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 9, 2024

ELUTIA INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39577**	**47-4790334**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

12510 Prosperity Drive, Suite 370, Silver Spring, MD 20904
(Address of principal executive offices) (Zip Code)

(240) 247-1170
(Registrant's telephone number, including area code)

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	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 9, 2024, Elutia Inc. (the "Company" or "Elutia") issued a press release announcing its results for the first quarter ended March 31, 2024. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Press Release of Elutia Inc., dated May 9, 2024
104	Cover Page Interactive Data File (formatted as Inline XBRL document)

SIGNATURES

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

ELUTIA INC.
(Registrant)

Date: May 9, 2024

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

Exhibit 99.1

Elutia Announces First Quarter 2024 Results: SimpliDerm® Sales Increase 55%,
CanGaroo®RM on Track for Second Quarter 2024 FDA Clearance

SILVER SPRING, Md., May 9, 2024 — Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company"), a company pioneering drug-eluting biomatrix products, today provided a business update and financial results for the first quarter ended March 31, 2024.

Business Highlights:

- Generated strong revenue growth for proprietary product lines in the first quarter of 2024, led by SimpliDerm net sales increasing 55% compared to the first quarter of 2023
- FDA interactions regarding CanGarooRM, Elutia's antibiotic-eluting biologic envelope, continue to be positive
- Addressing the final details for CanGarooRM clearance; anticipate FDA decision in the second quarter of 2024
- Preparing for launch of CanGarooRM in the second half of 2024

"We are progressing through the regulatory process for CanGarooRM with one goal: FDA clearance in the second quarter for the world's first antibiotic-eluting biologic envelope," stated Dr. Randy Mills, Elutia's Chief Executive Officer. "The pacemaker and implantable defibrillator protection market is valued at $600 million and has only one legacy player offering a fully synthetic envelope. We aim to disrupt this space with our proprietary technology that is both antimicrobial and regenerative, thereby setting a new standard for excellence in patient outcomes."

Dr. Mills continued, "Our Women's Health team is successfully executing a similar strategy with SimpliDerm, achieving robust sales growth of 55%. This sharp sales increase spotlights the crucial role SimpliDerm plays in supporting a woman's recovery following mastectomy. I offer my sincere thanks to the entire Elutia CRU for delivering another spectacular quarter."

CanGarooRM Update

Following the successful submission of the 510(k) premarket notification to the FDA in December 2023, Elutia has been in positive, ongoing discussions with the Agency and expects to close out any remaining inquiries within the month. As a result, the Company anticipates a positive FDA decision by the end of June 2024.

With only one competitor in the $600 million pacemaker and implantable defibrillator protection market, CanGarooRM represents immense potential in the drug-eluting market. In anticipation of the pending regulatory clearance, Elutia continues to fortify its operational and commercial strength and expects to initiate manufacturing and commercial introduction of CanGarooRM in the second half of this year.

First Quarter 2024 Financial Results

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

- Overall net sales were $6.7 million, an increase of 5%.
- Net sales of SimpliDerm were $3.6 million, compared to $2.3 million, an increase of 55%, as customer awareness and acceptance accelerated within the $1.6 billion market for use of the product in breast reconstruction surgeries.
- Net sales of CanGaroo were $2.4 million, consistent with the prior-year quarter, as the Company prepares for the clearance and market introduction of CanGarooRM.
- Net sales of Cardiovascular products were $0.8 million, a decline of 56%, reflecting the transition in the United States to indirect sales through the Company's exclusive distribution relationship with LeMaitre Vascular.
- Gross margin on a GAAP basis was 42%, compared to 53%. The year-over-year reduction was primarily due to the transition to indirect sales within the Cardiovascular product line associated with the LeMaitre Vascular distribution relationship mentioned above.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 55%, compared to 66%.
- Total operating expenses were $11.3 million, compared to $11.7 million. The overall decline included reductions in sales and marketing, research and development, and litigation costs, offset by an increase in general and administrative resulting primarily from higher non-cash stock-based compensation expense.
- Loss from operations was $8.5 million, compared to $8.3 million.
- Net loss was $18.0 million, compared to a net loss of $8.0 million. The increased net loss was primarily due to a $9.6 million non-cash charge in the first quarter of 2024 related to the revaluation of the Company's liability on its outstanding warrants.
- Adjusted EBITDA (a non-GAAP measure that excludes from net loss certain non-operating, non-cash and non-recurring items) was a loss of $3.6 million, compared to a loss of $4.8 million. A reconciliation of net loss to adjusted EBITDA is included in the accompanying financial tables.
- Cash balance as of March 31, 2024 was $12.6 million.

Conference Call

Elutia will host a conference call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time to discuss its first quarter 2024 financial results and performance.

The conference call can be accessed using the following information:

Webcast: Click here
U.S. Investors: 877-407-8029
International Investors: 201-689-8029
Conference ID: 13746000

Individuals interested in listening to the conference call are required to register online. Participants are recommended to log in approximately 10 minutes before the start of the call. A live and archived webcast of the event and the accompanying presentation materials will be available on the "Investors" section of the Elutia website at investors.elutia.com.

About Elutia

Elutia develops and commercializes biologic products to improve compatibility between medical devices and the patients who need them. With a growing population in need of implantable technologies, Elutia's mission is humanizing medicine so patients can thrive without compromise. For more information, visit www.Elutia.com.

Non-GAAP Disclosure

In addition to the Company's financial results determined in accordance with U.S. GAAP, the Company provides non-GAAP measures that it determines to be useful in evaluating its operating performance and liquidity. The Company presents in this press release the following non-GAAP financial measures: earnings before interest, taxes, depreciation and amortization ("EBITDA"), adjusted earnings before interest, taxes, depreciation and amortization ("adjusted EBITDA"), adjusted gross margin and adjusted gross profit. The Company defines EBITDA as GAAP net loss excluding interest expense, income tax expense, depreciation and amortization, and the Company defines adjusted EBITDA as EBITDA excluding income from discontinued operations, stock-based compensation, FiberCel litigation costs, loss on extinguishment of debt, net of gain on debt forgiveness, loss on revaluation of warranty liability and gain on revaluation of revenue interest obligation. The Company defines adjusted gross profit and adjusted gross margin as GAAP gross profit and GAAP gross margin, respectively, excluding amortization of acquired intangible assets. The amortization of these intangible assets will recur in future periods until such intangible assets have been fully amortized. Management believes that presentation of non-GAAP financial measures provides useful supplemental information to investors and facilitates the analysis of the Company's core operating results and comparison of operating results across reporting periods. The Company uses this non-GAAP financial information to establish budgets, manage the Company's business, and set incentive and compensation arrangements. Non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental information purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. For a reconciliation of these non-GAAP measures to GAAP, see below "Non-GAAP Reconciliations of EBITDA and Adjusted EBITDA" and "Non-GAAP Reconciliations of Adjusted Gross Profit and Adjusted Gross Margin."

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements can be identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "promise" or similar references to future periods. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including any statements and information concerning our future interactions with the U.S. Food and Drug Administration ("FDA") regarding CanGarooRM; expectations for FDA clearance of CanGarooRM, including the timing and anticipated success thereof; preparations for the launch of CanGarooRM, including the timing and anticipated success thereof; the size of the pacemaker and implantable defibrillator protection market and the potential of CanGarooRM to compete in that market; and our future strategy with respect to SimpliDerm. These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied in the forward-looking statements, including, but not limited to the following: our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates; our ability to continue as a going concern; 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 related to FiberCel and VBM and avoid a material adverse financial consequence; our ability to achieve or sustain profitability; our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings; our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales; our dependence on a limited number of third-party suppliers and manufacturers, which, in certain cases are exclusive suppliers for products essential to our business; our ability to successfully realize the anticipated benefits of the sale of our Orthobiologics Business; physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products; the continued and future acceptance of our products by the medical community; 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; and 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, 2023, 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:
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ELUTIA INC.
CONSOLIDATED BALANCE SHEET DATA
(Unaudited, in thousands)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 12,551	$ 19,276
Accounts receivable, net	4,406	3,263
Inventory	3,052	3,853
Receivables of litigation costs	2,031	2,696
Prepaid expense and other assets	1,946	2,165
Total current assets	23,986	31,253
Property and equipment, net	171	172
Intangible assets, net	10,822	11,671
Operating lease right-of-use assets, and other	383	332
Total assets	$ 35,362	$ 43,428
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	$ 14,085	$ 12,676
Current portion of long-term debt and revenue interest obligation	8,174	15,062
Contingent liability for FiberCel litigation	15,591	15,024
Current operating lease liabilities	217	275
Total current liabilities	38,067	43,037
Long-term debt	19,738	20,356
Long-term revenue interest obligation	7,659	5,360
Warrant liability	19,503	12,760
Other long-term liabilities	694	515
Total liabilities	85,661	82,028
Stockholders' equity (deficit):		
Common stock	24	23
Additional paid-in capital	143,315	137,021
Accumulated deficit	(193,638)	(175,644)
Total stockholders' equity (deficit)	(50,299)	(38,600)
Total liabilities and stockholders' equity	$ 35,362	$ 43,428

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

	Three months ended March 31,	
	2024	**2023**
Net sales	$ 6,694	$ 6,392
Cost of goods sold	3,851	3,018
Gross profit	2,843	3,374
Operating expenses:		
Sales and marketing	3,309	4,691
General and administrative	5,056	3,520
Research and development	1,172	1,591
FiberCel litigation costs	1,785	1,911
Total operating expenses	11,322	11,713
Loss from continuing operations	(8,479)	(8,339)
Interest expense	1,313	1,430
Other (income) expense, net	8,194	-
Loss before provision for income taxes	(17,986)	(9,769)
Provision for income taxes	8	12
Net loss from continuing operations	(17,994)	(9,781)
Income from discontinued operations	-	1,807
Net Loss	(17,994)	(7,974)
Net loss from continuing operations per share basic and diluted	$ (0.75)	$ (0.61)
Net income (loss) from discontinued operations per share basic and diluted	$ -	$ 0.11
Weighted average common shares outstanding - basic and diluted	23,912,326	16,149,567

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 March 31,	
	2024	**2023**
Net sales	$ 6,694	$ 6,392
Gross profit	2,843	3,374
Intangible asset amortization expense	849	849
Adjusted gross profit (non-GAAP)	$ 3,692	$ 4,223
Gross margin	42.5%	52.8%
Adjusted gross margin percentage (non-GAAP)	55.2%	66.1%

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

	Three months ended March 31,	
	2024	**2023**
Net loss	$ (17,994)	$ (7,974)
Interest expense [(1)]	1,313	1,430
Provision for income taxes	8	12
Depreciation and amortization	864	947
Earnings before interest, taxes, depreciation and amortization (“EBITDA”) (non-GAAP)	(15,809)	(5,585)
Income from discontinued operations	-	(1,807)
Stock-based compensation	2,197	684
FiberCel litigation costs [(2)]	1,785	1,911
Loss on revaluation of warranty liability [(3)]	9,637	-
Gain on revaluation of revenue interest obligation [(4)]	(1,443)	-
Adjusted EBITDA (non-GAAP)	$ (3,633)	$ (4,797)

(1) Represents interest expense recorded on all outstanding long-term debt as well as the revenue interest obligation.
(2) Represents FiberCel litigation costs consisting primarily of legal fees and the estimated and actual costs to resolve the outstanding FiberCel litigation cases offset by the estimated amounts recoverable and recovered under insurance, indemnity and contribution agreements for such costs.
(3) Represents non-cash expense attributable to the revaluation of Common Warrants and Prefunded Warrants issued in connection with a private offering of Class A common stock on September 21, 2023.
(4) Represents the gain on the revaluation of the revenue interest obligation. At each reporting period, the value of the revenue interest obligation is re-measured based on current estimates of future payments, with changes to be recorded in the consolidated statements of operations using the catch-up method.