

Axogen, Inc Reports 2022 Second Quarter Financial Results

ALACHUA, Fla. and TAMPA, Fla., Aug. 03, 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 second quarter ended June 30, 2022.

Second Quarter 2022 and Business Highlights

- Net revenue was \$34.5 million during the second quarter, an increase of 3% over the second quarter of 2021.
- Excluding revenue from Avive[®] Soft Tissue Membrane of \$1.8 million in the second quarter of 2021, revenue in the second quarter of 2022 increased 9%. The company voluntarily suspended market availability of Avive on June 1, 2021.
- Gross margin was 81.8% for the quarter compared to 78.9% in the second quarter of 2021 which includes the impact of a one-time charge of approximately \$1.4 million reflecting the write-down of inventory and related production costs related to the suspension of Avive.
- Adjusted net loss for the quarter was \$2.6 million, or \$0.06 per share, compared to adjusted net loss of \$3.7 million, or \$0.09 per share, in the second quarter of 2021.
- Adjusted EBITDA loss was \$1.6 million for the quarter, compared to an adjusted EBITDA loss of \$2.4 million in the second quarter of 2021.
- The balance of all cash and cash equivalents and investments on June 30, 2022 was \$64.3 million, as compared to a balance of \$73.7 million on March 31, 2022. The net change includes capital expenditures of \$3.9 million related to the construction of our new processing facility in Dayton, OH, and \$5.5 million net operating cash burn including a \$1.8 million increase in inventory primarily related to accelerated purchases of certain production materials and donor inventory.

"We are pleased with our execution in the quarter as procedure volumes improved and hospitals continued to adapt to evolving challenges," commented Karen Zaderej, chairman, CEO, and president of Axogen, Inc. "As we announced in May, we are happy with the positive top-line results of our RECONSM study, which is a meaningful addition to our growing body of clinical data. We are well positioned as we enter the second half of the year and look forward to leveraging our data and broad commercial capabilities to drive engagement and adoption with surgeons seeking advanced solutions for their peripheral nerve injury patients."

Additional Operational and Business Highlights

- Core Accounts totaled 299, an increase of 4% sequentially. Excluding the impact of Avive purchases in the second quarter of 2021, Core Accounts grew 1% over an adjusted prior year level of 294 which excludes the impact of Avive. Revenue from Core Accounts continued to represent approximately 60% of total revenue.
- Active Accounts totaled 941, an increase of 2% sequentially. Excluding the impact of Avive purchases in the second quarter of 2021, Active accounts grew 2% over an adjusted prior year level of 921. Revenue from the top 10% of Active Accounts continued to represent approximately 35% of total revenue.
- Announced positive top-line results from the RECON Phase 3 Study of Avance[®], which met its primary endpoint and will provide Level 1 clinical evidence in support of Avance Nerve Graft for peripheral nerve repairs.
- Completed enrollment of 86 subjects in the comparative phase study of REPOSESM (Axoguard Nerve Cap[®] compared to standard of care) in July. We anticipate topline data read out from the study in the fourth quarter of 2023.
- Ended the quarter with eight new peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio, which now totals 196.
- Ended the quarter with 116 direct sales representatives, consistent with the first quarter of 2022, and compared to 109 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 in the conference call by phone may do so by dialing toll free at (888) 428-7458 or use the direct dial-in number at (404) 267-0368. 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 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. Actual results or event could differ materially from those described in any forward-looking statements as a result of various factors, including, 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 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 risks and 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.

About Non-GAAP Financial Measures

To supplement our condensed consolidated financial statements, we use the non-GAAP financial measures of EBITDA, which measures earnings before interest, income taxes, depreciation and amortization, and Adjusted EBITDA which further excludes non-cash stock compensation expense and litigation and related expenses. We also use the non-GAAP financial measures of Adjusted Net Income or Loss and Adjusted Net Income or Loss Per Common Share - basic and diluted which excludes non-cash stock compensation expense and litigation and related expenses from Net Loss and Net Loss Per Common Share - basic and diluted, respectively. These non-GAAP measures are not based on any comprehensive set of accounting rules or principles and should not be considered a substitute for, or superior to, financial measures calculated in accordance with GAAP, and may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures should be read in conjunction with our financial statements prepared in accordance with GAAP. The reconciliations of Axogen's GAAP financial measures to the corresponding non-GAAP measures should be carefully evaluated.

We use these non-GAAP financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. We believe that these non-GAAP financial measures provide meaningful supplemental information regarding our performance and that both management and investors benefit from referring to these non-GAAP financial measures in assessing our performance and when planning, forecasting, and analyzing future periods. We believe these non-GAAP financial measures are useful to investors because (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making and (2) they are used by our institutional investors and the analyst community to help them analyze the performance of our business.

Contact:
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Axogen, Inc.
Condensed Consolidated Balance Sheets
(unaudited)

(unaudited) (In Thousands, Except Share and Per Share Amounts)

	June 30, 2022		De	cember 31, 2021
Assets				
Current assets:				
Cash and cash equivalents	\$	11,822	\$	32,756
Restricted cash		6,251		6,251
Investments		46,210		51,330
Accounts receivable, net of allowance for doubtful accounts of \$595 and \$276, respectively		20,370		18,158
Inventory		19,222		16,693
Prepaid expenses and other		2,900		1,861
Total current assets		106,775		127,049
Property and equipment, net		70,988		62,923
Operating lease right-of-use assets		14,975		15,193
Intangible assets, net		3,346		2,859
Total assets	\$	196,084	\$	208,024
Liabilities and shareholders' equity				
Current liabilities:	•	04.000	•	00.450
Accounts payable and accrued expenses	\$	21,838	\$	22,459
Current maturities of long-term lease obligations		1,762		1,834
Total current liabilities		23,600		24,293
Long-term debt, net of debt discount and financing fees		45,263		44,821
Long-term lease obligations		20,655		20,798
Debt derivative liabilities		4,876		5,562
Total liabilities		94,394		95,474
Commitments and contingencies - see Note 12				
Shareholders' equity:				
Common stock, \$0.01 par value per share; 100,000,000 shares authorized; 42,134,504 and 41,736,950 shares issued and outstanding	ł	420		417
Additional paid-in capital		351,117		342,765
Accumulated deficit		(249,847)		(230,632)
Total shareholders' equity		101,690		112,550
Total liabilities and shareholders' equity	\$	196,084	\$	208,024

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

	Three Months Ended					Six Months Ended			
	June 30, 2022			lune 30, 2021	June 30, 2022		_	June 30, 2021	
Revenues	\$	34,454	\$	33,580	\$	65,461	\$	64,617	
Cost of goods sold		6,284		7,092		11,830		12,264	
Gross profit		28,170		26,488		53,631		52,353	
Costs and expenses:									
Sales and marketing		19,669		19,250		40,557		37,224	
Research and development		7,022		5,723		13,296		11,471	
General and administrative		9,403		8,669		19,021		17,032	
Total costs and expenses		36,094		33,642		72,874		65,727	
Loss from operations		(7,924)		(7,154)		(19,243)		(13,374)	
Other (expense) income:									
Investment income		32		29		(15)		63	
Interest expense		(249)		(565)		(603)		(1,010)	
Change in fair value of derivatives		434		(84)		686		(105)	
Other expense		(33)		(124)		(40)		(132)	
Total other expense, net		184		(744)		28		(1,184)	
Net loss	\$	(7,740)	\$	(7,898)	\$	(19,215)	\$	(14,558)	
Weighted average common shares outstanding — basic and diluted	4	1,994,618	4	1,080,898		11,900,000	_	40,894,405	
Loss per common share — basic and diluted	\$	(0.18)	\$	(0.19)	\$	(0.46)	\$	(0.36)	

Axogen, Inc. RECONCILIATION OF GAAP FINANCIAL MEASURES TO NON-GAAP FINANCIAL MEASURES

Three and Six Months ended June 30, 2022 and 2021 (unaudited)
(In Thousands, Except Per Share Amounts)

	Three Months Ended				Six Months Ended			
	June 30, 2022		June 30, 2021			June 30, 2022		June 30, 2021
Net loss	\$	(7,740)	\$	(7,898)	\$	(19,215)	\$	(14,558)
Depreciation and amortization expense		777		682		1,550		1,501
Investment income		(32)		(29)		15		(63)
Income tax expense		33		52		33		47
Interest expense		249		565		(603)		1,009
EBITDA - non GAAP	\$	(6,713)	\$	(6,628)	\$	(17,014)		(12,064)
	-							
Non cash stock-based compensation expense		4,910		3,805		7,588		6,499
Litigation and related costs		216		400		483		1,236
Adjusted EBITDA - non GAAP	\$	(1,587)	\$	(2,423)		(8,943)		(4,329)
Net loss	\$	(7,740)	\$	(7,898)	\$	(19,215)	\$	(14,558)
Non cash stock-based compensation expense		4,910		3,805		7,588		6,499
Litigation and related costs		216		400		483		1,236
Adjusted net loss - non GAAP	\$	(2,614)	\$	(3,693)		(11,143)		(6,823)
Weighted average common shares outstanding basic and diluted	4	1,994,618	4	1,080,898	4	41,900,000		40,894,405
Weighted average common shares outstanding - basis and	•	(0.40)	•	(0.40)	•	(0.40)	•	(0.00)
diluted	\$	(0.18)	\$	(0.19)		(0.46)		(0.36)
Non cash stock-based compensation expense	\$	0.12	\$	0.09	\$	0.18	\$	0.16
Litigation and related costs	\$	0.01	\$	0.01	\$	0.01	\$	0.03
Adjusted net loss per common share - basis and diluted - non GAAP	\$	(0.06)	\$	(0.09)	\$	(0.27)	\$	(0.17)

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

	Common Stock			Δ	Additional Paid-in	۸۵	cumulated	Total Shareholders'		
	Shares	Α	mount	Capital		AU	Deficit	Equity		
Three Months Ended June 30, 2022										
Balance at March 31, 2022	41,972,987	\$	420	\$	345,538	\$	(242,107)	\$	103,851	
Net loss			_		_		(7,740)		(7,740)	
Stock-based compensation	_		_		4,910				4,910	
Issuance of restricted and performance stock units	44,054		_		_		_		_	
Exercise of stock options and employee stock										
purchase plan	117,463				669				669	
Delenes et lune 20, 2022	42,134,504	\$	420	\$	351,117	\$	(249,847)	\$	101,690	
Balance at June 30, 2022				=		=				
Six Months Ended June 30, 2022										
Balance at December 31, 2021	41,736,950		417	\$	342,765	\$	(230,632)	\$	112,550	
Net loss	_		_		_		(19,215)		(19,215)	
Stock-based compensation	_		_		7,588		_		7,588	
Issuance of restricted and performance stock units	259,341		2		(2)					
Exercise of stock options and employee stock										
purchase plan	138,213		1	_	766				767	
Balance at June 30, 2022	42,134,504	\$	420	\$	351,117	\$	(249,847)	\$	101,690	
Three Months Ended June 30, 2021										
Balance at March 31, 2021	40,842,717	\$	408	\$	329,603	\$	(210,307)		119,704	
Net loss	.0,0 12,1 11	\$	_	\$	— —	\$	(7,898)	\$	(7,898)	
Stock-based compensation	_	Ψ.	_	Ψ	3,804	*	(.,ccc)	*	3,804	
Issuance of restricted and performance stock units	44,411	\$	_	\$	_	\$	_	\$	_	
Exercise of stock options and employee stock	,									
purchase plan	449,980		5		3,088				3,093	
Balance at June 30, 2021	41,337,108	\$	413	\$	336,495	\$	(218,205)	\$	118,703	
Six Months Ended June 30, 2021										
Balance at December 31, 2020	40,618,766	\$	406	\$	326,390	\$	(203,647)		123,149	
Net loss	_		_		_		(14,558)		(14,558)	
Stock-based compensation	_		_		6,499				6,499	
Issuance of restricted and performance stock units	138,944		1		(1)		_		_	
Exercise of stock options and employee stock	E70 200		•		2 607				2.642	
purchase plan	579,398	\$	413	\$	3,607	\$	(210.205)	\$	3,613	
Balance at June 30, 2021	41,337,108	Φ	413	<u>Ф</u>	336,495	Ф	(218,205)	D	118,703	

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

	Six Months Ended			
	J	une 30, 2022		June 30, 2021
Cash flows from operating activities:				
Net loss	\$	(19,215)	\$	(14,558)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		1,418		1,405
Amortization of right-of-use assets		859		960
Amortization of intangible assets		132		96
Amortization of debt discount and deferred financing fees		442		227
Provision for bad debt		550		(65)
Provision for inventory write-down		928		2,455
Change in fair value of derivatives		(686)		105
Investment losses		145		31
Stock-based compensation		7,588		6,499
Change in operating assets and liabilities:				
Accounts receivable		(2,719)		(498)
Inventory		(3,458)		(3,341)
Prepaid expenses and other		(1,081)		199
Accounts payable and accrued expenses		(786)		(5,061)
Operating lease obligations		(856)		35
Cash paid for interest portion of operating and finance leases		_		(1)
Contract and other liabilities				(3)
Net cash used in operating activities		(16,739)		(11,515)
Cash flows from investing activities:				
Purchase of property and equipment		(9,086)		(10,924)
Purchase of investments		(6,024)		(23,966)
Proceeds from sale of investments		11,000		32,295
Cash payments for intangible assets		(852)		(692)
Net cash used in investing activities		(4,962)		(3,287)
Cook flavor from financing cetholitics				
Cash flows from financing activities: Proceeds from the issuance of long-term debt				15,000
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Cash paid for debt portion of finance leases Proceeds from exercise of stock options and ESPP stock purchases		(1) 767		(8) 3,612
		766	-	18,604
Net cash provided by financing activities				
Net decrease in cash, cash equivalents, and restricted cash		(20,935)		3,802
Cash, cash equivalents, and restricted cash, beginning of period	<u> </u>	39,007	φ	55,609
Cash, cash equivalents, and restricted cash, end of period	<u>\$</u>	18,073	\$	59,411
Supplemental disclosures of cash flow activity:				
Cash paid for interest, net of capitalized interest	\$	_	\$	739
Supplemental disclosure of non-cash investing and financing activities:				
Acquisition of fixed assets in accounts payable and accrued expenses	\$	1,817	\$	3,035
Obtaining a right-of-use asset in exchange for a lease liability	\$	700	\$	371
Embedded derivative associated with the long-term debt	\$	_	\$	1,173
Acquisition of intangible assets in accounts payable and accrued expenses	\$	186	\$	190



Source: Axogen, Inc.