May 4, 2022

Axogen, Inc Reports 2022 First Quarter Financial Results

ALACHUA, Fla. and TAMPA, Fla., May 04, 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 first quarter ended March 31, 2022.

First Quarter 2022 and Business Highlights

- Net revenue was $31.0 million during the first quarter, matching the first quarter of 2021.
- Excluding Avive® revenue of $1.7 million in the first quarter of 2021, revenue in the first quarter of 2022 increased 6%. The company voluntarily suspended market availability of Avive Soft Tissue Membrane on June 1, 2021.
- Gross margin was 82.1% for the quarter compared to 83.3% in the first quarter of 2021.
- First quarter adjusted net loss was $8.5 million, or $0.20 per share, compared with an adjusted net loss of $3.1 million, or $0.08 per share, in the first quarter of 2021.
- Adjusted EBITDA loss was $7.4 million for the quarter, compared to an adjusted EBITDA loss of $1.9 million in the first quarter of 2021.
- The balance of all cash and cash equivalents and investments on March 31, 2022 was $73.7 million, compared to a balance of $90.3 million on December 31, 2021. The net change includes capital expenditures of $5.0 million related to the construction of our new processing facility in Dayton, OH, and $7.6 million related to items which typically occur in the first quarter, including bonuses, sales meeting and awards, and insurance premiums.
- Core Accounts as of March 31, 2022 were 288, a 5% increase compared to 274 as of March 31, 2021. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts as of March 31, 2022 were 926, a 1% increase from 919 as of March 31, 2021. Revenue from the top 10% of Active Accounts continued to represent approximately 35% of total revenue.

“We are pleased with our progress and execution as procedure trends improved during the quarter. Our outlook for the year remains on track, and we expect continued growth as surgeons adopt the Axogen nerve repair algorithm,” commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “We are also pleased to announce today that our RECON℠ study achieved its primary endpoint representing a critical milestone towards transitioning Avance® Nerve Graft to a licensed biologic and further supporting the expanded adoption of Avance.”

Additional Operational and Business Highlights

- Separately announced today, RECON Phase 3 Study of Avance met its primary endpoint. This study will provide the first ever Level 1 clinical evidence in support of Avance Nerve Graft for peripheral nerve repairs.
- REPOSE℠ Pilot Study results using Axoguard Nerve Cap® for protecting and preserving terminated nerve ends were published in *Foot and Ankle Surgery: Techniques, Reports & Case.*
- Initiated REPOSE-XL℠, a clinical study of large-diameter Axoguard Nerve Cap.
- Ended the quarter with 188 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio.
- Published inaugural Environmental, Social, and Governance (ESG) report highlighting the company's corporate responsibility and sustainability initiatives.
- Ended the quarter with 116 direct sales representatives, compared to 115 at year end and 106 one year ago.

2022 Financial Guidance

The Company continues to expect 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 1-866-682-6100 or use the direct dial-in number at (862) 298-0702. 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 RECON

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 REPOSE

A Multicenter, Prospective, Randomized and Subject Blinded Comparative Study of Axoguard Nerve Cap and Neurectomy for the Treatment of Symptomatic Neuroma and Prevention of Recurrent End-Neuroma Pain (REPOSE) is the company's post-market study comparing placement of Axoguard Nerve Cap to standard neurectomy alone for subjects with symptomatic neuroma pain. The study design includes a 15-subject open label pilot phase and up to 86 subjects in a randomized comparative phase. The study requires a one year follow-up period for all subjects and is designed to assess changes in pain scores as

measured by Visual Analog Scale, quality of life outcomes, medication usage, and subject satisfaction.

About REPOSE-XL
The 15-subject, multicenter, prospective, single arm pilot safety and feasibility study is intended to evaluate the use of Axoguard Nerve Cap in large-diameter sizes to protect and preserve terminated nerve ends after limb trauma or amputation to optimize subsequent reconstructive procedures. The diameters of the Nerve Cap under investigation range from 5 to 7 millimeters, compared to the current commercially available Axoguard Nerve Cap, which ranges from 2 to 4 millimeters. The aim of the study is to demonstrate the reduction or mitigation of nerve pain with use of the Nerve Cap and its effect on limb function. Patient follow-up is up to 15 months with functional assessments at shorter intervals. This study is supported, in part, with funding by a grant from the United States Department of Defense Peer Reviewed Orthopedic Research Program.

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, including but not limited to global supply chain issues, 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, geopolitical, and economic developments, including global business disruption caused by Russia's invasion of Ukraine and related sanctions, 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)

Axogen, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In Thousands, Except Per Share Amounts)

Axogen, Inc.
RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES
Three Months ended March 31, 2022 and 2021
(unaudited)
(In Thousands, Except Per Share Amounts)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 14,559	$ 32,756
Restricted cash	6,251	6,251
Investments	52,859	51,330
Accounts receivable, net of allowance for doubtful accounts of $366 and $276, respectively	18,590	18,158
Inventory	17,400	16,693
Prepaid expenses and other	2,816	1,861
Total current assets	112,475	127,049
Property and equipment, net	66,954	62,923
Operating lease right-of-use assets	15,406	15,193
Intangible assets, net	3,190	2,859
Total assets	$ 198,025	$ 208,024
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 20,872	$ 22,459
Current maturities of long-term lease obligations	2,073	1,834
Total current liabilities	22,945	24,293
Long-term debt, net of debt discount and financing fees	45,041	44,821
Long-term lease obligations	20,878	20,798
Debt derivative liabilities	5,310	5,562
Total liabilities	94,174	95,474
Commitments and contingencies - see Note 12		
Shareholders' equity:		
Common stock, $0.01 par value per share; 100,000,000 shares authorized; 41,972,987 and 41,736,950 shares issued and outstanding	420	417
Additional paid-in capital	345,538	342,765
Accumulated deficit	(242,107)	(230,632)
Total shareholders' equity	103,851	112,550
Total liabilities and shareholders' equity	$ 198,025	$ 208,024

Note: In the Press Release dated February 22, 2022, the Company presented a revised calculation of EBITDA and Adjusted EBITDA which included an adjustment for the amortization of the right of use assets. The Company has since reverted to its former presentation which allows investors to more readily assess operating performance among peer companies.

Axogen, Inc.
Condensed Consolidated Statements of Changes in Shareholders' Equity
(unaudited)
(In Thousands, Except Share Amounts)

Axogen, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In Thousands)

	Three Months Ended	
	March 31, 2022	March 31, 2021
Revenues	$ 31,007	$ 31,037
Cost of goods sold	5,546	5,172
Gross profit	25,461	25,865
Costs and expenses:		
Sales and marketing	20,888	17,973
Research and development	6,275	5,748
General and administrative	9,618	8,364
Total costs and expenses	36,781	32,085
Loss from operations	(11,320)	(6,220)
Other (expense) income:		
Investment income	(46)	34
Interest expense	(354)	(444)
Change in fair value of derivatives	252	(22)
Other expense	(7)	(8)
Total other (expense) income, net	(155)	(440)
Net loss	$ (11,475)	$ (6,660)
Weighted average common shares outstanding — basic and diluted	41,804,330	40,705,840
Loss per common share — basic and diluted	$ (0.27)	$ (0.16)

	Three months ended	
	March 31, 2022	March 31, 2021
Net loss	$ (11,475)	$ (6,660)
Depreciation and amortization expense	773	819
Investment income	46	(34)
Income tax expense	—	(5)
Interest expense	354	444
EBITDA - non GAAP	$ (10,302)	$ (5,436)
Non cash stock-based compensation expense	2,678	2,694
Litigation and related costs	267	836
Adjusted EBITDA - non GAAP	$ (7,357)	$ (1,906)
Net loss	$ (11,475)	$ (6,660)
Non cash stock-based compensation expense	2,678	2,694
Litigation and related costs	267	836
Adjusted net loss - non GAAP	$ (8,530)	$ (3,130)
Weighted average common shares outstanding - basic and diluted	$ (0.27)	$ (0.16)
Non cash stock-based compensation expense	0.06	0.07
Litigation and related costs	0.01	0.02
Adjusted net loss per common share - basic and diluted - non GAAP	$ (0.20)	$ (0.08)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Three Months Ended March 31, 2022					
Balance at December 31, 2021	41,736,950	$ 417	$ 342,765	$ (230,632)	$ 112,550
Net loss	—	—	—	(11,475)	(11,475)
Stock-based compensation	—	—	2,678	—	2,678
Issuance of restricted and performance stock units	215,287	2	(2)	—	—
Exercise of stock options and employee stock purchase plan	20,750	1	97	—	98
Balance at March 31, 2022	41,972,987	$ 420	$ 345,538	$ (242,107)	$ 103,851
Three Months Ended March 31, 2021					
Balance at December 31, 2020	40,618,766	$ 406	$ 326,390	$ (203,647)	$ 123,149
Net loss	—	—	—	(6,660)	(6,660)
Stock-based compensation	—	—	2,694	—	2,694
Issuance of restricted and performance stock units	94,533	1	(1)	—	—
Exercise of stock options and employee stock purchase plan	129,418	1	520	—	521
Balance at March 31, 2021	40,842,717	$ 408	$ 329,603	$ (210,307)	$ 119,704

Source: Axogen, Inc.

	Three Months Ended	
	March 31, 2022	March 31, 2021
Cash flows from operating activities:		
Net loss	$ (11,475)	$ (6,660)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	704	772
Amortization of right-of-use assets	427	500
Amortization of intangible assets	69	47
Amortization of debt discount and deferred financing fees	220	112
Provision for bad debt	267	(26)
Provision for inventory write-down	459	783
Change in fair value of derivatives	(252)	22
Investment losses	96	15
Stock-based compensation	2,678	2,694
Change in operating assets and liabilities:		
Accounts receivable	(624)	(2,181)
Inventory	(1,166)	(1,642)
Prepaid expenses and other	(1,030)	(313)
Accounts payable and accrued expenses	(1,104)	(5,061)
Operating lease obligations	(320)	119
Cash paid for interest portion of finance leases	—	—
Contract and other liabilities	—	(1)
Net cash used in operating activities	(11,051)	(10,820)
Cash flows from investing activities:		
Purchase of property and equipment	(5,037)	(3,095)
Purchase of investments	(6,024)	(15,279)
Proceeds from sale of investments	4,400	19,400
Cash payments for intangible assets	(580)	(156)
Net cash (used in) provided by investing activities	(7,241)	870
Cash flows from financing activities:		
Cash paid for debt portion of finance leases	(2)	(4)
Proceeds from exercise of stock options and ESPP stock purchases	97	521
Net cash provided by financing activities	95	517
Net decrease in cash, cash equivalents, and restricted cash	(18,197)	(9,433)
Cash, cash equivalents, and restricted cash, beginning of period	39,007	55,609
Cash, cash equivalents, and restricted cash, end of period	$ 20,810	$ 46,176
Supplemental disclosures of cash flow activity:		
Cash paid for interest, net of capitalized interest	$ —	$ 312
Supplemental disclosure of non-cash investing and financing activities:		
Acquisition of fixed assets in accounts payable and accrued expenses	$ 1,119	$ 4,836
Obtaining a right-of-use asset in exchange for a lease liability	$ 641	$ 321
Acquisition of intangible assets in accounts payable and accrued expenses	$ 239	$ 166