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): March 7, 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 March 7, 2024, Elutia Inc. (the "Company" or "Elutia") issued a press release announcing its results for the fourth quarter and full year ended December 31, 2023. 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 March 7, 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: March 7, 2024

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

Exhibit 99.1

Elutia Reports Fourth Quarter and Full Year 2023 Financial Results: Anticipates CanGarooRM® Clearance Decision in First Half of 2024

SILVER SPRING, Md., March 7, 2024 — Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company") today provided a business update and reported financial results for the fourth quarter and full year ended December 31, 2023.

Business Highlights:

- Achieved strong annual revenue growth for both proprietary product lines, with sales increasing for SimpliDerm by 38% and CanGaroo by 3.4%.
- Submitted a 510(k) premarket notification to the U.S. Food and Drug Administration ("FDA" or "Agency") for CanGarooRM, Elutia's next-generation drug-eluting biomatrix product.
- FDA review and interaction for CanGarooRM has resulted in no requests for additional data to date. The Company remains on track for a clearance decision in the first half of 2024.
- Successfully closed the divestiture of the orthobiologics business, generating gross cash proceeds of $14.6 million.
- Established a Strategic Advisory Committee of industry experts to prepare for commercial launch of CanGarooRM.

"After years of pioneering development, we are on the verge of introducing the drug-eluting biomatrix that promises to remove compromise from patient care," stated Dr. Randy Mills, Elutia's Chief Executive Officer. "In 2023, we completed the groundwork for our flagship product, CanGarooRM, resulting in a high-quality submission to FDA. Since then, our interactions with the Agency have been positive, and we look forward to a clearance decision in the first half of this year."

Dr. Mills continued, "I'd like to thank our dedicated commercial and operational teams, who, throughout this process, have stayed laser-focused, delivering robust sales figures across our SimpliDerm and CanGaroo product lines. They are now focused on a coordinated and disciplined product rollout of CanGarooRM, ensuring its full potential is realized."

CanGarooRM Update

In December 2023, Elutia submitted a 510(k) premarket notification to the FDA for CanGarooRM following a successful pre-submission meeting with the FDA. The Company is in ongoing discussions with FDA regarding the submission. To date, clarification requests from the Agency have been limited to items within the new submission, and no additional data has been requested. Elutia expects the FDA's clearance decision in the first half of 2024 and is preparing for commercial launch.

CanGarooRM is uniquely positioned for success in the drug-eluting envelope market, estimated at over $600 million annually in the United States. As the second market entrant and the only product offering a combination of a biological envelope and potent antibiotics, CanGarooRM is poised to compete effectively. Surgeons particularly appreciate the handling characteristics of a natural biological product. Elutia has developed a focused launch plan, leveraging the Company's proprietary sales force and distribution network. The Company's commercial team, equipped with extensive product knowledge and experience, is ready to engage healthcare professionals to drive adoption.

2023 Financial Results

For the year ended December 31, 2023, as compared to 2022 (where applicable):

- Overall net sales were $24.7 million, compared to $23.8 million. The increase was driven by a $2.8 million increase in Women's Health sales and a $0.3 million increase in Device Protection. Growth in Women's Health and Device Protection was partially offset by a reduction in sales in the Cardiovascular line of business due to the commencement of the Company's distribution agreement with LeMaitre Vascular, which provides for sales at a contracted price to the distributor, whereas sales prior to such agreement were made at end-user pricing.
- Gross margin on a GAAP basis, which includes amortization of acquired intangible assets, was 45%, compared to 49%. The reduction was primarily due to the commencement of the LeMaitre Vascular distribution agreement described above.
- Adjusted gross margin (a non-GAAP measure that excludes amortization of acquired intangible assets) was 58%, compared to 63%. A reconciliation of adjusted gross margin to gross margin is provided in the financial tables below.
- Total operating expenses were $41.6 million, compared to $46.8 million. The reduction resulted from efforts to optimize the Company's operations, primarily in sales and marketing and research and development.
- Net loss was $37.7 million, compared to a net loss of $32.9 million.
- Adjusted EBITDA (a non-GAAP measure) was a loss of $14.6 million, compared to a loss of $22.9 million, reflecting the significant improvement in the Company's operational performance. Adjusted EBITDA excludes from net loss certain non-operating, non-cash and non-recurring items. A reconciliation of adjusted EBITDA to net loss is provided in the financial tables below.
- Cash was $19.3 million as of December 31, 2023.

Fourth Quarter 2023 Financial Results

For the three-month period ended December 31, 2023, as compared to the same period of 2022:

- Overall net sales were $5.9 million, compared to $6.6 million. The decrease of 11% was primarily due to a $1.3 million decrease in sales of Cardiovascular products resulting from the commencement of the LeMaitre Vascular distribution relationship, partially offset by a $0.8 million increase in SimpliDerm sales.
- Gross margin on a GAAP basis was 36%, compared to 47%. The year-over-year reduction was primarily due to the commencement of the LeMaitre Vascular distribution relationship for the Company's Cardiovascular products.
- Adjusted gross margin (a non-GAAP measure) was 51%, compared to 59%.
- Total operating expenses were $10.6 million, compared to $12.6 million.
- Net loss was $9.3 million, compared to a net loss of $5.4 million.
- Adjusted EBITDA (a non-GAAP measure) was a loss of $4.5 million, compared to a loss of $4.6 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 fourth quarter and full year 2023 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: 13744499

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 results of operations, financial position, and business strategy; expectations regarding our products and their targeted effects; plans for our sales and marketing growth; expectations regarding our recently completed sale of our Orthobiologics Business to Berkeley Biologics, LLC ("Berkeley"), including potential payment of post-closing earnout payments; our anticipated expansion of our product development and research activities; increases in expenses and seasonality; expectations regarding our competitive advantages, and overall clinical and commercial success; expectations regarding the pending lawsuits and claims related to our recall of a single lot of Fiber Viable Bone Matrix ("FiberCel"), amounts recoverable under insurance, indemnity and contribution agreements and the impact of such lawsuits and claims on our future financial position; expectations regarding the potential emergence of lawsuits, claims and regulatory findings related to our recall of a single lot of the viable bone matrix ("VBM") products, amounts recoverable under insurance, indemnity and contribution agreements and the impact of such lawsuits and claims on our future financial position; our expectations and plans regarding pursuit of any strategic transactions; and our expectations relating to the U.S. Food and Drug Administration ("FDA") regulatory process for the CanGarooRM® Antibacterial Envelope, including our expectations with respect to the timing and outcome of any FDA approval decisions, 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, 2022, 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:
Matt Steinberg
FINN Partners
matt.steinberg@finnpartners.com

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 19,276	$ 16,989
Accounts receivable, net	3,263	3,774
Inventory	3,853	4,240
Receivables of FiberCel litigation costs	2,696	13,813
Prepaid expense and other assets	2,165	2,387
Current assets of discontinued operations	-	9,496
Total current assets	31,253	50,699
Property and equipment, net	172	245
Intangible assets, net	11,671	15,069
Operating lease right-of-use assets, and other	332	320
Noncurrent assets of discontinued operations	-	2,508
Total assets	$ 43,428	$ 68,841
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	$ 12,676	$ 11,104
Current portion of long-term debt and revenue interest obligation	15,062	8,990
Contingent liability for FiberCel litigation	15,024	17,360
Current operating lease liabilities	275	232
Current liabilities of discontinued operations	-	4,929
Total current liabilities	39,796	42,615
Long-term debt	20,356	24,260
Long-term revenue interest obligation	5,360	5,916
Warrant liability in connection with PIPE offering	12,760	-
Other long-term liabilities	515	127
Noncurrent liabilities of discontinued operations	-	956
Total liabilities	82,028	73,874
Stockholders' equity (deficit):		
Common stock	23	16
Additional paid-in capital	137,021	132,939
Accumulated deficit	(175,644)	(137,988)
Total stockholders' equity (deficit)	(38,600)	(5,033)
Total liabilities and stockholders' equity	$ 43,428	$ 68,841

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,	
	2023	2022	2023	2022
Net sales	$ 5,875	$ 6,592	$ 24,745	$ 23,849
Cost of goods sold	3,751	3,526	13,692	12,210
Gross profit	2,124	3,066	11,053	11,639
Operating expenses:				
Sales and marketing	2,572	4,178	13,087	17,850
General and administrative	3,967	3,263	14,104	16,051
Research and development	1,381	1,860	4,399	7,727
FiberCel litigation costs	2,711	3,292	9,989	5,200
Total operating expenses	10,631	12,593	41,579	46,828
Loss from continuing operations	(8,507)	(9,527)	(30,526)	(35,189)
Interest expense	1,511	1,452	5,796	5,118
Other (income) expense, net	5,211	(4,962)	4,899	(4,159)
Loss before provision for income taxes	(15,229)	(6,017)	(41,221)	(36,148)
Provision for income taxes	(8)	(2)	28	34
Net loss from continuing operations	(15,221)	(6,015)	(41,249)	(36,182)
Income from discontinued operations	5,905	575	3,593	3,285
Net Loss	(9,316)	(5,440)	(37,656)	(32,897)
Net loss from continuing operations per share basic and diluted	$ (0.66)	$ (0.42)	$ (2.27)	$ (2.62)
Net income (loss) from discontinued operations per share basic and diluted	$ 0.25	$ 0.04	$ 0.20	$ 0.24
Weighted average common shares outstanding - basic and diluted	23,195,190	14,468,823	18,160,822	13,832,887

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,	
	2023	2022	2023	2022
Net sales	$ 5,875	$ 6,592	$ 24,745	$ 23,849
Gross profit	2,124	3,066	11,053	11,639
Intangible asset amortization expense	851	850	3,398	3,398
Adjusted gross profit (Non-GAAP)	$ 2,975	$ 3,916	$ 14,451	$ 15,037
Gross margin	36.2%	46.5%	44.7%	48.8%
Adjusted gross margin percentage (Non-GAAP)	50.6%	59.4%	58.4%	63.1%

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,	
	2023	2022	2023	2022
Net loss	$ (9,316)	$ (5,440)	$ (37,656)	$ (32,897)
Interest expense [1]	1,511	1,452	5,796	5,118
Provision (benefit) for income taxes	(8)	(2)	28	34
Depreciation and amortization	868	919	3,618	3,566
Earnings before interest, taxes, depreciation and amortization ("EBITDA") (Non-GAAP)	(6,945)	(3,071)	(28,214)	(24,179)
Income from discontinued operations	(5,905)	(575)	(3,593)	(3,285)
Stock-based compensation	424	750	2,296	3,503
FiberCel litigation costs [2]	2,711	3,292	9,989	5,200
Loss on extinguishment of debt, net of gain on debt forgiveness [3]	-	-	-	803
Loss on revaluation of warranty liability [4]	5,210	-	4,898	-
Gain on revaluation of revenue interest obligation [5]	-	(4,962)	-	(4,962)
Adjusted EBITDA (Non-GAAP)	$ (4,505)	$ (4,566)	$ (14,624)	$ (22,920)

(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 loss related to debt refinancing in August 2022 and the associated prepayment fees, payment of unaccrued exit fees and the write-off of unamortized deferred financing costs, which collectively resulted in a loss of $1.2 million. Such loss was offset by other income of $0.4 million related to the forgiveness of interest accrued on the promissory note to a tissue supplier upon repayment of such note in August 2022.
(4) 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.
(5) 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.