UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2024
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 001-39577

Elutia Inc.
(Exact name of registrant as specified in its charter)

Delaware	**47-4790334**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

N/A

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, par value $0.001 per share	ELUT	The Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 7, 2024, there were 29,746,935 shares of the registrant's Class A common stock and 4,313,406 shares of the registrant's Class B common stock outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including, without limitation, statements regarding 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 the potential payment of post-closing earnout payments from the sale of our Orthobiologics Business to Berkeley Biologics, LLC ("Berkeley"); 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") and viable bone matrix ("VBM"), amounts recoverable under insurance, indemnity and contribution agreements and the impact of such lawsuits and claims on our future financial position; and our expectations and plans regarding pursuit of any strategic transactions are forward-looking statements. These statements involve 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 by the forward-looking statements.

Without limiting the foregoing, the words "aim," "believe," "may," "will," "should," "expect," "exploring," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "seeks," or "continue" or the negative of these terms or other similar expressions, are intended to identify forward-looking statements, although not all forward-looking statements contain these words. These forward-looking statements are not a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

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;
- our ability to achieve or sustain profitability;
- 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;
- the continued and future acceptance of our products by the medical community;
- our ability to market and sell our newly approved EluPro® antibacterial envelope device;
- 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;
- 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 regulatory approval or other marketing authorizations by the U.S. Food and Drug Administration and comparable foreign authorities for our products and product candidates; and
- our ability to obtain, maintain and adequately protect our intellectual property rights.

These and other important factors discussed in Part I, Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Part II, Item 1A. “Risk Factors” in this Quarterly Report, and in Part I, Item 1A. “Risk Factors” and Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the “Annual Report”) and in our other filings with the Securities and Exchange Commission (the “SEC”), each of which filings are accessible on the SEC’s website at www.sec.gov and the Investor Relations page of our website at https://investors.Elutia.com/financials/sec-filings, could cause actual results to differ materially from those indicated by the forward-looking statements made in this Quarterly Report.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

As used in this Quarterly Report, unless otherwise specified or the context otherwise requires, references to “we,” “us,” “our,” the “Company” and “Elutia” refer to the operations of Elutia Inc. and its consolidated subsidiaries.

WEBSITE DISCLOSURE

We may use our website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investor Relations sections of its website at *www.Elutia.com*. In addition, you may automatically receive email alerts and other information about the Company when you enroll your email address by visiting the “Email Alerts” option under the IR Resources menu of the Investor Relations of our website at *www.Elutia.com*. The reference to our website address does not constitute incorporation by reference of the information contained on or available through our website, and you should not consider such information to be a part of this Quarterly Report.

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This Quarterly Report includes our trademarks, trade names and service marks, including, without limitation, "Elutia®," "CanGaroo®," "EluPro®," "CanGarooRM®," "ProxiCor®," "Tyke®," "VasCure®," "SimpliDerm®," "SimpliDerm Ellipse®" and our logo, which are our property and are protected under applicable intellectual property laws. This Quarterly Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks may appear in this Quarterly Report without the ®, TM and SM symbols, but such references are not intended to indicate, in any way, that we or the applicable owner forgo or will not assert, to the fullest extent permitted under applicable law, our rights or the rights of any applicable licensors to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this Quarterly Report concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe the information from these third-party publications, research, surveys and studies included in this Quarterly Report is reliable. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are subject to a high degree of uncertainty and risk due to a variety of factors, including those described in this Quarterly Report under "Forward-Looking Statements" and Part I, Item 1A. "Risk Factors" in our Annual Report which can be found at https://investors.Elutia.com/financials/sec-filings. These and other factors could cause our future performance to differ materially from our assumptions and estimates.

TABLE OF CONTENTS

		Page
FORWARD-LOOKING STATEMENTS		1
WEBSITE DISCLOSURE		2
TRADEMARKS, TRADE NAMES AND SERVICE MARKS		3
INDUSTRY AND OTHER DATA		3
PART I – FINANCIAL INFORMATION		
Item 1.	Financial Statements (Unaudited)	
	Condensed Consolidated Balance Sheets	5
	Condensed Consolidated Statements of Operations	6
	Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit)	7
	Condensed Consolidated Statements of Cash Flows	8
	Notes to Condensed Consolidated Financial Statements	10
Item 2.	Management's Discussion and Analysis of Financial Condition and Results Of Operations	28
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	43
Item 4.	Controls and Procedures	43
PART II – OTHER INFORMATION		
Item 1.	Legal Proceedings	44
Item 1A.	Risk Factors	44
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	44
Item 3.	Defaults Upon Senior Securities	44
Item 4.	Mine Safety Disclosures	44
Item 5.	Other Information	44
Item 6.	Exhibits	45
Signatures		47

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

ELUTIA INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands, Except for Share and Per Share Data)

(UNAUDITED)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 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 expenses 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	$ 3,140	$ 2,285
Accrued expenses	7,335	9,485
Payables to tissue suppliers	798	906
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
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Class A Common stock, $0.001 par value per share, 200,000,000 shares authorized as of June 30, 2024 and December 31, 2023, and 23,963,101 and 18,884,196 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	24	19
Class B Common stock, $0.001 par value per share, 20,000,000 shares authorized as of June 30, 2024 and December 31, 2023 and 4,313,406 issued and outstanding as of June 30, 2024 and December 31, 2023	4	4
Additional paid-in capital	157,452	137,021
Accumulated deficit	(221,818)	(175,644)
Total stockholders' deficit	(64,338)	(38,600)
Total liabilities and stockholders' deficit	**$ 41,904**	**$ 43,428**

The accompanying notes are an integral part of these condensed consolidated financial statements.

ELUTIA INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Data)

(UNAUDITED)

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 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
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, net	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
Loss on revaluation of warrant liability	18,337	—	27,974	—
Other expense (income), net	257	—	(1,186)	—
Loss before provision for income taxes	(28,371)	(7,718)	(46,357)	(17,487)
Income tax expense (benefit)	(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)
Net loss per share - basic and diluted	$ (1.13)	$ (0.65)	$ (1.89)	$ (1.15)
Weighted average common shares outstanding - basic and diluted	24,900,167	16,223,919	24,408,651	16,208,905

The accompanying notes are an integral part of these condensed consolidated financial statements.

ELUTIA INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
(In Thousands, Except Share Amounts)

(UNAUDITED)

	Class A Common Stock		Class B Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, March 31, 2024	**20,036,508**	**$ 20**	**4,313,406**	**$ 4**	**$ 143,315**	**$ (193,638)**	**$ (50,299)**
Issuance of common stock in connection with registered direct offering, net of issuance costs of $1.1 million	3,175,000	3	—	—	9,669	—	9,672
Exercises of Common Warrants and Prefunded Warrants	551,664	1	—	—	2,073	—	2,074
Vesting of restricted stock units, net of shares withheld and taxes paid	199,929	—	—	—	(316)	—	(316)
Stock-based compensation	—	—	—	—	2,711	—	2,711
Net loss	—	—	—	—	—	(28,180)	(28,180)
Balance, June 30, 2024	**23,963,101**	**$ 24**	**4,313,406**	**$ 4**	**$ 157,452**	**$ (221,818)**	**$ (64,338)**
Balance, March 31, 2023	**11,876,792**	**$ 12**	**4,313,406**	**$ 4**	**$ 133,771**	**$ (145,962)**	**$ (12,175)**
Vesting of restricted stock units, net of shares withheld and taxes paid	59,649	—	—	—	(19)	—	(19)
Stock-based compensation	—	—	—	—	687	—	687
Net loss	—	—	—	—	—	(10,621)	(10,621)
Balance, June 30, 2023	**11,936,441**	**$ 12**	**4,313,406**	**$ 4**	**$ 134,439**	**$ (156,583)**	**$ (22,128)**

	Class A Common Stock		Class B Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2023	**18,884,196**	**$ 19**	**4,313,406**	**$ 4**	**$ 137,021**	**$ (175,644)**	**$ (38,600)**
Issuance of common stock in connection with registered direct offering, net of issuance costs of $1.1 million	3,175,000	3	—	—	9,669	—	9,672
Exercises of Common Warrants and Prefunded Warrants	1,627,489	2	—	—	6,106	—	6,108
Issuance of common stock under Employee Stock Purchase Plan	65,459	—	—	—	70	—	70
Vesting of restricted stock units, net of shares withheld and taxes paid	210,957	—	—	—	(322)	—	(322)
Stock-based compensation	—	—	—	—	4,908	—	4,908
Net loss	—	—	—	—	—	(46,174)	(46,174)
Balance, June 30, 2024	**23,963,101**	**$ 24**	**4,313,406**	**$ 4**	**$ 157,452**	**$ (221,818)**	**$ (64,338)**
Balance, December 31, 2022	**11,823,445**	**$ 12**	**4,313,406**	**$ 4**	**$ 132,939**	**$ (137,988)**	**$ (5,033)**
Issuance of common stock under Employee Stock Purchase Plan	41,277	—	—	—	148	—	148
Vesting of restricted stock units	71,719	—	—	—	(19)	—	(19)
Stock-based compensation	—	—	—	—	1,371	—	1,371
Net loss	—	—	—	—	—	(18,595)	(18,595)
Balance, June 30, 2023	**11,936,441**	**$ 12**	**4,313,406**	**$ 4**	**$ 134,439**	**$ (156,583)**	**$ (22,128)**

The accompanying notes are an integral part of these condensed consolidated financial statements.

ELUTIA INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

(UNAUDITED)

	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Net loss	$ (46,174)	$ (18,595)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,726	1,901
Gain on sale of Orthobiologics Business	(180)	—
Loss on revaluation of warrant liability	27,974	—
Gain on revaluation of revenue interest obligation	(1,443)	—
Amortization of deferred financing costs and debt discount	108	107
Interest expense recorded as additional revenue interest obligation and long-term debt	1,450	1,619
Stock-based compensation	4,908	1,371
Bad debt expense	—	834
Losses associated with viable bone matrix recall and market withdrawal	—	1,984
Changes in operating assets and liabilities:		
Accounts receivable	(255)	(321)
Inventory	738	(1,206)
Receivables of litigation costs	(1,725)	4,937
Prepaid expenses and other	1,345	652
Accounts payable and accrued expenses and payables to tissue suppliers	(751)	1,828
Contingent liability for legal proceedings	5,174	(2,890)
Other liabilities	132	224
Net cash used in operating activities	**(6,973)**	**(7,555)**
INVESTING ACTIVITIES:		
Proceeds from sale of Orthobiologics Business	180	—
Expenditures for property, plant and equipment	(13)	(267)
Net cash provided by (used in) investing activities	**167**	**(267)**
FINANCING ACTIVITIES:		
Proceeds from direct registered offering and warrants, net of offering costs	12,390	—
Repayments of long-term debt	(2,000)	—
Proceeds from exercises of Common Warrants and Prefunded Warrants	1,928	—
Payments on revenue interest obligation	(5,200)	—
Repayments of insurance premium financings	(1,148)	—
Payments for taxes upon vesting of restricted stock units	(322)	(19)
Proceeds from issuance of common stock under Employee Stock Purchase Plan	70	148
Net cash provided by financing activities	**5,718**	**129**
Net decrease in cash and restricted cash	**(1,088)**	**(7,693)**
Cash and cash equivalents, beginning of period	**19,276**	**16,989**
Cash and cash equivalents, end of period	**$ 18,188**	**$ 9,296**
Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:		
Cash paid for interest	$ 3,492	$ 1,100
Fair value of warrants issued	$ 2,464	$ —
Operating lease right-of-use asset extensions executed	$ 1,379	$ —
Conversion of Common Warrants and Prefunded Warrants to common stock	$ 4,180	$ —

The accompanying notes are an integral part of these condensed consolidated financial statements.

ELUTIA INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

Note 1. Organization and Description of Business

Elutia Inc. (together with its consolidated subsidiaries, "Elutia” or the “Company”) is a commercial-stage company leveraging its unique understanding of biologics to improve the interaction between implanted medical devices and patients by reducing complications associated with these surgeries. The Company has developed a portfolio of products using both human and porcine tissue that are designed to be as close to natural biological material as possible. Elutia’s portfolio of products spans the Device Protection, Women’s Health and Cardiovascular markets. These products are primarily sold to healthcare providers or commercial partners.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Liquidity

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company’s condensed consolidated financial statements and accompanying notes included in the Company's annual report on Form 10-K (“Annual Report”) for the fiscal year ended December 31, 2023. The financial information as of June 30, 2024 and for the three and six months ended June 30, 2024 and 2023 is unaudited, but in the opinion of management, all adjustments considered necessary for a fair statement of the results for these interim periods have been included. The condensed consolidated balance sheet data as of December 31, 2023 was derived from audited financial statements but does not include all disclosures required by GAAP. The results of the Company’s operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or any future year or period.

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation.

On November 8, 2023, the Company completed the sale of substantially all of the assets relating to its Orthobiologics segment (the “Orthobiologics Business”) to Berkeley Biologics, LLC (“Berkeley”). The Orthobiologics Business was comprised of assets relating to researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing the Company’s Orthobiologics products, and the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products. The assets sold represent the entirety of the Company’s Orthobiologics segment. In the sale, the Company received approximately $14.6 million, and the Company may earn up to an additional $20 million, in the aggregate, in the form of earn-out payments. The earn-out payments are equal to 10% of the actual revenue earned by Berkeley in each of the five years after the closing of the sale from sales of specified Orthobiologics products under the purchase agreement (including improvements, modifications, derivatives and enhancements related to those products). There were no earn-out payments earned or paid in the three or six months ended June 30, 2024. Additionally, the purchase agreement provides for a customary indemnity holdback in the amount of $1.5 million to be retained by Berkeley for 24 months after close. The Company recognized a gain of approximately $6.0 million on the sale of the Orthobiologics Business in the fourth quarter of 2023 and an additional gain of $0.2 million in the second quarter of 2024 from an adjustment payment related to the final working capital received by Berkeley at the sale date. The indemnity holdback is available as a source of recovery for Berkeley for claims of indemnification under the purchase agreement, and some or all of the holdback may be retained by Berkeley if Berkeley is successful in asserting a claim or claims for indemnification against the Company. Should the Company receive incremental proceeds in the future through an earn-out payment or payment of the holdback amount, an additional gain will be recorded upon the receipt of such amounts. See Note 4 for further discussion of the sale of the Orthobiologics Business and the presentation of such business as discontinued operations for the three and six months ended June 30, 2023. Unless indicated otherwise, the information in the notes to condensed consolidated financial statements for the three and six months ended June 30, 2023 relates to continuing operations.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. For the six months ended June 30, 2024, the Company incurred a net loss of $46.2 million, and as of June 30, 2024, the Company had an accumulated deficit of $221.8 million. In addition, during the six months ended June 30, 2024, the Company used $7.0 million of cash in operating activities and expects to continue to incur cash outflows in 2024. Because of the numerous risks and uncertainties associated with the Company's commercialization and development efforts, the Company is unable to predict when it will become profitable, and it may never become profitable. The Company's inability to achieve and then maintain profitability would negatively affect its business, financial condition, results of operations and cash flows. Furthermore, even if the Company does achieve profitability, it may not be able to sustain or increase profitability on an ongoing basis, or, in general, be able to satisfy its obligations, including those related to the FiberCel Litigation and VBM Litigation described in Note 10, when they become due.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, we may seek to raise capital through the issuance of common stock or pursue asset sales or other transactions, such as the sale of the Orthobiologics Business described above. However, such transactions may not be successful, and we may not be able to raise additional equity, refinance our debt instruments, or sell assets on acceptable terms, or at all. As such, based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the condensed consolidated financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as a going concern within one year after the issuance of the condensed consolidated financial statements.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. That is, the accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions relating to inventories, receivables, long-lived assets, the valuation of stock-based awards, the valuation of the revenue interest obligation, the valuation of the warrant liability, the contingent liabilities for legal proceedings and deferred income taxes are made at the end of each financial reporting period by management. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates.

Net Loss per Share Attributable to Common Stockholders

Our common stock has a dual class structure, consisting of Class A common stock, $0.001 par value per share (the "Class A common stock") and Class B common stock, $0.001 par value per share (the "Class B common stock"). Other than voting rights, the Class B common stock has the same rights as the Class A common stock, and therefore both are treated as the same class of stock for purposes of the earnings per share calculation. Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average shares outstanding during the period. For purposes of the diluted net income (loss) per share attributable to common stockholders calculation, stock options, restricted stock units ("RSUs") and warrants are considered to be common stock equivalents. All common stock equivalents have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for both periods presented.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value:

Level 1 - Valuations based on quoted prices for identical assets and liabilities in active markets.

Level 2 - Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

Level 3 - Valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The estimated fair value of financial instruments disclosed in the financial statements has been determined by using available market information and appropriate valuation methodologies. The carrying value of all current assets and current liabilities approximates fair value because of their short-term nature.

Cash and Cash Equivalents

The Company maintains its cash balances at banks and financial institutions. The balances are insured up to the legal limit. The Company maintains cash balances that may, at times, exceed this insured limit. The Company considers cash on hand, demand deposits in a bank, money market funds, and all highly liquid investments with an original maturity of 90 days or less to be cash and cash equivalents.

Accounts Receivable and Allowances

Accounts receivable in the accompanying balance sheets are presented net of allowances for credit losses. The Company grants credit to customers in the normal course of business, but generally does not require collateral or any other security to support its receivables.

The Company evaluates the collectability of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to the Company, a provision to the allowance for doubtful accounts is recorded to reduce the net recognized receivable to the amount that is reasonably expected to be collected. For all other customers, a provision to the allowance for credit losses is recorded based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowance for doubtful accounts are recorded to general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered.

Inventory

Inventory, consisting of purchased materials, direct labor and manufacturing overhead, is stated at the lower of cost or net realizable value, with cost determined generally using the average cost method. At each balance sheet date, the Company also evaluates inventory for excess quantities, obsolescence or shelf-life expiration. This evaluation includes analysis of the Company's current and future strategic plans, historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions and a review of the shelf-life expiration dates for products. To the extent that management determines there is excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products prior to their expiration, the Company adjusts the carrying value to estimated net realizable value.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed on the straight-line method over the following estimated useful lives of the assets:

Processing and research equipment	5 to 10 years
Office equipment and furniture	3 to 5 years
Computer hardware and software	3 years

Leasehold improvements are amortized on the straight-line method over the shorter of the lease term or the estimated useful life of the asset. Repairs and maintenance costs are expensed as incurred.

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No 2016-02, *Leases* to increase the transparency and comparability about leases among entities. ASU 2016-02 and certain additional ASUs are now codified as ASC 842, *Leases*. ASC 842 supersedes the lease accounting guidance in ASC 840 and requires lessees to recognize a lease liability and a corresponding lease asset for virtually all lease contracts. The Company determines if an arrangement contains a lease at inception. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from that lease. For leases with a term greater than 12 months, ROU assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term. The lease term includes the option to extend the lease when it is reasonably certain the Company will exercise that option. When available, the Company uses the rate implicit in the lease to discount lease payments to present value. In the case the implicit rate is not available, the Company uses its incremental borrowing rate based on information available at the lease commencement date, including publicly available data for instruments with similar characteristics, to determine the present value of lease payments. The Company combines lease and non-lease elements for office leases.

During the six months ended June 30, 2024, the Company entered into lease extensions in Silver Spring, Maryland and Roswell, Georgia and entered into a new lease in San Diego, California, which collectively resulted in operating lease right-to-use assets and liabilities of $1.4 million. Such new leases will result in future cash obligations of $0.3 million for the six months ended December 31, 2024 and $0.6 million, $0.7 million and $0.1 million for the years ended December 31, 2025, 2026 and 2027, respectively.

Long-Lived Assets

Purchased intangible assets with finite lives are carried at acquired fair value, less accumulated amortization. Amortization is computed over the estimated useful lives of the respective assets.

The Company periodically evaluates the period of depreciation or amortization for long-lived assets to determine whether current circumstances warrant revised estimates of useful lives. The Company reviews its property and equipment and intangible assets for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Impairment exists when the carrying value of the company's asset exceeds the related estimated undiscounted future cash flows expected to be derived from the asset. If impairment exists, the carrying value of that asset is adjusted to its fair value. A discounted cash flow analysis is used to estimate an asset's fair value, using assumptions that market participants would apply. The results of impairment tests are subject to management's estimates and assumptions of projected cash flows and operating results. Changes in assumptions or market conditions could result in a change in estimated future cash flows and could result in a lower fair value and therefore an impairment, which could impact reported results. There were no impairment losses for the three and six months ended June 30, 2024 or 2023.

Warrant Liability

The Company accounts for its warrants in accordance with ASC 815, *Derivatives and Hedging – Contracts in Entity's Own Equity*, as either liabilities or as equity instruments depending on the specific terms of the warrant agreement.

The Prefunded and Common Warrants issued in connection with the September 2023 private placement (see Note 9) are classified as liabilities and are recorded at fair value. The warrants are subject to re-measurement at each settlement date and at each balance sheet date and any change in fair value is recognized in other expense (income), net in the condensed consolidated statements of operations. The Company estimates the fair value of the warrant liability using a Black-Scholes pricing model. We are required to make assumptions and estimates in determining an appropriate term, risk-free interest rate, volatility factor, dividend yield, and the fair value of common stock. Any significant adjustments to the unobservable inputs would have a direct impact on the fair value of the warrant liability.

Revenue Recognition

The Company's revenue is generated from contracts with customers in accordance with ASC 606. The core principle of ASC 606 is that the Company recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The ASC 606 revenue recognition model consists of the following five steps: (1) identify the contracts with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

As noted above, the Company enters into contracts to primarily sell and distribute products to healthcare providers or commercial partners. Revenue is recognized when the Company has met its performance obligations pursuant to its contracts with its customers in an amount that the Company expects to be entitled to in exchange for the transfer of control of the products to the Company's customers. For all product sales, the Company has no further performance obligations and revenue is recognized at the point control transfers which occurs either when: i) the product is shipped via common carrier; or ii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement.

A portion of the Company's product revenue is generated from consigned inventory maintained at hospitals and from inventory physically held by distributors and direct sales representatives. For these types of products sales, the Company retains control until the product has been used or implanted, at which time revenue is recognized.

The Company elected to account for shipping and handling activities as a fulfillment cost rather than a separate performance obligation. Amounts billed to customers for shipping and handling are included as part of the transaction price and recognized as revenue when control of the underlying products is transferred to the customer. The related shipping and freight charges incurred by the Company are included in sales and marketing costs.

Contracts with customers state the final terms of the sale, including the description, quantity, and price of each implant distributed. The payment terms and conditions in the Company's contracts vary; however, as a common business practice, payment terms are typically due in full within 30 to 60 days of delivery. The Company, at times, extends volume discounts to customers.

The Company permits returns of its products in accordance with the terms of contractual agreements with customers. Allowances for returns are provided based upon analysis of the Company's historical patterns of returns matched against the revenues from which they originated. The Company records estimated returns as a reduction of revenue in the same period revenue is recognized.

Stock-Based Compensation Plans

The Company accounts for its stock-based compensation plans in accordance with ASC 718, *Accounting for Stock Compensation*. ASC 718 requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors, including employee stock options and restricted stock. Stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense on a straight-line basis over the requisite service period of the entire award.

Research and Development Costs

Research and development costs, which include mainly salaries, outside services and supplies, are expensed as incurred.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash. The Company's cash balances with the individual institutions may at times exceed the federally insured limits.

There were two customers that represented 14% and 11%, respectively, of the Company's net sales for the six months ended June 30, 2024. Additionally, there were two customers that represented 26% and 12%, respectively, of the Company's accounts receivable as of June 30, 2024.

Comprehensive Income (Loss)

Comprehensive income (loss) comprises net income (loss) and other changes in equity that are excluded from net income (loss). For the three and six months ended June 30, 2024 and 2023, the Company's net loss equaled its comprehensive loss and accordingly, no additional disclosure is presented.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred income taxes are recorded to reflect the tax consequences on future years for differences between the tax basis of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to amounts that are more likely than not to be realized.

The Company is subject to income taxes in the federal and state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply. In accordance with the authoritative guidance on accounting for uncertainty in income taxes, the Company recognizes tax liabilities for uncertain tax positions when it is more likely than not that a tax position will not be sustained upon examination and settlement with various taxing authorities. Liabilities for uncertain tax positions are measured based upon the largest amount of benefit that is more likely than not (greater than 50%) of being realized upon settlement. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense.

Note 3. Recently Issued Accounting Standards

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. This update improves reportable segment disclosure requirements, primarily through enhanced disclosures of significant segment expenses. The amendments in this update should be applied retrospectively to all prior periods presented in the condensed consolidated financial statements and are effective for fiscal years beginning after December 31, 2023 and interim periods within fiscal years beginning after December 31, 2024. Early adoption is permitted. The Company is currently evaluating the potential impact of this guidance on its condensed consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvement to Income Tax Disclosures. This update improves income tax disclosure requirements, primarily through enhanced transparency and decision usefulness of disclosures. The amendments in this update should be applied prospectively with the option to apply retrospectively and are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the potential impact of this guidance on its condensed consolidated financial statements.

Note 4. Sale of Orthobiologics Business

As described in Note 2, on November 8, 2023, the Company completed the sale of its Orthobiologics Business. Accordingly, the Orthobiologics Business is reported as discontinued operations in accordance with ASC 205-20 - *Discontinued Operations* and the amounts for the three and six months ended June 30, 2023 have been recast to conform to this discontinued operations presentation.

In accordance with ASC 205-20, only expenses specifically identifiable and related to a business to be disposed may be presented in discontinued operations. The following table shows the financial results of the discontinued operations for the three and six months ended June 30, 2023. Additionally, a gain of $0.2 million was recognized in the second quarter of 2024 related to the final working capital adjustment received from Berkeley.

	Three Months Ended June 30, 2023	Six Months Ended June 30, 2023
Net sales	$ 3,945	$ 10,603
Cost of goods sold	5,678	9,378
Gross profit	(1,733)	1,225
Sales and marketing	596	1,262
General and administrative	143	304
Research and development	304	513
Total operating expenses	1,043	2,079
Interest expense	115	230
Net income	$ (2,891)	$ (1,084)

Total operating and investing cash flows of discontinued operations for the six months ended June 30, 2023 are comprised of the following:

	Six Months Ended June 30, 2023
Significant operating non-cash reconciliation items	
Depreciation	$ 117
Stock-based compensation	65
Changes in operating assets and liabilities:	
Accounts receivable	(607)
Inventory	(183)
Prepaid expenses and other	(557)
Accounts payable and accrued expenses and other current liabilities	1,156
Obligations to tissue suppliers	(228)
Significant investing items	
Expenditures for property, plant and equipment	224

Note 5. Stock-Based Compensation

In 2015, the Company established the Elutia Inc. 2015 Stock Option/Stock Issuance Plan, as amended (the “2015 Plan”) which provided for the granting of incentive and non-qualified stock options to employees, directors and consultants of the Company. On October 7, 2020, in connection with the Company’s initial public offering (“IPO”), the Company adopted the Elutia Inc. 2020 Incentive Award Plan, and on June 8, 2023, the Company’s stockholders approved the amendment and restatement of that plan (as amended and restated, the “2020 Plan”), which authorizes the grant of incentive and non-qualified stock options, restricted stock, restricted stock units and stock appreciation rights to employees, directors and consultants. Shares of Class A common stock totaling 1,636,000 were initially reserved for issuance pursuant to the 2020 Plan, and in June 2023, the number of shares of Class A common stock reserved for issuance under the 2020 Plan was increased by 2,000,000 shares. In addition, the shares reserved for issuance under the 2020 Plan also include shares reserved but not issued under the 2015 Plan as well as an annual increase as set forth in the 2020 Plan. As of June 30, 2024, the Company had 405,909 shares of Class A common stock available for issuance under the 2020 Plan.

Stock Options

The Company's policy is to grant stock options at an exercise price equal to 100% of the market value of a share of Class A common stock at closing on the date of the grant. The Company's stock options generally have contractual terms of ten years and vest over a period of either three or four years from the date of grant.

A summary of stock option activity under the Company's 2015 Plan and 2020 Plan for the six months ended June 30, 2024 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2023	1,501,193	$ 8.37	7.8	$ -
Granted	1,790,654	$ 3.59		
Forfeited	(53,433)	$ 10.85		
Outstanding, June 30, 2024	3,238,414	$ 5.23	7.8	$ 3,034
Vested and exercisable, June 30, 2024	1,138,985	$ 6.80	8.0	$ 776

The weighted average grant date fair value of options granted during the six months ended June 30, 2024 was $2.38. As of June 30, 2024, there was approximately $4.6 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted-average period of 2.1 years.

The Company uses the Black-Scholes model to value its stock option grants that vest based on the passage of time or the achievement of certain performance criteria and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of stock options is determined on the grant date using assumptions for the estimated fair value of the underlying common stock, expected term, expected volatility, dividend yield, and the risk-free interest rate. Before the completion of the Company's IPO, the Board of Directors determined the fair value of common stock considering the state of the business, input from management, third party valuations and other considerations. The Company uses the simplified method for estimating the expected term used to determine the fair value of options. The expected volatility of the Class A common stock is partially based on the historical volatility of comparable companies in the industry whose share prices are publicly available. The Company uses a zero-dividend yield assumption as the Company has not paid dividends since inception nor does it anticipate paying dividends in the future. The risk-free interest rate approximates recent U.S. Treasury note auction results with a similar life to that of the option. The period expense is then determined based on the valuation of the options and is recognized on a straight-line basis over the requisite service period for the entire award.

The following weighted-average assumptions were used to determine the fair value of time-based options granted during the three and six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,	
	2024	2023
Expected term (years)	5.9	6.0
Risk-free interest rate	3.3 %	3.9 %
Volatility factor	100.9 %	63.8 %
Dividend yield	—	—

During the six months ended June 30, 2024, the Company granted 397,640 options that vest on a defined date following the U.S. Food and Drug Administration's ("FDA") clearance of the Company's EluPro (referred to as

CanGarooRM during development) product. With the FDA's approval of EluPro in June 2024, such vesting will occur in mid-August 2024. Consistent with the above, these performance vesting options have been valued using the Black-Scholes model. The Company also granted 162,500 stock options that vest in equal installments upon the achievement of certain share price thresholds for twenty consecutive days of trading at each respective threshold. For these stock options, the Company accounted for the awards as market condition awards and used an option pricing model, the Monte Carlo model, to determine the fair value of the respective equity instruments and an expense recognition term of approximately three years. As of June 30, 2024, there were a total of 345,011 stock options outstanding that are market condition stock option awards.

Restricted Stock Units

Restricted stock units ("RSUs") represent rights to receive common shares at a future date. There is no exercise price and no monetary payment is required for receipt of restricted stock units or the shares issued in settlement of the award.

A summary of the RSU activity under the Company's 2020 Plan for the six months ended June 30, 2024 is as follows:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2023	335,608	$ 3.64
Granted	2,267,500	$ 3.59
Vested	(303,844)	$ 3.93
Forfeited	(81,048)	$ 2.72
Unvested, June 30, 2024	2,218,216	$ 3.59

The total fair value of the RSUs granted during the six months ended June 30, 2024 was $8.2 million. For the performance vesting RSUs, the fair value was based on the fair market value of the Company's Class A common stock on the date of grant. The market condition RSUs are valued as described below. The respective fair values are amortized to expense on a straight-line basis over the vesting period of generally three to four years.

As of June 30, 2024, $5.9 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of 2.2 years

During the six months ended June 30, 2024, the Company granted 560,625 RSUs that vest on a defined date following the FDA's clearance of the Company's EluPro product. With the FDA's approval of EluPro in June 2024, such vesting will occur in mid-August 2024. These performance vesting RSUs have been valued using the fair value of the Company's Class A common stock on the date of grant. The Company has also granted 162,500 RSUs that vest in equal installments upon the achievement of certain share price thresholds for twenty consecutive days of trading at each respective threshold. For these RSUs, the Company accounted for the awards as market condition awards and used a Monte Carlo model to determine the fair value of these RSUs as well as the expense recognition term of approximately three years using the graded vesting method. As of June 30, 2024, there were 252,394 RSUs outstanding that were market condition RSU awards.

Employee Stock Purchase Plan

The Company makes shares of its Class A common stock available for purchase under its 2020 Employee Stock Purchase Plan (the "ESPP"). The ESPP provides for separate six-month offering periods that begin in March and September of each year. Under the ESPP, employees may purchase a limited number of shares of Elutia Class A common stock at 85% of the fair market value on either the first day of the offering period or the purchase date, whichever is lower. The ESPP is considered compensatory for purposes of stock-based compensation expense. The number of shares reserved under the ESPP will automatically increase on the first day of each fiscal year through January 1, 2030, in an amount as set forth in the ESPP. As of June 30, 2024, the total shares of Class A common stock authorized for issuance under the

ESPP was 774,341, of which 502,325 remained available for future issuance. During the three and six months ended June 30, 2024, 65,459 shares of Class A common stock were issued under the ESPP.

Stock-Based Compensation Expense

Stock-based compensation expense recognized during the three and six months ended June 30, 2024 and 2023 was comprised of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Sales and marketing	$ 485	$ 158	$ 933	$ 301
General and administrative	1,778	440	3,201	893
Research and development	356	39	610	79
Cost of goods sold	92	42	164	82
Total stock-based compensation expense	$ 2,711	$ 679	$ 4,908	$ 1,355

Note 6. Inventory

Inventory was comprised of the following (in thousands):

	June 30, 2024	December 31, 2023
Raw materials	$ 341	$ 242
Work in process	498	286
Finished goods	2,276	3,325
Total	$ 3,115	$ 3,853

Note 7. Long-Term Debt

On August 10, 2022, the Company entered into a senior secured term loan facility with SWK Funding LLC, as agent, and other lenders party thereto for an aggregate principal amount of $25 million, and the Company amended the facility on May 12, 2023 (as amended, the "SWK Loan Facility"). An initial draw of $21 million was made in August 2022, with the additional $4 million drawn on December 14, 2022 upon satisfaction of the amended terms enabling such receipt. The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to $8 million, which has not been entered into to date. The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility starts on November 15, 2024, which amortization may be extended to November 17, 2025 if certain conditions have been satisfied. Principal payments during the amortization period will be limited based on revenue-based caps. As of June 30, 2024, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the aggregate principal amount funded with the balance paid at maturity. The SWK Loan Facility also includes both revenue and liquidity covenants, restrictions as to payment of dividends, and is secured by all assets of the Company, subject to certain customary exceptions. As of June 30, 2024, Elutia was in compliance with its financial covenants under the agreement governing the SWK Loan Facility ("SWK Loan Facility Agreement").

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate ("SOFR") loans and bear interest at a rate per annum equal to the sum of an applicable margin of (i) 7.75% and the "Term SOFR Rate" (based upon an interest period of 3 months), or (ii) if the Company has elected the PIK Interest option (as defined below), 3.75% and the "Term SOFR Rate." The Company may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% ("PIK Interest"), and such election may be made (x) until November 15, 2024 if certain conditions, as defined, have not been met, or (y) if such conditions have been satisfied, until November 17, 2025. The "Term SOFR Rate" is subject to a floor of 2.75%. The agreement governing the SWK Loan Facility also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination plus $62,500 and prepayment penalties equal to: (i) if such prepayment occurs prior to the first anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination plus remaining unpaid interest payments scheduled to be paid during the first year of the loan or

(ii) if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination. The weighted average interest rate on the SWK Loan Facility was 13.6% and 13.0% for the three months ended June 30, 2024 and 2023, respectively and 13.6% and 12.9% for the six months ended June 30, 2024 and 2023, respectively.

On August 10, 2022, the Company issued to SWK Funding LLC a warrant (“Class A Warrant”) to purchase, in the aggregate, up to 187,969 shares of Class A common stock of the Company, $0.001 par value per share at an exercise price of $6.65 per share. The Class A Warrant is immediately exercisable for up to 187,969 shares of Class A common stock from time to time on or after the Closing Date. The exercise price and number of shares of Class A common stock issuable upon exercise of the Class A Warrant are subject to adjustment in the event of stock dividends, stock splits and certain other events affecting the Class A common stock. Unless earlier exercised or terminated in accordance with its terms, the Class A Warrant will expire on the seventh anniversary of the Closing Date. Upon issuance, the Company valued the Class A Warrant at approximately $0.6 million using the Black-Scholes model. The recognition of the Class A Warrant as well as deferred financing costs of approximately $0.5 million incurred in securing the SWK Loan Facility served to reduce the recorded value of the associated debt. The debt discount and deferred financing costs will be recognized as interest expense through the maturity of the loan.

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility Agreement) to the Company’s total gross profit (as defined in the SWK Loan Facility Agreement) multiplied by the outstanding loans under the SWK Loan Facility and (y) the difference between $1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. No such mandatory prepayments were required during the three and six months ended June 30, 2024 and 2023.

Long-term debt was comprised of the following (in thousands):

	June 30, 2024	December 31, 2023
Term Loan Facility, net of unamortized discount and deferred financing costs	$ 22,322	$ 23,677
Current Portion	(3,449)	(3,321)
Long-Term Debt	$ 18,873	$ 20,356

The fair value of all debt instruments, which is based on inputs considered to be Level 2 under the fair value hierarchy, approximates the respective carrying values as of June 30, 2024 and December 31, 2023.

Note 8. Revenue Interest Obligation

On May 31, 2017, the Company completed an asset purchase agreement with CorMatrix Cardiovascular, Inc. (“CorMatrix”) and acquired all CorMatrix commercial assets and related intellectual property (the “CorMatrix Acquisition”). As part of the CorMatrix Acquisition, the Company assumed a restructured, long-term obligation (the “Revenue Interest Obligation”) to Ligand Pharmaceuticals Incorporated (“Ligand”) with an estimated present value on the acquisition date of $27.7 million. Subject to annual minimum payments of $2.75 million per year, the terms of the Revenue Interest Obligation required Elutia to pay Ligand, 5% of future sales of the products Elutia acquired from CorMatrix, including CanGaroo, ProxiCor, Tyke and VasCure, as well as products substantially similar to those products, such as the recently-approved EluPro product. Furthermore, a $5.0 million payment would be due to Ligand if cumulative sales of these products exceed $100 million and a second $5.0 million will be due if cumulative sales exceed $300 million during the ten-year term of the agreement which expires on May 31, 2027.

On January 10, 2024, the Company entered into an amendment to the Revenue Interest Obligation (the “Amended Revenue Interest Obligation”). Pursuant to the Amended Revenue Interest Obligation, the parties modified and restructured the Revenue Interest Obligation by revising the annual minimum payments for 2024 and each subsequent fiscal year during the term of the agreement from $2.75 million to $4.4 million. Such minimums are payable quarterly within 30 days after each quarter-end date. Additionally, the Company made payments totaling $3.0 million (50% paid in January 2024 and 50% paid in April 2024) in satisfaction of all royalty obligations for the first three fiscal quarters of 2023 and made a payment in February 2024 of $1.1 million in satisfaction of the royalty obligations for the fourth quarter of 2023. Furthermore, as part of the Amended Revenue Interest Obligation, Ligand waived the Company's obligation to make the $5.0 million milestone payment that became due to Ligand in the second quarter of 2023. Total payments to Ligand during the six months ended June 30, 2024 were $5.2 million comprised of the aforementioned 2023 amounts due and a 2024 quarterly minimum payment of $1.1 million.

The Company records the present value of the estimated total future payments under both the Revenue Interest Obligation and Amended Revenue Interest Obligation as a long-term obligation, with the short-term portion being recorded as described below. 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 condensed consolidated statements of operations using the catch-up method. The Amended Revenue Interest Obligation changed the timing and extent of future payments by the Company to Ligand and such change to the estimated future payments yielded a reduction to the total obligation of approximately $1.4 million during the six months ended June 30, 2024. The resulting gain was recognized as other expense (income), net in the accompanying condensed consolidated statement of operations. Interest expense related to the Revenue Interest Obligation of approximately $0.4 million and $0.5 million was recorded for the three months ended June 30, 2024 and 2023, respectively and approximately $0.9 million and $1.1 million was recorded for the six months ended June 30, 2024 and 2023, respectively.

As of June 30, 2024, the short-term portion of the Amended Revenue Interest Obligation is comprised of the newly established annual minimum payments of $4.4 million. As of December 31, 2023, the short-term portion of the Initial Revenue Interest Obligation is comprised of (i) the 2023 and 2024 minimum payments, (ii) the first $5.0 million sales milestone payment noted above and (iii) the unpaid portion of the 2022 minimum payments.

Note 9: Common Stock and Warrants

Registered Direct Offering of Common Stock and Warrants

On June 16, 2024, the Company sold, in a registered direct offering ("Registered Offering") an aggregate of (i) 3,175,000 shares of the Company's Class A common stock and (ii) prefunded warrants ("2024 Prefunded Warrants") to purchase up to an aggregate of 725,000 shares of Class A Common Stock. The public offering price for each share of Class A Common Stock was $3.40, and the public offering price for each 2024 Prefunded Warrant was $3.399, for aggregate gross proceeds of approximately $13.3 million, before deducting offering expenses. The 2024 Prefunded Warrants have an exercise price of $0.001 per share of Class A Common Stock, are exercisable immediately and will expire when exercised in full. The Company incurred transaction fees, including commissions and legal fees, of approximately $1.4 million in connection with the Registered Offering, of which $1.1 million were allocated to the issuance of the common stock.

Private Placement of Common Stock and Warrants

On September 21, 2023, the Company sold, in a private offering ("Private Offering") an aggregate of (i) 6,852,811 units ("Common Units") each comprised of (a) one share of the Company's Class A common stock and (b) a warrant ("Common Warrant") to purchase one and one half shares of Class A Common Stock, and (ii) 503,058 units (the "Prefunded Units"), each comprised of (a) a prefunded warrant ("2023 Prefunded Warrant") to purchase one share of Class A Common Stock, and (b) a Common Warrant. The Common Units were sold at a purchase price of $1.4275 per unit, and the Prefunded Units were sold at a purchase price of $1.4265 per unit, for aggregate gross proceeds of approximately $10.5 million, before deducting offering expenses. Each Common Warrant is exercisable at any time until the earlier of (a) 30 trading days after the clearance by the FDA of the Company's EluPro product or (b) five years from the date of the offering, at an exercise price per share of $1.4275. Each 2023 Prefunded Warrant is exercisable at any time at a nominal exercise price per share of $0.001 (with the remainder of the exercise price per share of Class A Common Stock having been prefunded to the Company). The Company incurred transaction fees, including commissions and legal fees, of approximately $1.1 million in connection with the Private Offering, of which $0.4 million were allocated to the issuance of the common stock.

See below for discussion of the accounting for the warrants and the allocation of the remainder of the transaction fees from both the Registered Offering and Private Offering.

Warrant Liabilities

The Company has concluded that the 2024 Prefunded Warrants from the Registered Offering and the Common Warrants and the 2023 Prefunded Warrants from the Private Offering do not meet the equity contract scope exception under ASC 815-40 as in the event of a (i) fundamental transaction such as a merger and (ii) failure to timely delivery warrant shares upon exercise, certain provisions may require the Company to adjust the settlement value that is not consistent with a fixed-for-fixed option pricing model.

As a result, with respect to the 2024 Prefunded Warrants, the Company allocated $2.5 million of the gross proceeds from the Registered Offering to such warrants based on their fair value. Similarly, with respect to the Common Warrants and 2023 Prefunded Warrants, the Company allocated $8.6 million of the gross proceeds from the Private Offering to such warrants based on their fair value. Additionally, the Company allocated a portion of the transaction fees from both the Registered Offering and the Private Offering to the respective warrants and expensed within other expense (income), net. Such expenses totaled $0.3 million during the three and six months ended June 30, 2024. No such expenses were recognized in the three and six months ended June 30, 2023.

The liability associated with the 2024 Prefunded Warrants, Common Warrants and 2023 Prefunded Warrants is recorded as warrant liability in the accompanying condensed consolidated balance sheet as of June 30, 2024 and December 31, 2023. A summary of the warrant activity for the six months ended June 30, 2024 is as follows:

	Common Warrants	2023 Prefunded Warrants	2024 Prefunded Warrants
Outstanding, December 31, 2023	11,033,804	503,058	—
Issued	-	—	725,000
Exercised	(1,366,025)	(261,470)	—
Outstanding, June 30, 2024	9,667,779	241,588	725,000

The valuation of the warrants is adjusted to fair value (Level 3) at each subsequent balance sheet date until the warrants are settled. The following table provides a rollforward of the aggregate fair value of the warrant liability for the six months ended June 30, 2024 (in thousands):

	Common Warrants	2023 Prefunded Warrants	2024 Prefunded Warrants	Total Offering Warrants
Warrant liability, December 31, 2023	$ 11,670	$ 1,090	$ -	$ 12,760
Fair value upon issuance	-	-	2,464	2,464
Fair value adjustment	25,670	1,172	1,132	27,974
Exercised	(3,116)	(1,064)	-	(4,180)
Warrant liability, June 30, 2024	$ 34,224	$ 1,198	$ 3,596	$ 39,018

The fair value adjustments, which include $18.3 million recognized during the three months ended June 30, 2024, were driven mainly by increases in the Company's stock price since December 31, 2023 and have been recorded as other expense (income), net in the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2024.

The Company calculated the fair value of the Common Warrants as of June 30, 2024 using the Black-Scholes option pricing model with the following inputs as of June 30, 2024 and December 31, 2023:

	June 30, 2024	December 31, 2023
Common stock price	$ 4.96	$ 2.16

Expected term (years)	0.1	0.7
Risk-free interest rate	5.5 %	5.1 %
Volatility factor	88.4 %	107.3 %
Dividend yield	— %	— %

The expected term of the Common Warrants was a significant unobservable input, which includes the Company's probability-weighted expectations relative to the timing of the clearance by the FDA of the Company's CanGarooRM antibiotic-eluting biologic envelope.

With the FDA's approval of EluPro in June 2024, the last exercise date for the Common Warrants was July 31, 2024. All Common Warrants outstanding as of June 30, 2024 were exercised by such date yielding exercise proceeds of $13.8 million in July 2024.

The Company has used the price of its Class A Common Stock to estimate the fair value of the 2024 Prefunded Warrants and 2023 Prefunded Warrants at each measurement date. The price of the Company's Class A Common Stock approximates fair value of the 2024 Prefunded Warrants and 2023 Prefunded Warrants due to the exercise price per share of $0.001.

Note 10. Commitments and Contingencies

Cook Biotech License and Supply Agreements

Elutia has entered into a license agreement with Cook Biotech ("Cook") for an exclusive, worldwide license to the porcine tissue for use in the Company's Cardiac Patch and CanGaroo products, subject to certain co-exclusive rights retained by Cook (the "Cook License Agreement"). The term of such license is through the date of the last to expire of the licensed Cook patents, which is anticipated to be July 2031. Along with this license agreement, Elutia entered into a supply agreement whereby Cook would be the exclusive supplier to Elutia of licensed porcine tissue. Under certain limited circumstances, Elutia has the right to manufacture the licensed product and pay Cook a royalty of 3% of sales of the Elutia-manufactured tissue. The supply agreement expires on the same date as the related license agreement. No royalties were paid to Cook during the three and six months ended June 30, 2024 or 2023. Elutia has also entered into an amendment to the Cook License Agreement (the "Cook Amendment") in order to add fields of exclusive use. Specifically, the Cook Amendment provides for a worldwide exclusive license to the porcine tissue for use with neuromodulation devices in addition to cardiovascular devices. The Cook Amendment includes license fee payments of $0.1 million per year in each of the years 2021 through 2026. Such license payments would accelerate if a change in control, as defined in the Cook Amendment, occurs within Elutia. The Company, in its sole discretion, can terminate the Cook License Agreement at any time.

Legal Proceedings

From time to time, the Company may be involved in claims and proceedings arising in the course of the Company's business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. Where the available information is only sufficient to establish a range of probable liability, and no point within the range is more likely than any other, the lower end of the range has been used. When a material loss contingency is reasonably possible, but not probable, the Company does not record a liability, but instead discloses the nature of the matter and an estimate of the loss or range of loss, to the extent such estimate can be made. Accruals recorded are adjusted periodically as assessments change or additional information becomes available, and management's judgments may be materially different than the actual outcomes.

FiberCel Litigation

As previously disclosed, in June 2021, the Company announced a voluntary recall of a single lot of FiberCel fiber viable bone matrix ("FiberCel"). Since September 2021, 110 product liability lawsuits or claims have been filed or asserted against the Company involving FiberCel. As of June 30, 2024, there were 81 active lawsuits or claims filed or asserted against the Company. The lawsuits, which have been filed against Elutia, certain Medtronic entities, and others, allege that the plaintiffs were exposed to and/or contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during orthopedic fusion operations. Such lawsuits were filed in various U.S. federal courts and in state courts in Indiana, Delaware, Florida, Kentucky Maryland, Illinois and Ohio. The Company refers to all of the aforementioned litigation, or claim notices, collectively as the “FiberCel Litigation.”

Viable Bone Matrix Litigation

In July 2023, the Company announced a voluntary recall of a single lot of a certain viable bone matrix (“VBM”) product and the market withdrawal of all of its VBM products produced after a specified date (the “VBM Recall”). Notice of the voluntary recall was issued to centers after the Company learned of post-surgical Mycobacterium tuberculosis (“MTB”) infections in two patients treated with a VBM product from a single donor lot. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism.

It is the Company’s understanding that 36 individuals received tissue from the recalled VBM lot and since November 2023, 21 lawsuits or claims have been filed or asserted against the Company. The lawsuits, which have been filed against Elutia and others, allege that the plaintiffs were exposed to and/or contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of VBM during orthopedic fusion operations. To date, these lawsuits have been filed in California Superior Court (collectively, the “California State Complaints”), the United States District Court for the Eastern District of Louisiana (collectively, the “Louisiana Federal Complaints”), and the United States District Court for the Western District of Texas (the “Texas Federal Complaint”).

Plaintiffs in the California State Complaints assert that the defendants are strictly liable or have breached the duty of care owed to plaintiffs by failing to exercise reasonable care in designing, manufacturing, marketing, and labeling VBM and seek various types of damages, including economic damages, non-economic damages, and loss of consortium damages. The Plaintiffs in one of the California State Complaints also assert claims for fraudulent inducement, misrepresentation, and intentional infliction of emotional distress. Plaintiffs in the Louisiana Federal Complaints generally assert causes of action under the Louisiana Product Liability Act, citing design defects, manufacturing defects, and failure to properly warn, and several plaintiffs allege loss of consortium. Plaintiffs in these actions also assert that defendants are strictly liable or have breached the duty of care owed to plaintiffs by failing to exercise reasonable care in designing, manufacturing, marketing and labeling VBM and seek economic damages, non-economic damages and loss of consortium. Some plaintiffs in the Louisiana Federal Complaints also allege claims for breach of implied warranty and breach of express warranty, medical monitoring, and punitive damages. Plaintiffs in the Texas Federal Complaint assert violations of the Texas Business and Commerce Code, citing alleged breaches of the warranties of merchantability and fitness for a particular purpose. Plaintiffs further assert that the defendants breached the duty of care owed to plaintiffs by failing to exercise reasonable care in designing, manufacturing, marketing, and labeling VBM and seek various types of damages, including economic damages, non-economic damages, exemplary damages, and loss of consortium damages. The Company refers to all of the aforementioned litigation, or claim notices, collectively as the “VBM Litigation.”

Medtronic Litigation

In June 2024, the Company filed an action against Medtronic Sofamor Danek USA, Inc. (“Medtronic”) in the Superior Court of the State of Delaware. The Company’s complaint alleges breach of the 2019 Tissue Product Supply Agreement (the “Supply Agreement”) between the Company and Medtronic. In particular, the complaint alleges that Medtronic did not honor its contractual obligations to obtain insurance coverage and to defend and indemnify the Company for over 100 lawsuits against the Company alleging claims arising from the use of FiberCel products distributed by Medtronic. The complaint does not specify the amount of damages owed by Medtronic for these breaches. Medtronic responded to the complaint on July 31, 2024, denying Elutia’s claims and asserting a single counterclaim alleging that Elutia breached certain representations and warranties under the Supply Agreement and owes ongoing indemnity obligations to Medtronic. The counterclaim does not specify the amount of any alleged damages. Medtronic has brought a motion for judgment on the pleadings as to Elutia’s claims, and a hearing is set for November 1, 2024. Given the early stages of this matter and the Company’s intention to vigorously defend this counterclaim, we do not consider a loss to be probable or estimable at this time.

Contingent Liability for Legal Proceedings

FiberCel Litigation

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Since August 2022, the Company has engaged in a process to negotiate and attempt to resolve many of the cases in the FiberCel Litigation. In total, Elutia's liability in 29 of the cases has been settled for a total cash outlay of approximately $9.1 million. For the remaining 81 cases for which settlements have not been reached or the settlements have been reached but have not yet been paid, the Company estimated a probable loss related to each case and has recorded a liability at an estimated amount of $16.4 million at June 30, 2024, which is recorded as Contingent Liability for Legal Proceedings in the accompanying condensed consolidated balance sheets.

In order to reasonably estimate the liability for the unsettled FiberCel Litigation cases, the Company, along with outside legal counsel, has assessed a variety of factors, including (i) the extent of the injuries incurred, (ii) recent experience on the settled claims, (iii) settlement offers made to the other parties to the litigation and (iv) any other factors that may have a material effect on the FiberCel Litigation. While the Company believes its estimated liability to be reasonable, the actual loss amounts are highly variable and are dependent upon the relevant facts and case by case resolutions. As more information is learned about asserted claims and potential future trends, adjustments may be made to this Contingent Liability for Legal Proceedings as appropriate. Management believes that it is reasonably possible that the Company could incur liabilities in excess of amounts accrued and the ultimate liability could be material to the Company's financial position, results of operations and cash flows in the period recognized. The Company, however, is unable to estimate the possible loss or range of loss in excess of the amount recognized at this time.

VBM Litigation

Since June 2023, the Company has also engaged in a process to negotiate and attempt to resolve many of the cases in the VBM Litigation. Certain settlements were reached during June 2024, but, at present, no settlements have been paid on the VBM Litigation cases. Consequently, for all of the VBM Litigation cases, including cases where settlements have been agreed but not yet paid as well as unasserted claims that the Company believes are probable of assertion, the Company estimated a probable loss at an estimated amount of $3.8 million at June 30, 2024, which is recorded as Contingent Liability for Legal Proceedings in the accompanying condensed consolidated balance sheets. The expense related to this estimate was recorded within Fibercel Litigation Costs, net in the accompanying condensed consolidated statement of operations, with the entirety of such expense offset by the insurance received or receivable as further described below.

In order to reasonably estimate the liability for the unsettled VBM Litigation cases and unasserted claims, the Company, along with outside legal counsel, has assessed a variety of factors, including (i) the extent of the injuries incurred, (ii) recent experience on the settled claims, (iii) settlement offers made to the other parties to the litigation and (iv) any other factors that may have a material effect on the VBM Litigation. While the Company believes its estimated liability to be reasonable, the actual loss amounts are highly variable and are dependent upon the relevant facts and case-by-case resolutions. As more information is learned about asserted and unasserted claims and potential future trends, adjustments may be made to this Contingent Liability for Legal Proceedings as appropriate. Management believes that it is reasonably possible that the Company could incur liabilities in excess of amounts accrued and the ultimate liability could be material to the Company's financial position, results of operations and cash flows in the period recognized. The Company, however, is unable to estimate the possible loss or range of loss in excess of the amount recognized at this time.

Defense costs for both the FiberCel Litigation and VBM Litigation are recognized in the accompanying condensed consolidated statements of operations as incurred, with the entirety of such expense related to the VBM Litigation offset by the insurance received or receivable as further described below.

Receivable of Litigation Costs

The Company has purchased insurance coverage that, subject to common contract exclusions, provided coverage for the FiberCel Litigation and VBM Litigation product liability losses as well as legal defense costs. Additionally, the

Company has various potential indemnity and/or contribution rights against third party sources with respect to certain product liability losses. When settlements are reached and/or amounts are recorded in the related Contingent Liability for Legal Proceedings, the Company calculates amounts due to be reimbursed pursuant to the terms of the coverage and related agreements, and pursuant to other indemnity or contribution claims, in respect of product liability losses and related defense costs. The amounts probable of reimbursement or recovery from this calculation are recorded as receivables. The determination that the recorded receivables are probable of collection is based on the terms of agreements reached in respect of indemnity and contribution claims as well as the advice of the Company's outside legal counsel. These receivables at June 30, 2024 totaled $4.4 million, with $0.4 million relating to the FiberCel Litigation and $4.0 million related to the VBM Litigation, and are recorded as Receivables of Litigation Costs in the accompanying condensed consolidated balance sheets.

At June 30, 2024, the Company continues to pursue additional amounts in respect of such indemnity and contribution claims which have not been reflected as part of this receivable. The Company will vigorously pursue its position with respect to these amounts.

As of both June 30, 2024 and 2023, the Company was not a party to, or aware of, any legal matters or claims with material financial exposure, except for the FiberCel Litigation, VBM Litigation and Medtronic matter.

Note 11. Net Loss Per Share

(in thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
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)
Denominator:				
Weighted average number of common shares - basic and diluted	24,900,167	16,223,919	24,408,651	16,208,905
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)
Net loss per share - basic and diluted	$ (1.13)	$ (0.65)	$ (1.89)	$ (1.15)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders:

	June 30,	
	2024	2023
Options to purchase common stock	3,238,414	1,666,549
Restricted stock units	2,218,216	303,935
Class A common stock warrants	187,969	187,969
Common Warrants	9,667,779	—
2023 Prefunded Warrants	241,588	—
2024 Prefunded Warrants	725,000	—
Total	16,278,966	2,158,453

Note 12. Segment Information

With the sale of the Orthobiologics Business, the Company now operates in three segments. These segments are based on financial information that is utilized by the Company's chief operating decision maker to assess performance and allocate resources. The Company determined its operating and reportable segments to be consistent with its major product groupings – Device Protection, Women's Health and Cardiovascular.

The Company's net sales disaggregated by segment were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net sales:				
Device protection	$ 2,639	2,221	$ 4,996	$ 4,571
Women's health	2,571	2,400	6,138	4,695
Cardiovascular	1,081	1,730	1,851	3,477
Total net sales	$ 6,291	$ 6,351	$ 12,985	$ 12,743

The Company's gross profit disaggregated by segment were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Gross profit:				
Device protection	$ 1,571	$ 1,499	$ 3,200	$ 3,294
Women's health	1,410	907	2,976	1,959
Cardiovascular	667	1,157	1,165	2,534
Gross profit, excluding intangible asset amortization	$ 3,648	3,563	7,341	7,787
Intangible asset amortization expense	849	849	1,699	1,699
Gross profit	$ 2,799	$ 2,714	$ 5,642	$ 6,088

The following table is a reconciliation of segment gross profit to the consolidated loss before provision for income taxes (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Gross profit, excluding intangible asset amortization	$ 3,648	$ 3,563	$ 7,341	$ 7,787
Adjustments:				
Intangible asset amortization expense	(849)	(849)	(1,699)	(1,699)
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, net	(2,289)	(1,271)	(4,074)	(3,182)
Loss from operations	(8,510)	(6,309)	(16,989)	(14,648)
Interest expense	1,267	1,409	2,580	2,839
Loss on revaluation of warrant liability	18,337	—	27,974	—
Other expense (income), net	257	—	(1,186)	—
Loss before provision for income taxes	$ (28,371)	$ (7,718)	$ (46,357)	$ (17,487)

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report, as well as the audited financial statements and the related notes thereto, and the discussion under Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report. This discussion contains forward-looking statements reflecting our current expectations, estimates, plans and assumptions concerning events and financial trends that involve risks and may affect our future operating results and financial position. Actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the sections entitled "Forward-Looking Statements" and Part II, Item 1A. "Risk Factors" of this Quarterly Report and in the section entitled "Risk Factor Summary" and in Part I, Item IA. "Risk Factors" of our Annual Report.

Overview

At Elutia, our mission is to humanize medicine so that patients can thrive without compromise. As a commercial-stage company, we seek to leverage our unique understanding of biologics to improve the interaction between implanted medical devices and patients by reducing complications associated with these surgeries. These complications include device migration, erosion, non-union of implants as well as implant rejection. In addition, our products are designed to mitigate the formation of scar and fibrotic capsule formation that commonly occurs with device implants and is linked with additional risk factors including infection and capsular contracture.

We estimate that, over the past two years, more than 600,000 surgical procedures were performed per year in the United States in which the patient was implanted with medical devices such as pacemakers, defibrillators, neuro-stimulators or tissue expanders for breast reconstruction. This number has been driven by advances in medical device technologies, reimbursement models focused on patient outcomes, and an aging population with a growing incidence of comorbidities, including diabetes, obesity and cardiovascular and peripheral vascular diseases. These comorbidities can exacerbate various immune responses and contribute to other complications upon device implant.

Our products are targeted to address unmet clinical needs with the goal of promoting healthy tissue formation and avoiding complications associated with medical device implants, such as scar tissue formation, capsular contraction, erosion, migration and implant rejection. These products currently focus on our priority markets – Device Protection and Women's Health.

In Device Protection, we sell CanGaroo, a "first-to-market" biological envelope, protected by a global patent portfolio, that is indicated for use with implantable electronic devices including cardiac and neurostimulator devices. CanGaroo is designed to create a secure pocket to hold the device and mitigate complications such as device migration and erosion. The CanGaroo product is a biomatrix comprised of extracellular matrix ("ECM"), which has been shown to support healthy wound healing. Because of this inherent ECM trait, CanGaroo may facilitate re-operative procedures by mitigating scar formation and fibrosis. The CanGaroo envelope is also the only envelope designed for subcutaneous implantable cardiac defibrillators, a growing market. Additionally, in June 2024, we received clearance from the U.S. Food and Drug Administration ("FDA") for our antibiotic-eluting bioenvelope, EluPro (referred to as CanGarooRM during development). Specifically designed to prevent post-operative complications for devices such as pacemakers and defibrillators, EluPro provides antibiotic delivery combined with advanced tissue engineering to create a bioenvelope that over time remodels 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. EluPro is the only drug-eluting biomatrix ("DEB") offering in the $600 million U.S. implantable electronic device protection market.

In Women's Health, we have developed both patented and proprietary technologies, culminating in the creation of SimpliDerm—a novel biological matrix meticulously designed to leverage the inherent science of natural healing processes. SimpliDerm's design uses human acellular dermal matrices with heightened structural integrity and superior handling capabilities, which may mitigate inflammation and tissue incorporation, leading to a better healing experience. We believe that these acellular dermal matrices represent an optimal choice for tissue repair and reconstruction, finding applications in fields such as sports medicine, hernia repair, and trauma reconstruction. These matrices are also useable in breast reconstruction surgeries, particularly for women undergoing mastectomy as part of cancer treatment.

With respect to pipeline products, we are pioneering DEB to help solve problems unaddressed by available options. As described above, EluPro is our first DEB product offering. We also intend to leverage our DEB platform technology by developing and commercializing products for markets with similar unmet needs, including neurostimulation, wound care and breast reconstruction.

CanGaroo and EluPro, upon its commercial introduction in the third quarter of 2024, are sold through our internal sales force, independent sales agents and our marketing partner, Boston Scientific. SimpliDerm is sold through both independent sales agents and our distributor, Tiger Aesthetics Medical after their acquisition of the assets of Sientra in April 2024.

We also sell legacy products into the Cardiovascular market. In Cardiovascular, we sell our specialized porcine small intestine submucosa, which is also the tissue used to make CanGaroo, for use as an intracardiac and vascular patch as well as for pericardial reconstruction. In addition, our TYKE product is designed for use in the neonatal patient population. These cardiovascular products are sold in the United States through an exclusive agreement with LeMaitre Vascular and internationally through distributors.

We process all of our CanGaroo and cardiovascular products at our manufacturing facility in Roswell, Georgia and stock inventory of raw materials, supplies and finished goods at this location. We rely on a single or limited number of suppliers for certain raw materials and supplies. We have a long-term supply agreement with Cook Biotech (now owned by RTI Surgical), the porcine tissue supplier of our raw materials for our CanGaroo and cardiovascular products.

SimpliDerm has historically been processed by us at our Richmond, California facility; however, that facility was included with the sale of the Orthobiologics Business described below, and SimpliDerm is now being provided to us on a go-forward basis through a long-term supply agreement with the purchaser of the Orthobiologics Business, Berkeley Biologics, LLC.

Discontinued Operations – Sale of Orthobiologics Business

On November 8, 2023, we completed the sale of substantially all of the assets relating to our former Orthobiologics segment (the “Orthobiologics Business”) to Berkeley Biologics, LLC (“Berkeley”). The Orthobiologics Business was comprised of assets relating to researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing our Orthobiologics products, and the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products. The assets sold represent the entirety of our Orthobiologics segment. In the sale, we received approximately $14.6 million, and we may earn up to an additional $20 million, in the aggregate, in the form of earn-out payments. The earn-out payments are equal to 10% of the actual revenue earned by Berkeley in each of the five years after the closing of the sale from sales of specified Orthobiologics products under the purchase agreement (including improvements, modifications, derivatives and enhancements related to those products). There were no earn-out payments earned or paid in the three months ended June 30, 2024. Additionally, the purchase agreement provides for a customary indemnity holdback in the amount of $1.5 million to be retained by Berkeley for 24 months after close. We recognized a gain of approximately $6.0 million on the sale of the Orthobiologics Business in the fourth quarter of 2023 and an additional gain of $0.2 million in the second quarter of 2024 from an adjustment payment related to the final working capital received by Berkeley at the sale date. The indemnity holdback is available as a source of recovery for Berkeley for claims of indemnification under the purchase agreement, and some or all of the holdback may be retained by Berkeley if Berkeley is successful in asserting a claim or claims for indemnification against us. Should we receive incremental proceeds in the future through an earn-out payment or payment of the holdback amount, an additional gain will be recorded upon the receipt of such amounts.

Product Recalls

In June 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix, a bone repair product formerly manufactured under a contract with Medtronic PLC, which also distributed the product. The recall was issued after learning of postsurgical infections reported in several patients treated with the product, including some patients that tested positive for tuberculosis. Additionally, in July 2023, we announced a voluntary recall of a single lot of one of our viable bone matrix ("VBM") products and the market withdrawal of all of our VBM products produced after a specified date. Notice of the voluntary recall was issued to centers after we learned of post-surgical tuberculosis infections in two patients treated with product from a single donor lot of our VBM product. Both of these products were part of our Orthobiologics Business, which we have fully divested as described above. For information about legal proceedings in which we are involved and the possible future financial implications, see Note 10 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Impact of Inflation

Inflationary factors, such as increases in our cost of goods sold or other operating expenses, may adversely affect our operating results. While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we do not believe inflation had a material effect on our financial condition or results of operations during the three or six months ended June 30, 2024 and 2023. We cannot assure you, however, that we will be able to increase the selling prices of our products or reduce our operating expenses in an amount sufficient to offset the effects future inflationary pressures may have on our gross margin. Accordingly, we cannot assure you that our financial condition and results of operations will not be materially impacted by inflation in the future.

Components of Our Results of Operations

Net Sales

We recognize revenue on the sale of our products. Our device protection products are sold to hospitals and other healthcare facilities primarily through our direct sales force, commercial partners or independent sales agents. Our cardiovascular products are sold domestically through a distribution agreement with LeMaitre Vascular and internationally through commercial partners. Our women's health products are sold directly to hospitals and other healthcare facilities through independent sales agents or through our distribution agreement with Tiger Aesthetics Medical after their acquisition of the assets of Sientra in April 2024.

Expenses

In recent years, we have incurred significant costs in the operation of our business. We expect that our recurring operating costs will largely stabilize, or increase at modest rates, in the near future through the identification of efficiencies as we grow. We may, however, still experience more significant expense increases to the extent we expand our sales and marketing, product development and clinical and research activities. As a result, we will need to generate significant net sales in order to achieve profitability. Below is a breakdown of our main expense categories and the related expenses incurred in each category:

Cost of Goods Sold

Our cost of goods sold relate to purchased raw materials and the processing and conversion costs of such raw materials consisting primarily of salaries and benefits, supplies, quality control testing and the manufacturing overhead incurred at our processing facilities in Roswell, Georgia and our former Orthobiologics facility in Richmond, California. The Roswell facility has additional capacity, which if utilized, would further leverage our fixed overhead. Cost of goods sold also includes the amortization of intangibles generated from the CorMatrix Acquisition in 2017.

Sales and Marketing Expenses

Sales and marketing expenses are primarily related to our direct sales force, consisting of salaries, commission compensation, fringe benefits, meals and other expenses. Auto and travel costs also contribute to sales and marketing expenses. Outside of our direct sales force, we incur significant expenses relating to commissions to our CanGaroo and SimpliDerm commercial partners and independent sales agents. Additionally, this expense category includes distribution costs as well as market research, trade show attendance, advertising and public relations related to our products, and customer service expenses.

General and Administrative Expenses

General and administrative ("G&A") expenses consist primarily of compensation, consulting, legal, human resources, information technology, accounting, insurance and general business expenses. Our G&A expenses have increased as a result of operating as a public company, especially as a result of hiring additional personnel and incurring greater director and officer insurance premiums, greater investor relations costs, and additional costs associated with accounting, legal, tax-related and other services associated with maintaining compliance with exchange listing and SEC requirements.

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of salaries and fringe benefits, laboratory supplies, clinical studies and outside service costs. Over the last several years, our product development efforts have primarily related to activities associated with the development of EluPro (referred to as CanGarooRM during development), our initial DEB product offering. See above for discussion of the June 2024 FDA approval of EluPro. Future development efforts are expected to focus on (i) expanding the EluPro offering with additional sizes and product features and (ii) developing new products within the DEB product portfolio. We also conduct clinical studies to validate the performance characteristics of our products and to capture patient data necessary to support our commercial efforts.

FiberCel Litigation Costs

FiberCel litigation costs consist primarily of legal fees and the estimated costs to resolve the outstanding FiberCel litigation cases offset by the estimated and actual amounts recoverable under insurance, indemnity and contribution agreements for such costs.

Results of Operations

Comparison of the Three Months Ended June 30, 2024 and 2023

	Three Months Ended June 30,				Change 2023 / 2024	
	2024		2023			
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 6,291	100.0 %	$ 6,351	100.0 %	$ (60)	(0.9)%
Cost of goods sold	3,492	55.5 %	3,637	57.3 %	(145)	(4.0)%
Gross profit	2,799	44.5 %	2,714	42.7 %	85	3.1 %
Sales and marketing	3,330	52.9 %	3,022	47.6 %	308	10.2 %
General and administrative	4,689	74.5 %	3,861	60.8 %	828	21.4 %
Research and development	1,001	15.9 %	869	13.7 %	132	15.2 %
FiberCel litigation costs	2,289	36.4 %	1,271	20.0 %	1,018	80.1 %
Total operating expenses	11,309	179.8 %	9,023	142.1 %	2,286	25.3 %
Loss from operations	(8,510)	(135.3)%	(6,309)	(99.3)%	(2,201)	34.9 %
Interest expense	1,267	20.1 %	1,409	22.2 %	(142)	(10.1)%
Loss on revaluation of warrant liability	18,337	291.5 %	—	— %	18,337	NM
Other expense (income), net	257	4.1 %	—	— %	257	NM
Loss before provision of income taxes	(28,371)	(451.0)%	(7,718)	(121.5)%	(20,653)	267.6 %
Income tax expense	(11)	(0.2)%	12	0.2 %	(23)	(191.7)%
Net loss from continuing operations	(28,360)	(450.8)%	(7,730)	(121.7)%	(20,630)	266.9 %
Discontinued operations	180	2.9 %	(2,891)	(45.5)%	3,071	(106.2)%
Net loss	**$ (28,180)**	**(447.9)%**	**$ (10,621)**	**(167.2)%**	**$ (17,559)**	**(165.3)%**

NM = not meaningful

Net Sales

Net sales information for our products is summarized as follows:

	Three Months Ended June 30,				Change 2023 / 2024	
	2024		2023			
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Products:						
Device protection	$ 2,639	41.9 %	$ 2,221	35.0 %	$ 418	18.8 %
Women's health	2,571	40.9 %	2,400	37.8 %	171	7.1 %
Cardiovascular	1,081	17.2 %	1,730	27.2 %	$ (649)	(37.5)%
Total Net Sales	**$ 6,291**	**100.0 %**	**$ 6,351**	**100.0 %**	**$ (60)**	**(0.9)%**

Total net sales decreased $0.1 million, or 0.9%, to $6.3 million in the three months ended June 30, 2024 compared to $6.4 million in the three months ended June 30, 2023. Revenues from Device Protection and Women's Health increased compared to the prior year's second quarter due primarily to volume growth, and revenues from Cardiovascular decreased due to the commencement in April 2023 of our distribution agreement with LeMaitre Vascular which provides for sales at a contract price versus sales prior to such agreement being made at end-user pricing.

Cost of Goods Sold

Cost of goods sold and gross margin percentage information for our products is summarized as follows:

	Three Months Ended June 30,					
	2024		2023			
		Gross		Gross	Change 2023 / 2024	
(in thousands, except percentages)	Amount	Margin %	Amount	Margin %	$	%
Products:						
Device protection	$ 1,068	59.5 %	$ 722	67.5 %	$ 346	47.9 %
Women's health	1,161	54.8 %	1,493	37.8 %	(332)	(22.2)%
Cardiovascular	414	61.7 %	573	66.9 %	(159)	(27.7)%
Cost of goods sold, excluding intangible asset amortization	2,643	58.0 %	2,788	56.1 %	(145)	(5.2)%
Intangible asset amortization expense	849	(13.5)%	849	(13.4)%	—	— %
Total Cost of Goods Sold	**$ 3,492**	**44.5 %**	**$ 3,637**	**42.7 %**	**$ (145)**	**(4.0)%**

Total cost of goods sold decreased $0.1 million to $3.5 million in the three months ended June 30, 2024 compared to $3.6 million in the three months ended June 30, 2023. Gross margin was 44.5% in the three months ended June 30, 2024 compared to 42.7% in the three months ended June 30, 2023. Gross margin, excluding intangible asset amortization, was 58.0% in the three months ended June 30, 2024 compared to 56.1% in the three months ended June 30, 2023. The improvement in gross margin was primarily due to the Women's health business which experienced certain non-recurring production issues in the 2023 period which had a negative impact on gross margins. As noted above, with the sale of the Orthobiologics Business in November 2023, we no longer internally produce our women's health product, SimpliDerm.

Operating Expenses

Sales and Marketing

Sales and marketing expenses increased $0.3 million, or 10.2%, to $3.3 million in the three months ended June 30, 2024 compared to $3.0 million in the three months ended June 30, 2023. As a percentage of sales, sales and marketing expenses increased to 52.9% in the three months ended June 30, 2024 from 47.6% in the three months ended June 30, 2023. The increase in expense was largely attributable to the non-cash equity compensation grants made in January 2024.

General and Administrative

G&A expenses increased $0.8 million, or 21.4%, to $4.7 million in the three months ended June 30, 2024 compared to $3.9 million in the three months ended June 30, 2023. As a percentage of net sales, G&A expenses increased to 74.5% in the three months ended June 30, 2024 from 60.8% in the three months ended June 30, 2023. The increase in expense was primarily driven by the non-cash equity compensation grants made in January 2024.

Research and Development

R&D expenses were essentially flat between years slightly increasing to $1.0 million in the three months ended June 30, 2024 compared to $0.9 million in the three months ended June 30, 2023. Over the last several years, our R&D efforts have primarily related to activities associated with the development of EluPro (referred to as CanGarooRM during development). The June 2024 FDA approval of EluPro is discussed in further under the heading "Overview" above..

FiberCel Litigation Costs

FiberCel litigation costs increased to $2.3 million in the three months ended June 30, 2024 compared to $1.3 million in the three months ended June 30, 2023. The increase in expense was primarily due to the continued evaluation of the contingent FiberCel liability. See further discussion in Note 10 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest Expense

Interest expense was approximately $1.3 million in the three months ended June 30, 2024 compared to $1.4 million in the three months ended June 30, 2023. The decrease was primarily due to lower principal outstanding on the SWK debt in the current year period as a result of mandatory repayments in connection with our sale of the Orthobiologics Business in November 2023.

Discontinued Operations

Income from discontinued operations for the three months ended June 30, 2024 was $0.2 millon and loss from discontinued operations for the three months ended June 30, 2023 was $2.9 million. See Notes 1 and 4 to condensed consolidated financial statements included elsewhere in this Quarterly Report for further discussion.

Comparison of the Six Months Ended June 30, 2024 and 2023

	Six Months Ended June 30,				Change 2023 / 2024	
	2024		2023			
(in thousands, except percentages)	**Amount**	**% of Net Sales**	**Amount**	**% of Net Sales**	**$**	**%**
Net sales	$ 12,985	100.0 %	$ 12,743	100.0 %	$ 242	1.9 %
Cost of goods sold	7,343	56.5 %	6,655	52.2 %	688	10.3 %
Gross profit	5,642	43.5 %	6,088	47.8 %	(446)	(7.3)%
Sales and marketing	6,639	51.1 %	7,713	60.5 %	(1,074)	(13.9)%
General and administrative	9,745	75.0 %	7,381	57.9 %	2,364	32.0 %
Research and development	2,173	16.7 %	2,460	19.3 %	(287)	(11.7)%
FiberCel litigation costs	4,074	31.4 %	3,182	25.0 %	892	28.0 %
Total operating expenses	22,631	174.3 %	20,736	162.7 %	1,895	9.1 %
Loss from operations	(16,989)	(130.8)%	(14,648)	(114.9)%	(2,341)	(16.0)%
Interest expense	2,580	19.9 %	2,839	22.3 %	(259)	(9.1)%
Loss on revaluation of warrant liability	27,974	215.4 %	—	— %	27,974	NM
Other expense (income), net	(1,186)	(9.1)%	—	— %	(1,186)	NM
Loss before provision of income taxes	(46,357)	(357.0)%	(17,487)	(137.2)%	(28,870)	165.1 %
Income tax expense	(3)	(0.0)%	24	0.2 %	(27)	(112.5)%
Net loss from continuing operations	(46,354)	(357.0)%	(17,511)	(137.4)%	(28,843)	(164.7)%
Discontinued operations	180	1.4 %	(1,084)	(8.5)%	1,264	(116.6)%
Net loss	**$ (46,174)**	**(355.6)%**	**$ (18,595)**	**(145.9)%**	**$ (27,579)**	**(148.3)%**

NM = not meaningful

Net Sales

Net sales information for our products is summarized as follows:

	Six Months Ended June 30,				Change 2023 / 2024	
	2024		2023			
(in thousands, except percentages)	**Amount**	**% of Net Sales**	**Amount**	**% of Net Sales**	**$**	**%**
Products:						
Device protection	$ 4,996	38.5 %	$ 4,571	35.9 %	$ 425	9.3 %
Women's health	6,138	47.3 %	4,695	36.8 %	1,443	30.7 %
Cardiovascular	1,851	14.3 %	3,477	27.3 %	$ (1,626)	(46.8)%
Total Net Sales	**$ 12,985**	**100.0 %**	**$ 12,743**	**100.0 %**	**$ 242**	**1.9 %**

Total net sales increased $0.3 million, or 1.9%, to $13.0 million in the six months ended June 30, 2024 compared to $12.7 million in the six months ended June 30, 2023. Revenues from Device Protection and Women's Health increased compared to the prior year period due primarily to volume growth, and revenues from Cardiovascular decreased due to the commencement in April 2023 of our distribution agreement with LeMaitre Vascular which provides for sales at a contract price versus sales prior to such agreement being made at end-user pricing.

Cost of Goods Sold

Cost of goods sold and gross margin percentage information for our products is summarized as follows:

	Six Months Ended June 30,					
	2024		2023		Change 2023 / 2024	
(in thousands, except percentages)	**Amount**	**Gross Margin %**	**Amount**	**Gross Margin %**	**$**	**%**
Products:						
Device protection	$ 1,796	64.1 %	$ 1,277	72.1 %	$ 519	40.6 %
Women's health	3,162	48.5 %	2,736	41.7 %	426	15.6 %
Cardiovascular	686	62.9 %	943	72.9 %	(257)	(27.3)%
Cost of goods sold, excluding intangible asset amortization	5,644	56.5 %	4,956	61.1 %	688	13.9 %
Intangible asset amortization expense	1,699	(13.1)%	1,699	(13.3)%	—	— %
Total Cost of Goods Sold	**$ 7,343**	**43.5 %**	**$ 6,655**	**47.8 %**	**$ 688**	**10.3 %**

Total cost of goods sold increased $0.6 million to $7.3 million in the six months ended June 30, 2024 compared to $6.7 million in the six months ended June 30, 2023. Gross margin was 43.5% in the six months ended June 30, 2024 compared to 47.8% in the six months ended June 30, 2023. Gross margin, excluding intangible asset amortization, was 56.5% in the six months ended June 30, 2024 compared to 61.1% in the six months ended June 30, 2023. The decline in gross margin was primarily due to the Cardiovascular business which decreased due to the commencement of the LeMaitre Vascular distribution agreement described above.

Operating Expenses

Sales and Marketing

Sales and marketing expenses decreased $1.1 million, or 13.9%, to $6.6 million in the six months ended June 30, 2024 compared to $7.7 million in the six months ended June 30, 2023. As a percentage of sales, sales and marketing expenses decreased to 51.1% in the six months ended June 30, 2024 from 60.5% in the six months ended June 30, 2023. The decrease in expense was largely attributable to the previously announced reduction in force which occurred at the end of the first quarter of 2023 and primarily impacted certain members of sales and marketing management.

General and Administrative

G&A expenses increased $2.3 million, or 32.0%, to $9.7 million in the six months ended June 30, 2024 compared to $7.4 million in the six months ended June 30, 2023. As a percentage of net sales, G&A expenses increased to 75.0% in the six months ended June 30, 2024 from 57.9% in the six months ended June 30, 2023. The increase in expense resulted largely from the non-cash equity compensation grants made in January 2024.

Research and Development

R&D expenses decreased to $2.2 million in the six months ended June 30, 2024 compared to $2.5 million in the six months ended June 30, 2023. Over the last several years, our R&D efforts have primarily related to activities associated with the development of EluPro (referred to as CanGarooRM during development). See above for discussion of the June 2024 FDA approval of EluPro. Such related costs were less in the first half of 2024 versus the prior year's comparable period due to the reduction of efforts needed and expenses incurred as the development progressed toward anticipated completion.

FiberCel Litigation Costs

FiberCel litigation costs increased to $4.1 million in the six months ended June 30, 2024 compared to $3.2 million in the six months ended June 30, 2023. The increase in expense was primarily due to the continued evaluation of the contingent FiberCel liability. See further discussion in Note 10 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest Expense

Interest expense was approximately $2.6 million in the six months ended June 30, 2024 compared to $2.8 million in the six months ended June 30, 2023. The decrease was primarily due to lower principal outstanding on the SWK debt in the current year period as a result of mandatory repayments in connection with our sale of the Orthobiologics Business in November 2023.

Discontinued Operations

Income from discontinued operations for the six months ended June 30, 2024 was $0.2 millon and loss from discontinued operations for the six months ended June 30, 2023 was $1.1 million. See Notes 1 and 4 to condensed consolidated financial statements included elsewhere in this Quarterly Report for further discussion.

Non-GAAP Financial Measures

This Quarterly Report presents our gross margin, excluding intangible asset amortization, for the three and six months ended June 30, 2024 and 2023. We calculate gross margin, excluding intangible asset amortization, as gross profit, excluding amortization expense relating to intangible assets we acquired in the CorMatrix Acquisition, divided by net sales. Gross margin, excluding intangible asset amortization, is a supplemental measure of our performance, is not defined by or presented in accordance with U.S. generally accepted accounting principles (“GAAP”), has limitations as an analytical tool and should not be considered in isolation or as an alternative to our GAAP gross margin, gross profit or any other financial performance measure presented in accordance with GAAP. We present gross margin, excluding intangible asset amortization, because we believe that it provides meaningful supplemental information regarding our operating performance by removing the impact of amortization expense, which is not indicative of our overall operating performance. We believe this provides our management and investors with useful information to facilitate period-to-period comparisons of our operating results. Our management uses this metric in assessing the health of our business and our operating performance, and we believe investors’ understanding of our operating performance is similarly enhanced by our presentation of this metric. In addition, other companies, including companies in our industry, may use other measures to evaluate their performance, which could reduce the usefulness of this non-GAAP financial measure as a tool for comparison.

The following table presents a reconciliation of our gross margin, excluding intangible asset amortization, for the three and six months ended June 30, 2024 and 2023 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	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
Intangible asset amortization expense	849	849	1,699	1,699
Gross profit, excluding intangible asset amortization	$ 3,648	$ 3,563	$ 7,341	$ 7,787
Gross margin	44.5 %	42.7 %	43.5 %	47.8 %
Gross margin, excluding intangible asset amortization	58.0 %	56.1 %	56.5 %	61.1 %

Seasonality

Historically, we have experienced seasonality, with lower sales in our first and second quarters and higher sales in our fourth quarter, and we expect this trend to continue. We have experienced and may in the future experience, higher sales in the fourth quarter as a result of hospitals in the United States increasing their purchases of our products to coincide with the end of their budget cycles. Satisfaction of patient deductibles throughout the course of the year also results in increased sales later in the year, once patients have paid their annual insurance deductibles in full, which reduces their out-of-pocket costs. Conversely, our first quarter generally has lower sales than the preceding fourth quarter as patient deductibles are re-established with the new year, which increases their out-of-pocket costs.

Liquidity and Capital Resources

As of June 30, 2024, we had cash of approximately $18.2 million. Since inception, we have financed our operations primarily through amounts borrowed under our credit facilities, proceeds from our initial public offering (“IPO”), sales of our products and more recently, the sale of our Orthobiologics Business and proceeds from a follow-on offering and private placements of our common stock and warrants. Our historical cash outflows have primarily been associated with acquisitions and integration, manufacturing and administrative costs, general and marketing, research and development, clinical activity, purchase of property and equipment used in our production activities, litigation costs and investing in our commercial infrastructure through our direct sales force and our commercial partners in order to expand our presence and to promote awareness and adoption of our products. As of June 30, 2024, our accumulated deficit was $221.8 million.

On June 18, 2024, we sold, in a registered direct offering (“Registered Offering”) an aggregate of (i) 3,175,000 shares (“Common Shares”) of the Company’s Class A common stock and (ii) prefunded warrants (“2024 Prefunded Warrants”) to purchase up to an aggregate of 725,000 shares of Class A Common Stock. The public offering price for each share of Class A Common Stock was $3.40, and the public offering price for each 2024 Prefunded Warrant was $3.399, for aggregate gross proceeds of approximately $13.3 million, before deducting offering expenses. The 2024 Prefunded Warrants have an exercise price of $0.001 per share of Class A Common Stock, are exercisable immediately and will expire when exercised in full.

On September 21, 2023, we sold, in a private offering (“Private Offering”) an aggregate of (i) 6,852,811 units (“Common Units”), each comprised of (a) one share of our Class A common stock and (b) a warrant (“Common Warrant”) to purchase one and one half shares of Class A Common Stock, and (ii) 503,058 units (the “Prefunded Units”), each comprised of (a) a prefunded warrant (“2023 Prefunded Warrant”) to purchase one share of Class A Common Stock, and (b) a Common Warrant. The Common Units were sold at a purchase price of $1.4275 per unit, and the 2023 Prefunded Units were sold at a purchase price of $1.4265 per unit, for aggregate gross proceeds of approximately $10.5 million, before deducting offering expenses. Each Common Warrant is exercisable at any time until the earlier of (a) 30 trading days after the clearance by the FDA of our CanGarooRM antibiotic-eluting biologic envelope or (b) five years from the date of the offering, at an exercise price per share of $1.4275. Each 2023 Prefunded Warrant is exercisable at any time at a nominal exercise price per share of $0.001 (with the remainder of the exercise price per share of Class A Common Stock having been prefunded to us). With the FDA's approval of EluPro in June 2024 (referred to as CanGarooRM during development), the last exercise date for the Common Warrants was July 31, 2024. All Common Warrants outstanding as of June 30, 2024 were exercised by such date yielding exercise proceeds of $13.8 million in July 2024.

We expect our losses to continue for the foreseeable future and these losses will continue to have an adverse effect on our financial position. Because of the numerous risks and uncertainties associated with our commercialization and development efforts, including our ability to successfully commercialize our new EluPro product, we are unable to predict when we will become profitable, and we may never become profitable. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, we may seek to raise capital through the issuance of common stock, such as the Registerd Offering and Private Offering described above, pursue asset sale or other transactions, such as the sale of the Orthobiologics Business described above. However, such transactions may not be successful, and we may not be able to raise additional equity, refinance our debt instruments, or sell assets on acceptable terms, or at all. As such, based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as a going concern within one year after the issuance of the financial statements.

Cash Flows for the Six Months Ended June 30, 2024 and 2023

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (6,973)	$ (7,555)
Investing activities	167	(267)
Financing activities	5,718	129
Net decrease in cash	**$ (1,088)**	**$ (7,693)**

Cash Flows From Operating Activities

Net cash used in operating activities for the six months ended June 30, 2024 was $7.0 million compared to $7.6 million for the six months ended June 30, 2023. The year-over-year decrease was primarily due to a lower net loss (excluding non-cash items) as well as reductions in inventory held.

Cash Flows From Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2024 was $0.2 million compared to net cash used in investing activities of $0.3 million for the six months ended June 30, 2023. The current year period reflects the receipt of $0.2 million in the second quarter of 2024 from an adjustment payment related to the final working capital received by Berkeley at the sale date. The prior year period use of cash is related to the purchase of property and equipment for our production activities.

Cash Flows From Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2024 was $5.7 million compared to $0.1 million for the six months ended June 30, 2023. The year-over-year increase was caused primarily by the Registered Offering and warrant exercises which yielded proceeds of $14.1 million offset by repayments of long-term debt and payments on the revenue interest obligation which collectively totalled $7.2 million. No such activity occurred in the 2023 period.

Credit Facilities

General

On August 10, 2022 (the "Closing Date"), we entered into a senior secured term loan facility with SWK Funding LLC ("SWK"), as agent, and other lenders party thereto (as amended and modified subsequent to the Closing Date, the "SWK Loan Facility") for an aggregate principal amount of $25 million. An initial draw of $21 million was made on the Closing Date with the additional $4 million drawn on December 14, 2022 upon satisfaction of the amended terms enabling such receipt. The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to $8 million, which has not been entered into to date. As of June 30, 2024, we had $23.0 million of indebtedness outstanding under our SWK Loan Facility, with such balance being net of $0.7 million of unamortized discount and deferred financing costs.

Interest Rates

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate ("SOFR") loans and bear interest at a rate per annum equal to the sum of an applicable margin of (i) 7.75% and the "Term SOFR Rate" (based upon an interest period of 3 months), or (ii) if we have elected the PIK Interest option (as defined below), 3.75% and the "Term SOFR Rate." We may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% ("PIK Interest"), and such election may be made (x) until November 15, 2024 if certain conditions, as defined, have not been met, or (y) if such conditions have been satisfied, until November 17, 2025. The "Term SOFR Rate" is subject to a floor of 2.75%.

Mandatory Prepayments

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility) to the Company's total gross profit (as defined in the SWK Loan Facility) multiplied by the outstanding loans under the SWK Loan Facility, and (y) the difference between $1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. The closing of the sale of the Orthobiologics Business in November 2023 triggered the mandatory prepayment of $4.0 million. Of such amount, $2.0 million was paid shortly after closing of the divestiture of the Orthobiologics Business and the remainder was paid on February 15, 2024 based on mutual agreement between the parties. No such mandatory prepayments were required in the six months ended June 30, 2023.

Optional Prepayment

The agreement, as amended, governing the SWK Loan Facility also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination plus $62,500 and prepayment penalties equal to: (i) if such prepayment occurs prior to the first anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination plus remaining unpaid interest payments scheduled to be paid during the first year of the loan or (ii) if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, 2% of the aggregate principal amount funded prior to the termination.

Amortization and Final Maturity

The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility starts on November 15, 2024, which amortization may be extended to November 17, 2025 if the Extension Conditions (as defined in the SWK Loan Facility Agreement) have been satisfied. Principal payments during the amortization period will be limited based on revenue-based caps. As of June 30, 2024, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the outstanding principal on such principal payment commencement date with the balance paid at maturity.

Security

All obligations under the SWK Loan Facility are, and any future guarantees of those obligations will be, secured by, among other things, and in each case subject to certain exceptions, a first priority lien on and security interest in, upon, and to all of our assets, whether now owned or hereafter acquired, wherever located.

Covenants and Other Matters

The SWK Loan Facility Agreement that governs the SWK Loan Facility contains a number of covenants that, among other things and subject to certain exceptions, restrict our ability to:

- incur additional indebtedness;
- incur certain liens;
- pay dividends or make other distributions on equity interests;
- redeem, repurchase or refinance subordinated indebtedness;
- consolidate, merge or sell or otherwise dispose of assets;
- make investments, loans, advances, guarantees and acquisitions;
- enter into transactions with affiliates;
- amend or modify our governing documents;
- amend or modify certain material agreements; and
- alter the business conducted by us and our subsidiaries.

In addition, the SWK Loan Facility Agreement contains two financial covenants. The first covenant, which is measured quarterly, requires us to achieve a specified Minimum Aggregate Revenue (as defined in the SWK Loan Facility) for the preceding 12-month period or, alternatively, to maintain Consolidated Unencumbered Liquid Assets (as defined in the SWK Loan Facility) greater than either (i) the outstanding principal balance of the loan, or (ii) the aggregate operating cash burn (as defined in the SWK Loan Facility) for the preceding 12-month period. The second covenant requires us to maintain a minimum liquidity (as defined in the SWK Loan Facility) of the greater of (a) $5.0 million and (b) the sum of the operating cash burn for the two prior consecutive fiscal quarters then ended (the "Liquidity Covenant").

On March 27, 2024, we entered into an amendment to the SWK Loan Facility Agreement, which modified the Minimum Aggregate Revenue covenant under the SWK Facility to provide that as of the last business day of each fiscal quarter of the Company beginning with the first fiscal quarter of 2024, our required Minimum Aggregate Revenue (as defined in the SWK Facility) for the trailing twelve-month period must be equal to or greater than $20.0 million.

The SWK Loan Facility Agreement contains events of default, including, most significantly, a failure to timely pay interest or principal, insolvency, or an action by the FDA or such other material adverse event impacting the operations of Elutia. As of June 30, 2024, we were in compliance with the financial covenants and all other covenants.

Funding Requirements

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we expand our product development and clinical and research activities. In addition, we expect to continue to incur significant costs and expenses associated with operating as a public company.

As of June 30, 2024, we had $22.3 million of indebtedness outstanding, consisting of $23.0 million outstanding under our SWK Loan Facility, net of $0.7 million of unamortized discount and deferred financing costs. Such indebtedness currently has a principal payment commencement date of November 15, 2024, with quarterly principal payments in an amount equal to 5% of the outstanding principal. In addition, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated ("Ligand") pursuant to a long-term obligation to Ligand (the "Revenue Interest Obligation"). The Revenue Interest Obligation, as amended in January 2024, requires us to pay Ligand 5.0% of future sales of our CanGaroo, ProxiCor, Tyke and VasCure products, and substantially similar products, through May 31, 2027, subject to annual minimum payments of $4.4 million.

If our available cash balances and cash flow from operations are insufficient to satisfy our liquidity requirements, we may seek to raise additional capital through equity offerings, debt financings, or asset sale or other transactions. However, such transactions may not be successful and we may not be able to raise additional equity or debt, or sell or license assets on acceptable terms, or at all. We may also consider raising additional capital in the future to expand our business, pursue strategic investments or take advantage of financing opportunities. Our present and future funding requirements will depend on many factors, including, among other things:

- continued patient, physician and market acceptance of our products;
- the scope, rate of progress and cost of our current and future pre-clinical and clinical studies;
- the cost of our research and development activities and the cost and timing of commercializing new products or technologies;
- the cost and timing of expanding our sales and marketing capabilities;
- the cost of filing and prosecuting patent applications and maintaining, defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights;
- the costs of defending against or the damages payable in connection with the FiberCel Litigation and any future litigation that we may be subject to (to the extent above the applicable insurance coverage);
- the cost and timing of additional regulatory approvals;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments;
- the expenses we incur in manufacturing and selling our products;
- the extent to which we acquire or invest in products, technologies and businesses in the future, although we may currently have no commitments or agreements relating to any of these types of transactions;
- the costs of operating as a public company;

- unanticipated general, legal and administrative expenses; and
- the effects on any of the above from any pandemic, epidemic or outbreak of infectious disease.

In addition, our operating plans may change as a result of any number of factors, including those set forth above and other factors currently unknown to us, and we may need additional funds sooner than anticipated. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares of our common stock and/or declaring dividends. If we raise funds through collaborations, licensing agreements or other strategic alliances, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay the development or commercialization of our products, license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize and reduce marketing, customer support or other resources devoted to our products or cease operations. See our Annual Report, Part I, Item 1A. "Risk Factors — Risks Related to Our Business — *Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all*."

Based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as a going concern within one year after the issuance of the financial statements.

Critical Accounting Policies and Estimates

The preparation of our unaudited condensed consolidated financial statements in accordance with GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We have discussed the policies and estimates that we believe are critical and require the use of complex judgment in their application in our Annual Report, and, during the three and six months ended June 30, 2024, there were no material changes to those previously disclosed other than those outlined in Note 2, "Summary of Significant Accounting Policies."

Recent Accounting Pronouncements

Refer to Note 3, "Recently Issued Accounting Standards," to our condensed consolidated financial statements included elsewhere in this Quarterly Report for information regarding recently issued accounting pronouncements.

JOBS Act

Section 107 of the JOBS Act permits us, as an "emerging growth company," to take advantage of an extended transition period for adopting new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, for so long as we remain an emerging growth company, unless we subsequently choose to affirmatively and irrevocably opt out of the extended transition period, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are $1.235 billion or more; (ii) the last day of 2025; (iii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates is $700 million or more as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business, including risks relating to changes in interest rates, foreign currency and inflation. The following discussion provides additional information regarding these risks.

Interest Rate Risk

Our primary exposure to market risk relates to changes in interest rates. Borrowings under our SWK Loan Facility bear interest at variable rates, subject to an interest rate floor. Interest rate risk is highly sensitive due to many factors, including U.S. monetary and tax policies, U.S. and international economic factors and other factors beyond our control. A hypothetical 10% relative change in interest rates on our variable rate indebtedness outstanding at June 30, 2024 would not have had a material effect on our financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Credit Risk

As of June 30, 2024, our cash was maintained with two financial institutions in the United States. While our deposit accounts are insured up to the legal limit, the balances we maintain may, at times, exceed this insured limit. We believe these financial institutions have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our financial condition, results of operations or cash flows. As we grow our operations, our exposure to foreign currency risk could become more significant.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

The Company's management has evaluated, with the participation of the Chief Executive Officer and the Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of June 30, 2024.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. For information about legal proceedings in which we are involved, see Note 10 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Item 1A. Risk Factors.

Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described as risk factors, any one or more of which could, directly or indirectly, cause our actual operating results and financial condition to vary materially from past, or anticipated future, operating results and financial condition. For a discussion of these potential risks and uncertainties, see Part I, Item 1A. “Risk Factors” of our Annual Report. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, operating results and the price of our common stock. There have been no material changes in our risk factors to those included in our Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the three months ended June 30, 2024, none of our directors or officers (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K).

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
4.1	Form of Prefunded Warrant	8-K	001-39577	4.1	6/18/2024	
10.1	Second Amendment to Credit Agreement, dated March 27, 2024, by and among Elutia Inc., SWK Funding LLC, as Agent, and the Lenders from time to time party thereto.	8-K	001-39577	10.1	4/1/2024	
10.2	Placement Agency Agreement, dated June 16, 2024, by and between Elutia Inc. and Lake Street Capital Markets, LLC	8-K	001-39577	10.1	6/18/2024	
10.3	Form of Securities Purchase Agreement	8-K	001-39577	10.2	6/18/2024	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

* Filed herewith.

** Furnished herewith.

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 thereunto duly authorized.

ELUTIA INC.

Date: August 13, 2024	By: /s/ C. Randal Mills, Ph.D. C. Randal Mills, Ph.D. President and Chief Executive Officer *(principal executive officer)*
Date: August 13, 2024	By: /s/ Matthew Ferguson Matthew Ferguson Chief Financial Officer *(principal financial officer and principal accounting officer)*

Exhibit 31.1

CERTIFICATIONS

I, C. Randal Mills, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024 of Elutia Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2024

By: /s/ C. Randal Mills, Ph.D.
C. Randal Mills, Ph.D.
President and Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS

I, Matthew Ferguson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2024 of Elutia Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2024

By: /s/ Matthew Ferguson

Matthew Ferguson
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Elutia Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2024

By: /s/ C. Randal Mills, Ph.D.
C. Randal Mills, Ph.D.
President and Chief Executive Officer
(principal executive officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Elutia Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 13, 2024

By: /s/ Matthew Ferguson
Matthew Ferguson
Chief Financial Officer
(principal financial officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.