

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): August 13, 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 August 13, 2026, Elutia Inc. (the “Company” or “Elutia”) issued a press release announcing its results for the second quarter ended June 30, 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	<u>Press Release of Elutia Inc. dated August 13, 2026</u>
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: August 13, 2026

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



Elutia Secures Up to \$26 Million to Fund NXT-41x Through Commercial Launch; Reports Second Quarter 2026 Results

Independent Blinded Survey of 50 Plastic Surgeons Validates Demand; NXT-41 and NXT-41x Remain On-Track

- **Funded through launch:** secured up to \$26 million of capital without an equity offering
- **The unmet need is real:** 86% of surgeons surveyed say the matrices they use today increase infection risk
- **The demand is strong:** 96% of surgeons surveyed are interested in adopting NXT-41x; 92% responded they would champion it at their hospital value analysis committee
- **On track:** NXT-41 FDA clearance decision expected in 4Q 2026; NXT-41x FDA clearance decision expected in 1H 2027

GAITHERSBURG, Md., August 13, 2026 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company"), a pioneer in drug-eluting biomatrix technologies, today provided a business update and announced financial results for the second quarter ended June 30, 2026.

"We have intentionally focused Elutia where our strengths create the greatest value for patients and shareholders," said Dr. Randy Mills, Chief Executive Officer of Elutia. "We believe we are now funded through the anticipated clearance and full commercial launch of NXT-41x, our antibiotic-eluting biomatrix for use in plastic and reconstructive surgical procedures. And we did it without an equity offering.

"As we approach anticipated FDA clearance decisions and launch, surgeon interest in NXT-41x has exceeded our expectations. In an independent study of 50 board-certified plastic and reconstructive surgeons, 86% said matrices used today increase infection risk, 96% believed our antibiotic combination would be effective at preventing infection, and 92% said they would help get NXT-41x approved at their hospital's value analysis committee.

"Having successfully created value with this technology in the pacemaker market, we are now applying it to a larger market with a substantially greater unmet need. And we believe we have the team and capital to execute."

Capital Secured to Support NXT-41x Through Clearance and Commercial Launch

Elutia has secured up to \$26 million of additional capital to support the Company through the anticipated clearance of NXT-41x and its first full year of commercial launch in 2028, without an equity offering:

- \$15 million credit facility, including \$10 million funded at closing and an additional \$5 million available following NXT-41x FDA clearance
- Up to \$11 million from the SimpliDerm divestiture, including \$8 million in cash at closing and up to \$3 million in contingent technology transfer and commercial milestone payments

In addition, the Company anticipates receiving the full \$8 million held in escrow from the 2025 divestiture of the BioEnvelope business, with release expected in the fourth quarter of this year.

Independent Blinded Survey Validates Surgeon Demand for NXT-41x

An independent market research firm conducted a blinded survey of 50 board-certified plastic and reconstructive surgeons across 28 states. The surgeons average 11.6 years in practice and perform about 140 complex reconstructive procedures annually.

Surgeons Say the Problem Is Real

- Surgeons estimate a 17% surgical-site infection rate in the published literature for these procedures.
- 86% (95% confidence interval (CI): 74–93%) report that matrices used today increase infection risk.

Surgeons View NXT-41x as Differentiated and Mechanistically Sound

- 98% (CI: 90–99.6%) rated NXT-41x new and different from products available today.
- 96% (CI: 87–99%) rated the combination of rifampin and minocycline effective, with 64% (CI: 50–76%) describing it as extremely effective at reducing surgical site infections. No respondents rated the combination ineffective.

Surgeon Intent to Adopt NXT-41x Is Strong

- 100% (CI: 93–100%) indicated they would use NXT-41x in diabetic patients and in patients with high BMI, who together represent approximately one third of all reconstruction patients.
- 96% (CI: 87–99%) expressed interest in incorporating NXT-41x into their general practice.
- 92% (CI: 81–97%) indicated willingness to approach their hospital value analysis committee in support of NXT-41x.

Interest measures are based on ratings of 4 or 5 on a five-point scale. All results are reported with 95% Wilson confidence intervals; where responses were unanimous, the lower bound of the interval is 93%.

Regulatory Review and Manufacturing Progressing on Schedule

Regulatory and development activities for both NXT-41 (biologic surgical matrix without drug) and NXT-41x continue to advance according to plan. Elutia recently held a productive meeting with the FDA regarding the NXT-41 submission, which remains on track. The Company continues to expect FDA clearance for NXT-41 in the fourth quarter of 2026 and for NXT-41x in the first half of 2027.

Elutia also completed the installation and operational qualification of its automated drug-coating system for commercial manufacturing. The system is designed to support target gross margins in excess of 80% at scale.

Product Divestitures Further Sharpen the Company's Focus

On July 16, 2026, Elutia signed a definitive agreement to sell its SimpliDerm business for up to \$11 million in total consideration, including up to \$3 million in contingent technology transfer and commercial milestone payments over the 18 months following closing, with closing expected in the third quarter of 2026. The Company's previously announced strategic process for its Cardiovascular business also continues to advance. Together with the 2025 divestiture of the BioEnvelope business, these transactions extend Elutia's runway and focus the organization on the launch of NXT-41x in the second half of 2027.

Funded Catalysts Ahead

Milestone	Expected Timing
SimpliDerm business divestiture closing	3Q 2026
Potential cardiovascular business transaction	2H 2026
\$8 million BioEnvelope escrow release	4Q 2026
NXT-41 FDA clearance decision	4Q 2026
NXT-41x FDA clearance decision	1H 2027
NXT-41x commercial soft launch	2H 2027
NXT-41x full commercial launch	2028

Second Quarter 2026 Financial Results

Net sales and operating results discussed below reflect continuing operations. For the three-month period ended June 30, 2026, as compared to the same period of 2025:

- Overall net sales were \$2.4 million, compared to \$2.7 million. The decrease was the result of \$0.7 million reduction in SimpliDerm revenue due to a production disruption with the product's contract manufacturer, offset by a \$0.4 million increase in Cardiovascular revenue due to the transition back to direct sales.
- Gross margin on a GAAP basis was 59.6%, compared to 52.9%.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 70.7%, compared to 62.7%. A reconciliation of GAAP gross margin to adjusted gross margin is included in the accompanying financial tables.
- Total operating expenses were \$9.4 million, compared to \$9.8 million. The decrease was driven by a \$1.9 million reduction in net litigation costs, partially offset by a \$1.5 million increase in research and development expense supporting the NXT-41 and NXT-41x programs.
- Loss from operations was \$8.0 million, compared to \$8.4 million.
- Net loss from continuing operations was \$7.6 million, compared to \$7.1 million.
- There was no loss from discontinued operations in the second quarter of 2026, compared to a loss of \$2.5 million in the second quarter of 2025.
- Net loss was \$7.6 million, compared to \$9.6 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 \$4.6 million, compared to a loss of \$3.0 million. A reconciliation of net loss to adjusted EBITDA is included in the accompanying financial tables.
- Cash and cash equivalents at June 30, 2026 were \$19.9 million. This cash position is expected to be augmented by up to an additional \$34 million from signed transactions, including \$10 million already received from Avenue Capital Group pursuant to a new loan agreement, \$8 million held in escrow in connection with the 2025 divestiture of the BioEnvelope business, up to \$11 million from the sale of the SimpliDerm business and an additional \$5 million available from the Avenue Capital loan facility following FDA clearance of NXT-41x.

Conference Call

Elutia will host a conference call on August 13, 2026 at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time to discuss its second quarter 2026 financial results and business 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 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 or loss from discontinued operations, stock-based compensation, FiberCel and VBM litigation costs, loss or gain on revaluation of warrant liability, warrant issuance expenses and loss or 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 our future interactions with the U.S. Food and Drug Administration ("FDA") regarding NXT-41 and NXT-41x; expectations for FDA clearance of NXT-41 and NXT-41x, including the timing and anticipated success thereof; preparations for the commercial launch of NXT-41x, including the timing, scale and anticipated success thereof; the sufficiency of our capital resources to fund the Company through anticipated FDA clearance and the first full year of commercial launch of NXT-41x without an equity offering; the availability of the additional \$5 million tranche under our Avenue Capital financing; the expected closing of the sale of our SimpliDerm business and our receipt of the associated contingent technology transfer and commercial milestone payments; the outcome and timing of the previously announced strategic process for our Cardiovascular business; the anticipated release of the \$8 million held in escrow in connection with the divestiture of the BioEnvelope business; the results, interpretation and predictive value of the independent blinded surgeon survey described in this press release, including surgeons' stated intent to adopt NXT-41x and to support it before hospital value analysis committees; the size of the plastic and reconstructive surgery market and the potential of the Company's next-generation drug-eluting biomatrix pipeline to compete in that market; expectations regarding manufacturing capacity, scale and target gross margins; and any statements regarding future liability with respect to the FiberCel and VBM litigation. 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: 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 comply with the covenants under, and to draw the remaining availability under, our credit facility; physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products; our ability to achieve or sustain profitability; our ability to regain compliance with Nasdaq's minimum bid price requirement and otherwise maintain compliance with any other listing requirement of Nasdaq Capital Market, and our ability to maintain a listing of our Class A common stock on the Nasdaq Capital Market; our ability to raise funds in the future in the amounts and at the times needed; our ability to service our indebtedness; the risk of product liability claims and our ability to obtain or maintain adequate product liability insurance; risks relating to the pending sale of the SimpliDerm business, including the occurrence of any event, change or circumstance that could delay the sale of the SimpliDerm business or give rise to termination of the related asset purchase agreement, the risk that the technology transfer and commercial milestone payments from the sale of the SimpliDerm business are reduced, delayed, or not earned or received, the outcome of any legal proceedings instituted against us following announcement of the sale of the SimpliDerm business, the inability to consummate the sale of the SimpliDerm business due to failure to satisfy closing conditions; the risk that the sale of the SimpliDerm business disrupts our current plans and operations, including distraction of management and employees, and costs related to the sale of the SimpliDerm business; our ability to complete any strategic transaction involving our Cardiovascular business, on the anticipated timeline and terms, or at all, and to realize the anticipated benefits of that transaction; our ability to defend against the various lawsuits and claims related to our former FiberCel and other bone viable matrix ("VBM") products and avoid a material adverse financial consequence; the continued and future acceptance of our products by the medical community; our dependence on 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 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, 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, 2025, 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:

Elutia Investor Relations
ir@elutia.com

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

Assets	June 30, 2026	December 31, 2025
Current assets:		
Cash and cash equivalents	\$ 19,896	\$ 36,350
Accounts receivable, net	1,438	1,734
Inventory	2,649	2,617
Insurance receivables of litigation costs	3,854	4,846
Prepaid expense and other current assets	9,378	10,271
Total current assets	37,215	55,818
Property and equipment, net	2,922	2,511
Intangible assets, net	990	1,529
Operating lease right-of-use assets, and other	2,522	2,492
Total assets	\$ 43,649	\$ 62,350
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,329	\$ 9,143
Current portion of revenue interest obligation	6,412	4,400
Contingent liability for legal proceedings	5,619	11,241
Current operating lease liabilities	685	355
Total current liabilities	21,045	25,139
Long-term revenue interest obligation	—	2,828
Warrant liability	3,163	3,124
Long-term operating lease liabilities	3,695	3,587
Total liabilities	27,903	34,678
Stockholders' equity:		
Common stock	44	43
Additional paid-in capital	207,030	203,842
Accumulated deficit	(191,328)	(176,213)
Total stockholders' equity	15,746	27,672
Total liabilities and stockholders' equity	\$ 43,649	\$ 62,350

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

	Three months ended June 30,		Six months ended June 30,	
	2026	2025	2026	2025
Net sales	\$ 2,427	\$ 2,747	\$ 5,541	\$ 5,698
Cost of goods sold	980	1,294	2,292	2,863
Gross profit	1,447	1,453	3,249	2,835
Operating expenses:				
Sales and marketing	1,366	1,273	2,846	2,268
General and administrative	3,454	3,552	7,545	7,273
Research and development	2,527	989	4,500	1,860
Litigation costs, net	2,057	4,004	2,663	6,576
Total operating expenses	9,404	9,818	17,554	17,977
Loss from operations	(7,957)	(8,365)	(14,305)	(15,142)
Interest income, net	(35)	(491)	(143)	(307)
Other (income) expense, net	(284)	(791)	1,300	(5,873)
Loss before provision for income taxes	(7,638)	(7,083)	(15,462)	(8,962)
Provision for income taxes	8	8	78	16
Net loss from continuing operations	(7,646)	(7,091)	(15,540)	(8,978)
Loss income from discontinued operations	—	(2,519)	425	(4,565)
Net loss	\$ (7,646)	\$ (9,610)	\$ (15,115)	\$ (13,543)
Net loss per share — basic	\$ (0.17)	\$ (0.23)	\$ (0.35)	\$ (0.34)
Net loss per share — diluted	\$ (0.17)	\$ (0.26)	\$ (0.35)	\$ (0.47)
Weighted average common shares outstanding — basic	44,223,722	41,782,556	43,622,360	40,239,372
Weighted average common shares outstanding — diluted	44,223,722	46,308,642	43,622,360	44,765,897

ELUTIA INC.
NON-GAAP GROSS PROFIT AND NON-GAAP GROSS MARGIN RECONCILIATIONS
(Unaudited, in thousands)

	Three months ended June 30,		Six months ended June 30,	
	2026	2025	2026	2025
Net sales	\$ 2,427	\$ 2,747	\$ 5,541	\$ 5,698
Gross profit	1,447	1,453	3,249	2,835
Intangible asset amortization expense	270	270	540	542
Adjusted gross profit (Non-GAAP)	\$ 1,717	\$ 1,723	\$ 3,789	\$ 3,377
Gross margin	59.6%	52.9%	58.6%	49.8%
Adjusted gross margin percentage (Non-GAAP)	70.7%	62.7%	68.4%	59.3%

ELUTIA INC.
EBITDA AND ADJUSTED EBITDA RECONCILIATIONS
(Unaudited, in thousands)

	Three months ended June 30,		Six months ended June 30,	
	2026	2025	2026	2025
Net loss	\$ (7,646)	\$ (9,610)	\$ (15,115)	\$ (13,543)
Interest income expense, net(1)	(35)	(491)	(143)	(307)
Provision for income taxes	8	8	78	16
Depreciation and amortization	348	312	679	598
Earnings before interest, taxes, depreciation and amortization ("EBITDA") (Non-GAAP)	(7,325)	(9,781)	(14,501)	(13,236)
Loss (income) from discontinued operations(2)	—	2,519	(425)	4,565
Stock-based compensation	905	1,028	1,836	2,116
Litigation costs, net(3)	2,057	4,004	2,663	6,576
(Gain) loss on revaluation of warrant liability(4)	(226)	(2,233)	1,429	(7,420)
Warrant issuance expenses	—	—	—	105
Loss on revaluation of revenue interest obligation(5)	—	1,442	—	1,442
Adjusted EBITDA (Non-GAAP)	\$ (4,589)	\$ (3,021)	\$ (8,998)	\$ (5,852)

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

(2) Represents the financial results of the BioEnvelope business sold to Boston Scientific Corporation on October 1, 2025.

(3) 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.

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

(5) Represents the non-cash 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.