Elutia Reports Fourth Quarter and Full Year 2025 Financial Results; Initiates NXT-41 Regulatory Process

March 11, 2026

– Base biologic matrix NXT-41 submitted to FDA; on track for anticipated FDA clearance in second half of 2026 and full NXT-41x clearance in 1H27 –

– $44.4 million in cash and escrowed proceeds at year-end –

– Conference call today at 5:00 p.m. ET / 2:00 p.m. PT –

GAITHERSBURG, Md., March 11, 2026 (GLOBE NEWSWIRE) -- 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, 2025.

Business Highlights:

- **NXT-41x Development Program On Track:** Elutia continues to advance development of NXT-41x, a next-generation antibiotic-eluting biomatrix for plastic and reconstructive surgery. The Company has submitted the 510(k) application for the base biologic matrix, NXT-41, to FDA and anticipates clearance later this year. Clearance for the full NXT-41x drug-eluting biologic is anticipated in the first half of 2027. Surgeon engagement and feedback continue to support the potential of NXT-41x in the $1.5 billion U.S. breast cancer surgery market, where post-operative infection rates remain at 15–20%.
- **Leadership and Commercial Readiness:** Elutia strengthened its Board and leadership team to support commercialization of the NXT-41x platform. Guido J. Neels, Operating Partner at EW Healthcare Partners and former Chief Operating Officer of Guidant Corporation, joined the Company's Board of Directors. Pete Ligotti joined the Company as Chief Commercial Officer following a 20-year career at Integra Life Sciences and will lead the Company's overall commercialization strategy and launch readiness activities.
- **BioEnvelope Sale Closed:** On October 1, 2025, Elutia closed the $88 million cash sale of its EluPro™ and CanGaroo BioEnvelope business to Boston Scientific Corporation, validating the strength of the Company's proprietary drug-eluting biologics platform and providing capital to fund development and launch of NXT-41x.
- **Transformed Balance Sheet:** During the fourth quarter, the Company repaid the full $26.9 million in outstanding principal, accrued interest, and accrued exit fees associated with its loan facility with SWK Holdings. As of December 31, 2025, cash on hand was $36.4 million with an additional $8.0 million held in escrow related to the BioEnvelope divestiture, expected to be released in the fourth quarter of 2026.
- **SimpliDerm Strategic Process Initiated:** Given the progress and growing confidence in the NXT-41x program, Elutia has initiated a process to explore strategic options for its patented SimpliDerm product line. The process aims to sharpen the company's time and resources on the upcoming launch and commercialization of NXT-41x.

"2025 was the year we proved our drug-eluting biologic platform works, and the market wants it," said Dr. Randy Mills, Chief Executive Officer of Elutia. "With the $88 million BioEnvelope divestiture to Boston Scientific, we were able to remove debt and legacy distractions and transform Elutia into a high-velocity organization that's about to shake up the stagnant $1.5 billion breast cancer surgery market. The current standard of care fails one in three women, and to us, that's unacceptable. We are Ridiculously Relentless about ensuring that when a woman undergoes reconstruction, her recovery isn't hijacked by a preventable complication, and we think NXT-41x will do just that. I want to thank the Elutia CRU for an outstanding year and welcome our new members to the team as we fight to ensure our mothers and daughters thrive without compromise."

Fourth Quarter 2025 Financial Results
Net sales and operating results discussed below reflect continuing operations and exclude the divested BioEnvelope business. For the three-month period ended December 31, 2025, as compared to the same period of 2024:

- Overall net sales were $3.3 million, compared to $2.8 million in Q4 2024, an increase of 16%.
- Net sales of SimpliDerm were $2.1 million, compared to $2.3 million in Q4 2024.
- Net sales of Cardiovascular products were $1.2 million, compared to $0.5 million in Q4 2024.
- Gross margin on a GAAP basis was 58.5%, compared to 46.9%.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 66.8%, compared to 56.5%. A reconciliation of GAAP gross margin to adjusted gross margin is included in the accompanying financial tables.
- Total operating expenses were $8.5 million, compared to $8.8 million.

- Loss from continuing operations was $6.6 million, compared to $7.5 million.
- Net loss from continuing operations was $6.5 million, compared to a loss of $7.2 million.
- Income from discontinued operations was $77.3 million, primarily reflecting the gain on the sale of the BioEnvelope business to Boston Scientific Corporation.
- Net income (which includes the gain on the sale of the BioEnvelope business) was $70.8 million, compared to a net loss of $9.1 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 $4.2 million, compared to a loss of $3.4 million. A reconciliation of net income (loss) to adjusted EBITDA is included in the accompanying financial tables.
- Cash balance as of December 31, 2025, was $36.4 million. An additional $8.0 million related to the BioEnvelope divestiture is held in escrow and is expected to be released in the fourth quarter of 2026.
- As of December 31, 2025, there were 42.8 million shares of Class A common stock outstanding with an additional 4.5 million pre-funded warrants outstanding.

Full Year 2025 Financial Results
Net sales and operating results discussed below reflect continuing operations and exclude the divested BioEnvelope business. For the year ended December 31, 2025, as compared to the same period of 2024:

- Overall net sales were $12.3 million, compared to $14.5 million, reflecting the changes in the SimpliDerm and cardiovascular distribution models.
- Net sales of SimpliDerm were $9.1 million, compared to $11.6 million.
- Net sales of Cardiovascular products were $3.2 million, compared to $2.9 million.
- Gross margin on a GAAP basis was 53.7%, compared to 46.4%.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 62.4%, compared to 53.9%. A reconciliation of GAAP gross margin to adjusted gross margin is included in the accompanying financial tables.
- Total operating expenses were $33.5 million, compared to $37.4 million.
- Net loss from continuing operations was $15.9 million, compared to a loss of $45.3 million.
- Income from discontinued operations was $69.3 million, primarily reflecting the gain on the sale of the BioEnvelope business.
- Net income (including the gain on the sale of the BioEnvelope business) was $53.4 million, compared to a net loss of $53.9 million.
- Adjusted EBITDA was a loss of $12.8 million, compared to a loss of $11.2 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 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time to discuss its fourth quarter and full year 2025 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, loss on early repayment of debt, 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 regarding the future success of new products in Elutia’s breast reconstruction business. 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; 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.

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

	Three months ended December 31,		Twelve months ended December 31,	
	2025	2024	2025	2024
Net sales	$ 3,271	$ 2,816	$ 12,293	$ 14,467
Cost of goods sold	1,357	1,494	5,697	7,752
Gross profit	1,914	1,322	6,596	6,715
Operating expenses:				
Sales and marketing	1,902	1,197	5,765	4,988
General and administrative	4,288	4,245	15,080	18,073
Research and development	1,215	727	4,163	2,998
Litigation costs, net	1,070	2,611	8,499	11,368
Total operating expenses	8,475	8,780	33,507	37,427
Loss from continuing operations	(6,561)	(7,458)	(26,911)	(30,712)
Interest (income) expense, net	(345)	138	(387)	934
Other expense (income), net	305	(443)	(10,666)	13,692
Loss from continuing operations before provision for income taxes	(6,521)	(7,153)	(15,858)	(45,338)
Income tax expense (benefit)	(11)	2	13	7
Net loss from continuing operations	(6,510)	(7,155)	(15,871)	(45,345)

Income (loss) from discontinued operations	77,301	(1,906)	69,251	(8,604)
Net income (loss)	$ **70,791**	$ **(9,061)**	$ **53,380**	$ **(53,949)**
Net income (loss) per share – basic	$ 1.66	$ (0.26)	$ 1.29	$ (1.86)
Net income (loss) per share – diluted	$ 1.48	$ (0.26)	$ 0.87	$ (1.86)
Weighted average shares outstanding – basic	42,721,201	34,845,672	41,416,850	29,071,113
Weighted average shares outstanding – diluted	47,243,564	34,845,672	45,942,787	29,071,113

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

Assets	**December 31, 2025**	**December 31, 2024**
Current assets:		
Cash and cash equivalents	$ 36,350	$ 13,239
Accounts receivable, net	1,734	2,276
Inventory	2,617	1,931
Insurance receivables of litigation costs	4,846	4,760
Prepaid expense and other current assets	10,271	1,986
Current assets of discontinued operations	–	1,980
Total current assets	55,818	26,172
Property and equipment, net	2,511	671
Intangible assets, net	1,529	2,600
Operating lease right-of-use assets, and other	2,492	179
Noncurrent assets of discontinued operations	–	6,505
Total assets	$ **62,350**	$ **36,127**
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable, accrued expenses and other	$ 9,143	$ 11,253
Current portion of long-term debt	–	1,250
Current portion of revenue interest obligation	4,400	4,400
Contingent liability for legal proceedings	11,241	20,432
Current operating lease liabilities	355	145
Current liabilities of discontinued operations	–	315
Total current liabilities	25,139	37,795
Long-term debt	–	22,603
Long-term revenue interest obligation	2.828	5,490
Warrant liability	3,124	16,076
Other long-term liabilities	3,587	16
Noncurrent liabilities of discontinued operations	–	407
Total liabilities	34,678	82,387
Stockholders' equity (deficit):		
Common stock	43	35
Additional paid-in capital	203,842	183,298
Accumulated deficit	(176,213)	(229,593)
Total stockholders' equity (deficit)	27,672	(46,260)
Total liabilities and stockholders' equity (deficit)	$ **62,350**	$ **36,127**

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 December 31,		Twelve months ended December 31,	
	2025	2024	2025	2024
Net sales	$ 3,271	$ 2,816	$ 12,293	$ 14,467
Gross profit	1,914	1,322	6,596	6,715
Intangible asset amortization expense	270	270	1,077	1,077
Adjusted gross profit (Non-GAAP)	**$ 2,184**	**$ 1,592**	**$ 7,673**	**$ 7,792**
Gross margin	58.5%	46.9%	53.7%	46.4%
Adjusted gross margin (Non-GAAP)	**66.8%**	**56.5%**	**62.4%**	**53.9%**

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

	Three months ended December 31,		Twelve months ended December 31,	
	2025	2024	2025	2024
Net income (loss)	$ 70,791	$ (9,061)	$ 53,380	$ (53,949)
Interest (income) expense, net(1)	(345)	138	(387)	934
Provision (benefit) for income taxes	(11)	2	13	7
Depreciation and amortization	297	281	1,174	1,124
EBITDA (Non-GAAP)	**70,732**	**(8,640)**	**54,180**	**(51,884)**
(Income) loss from discontinued operations	(77,301)	1,906	(69,251)	8,604
Stock-based compensation	947	1,162	4,397	7,043
Litigation costs, net(2)	1,070	2,611	8,499	11,368
(Gain) loss on revaluation of warrant liability(3)	(906)	(443)	(13,424)	14,878
Loss on early repayment of debt(4)	1,287	–	1,287	–
Warrant issuance expenses	–	–	105	257
Loss (gain) on revaluation of revenue interest obligation(5)	–	–	1,443	(1,443)
Adjusted EBITDA (Non-GAAP)	**$ (4,171)**	**$ (3,404)**	**$ (12,764)**	**$ (11,177)**

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

(4) Represents the loss recognized on the full repayment of the SWK loan facility prior to maturity through the proceeds from the sale of our BioEnvelope business.

(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.