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): August 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 August 7, 2024, Elutia Inc. (the "Company" or "Elutia") issued a press release announcing its results for the second quarter ended June 30, 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 August 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: August 7, 2024

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

Exhibit 99.1

Elutia Announces Second Quarter 2024 Results

Launch Production of EluPro® Underway, Commercial Team Expansion Continues, Financial Position Solidified

SILVER SPRING, Md., August 7, 2024 — Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company"), a pioneer in drug-eluting biomatrix products, today provided a business update and financial results for the second quarter ended June 30, 2024.

Business Highlights:

- Received FDA clearance for EluPro®, the first antibiotic-eluting BioEnvelope for protecting patients with implantable electronic devices, including pacemakers, defibrillators, and neuromodulation devices.
- Completed a successful FDA inspection of the EluPro and CanGaroo manufacturing facility in Roswell, GA.
- Commenced manufacturing of EluPro ahead of commercial launch.
- Received enthusiastic responses from potential industry partners, treating physicians and hospital purchasing organizations regarding EluPro's availability.
- Strengthened the balance sheet with approximately $29.0 million in gross proceeds from a registered direct offering and exercise of warrants.
- Appointed industry veteran Ryan Marques, Ph.D., MBA, as Vice President of Operations.
- Initiated the expansion of commercial teams for both EluPro and SimpliDerm.

"With the FDA clearance of EluPro, we are equipped with what we believe is a superior product, which is bringing us significant attention from a range of participants in the multi-billion-dollar pacemaker and defibrillator market," said Dr. Randy Mills, Elutia's Chief Executive Officer. "Additionally, our manufacturing and quality systems were evaluated by the FDA with no deficiencies noted, clearing the way for commercial production of EluPro. Simultaneously, we have initiated the value analysis committee submission process, all in a coordinated effort to ensure this revolutionary product reaches our surgeon partners, enabling them to provide the best care for their patients."

Dr. Mills continued, "With a robust financial position, we are laser focused on the successful launch of EluPro and further expanding our commercial footprint. We are systematically building our commercial teams for both EluPro and SimpliDerm and intensifying business development efforts to extend the reach of our drug-eluting biomatrix technology into adjacent markets covered under the EluPro approval. I want to thank our incredible team, who did a beautiful job executing on our plan to maximize the value of Elutia for all stakeholders."

Second Quarter 2024 Financial Results

For the three-month period ended June 30, 2024, as compared to the same period of 2023:

- Overall net sales were essentially unchanged at $6.3 million.
- Net sales of CanGaroo increased 19% to $2.6 million, compared to $2.2 million.
- Net sales of SimpliDerm increased 7% to $2.6 million, compared to $2.4 million.
- Net sales of Cardiovascular products were $1.1 million, a decrease of 38%, reflecting the start of the Company's exclusive distribution relationship with LeMaitre Vascular in April 2023.

- Gross margin on a GAAP basis was 45%, compared to 43%. The year-over-year increase was primarily due to rectifying non-production issues in the SimpliDerm product line.
- Adjusted gross margin (a non-GAAP measure which excludes non-cash amortization of intangibles) was 58%, compared to 56%.
- Total operating expenses were $11.3 million, compared to $9.0 million. The increase included higher general and administrative, sales and marketing and research and development expenses.
- Loss from operations was $8.5 million, compared to $6.3 million.
- Net loss was $28.2 million, compared to a net loss of $10.6 million. The increased net loss was primarily due to an $18.3 million non-cash charge in the second quarter of 2024 related to the revaluation of the Company's liability on warrants and pre-funded warrants related to the Company's September 2023 private placement financing.
- Adjusted EBITDA (a non-GAAP measure that excludes from net loss certain non-operating, non-cash and non-recurring items) was a loss of $2.9 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 balance as of June 30, 2024, was $18.2 million and does not reflect approximately $13.8 million in proceeds received from the exercise of outstanding warrants following the end of the quarter.

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 second 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: 13747696

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 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"); preparations for the launch of EluPro, including the timing and anticipated success thereof; the size of the pacemaker and implantable defibrillator protection market and the potential of EluPro to compete in that market; and the potential for applying our drug-eluting biomatrix technology into adjacent markets. 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 and claims related to our recalled FiberCel and other viable bone matrix products and avoid a material adverse financial consequence from those lawsuits and claims; 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 November 2023 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 18,188	$ 19,276
Accounts receivable, net	3,518	3,263
Inventory	3,115	3,853
Receivables of litigation costs	4,421	2,696
Prepaid expense and other current assets	1,109	2,165
Total current assets	30,351	31,253
Property and equipment, net	159	172
Intangible assets, net	9,972	11,671
Operating lease right-of-use assets, and other	1,422	332
Total assets	$ 41,904	$ 43,428
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	$ 11,273	$ 12,676
Current portion of long-term debt	3,449	3,321
Current portion of revenue interest obligation	4,400	11,741
Contingent liability for legal proceedings	20,198	15,024
Current operating lease liabilities	488	275
Total current liabilities	39,808	43,037
Long-term debt	18,873	20,356
Long-term revenue interest obligation	6,972	5,360
Warrant liability	39,018	12,760
Other long-term liabilities	1,571	515
Total liabilities	106,242	82,028
Stockholders' equity (deficit):		
Common stock	28	23
Additional paid-in capital	157,452	137,021
Accumulated deficit	(221,818)	(175,644)
Total stockholders' equity (deficit)	(64,338)	(38,600)
Total liabilities and stockholders' equity	$ 41,904	$ 43,428

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,	
	2024	**2023**	**2024**	**2023**
Net sales	$ 6,291	$ 6,351	$ 12,985	$ 12,743
Cost of goods sold	3,492	3,637	7,343	6,655
Gross profit	2,799	2,714	5,642	6,088
Operating expenses:				
Sales and marketing	3,330	3,022	6,639	7,713
General and administrative	4,689	3,861	9,745	7,381
Research and development	1,001	869	2,173	2,460
FiberCel litigation costs	2,289	1,271	4,074	3,182
Total operating expenses	11,309	9,023	22,631	20,736
Loss from operations	(8,510)	(6,309)	(16,989)	(14,648)
Interest expense	1,267	1,409	2,580	2,839
Other (income) expense, net	18,594	-	26,788	-
Loss before provision of income taxes	(28,371)	(7,718)	(46,357)	(17,487)
Provision for income taxes	(11)	12	(3)	24
Net loss from continuing operations	(28,360)	(7,730)	(46,354)	(17,511)
Income (loss) from discontinued operations	180	(2,891)	180	(1,084)
Net Loss	(28,180)	(10,621)	(46,174)	(18,595)
Net loss from continuing operations per share basic and diluted	$ (1.14)	$ (0.48)	$ (1.90)	$ (1.08)
Net income (loss) from discontinued operations per share basic and diluted	$ 0.01	$ (0.18)	$ 0.01	$ (0.07)
Weighted average common shares outstanding - basic and diluted	24,900,167	16,223,919	24,408,651	16,208,905

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 June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Net sales	$ 6,291	$ 6,351	$ 12,985	$ 12,743
Gross profit	2,799	2,714	5,642	6,088
Intangible asset amortization expense	849	849	1,699	1,699
Adjusted gross profit (Non-GAAP)	$ 3,648	$ 3,563	$ 7,341	$ 7,787
Gross margin	44.5%	42.7%	43.5%	47.8%
Adjusted gross margin percentage (Non-GAAP)	58.0%	56.1%	56.5%	61.1%

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

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Net loss	$ (28,180)	$ (10,621)	$ (46,174)	$ (18,595)
Interest expense[(1)]	1,267	1,409	2,580	2,839
Provision (benefit) for income taxes	(11)	12	(3)	24
Depreciation and amortization	862	943	1,726	1,880
Earnings before interest, taxes, depreciation and amortization ("EBITDA") (Non-GAAP)	(26,062)	(8,257)	(41,871)	(13,852)
Income from discontinued operations	(180)	2,891	(180)	1,084
Stock-based compensation	2,711	672	4,909	1,351
FiberCel litigation costs[(2)]	2,289	1,271	4,074	3,182
Loss on revaluation of warranty liability[(3)]	18,337	-	27,974	-
Gain on revaluation of revenue interest obligation[(4)]	-	-	(1,443)	-
Adjusted EBITDA (Non-GAAP)	$ (2,905)	$ (3,423)	$ (6,537)	$ (8,235)

(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.