue and income, current	1,545	547
Current portion of convertible notes	726	56,413
Finance lease, current	583	1,113
Operating lease, current	977	829
Total current liabilities	12,034	66,557

Finance lease, non-current	262	782
Operating lease, non-current	570	1,545
Deferred income, non-current	1,122	—
Other non-current liabilities	1,164	874
Accrued interest, related-party	—	663
Long-term debt, related-party	—	16,858
Convertible notes, non-current	36,102	—
Total liabilities	51,254	87,279

Commitments and contingencies (see Note 15)

ACCELERATE DIAGNOSTICS, INC.
CONSOLIDATED
BALANCE SHEETS (CONTINUED)
(in thousands, except share data)

	December 31, 2023	December 31, 2022
Stockholders' deficit:		
Preferred shares, $0.001 par value; 5,000,000 preferred shares authorized with no shares issued and outstanding as of December 31, 2023 and 3,954,546 issued and outstanding on December 31, 2022	—	4
Common stock, $0.001 par value; 450,000,000 common shares authorized with 14,569,500 shares issued and outstanding on December 31, 2023 and 200,000,000 common shares authorized with 9,747,755 shares issued and outstanding on December 31, 2022	14	10
Contributed capital	694,634	630,428
Treasury stock	(45,067)	(45,067)
Accumulated deficit	(668,857)	(607,239)
Accumulated other comprehensive loss	(612)	(400)
Total stockholders' deficit	(19,888)	(22,264)
Total liabilities and stockholders' deficit	$ 31,366	$ 65,015

See accompanying notes to consolidated financial statements.

ACCELERATE DIAGNOSTICS, INC. CONSOLIDATED
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)	Years Ended December 31, 2023	2022	2021
Net sales	$ 12,059	$ 12,752	$ 11,782
Cost of sales:			
Cost of sales of products and services	8,325	9,449	7,663
Inventory write-down	1,184	—	4,500
Total cost of sales	9,509	9,449	12,163
Gross profit (loss)	2,550	3,303	(381)
Costs and expenses:			
Research and development	25,353	26,915	21,943
Sales, general and administrative	31,225	39,193	49,236
Total costs and expenses	56,578	66,108	71,179
Loss from operations	(54,028)	(62,805)	(71,560)
Other (expense) income:			
Interest expense	(5,926)	(2,274)	(15,545)
Interest expense related-party	(1,817)	(1,497)	—
(Loss) gain on extinguishment of debt	(6,499)	3,565	9,793
(Loss) on extinguishment of debt related party	(6,755)	—	—
Gain on fair value adjustment	12,955	—	—
Foreign currency exchange gain (loss)	71	117	(413)
Interest income	1,123	551	88
Other expense, net	108	(227)	(20)
Total other (expense) income, net	(6,740)	235	(6,097)
Net loss before income taxes	(60,768)	(62,570)	(77,657)

(Provision) benefit for income taxes	(850)	77	(45)
Net loss	$ (61,618)	$ (62,493)	$ (77,702)
Basic and diluted net loss per share	$ (4.94)	$ (7.61)	$ (12.59)
Weighted average shares outstanding	12,477	8,216	6,173
Other comprehensive loss:			
Net loss	$ (61,618)	$ (62,493)	$ (77,702)
Net unrealized gain (loss) on available-for-sale investments	29	(14)	(34)
Foreign currency translation adjustment	(241)	(326)	(117)
Comprehensive loss	$ (61,830)	$ (62,833)	$ (77,853)

ACCELERATE DIAGNOSTICS, INC. CONSOLIDATED STATEMENT OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net loss	$ (61,618)	$ (62,493)	$ (77,702)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,254	3,000	2,518
Provision for bad debts	301	204	123
Amortization of investment discount	—	98	226
Equity-based compensation expense	5,387	10,625	22,047
Amortization of debt discount and issuance costs	3,278	474	11,542
Amortization of debt discount related party	1,033	834	—
Unrealized (gain) loss on equity investments	(114)	211	—
Loss (gain) on disposal of property and equipment	150	133	(75)
Loss (gain) on extinguishment of debt	6,499	(3,565)	(9,793)
Loss on extinguishment of debt with related party	6,755	—	—
Gain on fair value adjustments	(12,955)	—	—
Paid-in-kind interest	1,718	—	—
Inventory write-down	1,184	—	4,500
(Increase) decrease in assets:			
Deferred compensation plan	(39)	(298)	(484)
Accounts receivable	(234)	(100)	(893)
Inventory	446	(236)	(415)
Prepaid expense and other assets	965	(62)	1,014
Increase (decrease) in liabilities:			
Accounts payable	295	2,920	273
Accrued liabilities and other	(411)	(861)	(469)
Accrued interest	716	(437)	(283)
Accrued interest from related-party	784	663	—
Deferred revenue and income	2,120	96	75
Deferred compensation	290	66	473
Net cash used in operating activities	(40,196)	(48,728)	(47,323)
Cash flows from investing activities:			
Purchases of equipment	(1,035)	(554)	(603)
Purchase of marketable securities	—	(27,506)	(30,081)
Proceeds from sales of marketable securities	—	—	250
Maturities of marketable securities	9,695	40,477	38,738
Net cash provided by investing activities	8,660	12,417	8,304
Cash flows from financing activities:			
Proceeds from issuance of common stock to related party	4,000	—	—
Proceeds from issuance of common and preferred stock, net	—	32,872	42,880
Proceeds from exercise of options	—	7	1,620
Proceeds from issuance of common stocks under employee purchase plan	—	224	326
Proceeds from issuance of 5.00% Notes	10,000	—	—
Payment of debt	—	(80)	(360)
Payments on finance leases	(1,250)	(1,201)	—
Transaction costs related to debt and equity issuances	(3,731)	(192)	(1,240)
Net cash provided by financing activities	9,019	31,630	43,226

ACCELERATE DIAGNOSTICS, INC. CONSOLIDATED STATEMENT OF CASH FLOWS (CONTINUED)
(in thousands)

	Years Ended December 31,

	2023	2022	2021
Effect of exchange rate on cash	(250)	(312)	(90)
(Decrease) increase in cash and cash equivalents	(22,767)	(4,993)	4,117
Cash and cash equivalents, beginning of period	34,905	39,898	35,781
Cash and cash equivalents, end of period	$ 12,138	$ 34,905	$ 39,898
Non-cash investing activities:			
Net transfer of instruments from inventory to property and equipment, net	$ 401	$ 168	$ 688
Non-cash financing activities:			
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	$ —	$ —
Reclassification of bifurcated conversion option to contributed capital	$ 26,908	$ —	$ —
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	$ 819	$ —	$ —
Capital contribution from the exchange of secured note and accrued interest through the issuance of common stock with related party	$ 25,366	$ 29,847	$ —
Extinguishment of 2.50% Notes through issuance of common stock	$ —	$ 10,180	$ 38,902
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	$ —
Right-of-use assets obtained in exchange for finance lease obligations	$ 200	$ 3,096	$ —
Supplemental cash flow information:			
Interest paid	$ 122	$ 2,214	$ 4,288
Income taxes paid, net of refunds	$ 363	$ —	$ —

See accompanying notes to consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

For further information: Investor Inquiries & Media Contact: Laura Pierson, Accelerate Diagnostics, +1 520 365-3100, investors@axdx.com