
**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): May 14, 2026

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
(I.R.S. Employer
Identification No.)

20 Firstfield Road
Gaithersburg, MD 20878
(Address of principal executive offices) (Zip Code)

(240) 247-1170
(Registrant's telephone number, include 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:

Title of each class	Trading Symbols	Name of each exchange on which registered
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 May 14, 2026, Elutia Inc. (the “Company” or “Elutia”) issued a press release announcing its results for the first quarter ended March 31, 2026. 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 May 14, 2026
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.

Date: May 14, 2026

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

Elutia Reports First Quarter 2026 Results and Highlights NXT-41x Progress Toward \$1.5 Billion U.S. Plastic and Reconstructive Surgery Market

- *NXT-41 review advancing collaboratively with FDA, informing NXT-41x submission preparations*
- *Brought a new automated manufacturing process online, supporting a gross margin target of more than 80% at scale*
- *Chief Commercial Officer Pete Ligotti's initial surgeon engagement confirming significant unmet need and market opportunity*
- *Strong balance sheet with \$36.5 million in cash and escrowed proceeds from the BioEnvelope business divestiture*
- *Conference call today at 5:00 p.m. ET / 2:00 p.m. PT*

GAITHERSBURG, Md., May 14, 2026 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company"), a pioneer in drug-eluting biomatrix technologies, today reported a business update and financial results for the first quarter ended March 31, 2026.

Dr. Randy Mills, CEO of Elutia, said: "Up to 20% of women undergoing reconstructive surgery after mastectomy develop serious infections. To us, that is unacceptable. That's why we're developing NXT-41x.

"This quarter, we advanced every facet of our mission. The FDA review of NXT-41 is progressing well and is providing valuable insights for the NXT-41x submission. Our new automated manufacturing process is installed and operating, supporting gross margin targets above 80% at scale. Lastly, Pete Ligotti, our new Chief Commercial Officer, is in the field with surgeons, and their feedback confirms both the size and severity of the need.

"It is increasingly clear that in the estimated \$1.5 billion breast reconstructive surgery market, NXT-41x has the potential to be a blockbuster and improve outcomes for women with breast cancer. I'm proud of what this team has accomplished and their unwavering commitment to humanizing medicine so patients can thrive without compromise."

Business Highlights

NXT-41 510(k) Review Advancing. FDA review of the 510(k) submission for NXT-41, the base biologic matrix, is progressing through a collaborative dialogue with the agency. Anticipated clearance is on track for the fourth quarter of 2026. The Company's interactions with the FDA during this review have helped to refine the submission package for NXT-41x, an antibiotic-eluting product, with anticipated clearance in the first half of 2027.

Manufacturing Automation Supports an Expected Gross Margin Above 80%. Elutia advanced startup work on the at-scale production equipment required for NXT-41x, including a robotic coating system used to apply the drug-eluting layer to the biologic matrix. The Company expects this manufacturing platform to support a gross margin in excess of 80%, while enabling pricing designed to capture significant market share.

Commercial Launch Confidence Building. Pete Ligotti, Chief Commercial Officer, has spent his first months at Elutia in direct engagement with surgeons across the U.S. breast reconstruction community. Surgeon feedback is confirming the magnitude of the unmet need, with post-operative infection rates of 15 to 20 percent in a \$1.5 billion U.S. market that has seen no meaningful innovation in the standard of care. Elutia is conducting quantitative market research to independently validate the scale of the opportunity, helping refine target accounts, patient populations and commercialization priorities ahead of launch.

Strategic Processes for SimpliDerm and Cardiovascular Advancing. The previously announced exploration of a SimpliDerm divestiture is progressing well. Separately, the Company has also received multiple inbound inquiries for the acquisition of its Cardiovascular product line and is evaluating the opportunity. Elutia will provide further updates as appropriate.

Balance Sheet. Total cash and escrow funds at March 31, 2026, were \$36.5 million, comprised of \$28.5 million in cash on hand and \$8.0 million held in escrow related to the BioEnvelope business divestiture, with the escrowed funds expected to be released in the fourth quarter of 2026.

First Quarter 2026 Financial Results

Net sales and operating results discussed below reflect continuing operations. For the three-month period ended March 31, 2026, as compared to the same period of 2025:

- Overall net sales were \$3.1 million, compared to \$3.0 million, an increase of 6%.
- Net sales of SimpliDerm were \$2.1 million, compared to \$2.6 million.
- Net sales of Cardiovascular products were \$1.0 million, compared to \$0.3 million.
- Gross margin on a GAAP basis was 57.9%, compared to 46.8%.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 66.5%, compared to 55.9%. A reconciliation of GAAP gross margin to adjusted gross margin is included in the accompanying financial tables.
- Total operating expenses were \$8.2 million, consistent with the prior year period.
- Net loss from continuing operations was \$7.9 million, compared to a loss of \$1.9 million. The increase in net loss from continuing operations was driven primarily by a \$6.7 million unfavorable swing in other expense (income), net, which was comprised largely of a \$1.7 million non-cash loss on revaluation of warrant liabilities in Q1 2026 compared to a \$5.2 million non-cash gain in Q1 2025.
- Net loss was \$7.5 million, compared to a net loss of \$3.9 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 \$4.4 million, compared to a loss of \$2.8 million. A reconciliation of net income (loss) to adjusted EBITDA is included in the accompanying financial tables.
- Cash balance as of March 31, 2026 was \$28.5 million. An additional \$8.0 million related to the BioEnvelope business divestiture is held in escrow and is expected to be released in the fourth quarter of 2026.
- As of March 31, 2026, there were 44.2 million shares of Class A common stock outstanding with an additional 3.2 million pre-funded warrants outstanding.

Conference Call

Elutia will host a conference call today at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time to discuss its first quarter 2026 financial results and performance.

The conference call can be accessed using the following information:

Webcast: [Click here](#)

Dial-In: [Click here](#)

To receive the dial-in number, as well as your personalized PIN, you must register at the above link. Once registered, you will also have the option to have the system dial-out to you once the conference call begins. If you forget your PIN prior to the conference call, you can simply re-register.

Please log in approximately 10 minutes prior to the scheduled start time. A live and archived webcast of the event will be available on the “Investors” section of the Elutia website at <http://investors.elutia.com/>.

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 believes 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 loss from discontinued operations, stock-based compensation, FiberCel and other Viable Bone Matrix (VBM) litigation costs, loss or gain on revaluation of warrant liability and warrant issuance expenses. 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 regarding the size of the breast reconstruction market and the potential of the Company’s next-generation drug-eluting biomatrix pipeline to compete in that market, anticipated FDA clearances and the future success of new products in Elutia’s breast reconstruction business, including the timing and success of NXT-41 and NXT-41x, as well as any statements regarding any potential strategic process for any other businesses. These forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to us. 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: risks associated with shifting focus to our drug-eluting biomatrix solutions in the breast reconstruction area and away from our BioEnvelope business; our ability to successfully execute or achieve expected benefits from the divestiture of our BioEnvelope business; our

ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings, including NXT-41 and NXT-41x; our ability to obtain regulatory approval or other marketing authorizations by the U.S. Food and Drug Administration and comparable foreign authorities for our products and product candidates, including NXT-41 and NXT-41x; our ability to achieve or sustain profitability; our ability to maintain the listing of our common stock on the Nasdaq Capital Market; 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 former FiberCel and other VBM 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; our ability to defend against any other ongoing or future litigation that we are or may become subject to; the continued and future acceptance of our products by the medical community; our dependence on a limited number of third-party suppliers and manufacturers; 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, 2025, as such factors may be updated from time to time in Elutia’s other filings with the SEC, 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:

Elutia Investor Relations
ir@elutia.com

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

	Three months ended March 31,	
	2026	2025
Net sales	\$ 3,114	\$ 2,951
Cost of goods sold	1,312	1,569
Gross profit	1,802	1,382
Operating expenses:		
Sales and marketing	1,480	995
General and administrative	4,091	3,721
Research and development	1,973	871
Litigation costs, net	606	2,572
Total operating expenses	8,150	8,159
Loss from continuing operations	(6,348)	(6,777)
Interest (income) expense, net	(108)	184
Other expense (income), net	1,584	(5,082)
Loss from continuing operations before provision of income taxes	(7,824)	(1,879)
Income tax expense	70	8
Net loss from continuing operations	(7,894)	(1,887)
Income (loss) from discontinued operations	425	(2,046)
Net loss	\$ (7,469)	\$ (3,933)
Net loss per share - basic	\$ (0.17)	\$ (0.10)
Net loss per share - diluted	\$ (0.17)	\$ (0.21)
Weighted average common shares outstanding - basic	42,998,504	38,616,206
Weighted average common shares outstanding - diluted	42,998,504	42,913,111

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

Assets	<u>March 31, 2026</u>	<u>December 31, 2025</u>
Current assets:		
Cash and cash equivalents	\$ 28,488	\$ 36,350
Accounts receivable, net	2,068	1,734
Inventory	2,657	2,617
Insurance receivables of litigation costs	5,348	4,846
Prepaid expense and other current assets	<u>10,030</u>	<u>10,271</u>
Total current assets	48,591	55,818
Property and equipment, net	2,909	2,511
Intangible assets, net	1,260	1,529
Operating lease right-of-use assets, and other	<u>2,449</u>	<u>2,492</u>
Total assets	<u>\$ 55,209</u>	<u>\$ 62,350</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,685	\$ 9,143
Current portion of revenue interest obligation	5,500	4,400
Contingent liability for legal proceedings	8,016	11,241
Current operating lease liabilities	<u>524</u>	<u>355</u>
Total current liabilities	23,725	25,139
Long-term revenue interest obligation	1,873	2,828
Warrant liability	3,389	3,124
Long-term operating lease liabilities	<u>3,695</u>	<u>3,587</u>
Total liabilities	<u>32,682</u>	<u>34,678</u>
Stockholders' equity (deficit):		
Common stock	44	43
Additional paid-in capital	206,165	203,842
Accumulated deficit	<u>(183,682)</u>	<u>(176,213)</u>
Total stockholders' equity	<u>22,527</u>	<u>27,672</u>
Total liabilities and stockholders' equity	<u>\$ 55,209</u>	<u>\$ 62,350</u>

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

	Three months ended March 31,	
	2026	2025
Net sales	\$ 3,114	\$ 2,951
Gross profit	1,802	1,382
Intangible asset amortization expense	270	269
Adjusted gross profit (Non-GAAP)	\$ 2,072	\$ 1,651
Gross margin	57.9%	46.8%
Adjusted gross margin percentage (Non-GAAP)	66.5%	55.9%

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

	Three months ended March 31,	
	2026	2025
Net loss	\$ (7,469)	\$ (3,933)
Interest (income) expense, net ⁽¹⁾	(108)	184
Provision (benefit) for income taxes	70	8
Depreciation and amortization	330	286
EBITDA	(7,177)	(3,455)
(Income) loss from discontinued operations	(425)	2,046
Stock-based compensation	931	1,088
Litigation costs, net ⁽²⁾	606	2,572
(Gain) loss on revaluation of warrant liability ⁽³⁾	1,655	(5,187)
Warrant issuance expenses	-	105
Adjusted EBITDA	\$ (4,410)	\$ (2,831)

⁽¹⁾ Represents interest income offset by interest expense recorded on the revenue interest obligation.

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

⁽³⁾ Represents the non-cash revaluation of Prefunded Warrants issued in connection with a private offering in September 2023 and registered direct offerings in June 2024 and February 2025.