Elutia Reports Third Quarter 2026 Results: As Plastic Surgeons Cite Infection Risk in Every Breast Research Session During National Meeting, NXT-41x Heads to FDA This Quarter, Fully Funded Through Launch

November 5, 2026

- **Infection is a Major Unmet Need in Plastic and Reconstructive Surgery:** Infection risk was cited in all 11 breast research sessions at the American Society of Plastic Surgeons' annual meeting, with serious infection rates reported as high as 23%.
- **NXT-41x In Vivo Study Supports Planned Q4 2026 FDA Submission:** The GLP rabbit antibacterial study achieved its prespecified performance endpoints, with no viable bacteria recovered after either the 8-log MRSA challenges or the 6-log E. coli challenges, demonstrating robust eradication of relevant pathogens.
- **$26 Million in Capital Received:** Elutia added $26 million without an equity offering, which is expected to fund the company through the anticipated clearance and first full-year of NXT-41x commercialization in 2028.
- **Cardiovascular Revenue Grows 20%:** Elutia's cardiovascular business delivered 20% year-over-year revenue growth in the third quarter of 2026 and 65% growth for the first nine months of 2026.

GAITHERSBURG, Md., Nov. 05, 2026 (GLOBE NEWSWIRE) -- Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company"), a drug delivery company built to stop surgical infections, today provided a business update and announced financial results for the third quarter ended September 30, 2026.

> *"Patients and surgeons have been ignored for too long," said Dr. Randy Mills, Chief Executive Officer of Elutia. "Walking the ASPS annual meeting in Houston, I was astonished by the disconnect between what surgeons are worried about and what industry is offering. Infection came up in all 11 breast research sessions, with rates reported as high as 23%. Those numbers tell the story of an unacceptable problem and the definition of a serious unmet medical need.*
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> *"We are out to solve it, and will take the next step this quarter with the NXT-41x FDA submission. After adding $26 million without an equity offering, we believe we have the technology, the team, and the capital to advance NXT-41x toward anticipated clearance in the first half of 2027 and through the first full year of commercial launch in 2028. In doing so, we will help patients thrive without compromise."*

Infection Has Become a Major Focus at ASPS. No Commercial Product Addresses It.

At Plastic Surgery The Meeting 2026 (PSTM 2026), the annual meeting of the American Society of Plastic Surgeons held October 15 to 18 in Houston, the program highlighted a major gap between the prevalence and severity of surgical infections and the lack of products to address them.

Infection risk and prevention were discussed in all 11 breast research sessions, and 70 of 135 (51.9%) oral research presentations addressed infection.

Infection is common despite current best practices. Independent investigators presented data at the meeting showing:

- In a study of 1,094 breasts undergoing immediate implant-based surgery, infection rates were 17.6% in women who did not receive chemotherapy before surgery and 23.0% in those who did (Lopes A, et al., PSTM 2026).
- Another study of 419 breasts treated with perioperative and postoperative antibiotics found infection rates of 19.3% (Fernandez K et al., PSTM 2026).

More systemic antibiotics do not help. In a multicenter study of 4,647 patients at 170 healthcare organizations, extending antibiotics past 24 hours did not reduce infection at 30, 60 or 90 days (Yadav K, et al., PSTM 2026).

The gap on the floor. Despite the intense focus on infection across the scientific program, no commercially available product on the exhibit floor addressed infection in breast surgery. Elutia is developing NXT-41x to address this gap and deliver localized antibiotic therapy directly to the surgical site in reconstructive surgery.

NXT-41x Heads to FDA This Quarter

The FDA review of NXT-41 (biologic surgical matrix without drug) remains on track, with a clearance decision anticipated this quarter. Elutia also intends to submit NXT-41x, its leading drug delivery program, to FDA in the fourth quarter of 2026, following positive results from a key performance study supporting the submission.

NXT-41x demonstrates potent antibacterial activity. NXT-41x is a biologic matrix with an antibiotic coating on one side only. In a GLP rabbit study of infection, the bacterial challenge was applied directly to the uncoated side, a worst-case test. NXT-41x met its predetermined performance endpoints, achieving complete eradication of an 8-log MRSA and a 6-log E. coli challenge, with no viable bacteria recovered from either the matrix or the surrounding tissue. By contrast, 100% of animals implanted with a matrix without antibiotics developed heavy colonization by the offending pathogens. MRSA, short for methicillin-resistant Staphylococcus aureus, is a highly drug-resistant form of the most common pathogen in breast surgery, making these results especially relevant to surgeons and patients.

ELUTIA®
Medicine *Humanized*

Powerful Antibacterial Activity

In a 7-day GLP rabbit study, the antimicrobial effect of NXT-41x was tested against aggressive bacterial strains. The bacterial load was higher than would ever occur in a surgical procedure.

MRSA — **8-log challenge**

E. coli — **6-log challenge**

Matrix without antibiotics	NXT-41x
100%	**Zero**
of animals developed heavy colonization	**organisms detected at 7 days**
Heavy colonization by both pathogens	No viable bacteria recovered from either the matrix or the surrounding tissue

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Surgeons back the approach. At PSTM 2026, Elutia held an in-person meeting of its NXT-41x Surgeon Steering Committee, which provided very positive feedback on the design and performance of NXT-41x. Surgeons were clear: "It's about the drugs being in the right place at the right time." For NXT-41x, the right place means powerful antibiotics uniformly distributed across the entire surgical site, where systemic antibiotics fail to reach. The right time means 30 days of coverage, through drain removal.

Built for launch. Elutia's automated drug-coating system is positioned for commercial production, with at least $300 million in revenue capacity, and is designed to support gross margins above 80% at scale.

Funding Milestones Achieved

Elutia delivered all three funding milestones it named in August, on schedule:

- **October 1:** Boston Scientific released the full $8 million held in escrow from the 2025 sale of the BioEnvelope business, with no claims.
- **August 17:** Elutia closed the sale of its SimpliDerm business to Cellution Biologics Inc., receiving $8 million at closing. Elutia is also eligible to receive up to $3 million in contingent technology transfer and commercial milestone payments over 18 months.
- **August 11:** Elutia closed a $15 million loan facility with Avenue Capital Group, with $10 million funded at closing and an additional $5 million available following NXT-41x FDA clearance.

Collectively, these transactions added $26 million in 51 days, without an equity offering. The Company believes it has sufficient funding through NXT-41x clearance and launch. Upside to that runway includes the additional $5 million from Avenue Capital, up to $3 million in SimpliDerm milestone payments, and potential proceeds from the sale of the Cardiovascular business.

Cardiovascular sales grew 20% to $1.1 million in the third quarter, up from $0.9 million in the third quarter of 2025, and increased 65% for the first nine months, with a third quarter adjusted gross margin (non-GAAP) of 85%. The strategic process for the business remains on track for 2026. As the business grows, Elutia is considering a transaction only on terms that reflect its value. Elutia's current cash runway through the anticipated first full year of NXT-41x commercialization does not depend on a Cardiovascular transaction.

Funded Catalysts

Milestone	Expected Timing

Avenue loan, SimpliDerm close, $8 million holdback	Delivered
NXT-41 FDA clearance decision	4Q 2026
NXT-41x FDA submission	4Q 2026
Potential Cardiovascular transaction	4Q 2026
NXT-41x FDA clearance decision	1H 2027
NXT-41x commercial soft launch	2H 2027
NXT-41x full commercial launch	2028

Third Quarter 2026 Financial Results

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

- Net sales were $1.1 million, compared to $0.9 million, an increase of 20.4%.
- Gross margin on a GAAP basis was 61.7%, compared to 52.8%.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 85.5%, compared to 81.3%. A reconciliation of GAAP gross margin to adjusted gross margin is included in the accompanying financial tables.
- Total operating expenses were $7.6 million, compared to $6.4 million. The increase was driven by a $1.9 million increase in research and development expense supporting the NXT-41 and NXT-41x programs, partially offset by a $0.7 million reduction in net litigation costs.
- Loss from operations was $6.9 million, compared to $5.9 million.
- Net loss from continuing operations was $6.5 million, compared to $1.0 million.
- Income from discontinued operations was $5.2 million, compared to a loss of $2.8 million.
- Net loss was $1.3 million, compared to $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 $5.6 million, compared to a loss of $3.4 million. A reconciliation of net loss to adjusted EBITDA is included in the accompanying financial tables.
- Cash and cash equivalents at September 30, 2026 were $29.1 million. On October 1, 2026, the Company received the $8 million Boston Scientific holdback, which is not included in this balance.

Conference Call

Elutia will host a conference call on November 5, 2026 at 5:00 p.m. Eastern Time / 2:00 p.m. Pacific Time to discuss its third 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 Inc. (Nasdaq: ELUT) is a drug delivery company built to stop surgical infections. The Company developed and launched EluPro, the first antibiotic-eluting bioenvelope designed to protect patients receiving pacemakers and defibrillators, and in 2025 sold that business to Boston Scientific Corporation. Elutia's lead program, NXT-41x, builds on the same drug-eluting platform and is designed to deliver two powerful antibiotics directly to the surgical site, stopping infection before it starts. 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 and derivative liabilities, 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; the planned submission of NXT-41x to the FDA in the fourth quarter of 2026; 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 into 2029, including 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; our receipt of the contingent technology transfer and commercial milestone payments associated with the sale of our SimpliDerm business; the outcome and timing of the previously announced strategic process for our Cardiovascular business; the results, interpretation and predictive value of the GLP animal study of NXT-41x described in this press release; 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 submit NXT-41x to the FDA on the anticipated timeline and 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 comply with the covenants in, and to draw the second tranche term loan under, the Avenue Capital Group loan agreement; 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 sale of the SimpliDerm business, including the risk that the technology transfer and commercial milestone payments from the sale are reduced, delayed, or not earned or received and the outcome of any legal proceedings that may be instituted against us following the sale; 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; our ability to satisfy the remaining Ligand Pharmaceuticals Incorporated revenue interest obligation, which expires May 31, 2027; 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, including our dependence on Cook Biotech as sole supplier for our remaining Cardiovascular 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, 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.

Contacts

Investors:

Elutia Investor Relations

ir@elutia.com

Financial Tables

ELUTIA INC.

CONSOLIDATED BALANCE SHEET DATA

(Unaudited, in thousands)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 29,093	$ 36,350
Accounts receivable, net	1,466	1,734
Inventory	272	438
Insurance receivables of litigation costs	2,527	4,846
Prepaid expense and other current assets	8,809	10,271
Current assets of discontinued operations	—	2,179
Total current assets	42,167	55,818
Property and equipment, net	2,830	2,511
Intangible assets, net	720	1,529
Operating lease right-of-use assets, and other	2,476	2,492
Total assets	**$ 48,193**	**$ 62,350**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,962	$ 9,143
Current portion of revenue interest obligation	4,325	4,400
Contingent liability for legal proceedings	3,465	11,241
Other current liabilities	1,278	355
Total current liabilities	16,030	25,139
Long-term debt, net	8,098	—
Long-term revenue interest obligation	—	2,828
Warrant and derivative liabilities	4,201	3,124
Other long-term liabilities	4,539	3,587
Total liabilities	32,868	34,678
Stockholders' equity:		
Common stock	44	43
Additional paid-in capital	207,894	203,842
Accumulated deficit	(192,613)	(176,213)
Total stockholders' equity	15,325	27,672
Total liabilities and stockholders' equity	**$ 48,193**	**$ 62,350**

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,	
	2026	2025	2026	2025
Net sales	$ 1,137	$ 944	$ 3,306	$ 2,007
Cost of goods sold	435	446	1,299	1,248
Gross profit	702	498	2,007	759
Operating expenses:				
Sales and marketing	756	921	2,423	1,889
General and administrative	3,748	3,505	11,173	10,770
Research and development	2,977	1,088	7,477	2,948
Litigation costs, net	117	853	2,780	7,429
Total operating expenses	7,598	6,367	23,853	23,036
Loss from operations	(6,896)	(5,869)	(21,846)	(22,277)
Interest (income) expense, net	278	265	135	(42)
Other (income) expense, net	(679)	(5,098)	621	(10,971)
Loss before provision for income taxes	(6,495)	(1,036)	(22,602)	(11,264)
Provision for income taxes	8	8	86	24
Net loss from continuing operations	(6,503)	(1,044)	(22,688)	(11,288)
Income (loss) from discontinued operations	5,218	(2,824)	6,288	(6,123)
Net loss	**$ (1,285)**	**$ (3,868)**	**$ (16,400)**	**$ (17,411)**
Net loss per share — basic	$ (0.03)	$ (0.09)	$ (0.37)	$ (0.43)
Net loss per share — diluted	$ (0.04)	$ (0.19)	$ (0.37)	$ (0.66)
Weighted average common shares outstanding — basic	44,313,491	42,431,314	43,847,094	40,965,925
Weighted average common shares outstanding — diluted	47,538,170	46,957,199	43,847,094	45,492,271

ELUTIA INC.

NON-GAAP GROSS PROFIT AND NON-GAAP GROSS MARGIN RECONCILIATIONS

(Unaudited, in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Net sales	$ 1,137	$ 944	$ 3,306	$ 2,007
Gross profit	702	498	2,007	759
Intangible asset amortization expense	270	269	810	807
Adjusted gross profit (Non-GAAP)	**$ 972**	**$ 767**	**$ 2,817**	**$ 1,566**
Gross margin	61.7%	52.8%	60.7%	37.8%
Adjusted gross margin percentage (Non-GAAP)	**85.5%**	**81.3%**	**85.2%**	**78.0%**

ELUTIA INC.

EBITDA AND ADJUSTED EBITDA RECONCILIATIONS

(Unaudited, in thousands)

	Three months ended September 30,		Nine months ended September 30,	
	2026	2025	2026	2025
Net loss	$ (1,285)	$ (3,868)	$ (16,400)	$ (17,411)
Interest expense (income), net (1)	278	265	135	(42)
Provision for income taxes	8	8	86	24
Depreciation and amortization	350	279	1,029	877
Earnings before interest, taxes, depreciation and amortization ("EBITDA") (Non-GAAP)	(649)	(3,316)	(15,150)	(16,552)
(Income) loss from discontinued operations	(5,218)	2,824	(6,288)	6,123
Stock-based compensation	860	1,334	2,698	3,450
Litigation costs, net (2)	117	853	2,780	7,429
(Gain) loss on revaluation of warrant and derivative liabilities (3)	(661)	(5,098)	768	(12,518)
Warrant issuance expenses	—	—	—	105
Loss on revaluation of revenue interest obligation (4)	—	—	—	1,442
Adjusted EBITDA (Non-GAAP)	**$ (5,551)**	**$ (3,403)**	**$ (15,194)**	**$ (10,521)**

(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, Prefunded Warrants, Avenue Warrants and Avenue Conversion Option.

(4) Represents the non-cash revaluation of the revenue interest obligation.

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/746698a9-1b32-44ea-8324-de770595e29b