Accelerate Diagnostics Reports Third Quarter 2021 Financial Results

TUCSON, Ariz., Nov. 9, 2021 /PRNewswire/ -- Accelerate Diagnostics, Inc. (Nasdaq: AXDX) today announced preliminary financial results for the third quarter for the period ended September 30, 2021, which remain subject to quarter end closing adjustments.

"The resurgence of COVID hospitalizations impacted our commercial execution in the quarter," commented Jack Phillips, Chief Executive Officer of Accelerate Diagnostics, Inc. "Despite this recurring impediment to closing new accounts, I am pleased our team continued to build our funnel of prospective customers, and advance our development of Arc and Pheno 2.0."

Third Quarter 2021 Highlights

- Added 3 contracted instruments and brought 11 instruments live in the U.S. in the guarter.
- Ended the third quarter with 304 U.S. clinically live and revenue-generating instruments, with another 86 U.S. contracted instruments in the process of being implemented and not yet revenue-generating.
- Net sales were \$3.1 million, compared to \$3.6 million in the third quarter of 2020, or a 13% decline. Excluding instrument revenues, the business grew by 25% during this same period.
- Gross margin was 32% for the quarter, compared to 36% in the third quarter of 2020. The decline in gross margins resulted from escalating inflation to manufacturing costs and other factors.
- Selling, general, and administrative (SG&A) costs for the quarter were \$10.8 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 \$7.5 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 \$4.7 million, compared to \$5.0 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 \$3.7 million from the quarter of the prior year. This increase was the result of progress in our Arc and Pheno 2.0 development programs and associated investment.
- Net loss was \$9.0 million in the third quarter, resulting in \$0.15 net loss per share. Net loss excluding non-cash stock-based compensation expense for the third quarter was \$5.4 million.
- Net cash used in the quarter excluding financing was \$12.3 million.
- Reduced outstanding debt during the quarter by \$51 million dollars, a 30% reduction.
- Ended the quarter with total cash, investments, and cash equivalents of \$57.0 million.

Year-to-date 2021 Highlights

- Net sales were \$8.4 million year-to-date, compared to \$8.1 million from the same period of 2020, or an 5% increase. Instrument revenue declined, while consumable revenue grew by 24% over this period.
- Gross margin was 35% year-to-date, compared to 41% 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 \$37.7 million, compared to \$35.7 million from the same period of the prior year. SG&A costs excluding non-cash stock-based compensation were \$23.2 million year to date, compared to \$26.5 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 \$17.3 million year to date, compared to \$16.2 million from the same period of the prior year. R&D costs excluding non-cash stock-based compensation expense were \$13.0 million year to date, compared to \$13.4 million from the same period of the prior year. This decrease was the result of improved internal efficiencies, partially offset by increased investment in our Arc and Pheno 2.0 development programs.
- Net loss was \$54.9 million year to date, resulting in \$0.91 net loss per share. Net loss excluding non-cash stock-based compensation expense was \$35.8 million.
- Net cash used excluding financing was \$33.9 million

The foregoing preliminary financial results are subject to final quarter-end adjustment in the Form 10-Q for the quarter ended September 30, 2021. The Company expects to file the Form 10-Q by November 15, 2021, through the Securities and Exchange Commission's (SEC) website at http://www.sec.gov.

Audio Webcast and Conference Call

To listen to the 2021 third quarter financial results, call by phone, +1.877.883.0383 and enter Elite Entry Number: 7399350. 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 10160827 until November 30, 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 February 9, 2022.

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:

Thre	e Months En (in tho		Nine Months Ended September 30, (in thousands)						
	2021		2020		2021		2020		
\$	10,806	\$	11,465	\$	37,744	\$	35,738		
	3,281		3,208		14,461		9,235		
\$	7,525	\$	8,257	\$	23,283	\$	26,503		

Research and development
Non-cash equity-based compensation as a
component of research and development
Research and development less non-cash equity-
based compensation

Three Months Ended September 30, (in thousands)					Nine Months Ended September 30, (in thousands)						
	2021		2020		2021		2020				
\$	4,712	\$	5,001	\$	17,341	\$	16,191				
	266		1,349		4,340		2,807				
\$	4,446	\$	3,652	\$	13,001	\$	13,384				

Loss from operations
Non-cash equity-based compensation as a
component of loss from operations
Loss from operations less non-cash equity-based
compensation

ınre	ee Montns En (in tho	eptember 30, ls)	(in thousands)					
	2021		2020		2021		2020	
\$	(14,532)	\$	(15,165)	\$	(52,148)	\$	(48,618)	
	3,629		4,676		19,058		12,291	
\$	(10,903)	\$	(10,489)	\$	(33,090)	\$	(36,327)	

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. Examples of such forward looking statements or implications include Mr. Phillip's statements regarding our building funnel of prospective customers, and advancements in our development of Arc and Pheno 2.0. 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)

		eptember 30, 2021	D	ecember 31, 2020
	ι	Jnaudited		
ASSETS				
Current assets:				
Cash and cash equivalents	\$	35,725	\$	35,781
Investments		21,299		32,488
Trade accounts receivable		2,269		1,550
Inventory		9,732		9,216
Prepaid expenses		978		1,172
Other current assets		1,513		1,780
Total current assets		71,516		81,987

Property and equipment, net Right of use assets Other non-current assets		5,143 2,679 1,823		6,135 3,183 2,120
Total assets	\$	81,161	\$	93,425
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$	2,330	\$	1,290
Accrued liabilities		3,572		2,991
Accrued interest		143		1,262
Deferred revenue		469		376
Current portion of long-term debt		352		553
Current operating lease liability		645		497
Total current liabilities		7,511		6,969
Non-current operating lease liability		2,569		3,063
Other non-current liabilities		678		335
Long-term debt		72		4,659
Convertible notes		110,078		141,211
Total liabilities	\$	120,908	\$	156,237
Commitments and contingencies				
Stockholders' deficit:				
Preferred shares, \$0.001 par value;				
5,000,000 preferred shares authorized with 2,636,364 shares issued and outstanding on September 30,				
2021 and 5,000,000 preferred shares authorized with zero shares issued and outstanding on December				
31, 2020		3		_
Common stock, \$0.001 par value;				
100,000,000 common shares authorized with 64,937,030 shares issued and outstanding on September				
30, 2021 and 85,000,000 common shares authorized with 57,607,939 shares issued and outstanding on				
December 31, 2020		65		58
Contributed capital		553,134		475,072
Treasury stock		(45,067)		(45,067)
Accumulated deficit		(547,865)	((492,966)
Accumulated other comprehensive income		(17)		91
Total stockholders' deficit	_	(39,747)		(62,812)
Total liabilities and stockholders' deficit	\$	81,161	\$	93,425

ACCELERATE DIAGNOSTICS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS Unaudited (in thousands, except per share data)

		Three Mo	nths	Ended		Nine Mon	ths Ended		
	Sep	tember 30, 2021	Sep	otember 30, 2020	Sep	otember 30, 2021	Sep	otember 30, 2020	
Net sales	\$	3,122	\$	3,588	\$	8,439	\$	8,056	
Cost of sales		2,136		2,287		5,502		4,745	
Gross profit		986		1,301		2,937		3,311	
Costs and expenses:									
Research and development		4,712		5,001		17,341		16,191	
Sales, general and administrative		10,806		11,465		37,744		35,738	
Total costs and expenses		15,518		16,466		55,085		51,929	
Loss from operations		(14,532)		(15,165)		(52,148)		(48,618)	
Other income (expense):									
Interest expense		(4,211)		(3,955)		(12,477)		(11,540)	
Gain on extinguishment of debt		9,840		_		9,840		_	
Foreign currency exchange gain (loss)		(78)		229		(238)		191	
Interest income		_		149		55		753	
Other income (expense), net		(5)		(15)		69		(82)	
Total other income (expense), net		5,546		(3,592)		(2,751)		(10,678)	
Net loss before income taxes		(8,986)		(18,757)		(54,899)		(59,296)	
Provision for income taxes		_		_		_		_	
Net loss	\$	(8,986)	\$	(18,757)	\$	(54,899)	\$	(59,296)	
Basic and diluted net loss per share Weighted average shares outstanding	\$	(0.15) 61,146	\$	(0.33) 56,560	\$	(0.91) 60,250	\$	(1.07) 55,617	
vicignica average shares outstanding		31,170		30,300		00,230		33,017	
Other comprehensive loss:									
Net loss	\$	(8,986)	\$	(18,757)	\$	(54,899)	\$	(59,296)	
Net unrealized (loss) gain on debt securities available-for-sale		(3)		(117)		(21)		62	
Foreign currency translation adjustment		(27)		71		(87)		90	

Nine Months Ended

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

(in thousands)

	Se	ptember 30, 2021	September 30, 2020		
Cash flows from operating activities:					
Net loss	\$	(54,899)	\$ (59,296))	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation and amortization		1,875	2,270		
Amortization of investment discount		153	43		
Equity-based compensation		19,058	12,291		
Amortization of debt discount and issuance costs		9,250	8,256		
(Gain) loss on disposal of property and equipment		(202)	546		
Contributions to deferred compensation plan		(343)	(248))	
Gain on extinguishment of debt		(10,680)	_		
(Increase) decrease in assets:					
Accounts receivable		(719)	532		
Inventory and instruments in property and equipment		(527)	(1,734)		
Prepaid expense and other		860	(1,267))	
Increase (decrease) in liabilities:					
Accounts payable		1,017	76	1	
Accrued liabilities, and other		(436)	(759)	,	
Accrued interest		(1,059)	(1,071))	
Deferred revenue and income		93	67		
Deferred compensation		343	240		
Net cash used in operating activities		(36,216)	(40,051))	
Cash flows from investing activities:					
Purchases of equipment		(202)	(1,364))	
Purchases of marketable securities		(22,345)	(44,589)		
Maturities of marketable securities		33,601	41,707		
Net cash provided by investing activities		11,054	(4,246)		
Cash flows from financing activities:					
Proceeds from issuance of common and preferred stock		22,640	_		
Proceeds from exercise of options		1,456	4,458		
Proceeds from issuance of common stocks under employee purchase plan		245	296		
Proceeds from debt		_	5,552		
Payment of debt		(6)	(13)		
Transaction costs related to debt exchange not yet paid		840			
Net cash provided by financing activities		25,175	10,293		
Effect of exchange rate on cash		(69)	19	1	
Increase (decrease) in cash and cash equivalents		(56)	(33,985))	
Cash and cash equivalents, beginning of period		35,781	61,014		
Cash and cash equivalents, end of period	\$	35,725	\$ 27,029		
	Se	ptember 30,	ths Ended September 3	30,	
		2021	2020		

Non-cash investing activities: Net transfer of instruments from inventory to property and equipment \$ 508 \$ 1,284 Supplemental cash flow information: Interest paid \$ 4,288 \$ 4,288 Income taxes paid, net of refunds \$ 46 Extinguishment of Convertible Senior Notes through issuance of common stock \$ 34,545

See accompanying notes to condensed consolidated financial statements.

SOURCE Accelerate Diagnostics, Inc.

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