

Accelerate Diagnostics Reports Second Quarter 2021 Financial Results

TUCSON, Ariz., Aug. 5, 2021 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced financial results for the second quarter for the period ended June 30, 2021.

"Second quarter and year to date financial results were consistent with our expectations," commented Jack Phillips, Chief Executive Officer of Accelerate Diagnostics, Inc. "We also launched our AST focused test kit, concluded our multi-hospital registry study with compelling new data, and advanced other key commercial and product development priorities during the quarter."

Second Quarter 2021 Highlights

- Added 15 contracted instruments and brought 24 instruments live in the U.S. in the quarter.
- Ended the second quarter with 298 U.S. clinically live and revenue-generating instruments, with another 102 U.S. contracted instruments in the process of being implemented and not yet revenue-generating.
- Net sales were \$2.8 million, compared to \$2.1 million in the second quarter of 2020, or an 32% increase. Instrument revenue remained consistent while consumable revenue grew by 35%.
- Gross margin was 38% for the quarter, compared to 45% in the second quarter of 2020. 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 \$12.9 million, compared to \$11.3 million from the same quarter of the prior year. SG&A costs for the quarter excluding non-cash stock-based compensation were \$7.7 million, compared to \$8.3 million from the same quarter of the prior year. This decrease was the result of the ongoing benefits from cost-cutting efforts put in place during 2020.
- Research and development (R&D) costs for the quarter were \$5.7 million, compared to \$5.4 million from the same quarter of the prior year. R&D costs excluding non-cash stock-based compensation expense for the quarter were \$4.4 million, compared to \$5.0 million from the quarter of the prior year. This decrease was the result of improved internal efficiencies and lower external study-related costs.
- Net loss was \$21.7 million in the second quarter, resulting in \$0.36 net loss per share. Net loss excluding non-cash stock-based compensation expense for the second quarter was \$15.1 million.
- Net cash used in the quarter excluding financing was \$9.3 million

Year-to-date 2021 Highlights

- Net sales were \$5.3 million year-to-date, compared to \$4.5 million from the same period of 2020, or an 18% increase. Instrument revenue remained constant while consumable revenue grew by 24%.
- Gross margin was 37% year-to-date, compared to 45% from the same period in 2020. 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 \$26.9 million, compared to \$24.3 million from the same period of the prior year. SG&A costs excluding non-cash stock-based compensation were \$15.8 million year to date, compared to \$18.2 million from the same period of the prior year. This decrease was the result of the ongoing benefits from cost-cutting efforts put in place during 2020.
- Research and development (R&D) costs were \$12.6 million year to date, compared to \$11.2 million from the same period of the prior year. R&D costs excluding non-cash stock-based compensation expense were \$8.6 million year to date, compared to \$9.7 million from the same period of the prior year. This decrease was the result of improved internal efficiencies and lower external study-related costs.
- Net loss was \$45.9 million year to date, resulting in \$0.77 net loss per share. Net loss excluding non-cash stock-based compensation expense was \$30.5 million.
- Net cash used excluding financing was \$21.6 million
- Closed on two of three equal \$10.7 million tranches of previously announced insider financing for \$21.4 million.
- Closed a single transaction of \$0.8 million against our ATM financing vehicle.
- Ended the quarter with total cash, investments, and cash equivalents of \$68.8 million.

Full financial results for the quarter ending June 30, 2021 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 2021 second quarter financial results, call by phone, +1.877.883.0383 and enter Elite Entry Number: 5467079. 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 10157979 until August 26, 2021.

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 5, 2021.

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 June 30,		Six Months Ended June 30,	
	(in thousands)		(in thousands)	
	2021	2020	2021	2020
Sales, general and administrative Non-cash equity-based compensation as a component of sales, general and administrative	\$ 12,910	\$ 11,332	\$ 26,938	\$ 24,275
	5,188	3,022	11,180	6,027
Sales, general and administrative less non-cash equity-based compensation	\$ 7,722	\$ 8,310	\$ 15,758	\$ 18,248

	Three Months Ended June 30,		Six Months Ended June 30,	
	(in thousands)		(in thousands)	
	2021	2020	2021	2020
Research and development Non-cash equity-based compensation as a component of research and development	\$ 5,733	\$ 5,347	\$ 12,629	\$ 11,189
	1,328	335	4,074	1,458
Research and development less non- cash equity-based compensation	\$ 4,405	\$ 5,012	\$ 8,555	\$ 9,731

	Three Months Ended June 30,		Six Months Ended June 30,	
	(in thousands)		(in thousands)	
	2021	2020	2021	2020
Loss from operations Non-cash equity-based compensation as a component of loss from operations	\$ (17,590)	\$ (15,725)	\$ (37,616)	\$ (33,455)
	6,590	3,416	15,429	7,615
Loss from operations less non-cash equity-based compensation	\$ (11,000)	\$ (12,309)	\$ (22,187)	\$ (25,840)

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. 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 2, 2021, 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)

	June 30, 2021	December 31, 2020
	Unaudited	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 44,580	\$ 35,781
Investments	24,251	32,488
Trade accounts receivable	2,114	1,550
Inventory	9,572	9,216
Prepaid expenses	1,680	1,172
Other current assets	1,498	1,780
Total current assets	83,695	81,987
Property and equipment, net	5,548	6,135
Right of use assets	2,848	3,183
Other non-current assets	1,898	2,120
Total assets	\$ 93,989	\$ 93,425
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 1,877	\$ 1,290
Accrued liabilities	3,832	2,991
Accrued interest	1,262	1,262
Deferred revenue	282	376
Current portion of long-term debt	1,452	553
Current operating lease liability	612	497
Total current liabilities	9,317	6,969
Non-current operating lease liability	2,747	3,063
Other non-current liabilities	580	335
Long-term debt	3,805	4,659

Convertible notes	147,290	141,211
Total liabilities	<u>\$ 163,739</u>	<u>\$ 156,237</u>
Commitments and contingencies		
Stockholders' deficit:		
Preferred shares, \$0.001 par value; 5,000,000 preferred shares authorized and none outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 100,000,000 common shares authorized with 61,489,475 shares issued and outstanding on June 30, 2021 and 85,000,000 common shares authorized with 57,607,939 shares issued and outstanding on December 31, 2020	61	58
Contributed capital	514,122	475,072
Treasury stock	(45,067)	(45,067)
Accumulated deficit	(538,879)	(492,966)
Accumulated other comprehensive income (loss)	13	91
Total stockholders' deficit	<u>(69,750)</u>	<u>(62,812)</u>
Total liabilities and stockholders' deficit	<u>\$ 93,989</u>	<u>\$ 93,425</u>

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		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Net sales	\$ 2,798	\$ 2,125	\$ 5,316	\$ 4,468
Cost of sales	1,745	1,171	3,365	2,459
Gross profit	1,053	954	1,951	2,009
Costs and expenses:				
Research and development	5,733	5,347	12,629	11,189
Sales, general and administrative	12,910	11,332	26,938	24,275
Total costs and expenses	18,643	16,679	39,567	35,464
Loss from operations	(17,590)	(15,725)	(37,616)	(33,455)
Other income (expense):				
Interest expense	(4,177)	(3,835)	(8,267)	(7,584)
Foreign currency exchange gain (loss)	—	91	(159)	(37)
Interest income	12	224	55	604
Other income (expense), net	81	15	74	(67)
Total other expense, net	(4,084)	(3,505)	(8,297)	(7,084)
Net loss before income taxes	(21,674)	(19,230)	(45,913)	(40,539)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (21,674)</u>	<u>\$ (19,230)</u>	<u>\$ (45,913)</u>	<u>\$ (40,539)</u>
Basic and diluted net loss per share	\$ (0.36)	\$ (0.35)	\$ (0.77)	\$ (0.74)
Weighted average shares outstanding	61,049	55,445	59,790	55,139
Other comprehensive loss:				
Net loss	\$ (21,674)	\$ (19,230)	\$ (45,913)	\$ (40,539)

Net unrealized (loss) gain on debt securities available-for-sale	—	(44)	(18)	179
Foreign currency translation adjustment	22	34	(60)	19
Comprehensive loss	<u>\$ (21,652)</u>	<u>\$ (19,240)</u>	<u>\$ (45,991)</u>	<u>\$ (40,341)</u>

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended	
	June 30,	June 30,
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (45,913)	\$ (40,539)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,248	1,571
Amortization of investment discount	97	13
Equity-based compensation	15,429	7,615
Amortization of debt discount and issuance costs	6,079	5,426
(Gain) loss on disposal of property and equipment	(100)	527
Contributions to deferred compensation plan	(236)	(160)
(Increase) decrease in assets:		
Accounts receivable	(539)	550
Inventory and instruments in property and equipment	(524)	(1,979)
Prepaid expense and other	35	(360)
Increase (decrease) in liabilities:		
Accounts payable	564	390
Accrued liabilities, and other	736	(581)
Accrued interest	45	—
Deferred revenue and income	(94)	(39)
Deferred compensation	245	171
Net cash used in operating activities	<u>(22,928)</u>	<u>(27,395)</u>
Cash flows from investing activities:		
Purchases of equipment	(29)	(643)
Purchase of marketable securities	(15,699)	(21,509)
Maturities of marketable securities	23,992	27,844
Net cash provided by investing activities	<u>8,264</u>	<u>5,692</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	22,283	216
Proceeds from exercise of options	1,222	3,031
Proceeds from debt	—	4,791
Net cash provided by financing activities	<u>23,505</u>	<u>8,038</u>
Effect of exchange rate on cash	(42)	19
Increase (decrease) in cash and cash equivalents	8,799	(13,646)
Cash and cash equivalents, beginning of period	35,781	61,014
Cash and cash equivalents, end of period	<u>\$ 44,580</u>	<u>\$ 47,368</u>

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended	
	June 30,	June 30,
	2021	2020
Non-cash investing activities:		
Net transfer of instruments from inventory to property and equipment	\$ 500	\$ 1,288
Supplemental cash flow information:		
Interest paid	\$ 2,144	\$ 2,144
Income taxes paid, net of refunds	\$ —	\$ 26

See accompanying notes to condensed consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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<https://ir.axdx.com/2021-08-05-Accelerate-Diagnostics-Reports-Second-Quarter-2021-Financial-Results>