

Accelerate Diagnostics Reports Fourth Quarter and Full Year 2022 Financial Results

TUCSON, Ariz., March 29, 2023 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced financial results for the fourth quarter and year ended December 31, 2022.

"In 2022, we achieved another year of revenue growth thanks to our base book of satisfied customers," commented Jack Phillips, Chief Executive Officer of Accelerate Diagnostics, Inc., "Though we fell short of our guidance target, we're emboldened by our new partnership with Becton Dickinson and the significant product development milestones we've achieved. The Accelerate Team is fully committed to driving growth and delivering value to our stakeholders."

Fourth Quarter 2022 Highlights

- Added 3 contracted instruments and brought 5 instruments live in the U.S. in the quarter.
- Ended the fourth quarter with 328 U.S. clinically live and revenue-generating instruments, with another 69 U.S. contracted instruments in the process of being implemented and not yet revenue-generating.
- Net sales were \$3.0 million, compared to \$3.3 million in the fourth quarter of the prior year, or a 9% decrease. This decrease was driven by the timing of capital equipment sales, while recurring revenues grew by 8% compared to the same period in the prior year.
- Gross margin was 28% for the quarter, compared to an adjusted 35% in the fourth quarter of the prior year, excluding non-cash adjustments for inventory impairment. 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 \$8.8 million, compared to \$11.5 million from the same quarter of the prior year. SG&A costs for the quarter excluding non-cash stock-based compensation were \$6.8 million, compared to \$8.3 million from the same quarter of the prior year. SG&A reductions over these periods were driven by streamlining our spend within the scope of our BD collaboration.
- Research and development (R&D) costs for the quarter were \$6.0 million, compared to \$4.6 million from the same quarter of the prior year. R&D costs excluding non-cash stock-based compensation expense for the quarter were \$5.7 million, compared to \$4.8 million from the quarter of the prior year. This increase was the result of investment in our next generation AST platform.
- GAAP net loss was \$14.6 million in the fourth quarter, resulting in \$0.15 net loss per share. Net loss excluding non-cash stock-based compensation expense for the fourth quarter was \$12.2 million.
- Net cash used in the quarter excluding financing was \$9.8 million.
- We continue to work with the holders of our convertible notes, which have matured, and other key stakeholders, and have agreed to an extension of the forbearance period to facilitate those continued discussions.

Year-to-date 2022 Highlights

- Net sales were \$12.8 million year-to-date, compared to \$11.8 million from the same period of the prior year, or an 8% increase. Growth was driven from increases in recurring revenues.
- Gross margin was 26% year-to-date, compared to an adjusted gross margin of 35% for the same period of the prior year, excluding non-cash adjustments for inventory impairment. The overall 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 \$39.2 million, compared to \$49.2 million from the same period of the prior year. SG&A costs excluding non-cash stock-based compensation were \$30.7 million year to date, compared to \$31.6 million from the same period of the prior year.
- Research and development (R&D) costs were \$26.9 million year to date, compared to \$21.9 million from the same period of the prior year. R&D costs excluding non-cash stock-based compensation expense were \$25.5 million year to date, compared to \$17.8 million from the same period of the prior year. These increases were the result of accelerating investment in our next generation AST platform, Wave.
- GAAP net loss was \$62.5 million year to date, resulting in \$0.76 net loss per share. Net loss excluding non-cash stock-based compensation expense was \$51.9 million.
- Net cash used for the year was \$50.9 million, excluding financing.
- Ended the year with total cash, investments, and cash equivalents of \$45.6 million.

Full financial results for the year ended December 31, 2022 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

To listen to the 2022 fourth quarter financial results, call by phone, +1.877.883.0383 and enter Elite Entry Number: 6648486. 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 2450672 until April 19, 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 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 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 operating income (loss) reported in accordance with GAAP. The following tables present a reconciliation of SG&A expenses, R&D expenses and operating income (loss) excluding stock-based compensation to comparable GAAP measures for the periods indicated:

Three Months Ended December 31, Twelve Months Ended December 31, (in thousands)

	2022	2021	2022	2021
Sales, General and Administrative	\$ 8,772	\$ 11,493	\$ 39,193	\$ 49,236
Non-cash equity-based compensation as a component of sales, general and administrative	1,984	3,159	8,541	17,620
Sales, general and administrative less non-cash equity-based compensation	\$ 6,788	\$ 8,334	\$ 30,652	\$ 31,616

Three Months Ended December 31, Twelve Months Ended December 31, (in thousands)

	2022	2021	2022	2021
Research and Development	\$ 6,030	\$ 4,602	\$ 26,915	\$ 21,943
Non-cash equity-based compensation as a component of research and development	367	(238)	1,419	4,102
Research and development less non-cash equity-based compensation	\$ 5,663	\$ 4,840	\$ 25,496	\$ 17,841

Three Months Ended December 31, Twelve Months Ended December 31, (in thousands)

	2022	2021	2022	2021
Loss from operations	\$ (13,961)	\$ (19,413)	\$ (62,805)	\$ (71,560)
Non-cash equity-based compensation as a component of loss from operations	2,446	2,989	10,625	22,047
Loss from operations less non-cash equity-based compensation	\$ (11,515)	\$ (16,424)	\$ (52,180)	\$ (49,513)

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 web cast and conference call are forward-looking or may have forward-looking implications, such as, among others: the company's future financial performance; the company's future development plans and growth strategy, including plans and objectives relating to its future operations, products and performance, such as the development of the company's next generation AST platform; the company's expectations regarding the potential or benefits of its products and technologies; projections of future demand for the company's products; the anticipated impacts from the COVID-19 pandemic on the company, including to its business, results of operations, cash flows and financial position, as well as the company's future responses to the COVID-19 pandemic; the company's expectations relating to current supply chain impacts and inflationary pressures; the company's expectations regarding its commercial partnership with Becton, Dickinson and Company ("BD"), including anticipated benefits from such collaboration and BD's commercialization preparations and commitment to the company's long-term commercial partnership; the company's expectations and plans relating to regulatory approvals, including with respect to the U.S. Food and Drug Administration and 510(k) clearance for its Accelerate Arc products; and the company's expectations and plans regarding its financial condition, indebtedness and its liquidity and capital requirements, including, without limitation, as to the company's ability to continue as a going concern, obligations under the company's 2.50% Senior Convertible Notes due 2023 ("Notes") and discussions with holders of the Notes in connection with the related forbearance agreement. 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: general industry and market conditions; regulatory developments; the duration and severity of the ongoing COVID-19 pandemic, including any new variants that may become predominant, any government and other third-party responses to it, the consequences for the global economy and the businesses of the company's suppliers and customers, such as the possibility of customer demand fluctuations, supply chain constraints and inflationary pressures, and ultimate effect of the COVID-19 pandemic on the company's business, results of operations, cash flows and financial position, as well as the company's ability (or inability) to execute on its plans to respond to the COVID-19 pandemic; and difficulties in resolving the company's continuing financial condition and ability to obtain additional capital to meet its financial obligations, including, without limitation, difficulties in obtaining adequate capital resources to fund the company's operations and address its debt obligations, including under the Notes. 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.

ACCELERATE DIAGNOSTICS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	December 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 34,905	\$ 39,898
Investments	10,656	23,720
Trade accounts receivable, net	2,416	2,320
Inventory	5,194	5,067
Prepaid expenses	818	768
Other current assets	2,025	1,558
Total current assets	56,014	73,331
Property and equipment, net	3,478	5,389
Finance lease assets, net	2,422	—
Operating lease right of use assets, net	1,859	2,510
Other non-current assets	1,242	1,817
Total assets	\$ 65,015	\$ 83,047
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 4,501	\$ 1,983
Accrued liabilities	2,682	2,853
Accrued interest	472	909
Deferred revenue	547	451
Current portion of convertible notes	56,413	—
Current portion of long-term debt	—	80
Finance lease, current	1,113	—
Operating lease, current	829	669
Total current liabilities	66,557	6,945
Finance lease, non-current	782	—
Operating lease, non-current	1,545	2,381
Other non-current liabilities	874	808
Accrued interest, related-party	663	—
Long-term, debt related-party	16,858	—
Convertible notes	—	107,984
Total liabilities	87,279	118,118
Commitments and contingencies (see note 16)		
Stockholders' deficit:		
Preferred shares, \$0.001 par value;		
5,000,000 preferred shares authorized and 3,954,546 outstanding as of December 31, 2022 and 2021	4	4
Common stock, \$0.001 par value;		
200,000,000 common shares authorized with 97,477,546 shares issued and outstanding on December 31, 2022 and 100,000,000 common shares authorized with 67,649,018 shares issued and outstanding on December 31, 2021	97	68
Contributed capital	630,341	580,652
Treasury stock	(45,067)	(45,067)
Accumulated deficit	(607,239)	(570,668)
Accumulated other comprehensive loss	(400)	(60)
Total stockholders' deficit	(22,264)	(35,071)

Total liabilities and stockholders' deficit

\$ 65,015 \$ 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)

	Years Ended December 31,		
	2022	2021	2020
Net sales	\$ 12,752	\$ 11,782	\$ 11,165
Cost of sales:			
Cost of sales of products and services	9,449	7,663	6,706
Inventory write-down	—	4,500	—
Total cost of sales	9,449	12,163	6,706
Gross profit (loss)	3,303	(381)	4,459
Costs and expenses:			
Research and development	26,915	21,943	21,255
Sales, general and administrative	39,193	49,236	46,904
Total costs and expenses	66,108	71,179	68,159
Loss from operations	(62,805)	(71,560)	(63,700)
Other income (expense):			
Interest expense	(2,274)	(15,545)	(15,550)
Interest expense related-party	(1,497)	—	—
Gain on extinguishment of debt	3,565	9,793	—
Foreign currency exchange gain (loss)	117	(413)	252
Interest income	551	88	855
Other expense, net	(227)	(20)	(60)
Total other income (expense), net	235	(6,097)	(14,503)
Net loss before income taxes	(62,570)	(77,657)	(78,203)
Benefit (provision) for income taxes	77	(45)	(5)
Net loss	\$ (62,493)	\$ (77,702)	\$ (78,208)
Basic and diluted net loss per share	\$ (0.76)	\$ (1.26)	\$ (1.40)
Weighted average shares outstanding	82,161	61,727	56,010
Other comprehensive loss:			
Net loss	\$ (62,493)	\$ (77,702)	\$ (78,208)
Net unrealized loss on investments	(14)	(34)	(2)
Foreign currency translation adjustment	(326)	(117)	151
Comprehensive loss	\$ (62,833)	\$ (77,853)	\$ (78,059)

See accompanying notes to condensed consolidated financial statements.

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

	Years Ended December 31,		
	2022	2021	2020
Cash flows from operating activities:			
Net loss	\$ (62,493)	\$ (77,702)	\$ (78,208)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,000	2,518	2,997
Amortization of investment discount	98	226	99
Equity-based compensation expense	10,625	22,047	16,464
Amortization of debt discount and issuance costs	474	11,542	11,168
Amortization of debt discount related party	834	—	—
Realized loss on available-for-sale securities	—	—	3
Unrealized loss on equity investments	211	—	—
Loss (gain) on disposal of property and equipment	133	(75)	785
Gain on extinguishment of debt	(3,565)	(9,793)	—
Inventory write-down	—	4,500	—
(Increase) decrease in assets:			
Contributions to deferred compensation plan	(298)	(484)	(357)
Accounts receivable	(96)	(770)	1,592
Inventory	(236)	(415)	(1,356)
Prepaid expense and other assets	138	1,014	(2,087)
Increase (decrease) in liabilities:			
Accounts payable	2,920	273	(1,006)
Accrued liabilities and other	(861)	(469)	(909)
Accrued interest	(437)	(283)	—
Accrued interest from related-party	663	—	—
Deferred revenue and income	96	75	105
Deferred compensation	66	473	316
Net cash used in operating activities	(48,728)	(47,323)	(50,394)
Cash flows from investing activities:			

Purchases of equipment	(554)	(603)	(1,362)
Purchase of marketable securities	(27,506)	(30,081)	(46,933)
Proceeds from sales of marketable securities	—	250	—
Maturities of marketable securities	40,477	38,738	61,901
Net cash provided by investing activities	12,417	8,304	13,606
Cash flows from financing activities:			
Proceeds from issuance of common and preferred shares, net	32,872	42,880	359
Proceeds from exercise of options	7	1,620	6,062
Proceeds from issuance of common stocks under employee purchase plan	224	326	—
Proceeds from debt	—	—	5,578
Payment of debt	(80)	(360)	(366)
Payments on finance leases	(1,201)	—	—
Debt exchange and common stock issuance cost	(192)	(1,240)	—
Net cash provided by financing activities	31,630	43,226	11,633
Effect of exchange rate on cash	(312)	(90)	(78)
(Decrease) increase in cash and cash equivalents	(4,993)	4,117	(25,233)
Cash and cash equivalents, beginning of period	39,898	35,781	61,014
Cash and cash equivalents, end of period	\$ 34,905	\$ 39,898	\$ 35,781
Non-cash investing activities:			
Net transfer of instruments from inventory to property and equipment, net	\$ 168	\$ 688	\$ 1,525
Non-cash financing activities:			
Extinguishment of convertible senior notes through issuance of common stock	\$ 10,180	\$ 38,902	\$ —
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	\$ —	\$ —
Right-of-use assets obtained in exchange for finance lease obligations	\$ 3,096	\$ —	\$ —
Supplemental cash flow information:			
Interest paid	\$ 2,214	\$ 4,288	\$ 4,288
Income taxes paid, net of refunds	\$ —	\$ —	\$ 43

See accompanying notes to condensed consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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

<https://ir.axdx.com/2023-03-29-Accelerate-Diagnostics-Reports-Fourth-Quarter-and-Full-Year-2022-Financial-Results>