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): June 14, 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)**	**(I.R.S. 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, include 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 Symbols**	**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 7.01 Regulation FD Disclosure.

On June 17, 2024, Elutia Inc. (the "Company") published a press release announcing that the U.S. Food and Drug Administration ("FDA") had cleared its antibiotic-eluting bioenvelope, EluPro® (referred to as CanGaroo®RM in development). A copy of the press release is furnished as Exhibit 99.1 hereto.

The information in this Item 7.01 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 Section 18, 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 8.01 Other Information.

On June 14, 2024, the Company received written notice from the FDA that it had reviewed the Company's premarket notification report filed under Section 510(k) of the Federal Food, Drug and Cosmetic Act of 2022 (the "Act") related to the EluPro® antibacterial envelope device, that the FDA had determined "substantial equivalence" with respect to such device, and that such device may be marketed subject to the general controls provisions of the Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Exhibit Description**
99.1	Press Release of the Company dated June 17, 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.

Date: June 17, 2024

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

Exhibit 99.1

Elutia Announces FDA Clearance of EluPro®: The First Antibiotic-Eluting BioEnvelope Designed to Protect Patients with Implantable Cardiac Pacemakers and Defibrillators

EluPro becomes the only drug-eluting biologic envelope to receive FDA clearance in the $600 million U.S. implantable electronic device protection market

EluPro also granted clearance for indications beyond CIEDs, including neurostimulators and neuromodulators used for pain management, epilepsy, incontinence, and sleep apnea

SILVER SPRING, Md., June 17, 2024 — Elutia Inc. (Nasdaq: ELUT) ("Elutia" or the "Company"), a pioneer in drug-eluting biomatrix products, today announced that its Antibiotic-Eluting BioEnvelope, EluPro® (referred to as CanGaroo®RM during development), has received clearance from the U.S. Food and Drug Administration (FDA). Specifically designed to prevent post-operative complications for devices such as pacemakers and defibrillators, EluPro incorporates powerful antibiotic therapy combined with advanced tissue engineering to create a BioEnvelope that over time regenerates into a protective pocket of the patient's own tissue. Infection, migration, and skin erosion are some of the most frequently encountered complications of pacemaker surgery, occurring in up to five to seven percent of cases. These cause significant patient morbidity and mortality, increase the length of hospitalization, and can add more than $50,000 to healthcare costs per event. In development since 2019 and protected by intellectual property extending beyond 2032, EluPro is the only biologic offering in the $600 million U.S. implantable electronic device protection market.

The Company also announced that EluPro was granted clearance for indications beyond the cardiac implantable electronic devices (CIEDs), including neurostimulators and neuromodulators used for pain management, epilepsy, incontinence, and sleep apnea. These additional markets, estimated to be $8 billion worldwide, have not previously been served by a drug-eluting biomatrix and present significant additional growth opportunities for EluPro.

"When I implant a pacemaker or defibrillator, minimizing the risk of any future complications is crucial," said Dr. Benjamin D'Souza, Associate Professor of Medicine at the University of Pennsylvania and Section Chief of Cardiac Electrophysiology at Penn Presbyterian Medical Center. "However, the body's natural immunity can treat the device like a foreign object contributing to inflammation, causing device migration, potentially eroding through the skin, or sometimes causing a serious infection. Those are the specific problems EluPro was designed to solve. It combines the remodeling properties of regenerative medicine through extracellular matrix along with long-acting antibiotic delivery to create a healthy environment for every device implantation."

The EluPro BioEnvelope is constructed from reinforced layers of natural extracellular tissue matrix and designed to create a conforming envelope with optimal stability for implantable electronic devices. The walls of EluPro are embedded with powerful antibiotics rifampin and minocycline, engineered for extended delivery directly into the surgical site long after closure. This unique combination of drug and biomatrix supports the regeneration of a healthy, vascularized pocket from the patient's own tissue, mitigating a long-term foreign body response.

"Post-operative infection, migration and erosion can result in significant morbidity and mortality for patients receiving a pacemaker or defibrillator. That is why we developed the antibiotic-eluting BioEnvelope." said Dr. Randy Mills, Elutia's Chief Executive Officer. "While the approval of EluPro is a major value inflection for Elutia, we believe it is just the tip of the iceberg. We have created a platform to protect patients from the foreign body response that can inevitably develop with any long-term implantable device. We intend to rapidly extend our product offering to other indications as we fulfill our mission to humanize medicine so patients can thrive without compromise."

EluPro represents a significant opportunity in the $600 million U.S. implantable electronic device protection market, previously served by a single competitor. With over 600,000 devices implanted in the U.S. annually, EluPro addresses significant complications arising from these procedures. Elutia plans to launch EluPro into the CIED market nationwide in the second half of 2024 and is prioritizing adjacent markets in the neurostimulation and modulation space, where implantable medical devices result in high rates of addressable complications.

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.

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," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential," "promise," "opportunity" 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 regarding EluPro's potential future success in the CIED protection market or in device protection for other types of implantable devices, like neurostimulators or neuromodulators, and statements regarding market size. 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 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 our recalled FiberCel and other viable bone matrix products and avoid a material adverse financial consequence from those lawsuits; 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.

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