

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 6, 2025

ELUTIA INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-39577
(Commission
File Number)

47-4790334
(IRS Employer
Identification No.)

12510 Prosperity Drive, Suite 370, Silver Spring, MD 20904

(Address of principal executive offices) (Zip Code)

(240) 247-1170

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Class A Common Stock, \$0.001 par value per share	ELUT	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On March 6, 2025, Elutia Inc. (the “Company” or “Elutia”) issued a press release announcing its results for the fourth quarter and full year ended December 31, 2024. A copy of the Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Exhibit Description

[99.1](#) [Press Release of Elutia Inc., dated March 6, 2025](#)

104 Cover Page Interactive Data File (formatted as Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ELUTIA INC.
(Registrant)

Date: March 6, 2025

By: /s/ Matthew Ferguson
Matthew Ferguson
Chief Financial Officer



Elutia Announces Fourth Quarter and Full Year 2024 Financial Results: Strong Demand for EluPro™ in Pilot Launch Sets the Stage for Full Commercial Roll-Out

- Overall BioEnvelope sales up 18%, with same-center sales increasing 65% following EluPro commercialization -

SILVER SPRING, Md., March 6, 2025 — Elutia Inc. (Nasdaq: ELUT) (“Elutia” or the “Company”), a pioneer in drug-eluting biomatrix technologies, today provided a business update and financial results for the fourth quarter and full year ended December 31, 2024.

Business Highlights:

- **Strong Initial Market Uptake for EluPro:** Since its pilot launch in the fourth quarter, EluPro has been utilized across all major cardiac implantable electronic device (CIED) brands, accounting for over 30% of BioEnvelope (CanGaroo and EluPro) sales in the quarter. Early adoption in neurostimulator applications is also underway.
- **Robust Market Expansion:** Elutia closed 2024 with 67 approved EluPro accounts, averaging more than 15 new approvals per month through Value Analysis Committees (VACs). The Company now has approximately 100 actively ordering accounts.
- **Group Purchasing Agreements:** Sales growth is further supported by agreements with major national group purchasing organizations (GPOs), including Premier, Inc. and Southern Strategic Sourcing Partners (S3P).
- **Strong Independent Sales Agent Engagement:** The mix of BioEnvelope sales generated from EluPro by the Company’s independent or ‘1099’ sales agent network reached 45% in the quarter, highlighting EluPro’s strong value proposition and the scalability of its sales model.
- **Business Development Activity:** Engaged in active discussions with multiple parties exploring partnering opportunities.
- **Enhanced Financial Position:** Raised gross proceeds of approximately \$15 million in a registered direct offering that closed on February 4, 2025.

“Elutia closed out 2024 with the successful pilot launch of EluPro, the first ever FDA-cleared antibiotic-eluting biomatrix designed for use with CIEDs and neurostimulators,” said Dr. Randy Mills, CEO of Elutia. “EluPro has quickly gained traction with physicians and hospital groups, and we are building on this momentum through VACs and key GPO relationships. Most importantly, EluPro is helping patients. We believe it is the most complete solution for device protection in this \$600 million market.”

Full Year 2024 Financial Results

For the year ended December 31, 2024, as compared to the same period of 2023:

- Net sales for BioEnvelope products, including both EluPro and CanGaroo, increased by 5%, totaling \$9.9 million compared to \$9.4 million for the full year 2023.
 - Net sales of SimpliDerm increased 12% to \$11.6 million, compared to \$10.3 million.
 - Net sales of Cardiovascular products were \$2.9 million, a decrease of 42%, as LeMaitre Vascular continues transitioning Cardiovascular products into its sales strategy, in line with our exclusive distribution relationship.
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- Overall net sales decreased 1.5% to \$24.4 million, compared to \$24.7 million, driven by the change in the cardiovascular sales model.
- Gross margin on a GAAP basis was 43.9%, compared to 44.7%.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 57.9%, compared to 58.4%. A reconciliation of GAAP gross margin to adjusted gross margin is included in the accompanying financial tables.
- Total operating expenses were \$46.4 million, compared to \$41.6 million.
- Loss from operations was \$35.7 million, compared to \$30.5 million.
- Net loss from continuing operations was \$54.1 million, compared to a loss of \$41.2 million.
- Adjusted EBITDA (a non-GAAP measure that excludes from net loss certain non-operating, non-cash and non-recurring items) was a loss of \$12.9 million, compared to a loss of \$14.4 million. A reconciliation of net income (loss) to adjusted EBITDA is included in the accompanying financial tables.
- Cash balance as of December 31, 2024, was \$13.2 million. Following year-end, the company completed a registered direct offering resulting in gross proceeds of approximately \$15 million.

Fourth Quarter 2024 Financial Results

For the three-month period ended December 31, 2024, as compared to the same period of 2023:

- Net sales for BioEnvelope products, including both EluPro and CanGaroo, increased by 18%, totaling \$2.7 million compared to \$2.3 million in Q4 2023, reflecting strong initial sales of EluPro.
- Net sales of SimpliDerm decreased 23% to \$2.3 million, compared to \$3.0 million.
- Net sales of Cardiovascular products were \$0.5 million, a decrease of 20%.
- Overall net sales decreased 7% to \$5.5 million, compared to \$5.9 million.
- Gross margin on a GAAP basis was 42.5%, compared to 36.2%
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 58.1%, compared to 50.6%. A reconciliation of GAAP gross margin to adjusted gross margin is included in the accompanying financial tables.
- Total operating expenses were \$10.8 million, compared to \$10.6 million.
- Loss from operations was \$8.4 million, compared to \$8.5 million.
- Net loss from continuing operations was \$9.1 million, compared to a loss of \$15.2 million.
- Adjusted EBITDA (a non-GAAP measure that excludes from net loss certain non-operating, non-cash and non-recurring items) was a loss of \$3.8 million, compared to a loss of \$4.5 million. A reconciliation of net income (loss) to adjusted EBITDA is included in the accompanying financial tables.

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 fourth quarter and full year 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: 13751810

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 and market reception 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, market 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; our ability to prevail in lawsuits and claims seeking indemnity, contribution and insurance coverage for FiberCel and other viable bone matrix product liabilities; 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 that 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; 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, 2024, 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.

Investors:

Matt Steinberg
FINN Partners
matt.steinberg@finnpartners.com

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

	<u>December 31, 2024</u>	<u>December 31, 2023</u>
Assets		
Current assets:		
Cash	\$ 13,239	\$ 19,276
Accounts receivable, net	2,276	3,263
Inventory	3,911	3,853
Receivables of litigation costs	4,760	2,696
Prepaid expense and other current assets	1,986	2,165
Total current assets	<u>26,172</u>	<u>31,253</u>
Property and equipment, net	773	172
Intangible assets, net	8,273	11,671
Operating lease right-of-use assets, and other	909	332
Total assets	<u>\$ 36,127</u>	<u>\$ 43,428</u>
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	\$ 11,253	\$ 12,676
Current portion of long-term debt	1,250	3,321
Current portion of revenue interest obligation	4,400	11,741
Contingent liability for legal proceedings	20,432	15,024
Current operating lease liabilities	460	275
Total current liabilities	<u>37,795</u>	<u>43,037</u>
Long-term debt	22,603	20,356
Long-term revenue interest obligation	5,490	5,360
Warrant liability	16,076	12,760
Other long-term liabilities	423	515
Total liabilities	<u>82,387</u>	<u>82,028</u>
Stockholders' equity (deficit):		
Common stock	35	23
Additional paid-in capital	183,298	137,021
Accumulated deficit	(229,593)	(175,644)
Total stockholders' deficit	<u>(46,260)</u>	<u>(38,600)</u>
Total liabilities and stockholders' deficit	<u>\$ 36,127</u>	<u>\$ 43,428</u>

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

	<u>Three months ended December 31,</u>		<u>Twelve months ended December 31,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Net sales	\$ 5,468	\$ 5,875	\$ 24,375	\$ 24,745
Cost of goods sold	3,144	3,751	13,668	13,692
Gross profit	<u>2,324</u>	<u>2,124</u>	<u>10,707</u>	<u>11,053</u>
Operating expenses:				
Sales and marketing	2,918	2,572	12,546	13,087
General and administrative	4,393	3,967	18,659	14,104
Research and development	834	1,381	3,785	4,399
FiberCel litigation costs	2,611	2,711	11,368	9,989
Total operating expenses	<u>10,756</u>	<u>10,631</u>	<u>46,358</u>	<u>41,579</u>
Loss from operations	(8,432)	(8,507)	(35,651)	(30,526)
Interest expense	1,070	1,511	4,779	5,796
Other (income) expense, net	(443)	5,211	13,692	4,899
Income (loss) before provision of income taxes	<u>(9,059)</u>	<u>(15,229)</u>	<u>(54,122)</u>	<u>(41,221)</u>
Income tax expense	2	(8)	7	28
Net income (loss) from continuing operations	<u>(9,061)</u>	<u>(15,221)</u>	<u>(54,129)</u>	<u>(41,249)</u>
Income (loss) from discontinued operations	-	5,905	180	3,593
Net income (loss)	<u>(9,061)</u>	<u>(9,316)</u>	<u>(53,949)</u>	<u>(37,656)</u>
Net income (loss) attributable to common stockholders per share - basic and diluted	<u>\$ (0.26)</u>	<u>\$ (0.40)</u>	<u>\$ (1.86)</u>	<u>\$ (2.07)</u>
Weighted average common shares outstanding - basic and diluted	<u>34,845,672</u>	<u>23,195,190</u>	<u>29,071,113</u>	<u>18,160,822</u>

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

	<u>Three months ended December 31,</u>		<u>Twelve months ended December 31,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Net sales	\$ 5,468	\$ 5,875	\$ 24,375	\$ 24,745
Gross profit	2,324	2,124	10,707	11,053
Intangible asset amortization expense	851	851	3,398	3,398
Adjusted gross profit (Non-GAAP)	\$ 3,175	\$ 2,975	\$ 14,105	\$ 14,451
Gross margin	42.5%	36.2%	43.9%	44.7%
Adjusted gross margin percentage (Non-GAAP)	58.1%	50.6%	57.9%	58.4%

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

	<u>Three months ended December 31,</u>		<u>Twelve months ended December 31,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Net loss	\$ (9,061)	\$ (9,316)	\$ (53,949)	\$ (37,656)
Interest expense ⁽¹⁾	1,070	1,511	4,779	5,796
Provision (benefit) for income taxes	2	(8)	7	28
Depreciation and amortization	863	891	3,451	3,713
Earnings before interest, taxes, depreciation and amortization ("EBITDA") (Non-GAAP)	(7,126)	(6,922)	(45,712)	(28,119)
Income (loss) from discontinued operations	-	(5,905)	(180)	(3,593)
Stock-based compensation	1,207	452	7,891	2,406
FiberCel litigation costs ⁽²⁾	2,611	2,711	11,368	9,989
(Gain) loss on revaluation of warrant liability ⁽³⁾	(443)	4,452	14,878	4,140
Warrant issuance expenses	-	759	257	759
Gain on revaluation of revenue interest obligation ⁽⁴⁾	-	-	(1,443)	-
Adjusted EBITDA (Non-GAAP)	\$ (3,751)	\$ (4,453)	\$ (12,941)	\$ (14,418)

- (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 amounts 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 in September 2023 and a registered direct offering in June 2024.
- (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.