Elutia Announces Strong Third Quarter Results, Accelerating Toward Full Launch of EluPro® Antibiotic-Eluting BioEnvelope in 2025

November 14, 2024

Over 100 EluPro VAC Submissions and 19% SimpliDerm Growth Drive Momentum into 2025

SILVER SPRING, Md., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company"), a pioneer in drug-eluting biomatrix products, today provided a business update and financial results for the third quarter ended September 30, 2024.

Business Highlights:

- **First Commercial Use**: Announced the first patient implant of EluPro, the FDA-cleared antibiotic-eluting biologic envelope for pacemakers and neurostimulators.
- **Strong Initial Adoption**: EluPro is being utilized across all major cardiac implantable electronic device (CIED) brands and in neurostimulation procedures. EluPro now accounts for 25% of BioEnvelope (CanGaroo and EluPro) sales.
- **Robust VAC Engagement**: EluPro has now been submitted to over 100 hospital system value analysis committees (VACs), with 36 accounts now actively ordering.
- **Expanded Sales Presence**: Strengthened sales team in key markets including Southern California and the Northeast, balancing direct and independent representation for efficient, targeted coverage. Sales team now includes 12 direct reps, 34 independent reps, and 9 product consultants.
- **GPO Access**: Advanced discussions with major group purchasing organizations (GPOs), including private health systems and the Veterans Administration (VA), with favorable coverage decisions anticipated by early 2025 to expand EluPro's national availability.
- **Initiated Clinical Study**: Started a multi-center registry study to evaluate outcomes of patients receiving EluPro during cardiac implantable electronic device (CIED) implantation.
- **Peer Reviewed Publications:** Data published in *Frontiers in Drug Delivery* journal showcasing EluPro's effectiveness in eradicating bacteria linked to CIED infections, with additional manuscripts under review.
- **Business Development Activity**: Engaged in active discussions with multiple parties exploring opportunities for EluPro.

"We achieved several significant milestones this quarter, including the first implant of EluPro, marking a pivotal advancement for our team and the patients we serve," said Dr. Randy Mills, Elutia's Chief Executive Officer. "As we prepare for EluPro's full commercial launch in January 2025, we are energized by the strong initial market interest and clinical adoption. With EluPro's promising start and the continued momentum of SimpliDerm, we are redefining the BioEnvelope and reconstructive markets so that patients can thrive without compromise. I want to thank our unstoppable CRU for their exceptional efforts."

Third Quarter 2024 Financial Results

For the three-month period ended September 30, 2024, as compared to the same period of 2023:

- Overall net sales decreased 3.3% to $5.9 million, compared to $6.1 million.
- Net sales for BioEnvelope products, including both EluPro and CanGaroo, decreased by 12%, totaling $2.3 million compared to $2.6 million in Q3 2023, reflecting decreased sales of CanGaroo as customers anticipate the pending availability of EluPro in their accounts.
- Net sales of SimpliDerm increased 19% to $3.1 million, compared to $2.6 million.
- Net sales of Cardiovascular products were $0.6 million, a decrease of 40%, as LeMaitre Vascular continues transitioning Cardiovascular products into its sales strategy, in line with the Company's exclusive distribution relationship.
- Gross margin on a GAAP basis was 46%, approximately the same from the prior year period.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 61%, compared to 60%. A reconciliation of GAAP gross margin to adjusted gross margin is included in the accompanying financial tables.
- Total operating expenses were $13.0 million, compared to $10.2 million. The increase resulted primarily from higher non-cash equity compensation charges in the current year period.
- Loss from operations was $10.2 million, compared to $7.4 million.
- Net income from continuing operations was $1.3 million, compared to a loss of $8.5 million. The increase was primarily due to a $12.7 million non-cash gain in the third quarter of 2024 related to the revaluation of the Company's liability on warrants and pre-funded warrants related to the Company's 2023 and 2024 financings.
- Adjusted EBITDA (a non-GAAP measure that excludes from net loss certain non-operating, non-cash and non-recurring items) was a loss of $2.9 million, compared to a loss of $1.7 million. A reconciliation of net income (loss) to adjusted EBITDA is included in the accompanying financial tables.

- Cash balance as of September 30, 2024, was $25.7 million and includes approximately $13.8 million in proceeds received from the exercise of outstanding warrants at the start of the quarter.

Conference Call

Elutia will host a conference call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time to discuss its third quarter 2024 financial results and performance.

The conference call can be accessed using the following information:

Webcast: Click here
U.S. Investors: 877-407-8029
International Investors: 201-689-8029
Conference ID: 13749386

About Elutia

Elutia develops and commercializes drug-eluting biomatrix products to improve compatibility between medical devices and the patients who need them. With a growing population in need of implantable technologies, Elutia's mission is humanizing medicine so patients can thrive without compromise. For more information, visit www.Elutia.com.

Non-GAAP Disclosure

In addition to the Company's financial results determined in accordance with U.S. GAAP, the Company provides non-GAAP measures that it determines to be useful in evaluating its operating performance and liquidity. The Company presents in this press release the following non-GAAP financial measures: earnings before interest, taxes, depreciation and amortization ("EBITDA"), adjusted earnings before interest, taxes, depreciation and amortization ("adjusted EBITDA"), adjusted gross margin and adjusted gross profit. The Company defines EBITDA as GAAP net loss excluding interest expense, income tax expense, depreciation and amortization, and the Company defines adjusted EBITDA as EBITDA excluding income from discontinued operations, stock-based compensation, FiberCel litigation costs, loss on extinguishment of debt, net of gain on debt forgiveness, loss or gain on revaluation of warrant liability and gain on revaluation of revenue interest obligation. The Company defines adjusted gross profit and adjusted gross margin as GAAP gross profit and GAAP gross margin, respectively, excluding amortization of acquired intangible assets. The amortization of these intangible assets will recur in future periods until such intangible assets have been fully amortized. Management believes that presentation of non-GAAP financial measures provides useful supplemental information to investors and facilitates the analysis of the Company's core operating results and comparison of operating results across reporting periods. The Company uses this non-GAAP financial information to establish budgets, manage the Company's business, and set incentive and compensation arrangements. Non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental information purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. For a reconciliation of these non-GAAP measures to GAAP, see below "Non-GAAP Reconciliations of EBITDA and Adjusted EBITDA" and "Non-GAAP Reconciliations of Adjusted Gross Profit and Adjusted Gross Margin."

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements can be identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "promise" or similar references to future periods. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including any statements and information concerning the launch of EluPro, including the timing and anticipated success thereof. These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied in the forward-looking statements, including, but not limited to the following: our ability to successfully commercialize, marked and sell our newly approved EluPro product; our ability to continue as a going concern; our ability to achieve or sustain profitability; the risk of product liability claims and our ability to obtain or maintain adequate product liability insurance; our ability to defend against the various lawsuits and claims related to our recalled FiberCel and other viable bone matrix products and avoid a material adverse financial consequence from those lawsuits and claims; the continued and future acceptance of our products by the medical community; our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings; our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales; our dependence on a limited number of third-party suppliers and manufacturers, which, in certain cases are exclusive suppliers for products essential to our business; our ability to successfully realize the anticipated benefits of the November 2023 sale of our Orthobiologics business; physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products; our ability to compete against other companies, most of which have longer operating histories, more established products and/or greater resources than we do; pricing pressure as a result of cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could adversely affect our sales and profitability; our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates; and our ability to obtain, maintain and adequately protect our intellectual property rights; and other important factors which can be found in the "Risk Factors" section of Elutia's public filings with the Securities and Exchange Commission ("SEC"), including Elutia's Annual Report on Form 10-K for the year ended December 31, 2023, as such factors may be updated from time to time in Elutia's other filings with the SEC, including Elutia's Quarterly Reports on Form 10-Q, accessible on the SEC's website at www.sec.gov and the Investor Relations page of Elutia's website at https://investors.elutia.com. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. Any forward-looking statement made by Elutia in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, Elutia expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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ELUTIA INC.
CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

Assets	**September 30, 2024**	**December 31, 2023**
Current assets:		
Cash	$ 25,741	$ 19,276
Accounts receivable, net	2,931	3,263
Inventory	3,633	3,853
Receivables of litigation costs	4,582	2,696
Prepaid expense and other current assets	431	2,165
Total current assets	37,318	31,253
Property and equipment, net	693	172
Intangible assets, net	9,123	11,671
Operating lease right-of-use assets, and other	1,273	332
Total assets	$ 48,407	$ 43,428
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	$ 10,498	$ 12,676
Current portion of long-term debt	-	3,321
Current portion of revenue interest obligation	4,400	11,741
Contingent liability for legal proceedings	24,289	15,024
Current operating lease liabilities	491	275
Total current liabilities	39,678	43,037
Long-term debt	22,641	20,356
Long-term revenue interest obligation	6,244	5,360
Warrant liability	18,527	12,760
Other long-term liabilities	1,555	515
Total liabilities	88,645	82,028
Stockholders' equity (deficit):		
Common stock	34	23
Additional paid-in capital	180,260	137,021
Accumulated deficit	(220,532)	(175,644)
Total stockholders' deficit	(40,238)	(38,600)
Total liabilities and stockholders' deficit	$ 48,407	$ 43,428

ELUTIA INC.
CONSOLIDATED STATEMENT OF OPERATIONS
(Unaudited, in thousands, except share and per share data)

	Three months ended September 30,		**Nine months ended September 30,**	
	2024	**2023**	**2024**	**2023**
Net sales	$ 5,922	$ 6,127	$ 18,907	$ 18,870
Cost of goods sold	3,181	3,286	10,524	9,943
Gross profit	2,741	2,841	8,383	8,927
Operating expenses:				
Sales and marketing	2,989	2,802	9,628	10,514
General and administrative	4,521	2,757	14,266	10,137
Research and development	778	557	2,951	3,016
FiberCel litigation costs	4,683	4,096	8,757	7,278
Total operating expenses	12,971	10,212	35,602	30,945
Loss from operations	(10,230)	(7,371)	(27,219)	(22,018)
Interest expense	1,129	1,448	3,709	4,285
Other (income) expense, net	(12,653)	(312)	14,135	(312)

Income (loss) before provision of income taxes	1,294	(8,507)	(45,063)	(25,991)
Income tax expense	8	12	5	36
Net income (loss) from continuing operations	1,286	(8,519)	(45,068)	(26,027)
Income (loss) from discontinued operations	-	(1,228)	180	(2,315)
Net income (loss)	1,286	(9,747)	(44,888)	(28,342)
Net income (loss) attributable to common stockholders per share - basic	$ 0.03	$ (0.57)	$ (1.65)	$ (1.72)
Net income (loss) attributable to common stockholders per share - diluted	$ (0.33)	$ (0.57)	$ (1.65)	$ (1.72)
Weighted average common shares outstanding - basic	32,520,134	17,017,610	27,132,216	16,464,262
Weighted average common shares outstanding - diluted	35,520,938	17,017,610	27,132,216	16,464,262

ELUTIA INC.
NON-GAAP RECONCILIATIONS OF ADJUSTED GROSS PROFIT AND ADJUSTED GROSS MARGIN
(Unaudited, in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Net sales	$ 5,922	$ 6,127	$ 18,907	$ 18,870
Gross profit	2,741	2,841	8,383	8,927
Intangible asset amortization expense	849	849	2,547	2,547
Adjusted gross profit (Non-GAAP)	$ 3,590	$ 3,690	$ 10,930	$ 11,474
Gross margin	46.3%	46.4%	44.3%	47.3%
Adjusted gross margin percentage (Non-GAAP)	60.6%	60.2%	57.8%	60.8%

ELUTIA INC.
NON-GAAP RECONCILIATIONS OF EBITDA AND ADJUSTED EBITDA
(Unaudited, in thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Net income (loss)	$ 1,286	$ (9,747)	$ (44,888)	$ (28,342)
Interest expense[(1)]	1,129	1,448	3,709	4,285
Income tax expense	8	12	5	36
Depreciation and amortization	862	942	2,588	2,854
Earnings before interest, taxes, depreciation and amortization (“EBITDA”) (Non-GAAP)	3,285	(7,345)	(38,586)	(21,167)
Loss (income) from discontinued operations	-	1,228	(180)	2,315
Stock-based compensation	1,775	615	6,683	1,987
FiberCel litigation costs[(2)]	4,683	4,096	8,757	7,278
(Gain) loss on revaluation of warrant liability[(3)]	(12,653)	(1,070)	15,321	(1,070)
Warrant issuance expenses	-	758	257	758
Gain on revaluation of revenue interest obligation[(4)]	-	-	(1,443)	-
Adjusted EBITDA (Non-GAAP)	$ (2,910)	$ (1,718)	$ (9,191)	$ (9,899)

(1) Represents interest expense recorded on all outstanding long-term debt as well as the revenue interest obligation.

(2) Represents FiberCel litigation costs consisting primarily of legal fees and the estimated and actual costs to resolve the outstanding FiberCel litigation cases offset by the estimated amounts recoverable and recovered under insurance, indemnity and contribution agreements for such costs.

(3) Represents non-cash expense attributable to the revaluation of Common Warrants and Prefunded Warrants issued in connection with a private offering of Class A common stock on September 21, 2023.

(4) Represents the gain on the revaluation of the revenue interest obligation. At each reporting period, the value of the revenue interest obligation is re-measured based on current estimates of future payments, with changes to be recorded in the consolidated statements of operations using the catch-up method.