

February 22, 2022



Axogen, Inc. Reports 2021 Fourth Quarter and Full-Year Financial Results

ALACHUA, Fla. and TAMPA, Fla., Feb. 22, 2022 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today reported financial results and business highlights for the fourth quarter and full year ended December 31, 2021.

Fourth Quarter 2021 and Business Highlights

- Net revenue was \$31.5 million during the fourth quarter, a 3% decrease compared to fourth-quarter 2020 revenue of \$32.5 million.
- Fourth quarter revenue includes \$0.5 million from the reversal of a sales return reserve recorded in the second quarter of 2021 for Avive[®] Soft Tissue Membrane, for which the company voluntarily suspended market availability on June 1, 2021. Avive revenue in the fourth quarter of 2020 was approximately \$1.6 million.
- Gross margin was 82.8% for the quarter compared to 83.2% in the fourth quarter of 2020.
- Adjusted net loss was \$3.3 million for the quarter, or \$0.08 per share, for both the fourth quarter of 2021 and 2020.
- Adjusted EBITDA loss was \$1.7 million for the quarter, compared to an adjusted EBITDA loss of \$1.3 million in the fourth quarter of 2020.
- The balance of all cash, cash equivalents, and investments on December 31, 2021 was \$90.3 million, compared to a balance of \$98.1 million on September 30, 2021. The net change includes capital expenditures of \$5.8 million related to the construction of our new processing facility in Dayton, OH, and \$1.9 million of operating cash burn in the quarter.
- Core Accounts as of December 31, 2021 were 294, a 9% increase compared to 269 as of December 31, 2020. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts as of December 31, 2021 were 951, a 6% increase from 893 as of December 31, 2020. Revenue from the top 10% of Active Accounts continued to represent approximately 35% of total revenue.

“I am pleased with our full-year results in light of a difficult operating environment in the second half of the year,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We believe more surgeons and accounts are recognizing the value Axogen provides, and we enter 2022 with a strong commercial organization and a solid foundation of clinical evidence. We look forward to the release of the topline results of our RECON study in the second quarter and returning to a more normalized growth environment through the year.”

Full-Year 2021 Financial Results and Business Highlights

- Full-year 2021 revenue was \$127.4 million, a 13% increase compared to 2020 revenue of \$112.3 million.
- Avive revenue totaled approximately \$4.1 million and \$5.5 million for the years ended 2021 and 2020, respectively.
- Gross margin was 82.0% for the full year, compared to 80.8% in 2020.
- Adjusted net loss was \$13.7 million for the full year, or \$0.33 per share, compared to \$15.3 million, or \$0.38 per share, in 2020.
- Adjusted EBITDA loss was \$6.7 million for the full year, compared to an adjusted EBITDA loss of \$11.1 million in 2020.
- Ended the year with 115 direct sales representatives, compared to 111 at the end of 2020.
- Ended the year with 181 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.

2022 Financial Guidance

Management expects 2022 revenue will be in the range of \$135.0 million to \$142.0 million. This represents approximately 10% to 15% growth over 2021 revenue excluding the impact of \$4.1 million of Avive revenue in 2021. Full-year 2022 gross margin is expected to be above 80%.

Conference Call

The Company will host a conference call and webcast for the investment community today at 4:30 p.m. ET. Investors interested in participating by phone are invited to call toll free at 1-877-407-0993 or use the direct dial-in number at (201) 689-8795. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors page of the company's website at www.axogeninc.com and clicking on the webcast link.

Following the conference call, a replay will be available in the Investors section of the company's website at www.axogeninc.com under Investors.

About the RECON Clinical Study

RECON is a multicenter, prospective, randomized, subject and evaluator blinded comparative clinical study of nerve cuffs (manufactured conduits) and Avance[®] Nerve Graft, evaluating recovery outcomes for the repair of nerve discontinuities. The phase 3 pivotal study is designed to test for non-inferiority between the static two-point discrimination outcomes for Avance Nerve Graft and manufactured conduit. The study design also allows for a sequential test for superiority of Avance Nerve Graft, following the non-inferiority analysis.

About Axogen

Axogen (AXGN) is the leading company focused specifically on the science, development, and commercialization of technologies for peripheral nerve regeneration and repair. Axogen employees are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or transection to peripheral nerves by providing innovative, clinically proven, and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a

peripheral nerve, or the inability to properly reconnect peripheral nerves, can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products, including Avance Nerve Graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard Nerve Connector[®], a porcine submucosa extracellular matrix (ECM) coaptation aid for tensionless repair of severed peripheral nerves; Axoguard Nerve Protector[®], a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; and Axoguard Nerve Cap[®], a porcine submucosa ECM product used to protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma. The Axogen portfolio of products is available in the United States, Canada, Germany, the United Kingdom, Spain, South Korea, and several other countries.

Cautionary Statements Concerning Forward-Looking Statements

This press release contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events, or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “projects,” “forecasts,” “continue,” “may,” “should,” “will,” “goals,” and variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements may include, without limitation, statements related to the impact of COVID-19 on our business, hospital staffing challenges and its impact on our business, statements regarding our growth, our financial guidance and performance, product development, product potential, regulatory process and approvals, APC renovation timing and expense, sales growth, product adoption, market awareness of our products, anticipated capital requirements, including the potential of future financings, data validation, expected clinical study enrollment, timing and outcomes, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and our educational events, regulatory process and approvals and other factors, including legislative, regulatory, political and economic developments not within our control. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this press release should be evaluated together with the many uncertainties that affect our business and our market, particularly those risk factors described under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the most recently ended fiscal year, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances, or otherwise

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AXOGEN, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(In Thousands, Except Share and Per Share Amounts)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,756	\$ 48,767
Restricted cash	6,251	6,842
Investments	51,330	55,199
Accounts receivable, net	18,158	17,618
Inventory	16,693	12,529
Prepaid expenses and other	1,861	4,296
Total current assets	127,049	145,251
Property and equipment, net	62,881	38,398
Operating lease right-of-use assets	15,193	15,614
Finance lease right-of-use assets	42	64
Intangible assets, net	2,859	2,054
Total assets	\$ 208,024	\$ 201,381
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 22,459	\$ 21,968
Current maturities of long-term lease obligations	1,834	863
Total current liabilities	24,293	22,831
Long-term debt, net of financing fees	44,821	32,027
Debt derivative liabilities	5,562	2,497
Long-term lease obligations	20,798	20,874
Other long-term liabilities	—	3
Total liabilities	95,474	78,232
Shareholders' equity:		
Common stock, \$.01 par value per share; 100,000,000 shares authorized	417	406
Additional paid-in capital	342,765	326,390
Accumulated deficit	(230,632)	(203,647)
Total shareholders' equity	112,550	123,149
Total liabilities and shareholders' equity	\$ 208,024	\$ 201,381

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
Three Months and Years Ended December 31, 2021 and 2020
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended		Year Ended	
	December 31, 2021	December 31, 2020	December 31, 2021	December 31, 2020
Revenues	\$ 31,537	\$ 32,495	\$ 127,358	\$ 112,300
Cost of goods sold	5,428	5,463	22,931	21,581
Gross profit	26,109	27,032	104,427	90,719
Costs and expenses:				
Sales and marketing	17,734	19,805	73,328	69,659
Research and development	6,302	4,931	24,177	17,846
General and administrative	7,426	7,670	32,338	26,396
Total costs and expenses	31,462	32,406	129,843	113,901
Loss from operations	(5,353)	(5,374)	(25,416)	(23,182)
Other (expense) income:				
Investment income	13	29	93	605
Interest expense	71	(595)	(1,356)	(1,054)
Change in fair value of derivatives	124	(46)	(28)	(117)
Other expense	(141)	(24)	(278)	(38)
Total other (expense) income, net	67	(636)	(1,569)	(604)
Net loss	\$ (5,286)	\$ (6,010)	\$ (26,985)	\$ (23,786)
Weighted average common shares outstanding – basic and diluted	41,593	40,246	41,215	39,967
Loss per common share – basic and diluted	\$ (0.13)	\$ (0.15)	\$ (0.65)	\$ (0.60)
Adjusted net loss - non GAAP	\$ (3,272)	\$ (3,265)	\$ (13,697)	\$ (15,281)
Adjusted loss per common share – basic and diluted	\$ (0.08)	\$ (0.08)	\$ (0.33)	\$ (0.38)

AXOGEN, INC.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months and Years Ended December 31, 2021 and 2020
(unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended		Year Ended	
	December 31, 2021	December 31, 2020	December 31, 2021	December 31, 2020
Gross profit	\$ 26,109	\$ 27,032	\$ 104,427	\$ 90,719
Avive inventory write-down and production costs	-	-	1,429	-
Adjusted gross profit	<u>\$ 26,109</u>	<u>\$ 27,032</u>	<u>\$ 105,856</u>	<u>\$ 90,719</u>
Net loss	\$ (5,286)	\$ (6,010)	\$ (26,985)	\$ (23,786)
Depreciation and amortization expense	1,563	1,284 ⁽¹⁾	5,572	3,692
Investment income	(13)	(29)	(93)	(605)
Income tax expense	138	77	205	77
Interest expense	(71)	595	1,356	1,054
EBITDA - non GAAP	<u>\$ (3,669)</u>	<u>\$ (4,083) ⁽¹⁾</u>	<u>\$ (19,945)</u>	<u>\$ (19,568)</u>
Non cash stock-based compensation expense	1,509	2,745	10,919	8,470
Litigation and related costs	505	—	2,369	35
Adjusted EBITDA - non GAAP	<u>\$ (1,655)</u>	<u>\$ (1,338) ⁽¹⁾</u>	<u>\$ (6,657)</u>	<u>\$ (11,063)</u>
Net loss	\$ (5,286)	\$ (6,010)	\$ (26,985)	\$ (23,786)
Non cash stock-based compensation expense	1,509	2,745	10,919	8,470
Litigation and related costs	505	—	2,369	35
Adjusted net loss - non GAAP	<u>\$ (3,272)</u>	<u>\$ (3,265)</u>	<u>\$ (13,697)</u>	<u>\$ (15,281)</u>
Weighted average common shares outstanding – basic and diluted	<u>41,593</u>	<u>40,246</u>	<u>41,215</u>	<u>39,967</u>
Adjusted loss per common share – basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.08)</u>	<u>\$ (0.33)</u>	<u>\$ (0.38)</u>

(1) The Company has revised its definition of EBITDA and Adjusted EBITDA to include amortization of its right-of-use assets and amortization of debt discount and deferred financing fees. See Reconciliation of Revised EBITDA, Adjusted EBITDA, and Depreciation and Amortization.

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
Three Months and Years Ended December 31, 2021 and 2020
(unaudited)
(In Thousands)

	Common Stock		Additional Paid- in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
For the Three Months Ended December 31, 2021:					
Balance at September 30, 2021	41,559	\$ 415	\$ 340,212	\$ (225,346)	\$ 115,281
Net loss	-	-	-	(5,286)	(5,286)
Stock-based compensation	-	-	1,509	-	1,509
Issuance of restricted and performance stock units	48	-	-	-	-
Exercise of stock options and employee stock purchase plan	130	2	1,044	-	1,046
Balance at December 31, 2021	<u>41,737</u>	<u>\$ 417</u>	<u>\$ 342,765</u>	<u>\$ (230,632)</u>	<u>\$ 112,550</u>
For the Year Ended December 31, 2021:					
Balance at December 31, 2020	40,619	\$ 406	\$ 326,390	\$ (203,647)	\$ 123,149
Net loss	-	-	-	(26,985)	(26,985)
Stock-based compensation	-	-	10,919	-	10,919
Issuance of restricted and performance stock units	254	2	(2)	-	-
Exercise of stock options and employee stock purchase plan	864	9	5,458	-	5,467
Balance at December 31, 2021	<u>41,737</u>	<u>\$ 417</u>	<u>\$ 342,765</u>	<u>\$ (230,632)</u>	<u>\$ 112,550</u>
For the Three Months Ended December 31, 2020:					
Balance at September 30, 2020	40,124	\$ 401	\$ 318,949	\$ (197,637)	\$ 121,713
Net loss	-	-	-	(6,010)	(6,010)
Stock-based compensation	-	-	2,745	-	2,745
Issuance of restricted and performance stock units	81	-	-	-	-
Shares surrendered by employees to pay tax withholdings	(2)	1	(6)	-	(5)
Exercise of stock options and employee stock purchase plan	168	2	1,022	-	1,024
Exercise of Oberland option, net of settlement	248	2	3,680	-	3,682
Balance at December 31, 2020	<u>40,619</u>	<u>\$ 406</u>	<u>\$ 326,390</u>	<u>\$ (203,647)</u>	<u>\$ 123,149</u>
For the Year Ended December 31, 2020:					
Balance at December 31, 2019	39,590	\$ 396	\$ 311,618	\$ (179,861)	\$ 132,153
Net loss	-	-	-	(23,786)	(23,786)
Stock-based compensation	-	-	8,470	-	8,470
Issuance of restricted and performance stock units	249	2	(2)	-	-
Shares surrendered by employees to pay tax withholdings	(40)	-	(670)	-	(670)
Exercise of stock options and employee stock purchase plan	572	6	3,294	-	3,300
Exercise of Oberland option, net of settlement	248	2	3,680	-	3,682
Balance at December 31, 2020	<u>40,619</u>	<u>\$ 406</u>	<u>\$ 326,390</u>	<u>\$ (203,647)</u>	<u>\$ 123,149</u>

AXOGEN, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2021 and 2020
(unaudited)
(In Thousands)

	Year Ended	
	December 31, 2021	December 31, 2020
Cash flows from operating activities:		
Net loss	\$ (26,985)	\$ (23,786)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,721	1,507
Amortization of right-of-use assets	1,818	1,800
Amortization of intangible assets	202	153
Amortization of debt discount and deferred financing fees	831	232
Loss on disposal of equipment	-	3
Provision for bad debt	(41)	(105)
Provision for inventory write-down	3,314	2,242
Change in fair value of derivatives	28	117
Investment (gains) losses	68	(47)
Stock-based compensation	10,919	8,470
Change in operating assets and liabilities:		
Accounts receivable	(499)	(635)
Inventory	(7,478)	(910)
Prepaid expenses and other	2,435	(2,524)
Accounts payable and accrued expenses	(270)	4,958
Operating lease obligations	(463)	(1,086)
Cash paid for interest portion of finance leases	(2)	(3)
Contract and other liabilities	(3)	(12)
Net cash used in operating activities	(13,405)	(9,626)
Cash flows from investing activities:		
Purchase of property and equipment	(27,811)	(21,905)
Economic development grant proceeds	950	—
Purchase of investments	(68,699)	(77,806)
Proceeds from sale of investments	72,500	83,440
Cash payments for intangible assets	(589)	(692)
Net cash used in investing activities	(23,649)	(16,963)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	15,000	35,000
Proceeds from the paycheck protection program loan	—	7,820
Repayment of the paycheck protection program loan	—	(7,820)
Proceeds from issuance of common stock	—	3,500
Payments for debt issuance costs	—	(642)
Payments of employee tax withholding in exchange of common stock awards	—	(670)
Cash paid for debt portion of finance leases	(15)	(14)
Proceeds from exercise of stock options and ESPP stock purchases	5,467	3,300
Net cash provided by financing activities	20,452	40,474
Net (decrease) increase in cash, cash equivalents and restricted cash	(16,602)	13,885
Cash, cash equivalents and restricted cash, beginning of period	55,609	41,724
Cash, cash equivalents and restricted cash, end of period	\$ 39,007	\$ 55,609
Supplemental disclosures of cash flow activity:		
Cash paid for interest, net of capitalized interest	\$ 495	\$ 822
Supplemental disclosure of non-cash investing and financing activities		
Acquisition of fixed assets in accounts payable and accrued expenses	\$ 1,420	\$ 1,077

Obtaining a right-of-use asset in exchange for a lease liability	\$	1,375	\$	14,259
Acquisition of leasehold asset	\$	-	\$	5,250
Embedded derivative associated with the long-term debt	\$	3,037	\$	2,563
Acquisition of intangible assets in accounts payable and accrued expenses	\$	418	\$	-
Conversion of the Oberland option	\$	-	\$	182

AXOGEN, INC.

RECONCILIATION OF REVISED EBITDA, ADJUSTED EBITDA, and DEPRECIATION AND AMORTIZATION

Three Months Ended September 30, 2021 and 2020; June 30, 2021 and 2020; March 31, 2021 and 2020; December 31, 2020 and

Year Ended December 31, 2020

(unaudited)

(In Thousands)

The Company has revised its definition of EBITDA and Adjusted EBITDA to include amortization of its right-of-use assets and amortization of debt discount and deferred financing fees.

The tables below provide a reconciliation of EBITDA and Adjusted EBITDA as previously reported to the amounts calculated using the new definition.

	Three Months Ended		
	March 31, 2021	June 30, 2021	September 30, 2021
Depreciation and amortization expense, as previously reported	\$ 818	\$ 661	\$ 706
Amortization of ROU assets	500	460	458
Amortization of debt discount and deferred financing fees	112	115	157
Revised depreciation and amortization expense	\$ 1,430	\$ 1,236	\$ 1,321
EBITDA - non GAAP, as previously reported	\$ (5,437)	\$ (6,639)	\$ (6,035)
Amortization of ROU assets	500	460	458
Amortization of debt discount and deferred financing fees	112	115	157
Revised EBITDA - non GAAP	\$ (4,825)	\$ (6,064)	\$ (5,420)
Adjusted EBITDA - non GAAP, as previously reported	\$ (1,906)	\$ (2,435)	\$ (2,496)
Amortization of ROU assets	500	460	458
Amortization of debt discount and deferred financing fees	112	115	157
Revised Adjusted EBITDA - non GAAP	\$ (1,294)	\$ (1,860)	\$ (1,881)

	Three Months Ended				Year Ended
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020	December 31, 2020
Depreciation and amortization expense, as previously reported	\$ 343	\$ 346	\$ 439	\$ 556	\$ 1,660
Amortization of ROU assets	470	332	480	518	1,800
Amortization of debt discount and deferred financing fees	-	-	22	210	232
Revised depreciation and amortization expense	\$ 813	\$ 678	\$ 941	\$ 1,284	\$ 3,692
EBITDA - non GAAP, as previously reported	\$ (8,139)	\$ (7,907)	\$ (671)	\$ (4,811)	\$ (21,600)

Amortization of ROU assets	470	332	480	518	1,800
Amortization of debt discount and deferred financing fees	-	-	22	210	232
Revised EBITDA - non GAAP	\$ (7,669)	\$ (7,575)	\$ (169)	\$ (4,083)	\$ (19,568)
Adjusted EBITDA - non GAAP, as previously reported	\$ (7,583)	\$ (5,685)	\$ 2,276	\$ (2,066)	\$ (13,095)
Amortization of ROU assets	470	332	480	518	1,800
Amortization of debt discount and deferred financing fees	-	-	22	210	232
Revised Adjusted EBITDA - non GAAP	\$ (7,113)	\$ (5,353)	\$ 2,778	\$ (1,338)	\$ (11,063)



Source: Axogen, Inc.