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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 September 30, 2023
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)

Aziyo Biologics, Inc.
(Former name, former address and former fiscal year, if changed since last report)

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 November 9, 2023, there were 18,884,146 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; expectations regarding the voluntary recall of a single lot of a certain viable bone matrix product and the market withdrawal of all of our viable bone matrix ("VBM") products ("VBM Matter"), and any impact of the recall and suspension of sales of these products on the Company's business; plans for our sales and marketing growth; expectations regarding our recently completed sale of our Orthobiologics Business to Berkeley Biologics, LLC, including potential payment of post-closing earnout payments; our anticipated expansion of our product development and research activities; increases in expenses and seasonality; expectations regarding our competitive advantages, and overall clinical and commercial success; expectations regarding the pending lawsuits and claims related to our recall of a single lot of Fiber Viable Bone Matrix ("FiberCel"), amounts recoverable under insurance, indemnity and contribution agreements and the impact of such lawsuits and claims on our future financial position; expectations regarding the potential emergence of lawsuits, claims and regulatory findings related to the VBM Matter, amounts recoverable under insurance, indemnity and contribution agreements and the impact of such lawsuits and claims on our future financial position; our expectations and plans regarding pursuit of any strategic transactions; expectations regarding the continued listing of our stock on the Nasdaq Capital Market; and our expectations relating to the FDA regulatory process for the CanGarooRM Antibacterial Envelope 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;
- our ability to obtain regulatory approval or other marketing authorizations by the U.S. Food and Drug Administration ("FDA") and comparable foreign authorities for our products and product candidates;
- 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 ability to maintain our relationships with our existing contract manufacturing customers and enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products;

- our ability to successfully realize the anticipated benefits of the sale of our Orthobiologics Business;
- our ability to successfully execute or realize the anticipated benefits under our distribution arrangements with LeMaitre Vascular and Sientra;
- physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products;
- the continued and future acceptance of our products by the medical community;
- our dependence on a limited number of third-party suppliers;
- our ability to defend against the various lawsuits related to our recall of a single lot of FiberCel and avoid a material adverse financial consequence;
- with respect to earnout payments potentially payable in connection with the sale of our Orthobiologics Business, the ability of the sold business to generate specified revenues; and
- our ability to regain compliance with the listing standards of the Nasdaq Capital Market ("Nasdaq") and maintain the listing of our Class A common stock on Nasdaq.

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, 2022 (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®,” “ProxiCor®,” “Tyke®,” “VasCure®,” “ViBone®,” “OsteGro®,” “SimpliDerm®” and our logo, which are our property and are protected under applicable intellectual property laws. The “ViBone®” and “OsteGro®” tradenames were sold in connection with the divestiture of the Orthobiologics Business described in Note 1 to the condensed consolidated financial statements. 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.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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

(UNAUDITED)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 14,517	$ 16,989
Accounts receivable, net of credit loss reserve of $652 and $87, respectively	2,883	3,774
Inventory	6,503	4,240
Receivables of FiberCel litigation costs	7,452	13,813
Prepaid expenses and other current assets	452	2,387
Current assets of discontinued operations	7,320	9,496
Total current assets	39,127	50,699
Property and equipment, net	175	245
Intangible assets, net	12,520	15,069
Operating lease right-of-use assets and other	155	320
Noncurrent assets of discontinued operations	2,603	2,508
Total assets	**$ 54,580**	**$ 68,841**
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,962	$ 1,374
Accrued expenses and other current liabilities	10,723	8,830
Payables to tissue suppliers	707	900
Current portion of revenue interest obligation	11,053	8,990
Contingent liability for FiberCel litigation	15,702	17,360
Current operating lease liabilities	399	232
Current liabilities of discontinued operations	3,190	4,929
Total current liabilities	44,736	42,615
Long-term debt	25,278	24,260
Long-term revenue interest obligation	5,471	5,916
Warrant liability	7,550	—
Other long-term liabilities	433	127
Noncurrent liabilities of discontinued operations	585	956
Total liabilities	84,053	73,874
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Class A Common stock, $0.001 par value, 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022, and 18,852,930 and 11,823,445 shares issued and outstanding, as of September 30, 2023 and December 31, 2022, respectively	19	12
Class B Common stock, $0.001 par value, 20,000,000 shares authorized, as of September 30, 2023 and December 31, 2022 and 4,313,406 issued and outstanding as of September 30, 2023 and December 31, 2022	4	4
Additional paid-in capital	136,834	132,939
Accumulated deficit	(166,330)	(137,988)
Total stockholders' deficit	(29,473)	(5,033)
Total liabilities and stockholders' deficit	**$ 54,580**	**$ 68,841**

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net sales	$ 6,127	$ 5,849	$ 18,870	$ 17,262
Cost of goods sold	3,286	2,910	9,943	8,689
Gross profit	2,841	2,939	8,927	8,573
Sales and marketing	2,802	4,379	10,514	13,672
General and administrative	2,757	4,330	10,137	12,788
Research and development	557	1,723	3,016	5,867
FiberCel litigation costs, net	4,096	1,474	7,278	1,908
Total operating expenses	10,212	11,906	30,945	34,235
Loss from operations	(7,371)	(8,967)	(22,018)	(25,662)
Interest expense	1,448	1,247	4,285	3,666
Other income, net	(312)	803	(312)	803
Loss before provision for income taxes	(8,507)	(11,017)	(25,991)	(30,131)
Income tax expense	12	12	36	36
Net loss from continuing operations	(8,519)	(11,029)	(26,027)	(30,167)
Income (loss) from discontinued operations	(1,228)	1,119	(2,315)	2,710
Net loss	(9,747)	$ (9,910)	(28,342)	$ (27,457)
Net loss from continuing operations per share - basic and diluted	$ (0.50)	$ (0.81)	$ (1.58)	$ (2.22)
Net income (loss) from discontinued operations per share - basic and diluted	$ (0.07)	$ 0.08	$ (0.14)	$ 0.20
Net loss - basic and diluted	$ (0.57)	$ (0.73)	$ (1.72)	$ (2.02)
Weighted average common shares outstanding - basic and diluted	17,017,610	13,660,555	16,464,262	13,618,580

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, June 30, 2023	**11,936,441**	**$ 12**	**4,313,406**	**$ 4**	**$ 134,439**	**$ (156,583)**	**$ (22,128)**
Proceeds from sale of common stock in connection with private placement, net of issuance costs of $0.2 million	6,852,811	7	—	—	1,708	—	1,715
Proceeds from sale of common stock through Employee Stock Purchase Plan	63,628	—	—	—	72	—	72
Vesting of restricted stock units	50	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	615	—	615
Net loss	—	—	—	—	—	(9,747)	(9,747)
Balance, September 30, 2023	**18,852,930**	**$ 19**	**4,313,406**	**$ 4**	**$ 136,834**	**$ (166,330)**	**$ (29,473)**
Balance, June 30, 2022	**9,306,838**	**$ 9**	**4,313,406**	**$ 4**	**$ 121,256**	**$ (122,638)**	**$ (1,369)**
Proceeds from stock option exercises	1,881	—	—	—	10	—	10
Proceeds from sale of common stock through Employee Stock Purchase Plan	32,063	—	—	—	126	—	126
Vesting of restricted stock units, net of shares withheld and taxes paid	120,182	—	—	—	(395)	—	(395)
Issuance of warrants in connection with debt financing	—	—	—	—	560	—	560
Stock-based compensation	—	—	—	—	297	—	297
Net loss	—	—	—	—	—	(9,910)	(9,910)
Balance, September 30, 2022	**9,460,964**	**$ 9**	**4,313,406**	**$ 4**	**$ 121,854**	**$ (132,548)**	**$ (10,681)**

	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, 2022	**11,823,445**	**$ 12**	**4,313,406**	**$ 4**	**$ 132,939**	**$ (137,988)**	**$ (5,033)**
Proceeds from sale of common stock in connection with private placement, net of issuance costs of $0.2 million	6,852,811	7	—	—	1,708	—	1,715
Proceeds from sale of common stock through Employee Stock Purchase Plan	104,905	—	—	—	219	—	219
Vesting of restricted stock units, net of shares withheld and taxes paid	71,769	—	—	—	(19)	—	(19)
Stock-based compensation	—	—	—	—	1,987	—	1,987
Net loss	—	—	—	—	—	(28,342)	(28,342)
Balance, September 30, 2023	**18,852,930**	**$ 19**	**4,313,406**	**$ 4**	**$ 136,834**	**$ (166,330)**	**$ (29,473)**
Balance, December 31, 2021	**9,245,146**	**$ 9**	**4,313,406**	**$ 4**	**$ 118,599**	**$ (105,091)**	**$ 13,521**
Proceeds from stock option exercises	1,881	—	—	—	10	—	10
Additional issuance costs in connection with private placement	—	—	—	—	(110)	—	(110)
Proceeds from sale of common stock through Employee Stock Purchase Plan	74,408	—	—	—	317	—	317
Vesting of restricted stock units, net of shares withheld and taxes paid	139,529	—	—	—	(395)	—	(395)
Issuance of warrants in connection with debt financing	—	—	—	—	560	—	560
Stock-based compensation	—	—	—	—	2,873	—	2,873
Net loss	—	—	—	—	—	(27,457)	(27,457)
Balance, September 30, 2022	**9,460,964**	**$ 9**	**4,313,406**	**$ 4**	**$ 121,854**	**$ (132,548)**	**$ (10,681)**

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

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

(UNAUDITED)

	Nine Months Ended September 30,	
	2023	2022
Net loss	$ (28,342)	$ (27,457)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,854	2,796
(Gain) loss on extinguishment of debt and revaluation of warrant liability	(1,070)	311
Amortization of deferred financing costs and debt discount	161	63
Interest expense recorded as additional revenue interest obligation and long-term debt	2,473	1,983
Stock-based compensation	1,987	2,873
Bad debt expense	590	—
Losses associated with viable bone matrix recall and market withdrawal	1,984	—
Changes in operating assets and liabilities:		
Accounts receivable	1,045	(1,163)
Inventory	(2,490)	(638)
Receivables of FiberCel litigation costs	6,361	(17,234)
Prepaid expenses and other	1,609	467
Accounts payable and accrued expenses and other current liabilities	2,562	4,029
Obligations to tissue suppliers	(1,049)	743
Contingent liability for FiberCel litigation	(1,658)	17,643
Deferred revenue and other liabilities	305	(605)
Net cash used in operating activities	**(12,678)**	**(16,189)**
INVESTING ACTIVITIES:		
Expenditures for property, plant and equipment	(329)	(406)
Net cash used in investing activities	**(329)**	**(406)**
FINANCING ACTIVITIES:		
Proceeds from private placement and warrants, net of offering costs of $0.2 million	10,335	—
Additional issuance costs in connection with private placement	—	(110)
Net borrowings (repayments) under revolving line of credit	—	(4,763)
Proceeds from stock option exercises	—	10
Proceeds from long-term debt	—	21,000
Deferred financing costs	—	(468)
Repayments of long-term debt	—	(18,615)
Costs related to the extinguishment of debt	—	(633)
Payments on revenue interest obligation	—	(2,075)
Payments for taxes upon vesting of restricted stock units	(19)	(395)
Proceeds from sales of common stock through Employee Stock Purchase Plan	219	317
Net cash provided by (used in) financing activities	**10,535**	**(5,732)**
Net decrease in cash and restricted cash	**(2,472)**	**(22,327)**
Cash and restricted cash, beginning of period	**16,989**	**30,428**
Cash, end of period	**$ 14,517**	**$ 8,101**
Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:		
Cash paid for interest	$ 1,696	$ 5,047
Fair value of warrants issued	$ —	$ 560

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. (formerly known as Aziyo Biologics, Inc., together with its consolidated subsidiaries, "Elutia" or the "Company") is a regenerative medicine company, with a focus on patients receiving implantable medical devices. The Company has developed a portfolio of regenerative 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 span the device protection, women's health and cardiovascular markets. These products are primarily sold to healthcare providers or commercial partners.

On September 17, 2023, the Company executed an Asset Purchase Agreement (the "Purchase Agreement") with Berkeley Biologics, LLC ("Berkeley"), a Delaware limited liability company and wholly owned subsidiary of GNI Group, Ltd. On November 8, 2023, at the closing (the "Closing") of the transactions contemplated by the Purchase Agreement (the "Asset Purchase"), Berkeley purchased from the Company substantially all of the assets that are related to (i) the Company's prior business of researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing the Company's Orthobiologics products identified in the Purchase Agreement (the "Products"), and (ii) the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products (but excluding the business of contract manufacturing of acellular dermis products for use in the field of breast reconstruction, other than as a supplier to Elutia). The assets sold represent the entirety of the Company's Orthobiologics segment (the "Orthobiologics Business"). The Purchase Agreement provides for an aggregate purchase price, subject to certain adjustments pursuant to the terms of the Purchase Agreement, of up to $35 million in cash, with approximately $14.6 million, as adjusted, having been paid shortly after Closing and up to $20 million potentially payable after the Closing in the form of earn-out payments ("Earn-Out Payments"). For each of the five years following the Closing, Berkeley would be required to pay to the Company an Earn-Out Payment equal to 10% of the actual revenue earned by Berkeley in the applicable year that is derived from sales of those Products defined as "Earn-Out Products" under the Purchase Agreement, and from any improvements, modifications, derivatives and enhancements related to the Earn-Out Products, with the aggregate amount of Earn-Out Payments capped at $20 million.

The sale of the Orthobiologics Business represents a strategic shift that has a major effect on the Company's operations and financial results. Accordingly, this transaction is accounted for as Discontinued Operations for all periods presented in accordance with Accounting Standards Codification ("ASC") 205-20, *Discontinued Operations*. Unless indicated otherwise, the information in the notes to the Condensed Consolidated Financial Statements relates to continuing operations. See Note 4 for further discussion of the divestiture of the Orthobiologics Business.

On May 4, 2023, the Company received a letter from the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") notifying us that it did not meet the Market Value of Listed Securities ("MVLS") requirement for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "Market Value Standard"), and noting that the Company did not meet the requirements under Nasdaq Listing Rules 5550(b)(1) (Equity Standard) and 5550(b)(3) (Net Income Standard). The Original Notice provided that, in accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company would have a period of 180 calendar days from the date of the Original Notice, or until October 31, 2023 (the "Compliance Date"), to regain compliance with the Market Value Standard by having the Company's MVLS close at or above $35 million for a minimum of 10 consecutive business days prior to the Compliance Date.

On November 1, 2023, the Company received a delisting determination letter (the "Letter") from the Staff advising the Company that the Staff had determined that the Company did not regain compliance with the Market Value Standard by the Compliance Date. As a result, if not for the Company's appeal of the Staff's determination, trading of our common stock on the Nasdaq Capital Market would have been suspended at the opening of business on November 10, 2023, and Form 25-NSE would have been filed with the Securities and Exchange Commission to remove the Company's securities from listing and registration on the Nasdaq Capital Market. However, the Company timely submitted a hearing

request to Nasdaq's Hearings Panel (the “Panel”), which stayed the suspension of our common stock pending the panel's conclusion of the hearing process.

The Company’s hearing has been scheduled for February 15, 2024. At the hearing, the Company intends to present a plan to regain compliance with the Market Value Standard, and in the interim, the Company’s common stock will continue to trade on the Nasdaq Capital Market under the symbol “ELUT” at least pending the ultimate conclusion of the hearing.

There can be no assurance that the the Company’s plan will be accepted by the Panel or that, if it is, the Company will be able to regain compliance with the applicable Nasdaq listing requirements. If the Company cannot regain compliance with the Market Value Standard or under Nasdaq’s alternative continued listing requirements, and if the Company’s common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our collaborators, vendors, suppliers and employees, which could harm the Company’s business and future prospects.

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 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, 2022. The financial information as of September 30, 2023 and for the three and nine months ended September 30, 2023 and 2022 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, 2022 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.

The financial position and operating results of the disposed-of Orthobiologics Business have been reported as discontinued operations in the condensed consolidated financial statements in the current as well as prior comparative periods.

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 consolidated financial statements are issued. For the nine months ended September 30, 2023, the Company incurred a net loss of $28.3 million, and as of September 30, 2023, the Company had an accumulated deficit of $166.3 million. In addition, during the nine months ended September 30, 2023, the Company used $12.7 million of cash in operating activities, and expects to continue to incur cash outflows during the remainder of 2023. 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 flow.

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, the Company may seek to raise capital through the issuance of common stock, such as the private placement which we closed in September 2023 described in Note 9, pursue asset sale or other transactions, such as the completed sale of the Orthobiologics Business described in Note 4, or restructure our Revenue Interest Obligation. 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, the Company believes 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.

The accompanying 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.

Reclassifications

The Company determined in its fourth quarter of 2022 that its operating and reportable segments are consistent with its major product groupings – Device Protection, Women's Health, Cardiovascular and Orthobiologics prior to its divestiture. Segment results for the three and nine months ended September 30, 2022, have been recasted to conform to the new segment presentation, which now excludes Orthobiologics due to its divestiture noted above. Refer to the Segment Information in Note 12.

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 and warrants, the valuation of the revenue interest obligation, the contingent liability for the FiberCel Litigation 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

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.

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. Inventory write-downs for unprocessed and certain processed donor tissue are recorded based on the estimated amount of inventory that will not pass the quality control process based on historical data. 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.

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 nine months ended September 30, 2023 or 2022.

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.

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. Our Offering Warrants 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 Income, net in the 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.

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.

On June 19, 2023, Surgalign Holdings, Inc. ("Surgalign") and certain of its direct and indirect subsidiaries commenced voluntary proceedings under chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of Texas. As of September 30, 2023, the Company's gross accounts receivable from Surgalign totaled $0.6 million which has fully been reserved at September 30, 2023 due to the uncertainty of collection.

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 nine months ended September 30, 2023 and 2022, 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 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses* (Topic 326): *Disclosure Framework – Measurement of Credit Losses on Financial Instruments*, which requires financial assets measured at amortized cost, including trade receivables, be presented net of the amount expected to be collected. The measurement of all expected credit losses is based on relevant information about the credit quality of customers, past events, including historical experience, and reasonable and supportable forecasts that affect the collectability of the reported amount. In October 2019, the FASB voted to approve a proposal to defer the effective date of ASC 2016-13 for certain entities, including emerging growth companies that take advantage of the extended transition period, to fiscal years beginning after December 15, 2022. This ASU was effective for the Company beginning on January 1, 2023 and did not have a material impact on our condensed consolidated Financial Statements. The Company adopted this ASU using the modified retrospective transition method. Under this transition method, the new standard is applied from January 1, 2023 without restatement of comparative period amounts. The impact of transitioning to the new standard was immaterial and no adjustment was recorded to retained earnings for the cumulative effect of adopting this ASU on January 1, 2023. Results for reporting periods beginning after January 1, 2023 are presented under Topic 326 while prior period amounts continue to be reported in accordance with previously applicable GAAP.

Note 4. Divestiture of Orthobiologics Business

As described in Note 1, on September 17, 2023, the Company executed the Purchase Agreement for the sale of its Orthobiologics Business. Accordingly, the Orthobiologics Business is reported as discontinued operations in accordance with ASC 205-20 - *Discontinued Operations*. The related assets and liabilities of the Orthobiologics Business are classified as assets and liabilities of discontinued operations as of September 30, 2023 and December 31, 2022 in the condensed consolidated balance sheets and the results of operations from the Orthobiologics Business are reported as discontinued operations in the condensed consolidated statements of operations for the three and nine months ended September 30, 2023 and 2022. Applicable amounts in the prior year have been recast to conform to this discontinued operations presentation.

The following tables shows the assets and liabilities of the discontinued operations:

	September 30, 2023	December 31, 2022
Carrying amounts of the major classes of assets included in discontinued operations:		
Accounts receivable, net of credit loss reserve of $62 and $62, respectively	$ 2,311	$ 3,056
Inventory	4,055	5,812
Prepaid expenses and other current assets	954	628
Total current assets	7,320	9,496
Property and equipment, net	1,253	1,158
Operating lease right-of-use assets and other	1,350	1,350
Total non-current assets	2,603	2,508
Total assets of discontinued operations	**$ 9,923**	**$ 12,004**
Carrying amounts of the major classes of liabilities included in discontinued operations:		
Accounts payable	$ 401	$ 954
Accrued expenses and other current liabilities	906	1,273
Payables to tissue suppliers	1,395	2,252
Current operating lease liabilities	488	450
Total current liabilities	3,190	4,929
Long-term operating lease liabilities	585	956
Total liabilities of discontinued operations	**$ 3,775**	**$ 5,885**

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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net sales	$ 2,291	$ 6,540	$ 12,894	$ 19,260
Cost of goods sold	1,839	4,430	11,218	13,605
Gross profit	452	2,110	1,676	5,655
Sales and marketing	374	536	1,636	1,467
General and administrative	927	157	1,231	435
Research and development	262	243	776	988
Total operating expenses	1,563	936	3,643	2,890
Interest expense	117	55	348	55
Net income (loss)	$ (1,228)	$ 1,119	$ (2,315)	$ 2,710

Total operating and investing cash flows of discontinued operations for the nine months ended September 30, 2023 and 2022 are comprised of the following:

	Nine Months Ended September 30,	
	2023	2022
Significant operating non-cash reconciliation items		
Depreciation	213	149
Stock-based compensation	115	119
Changes in operating assets and liabilities:		
Accounts receivable	745	(384)
Inventory	1,757	4,288
Prepaid expenses and other	(326)	32
Accounts payable and accrued expenses and other current liabilities	(920)	427
Obligations to tissue suppliers	(857)	(318)
Significant investing items		
Expenditures for property, plant and equipment	287	271

The Company's Women's Health product, SimpliDerm, has historically been processed by Elutia at our Richmond, California facility; however, with the divestiture of the Orthobiologics Business, which includes such facility, SimpliDerm will be provided to us on a go forward basis through a long-term supply agreement with the purchaser, Berkeley.

Note 5. Stock-Based Compensation

In 2015, the Company established its 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, the Company adopted its 2020 Incentive Award Plan, which was amended and restated on June 8, 2023 (the "2020 Plan"). The 2020 Plan 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 3,636,000 have been reserved for issuance under the 2020 Plan. 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 September 30, 2023, the Company had 3,370,201 shares of Class A common stock available for issuance under the 2020 Plan.

On June 21, 2022, C. Randal Mills, Ph.D., a member of the Board of Directors (the "Board") of the Company, was appointed as the Company's Interim President and Chief Executive Officer, succeeding Ronald Lloyd, who stepped down as the Company's President and Chief Executive Officer and as a member of the Board. In connection with his appointment as the Interim President and Chief Executive Officer, Dr. Mills and the Company entered into an employment agreement for an initial term of 90 days (such period, the "Interim Period"). On August 9, 2022, Dr. Mills was appointed to the role of President and Chief Executive Officer of the Company, thereby ending the Interim Period, and his employment agreement was extended pursuant to the terms thereof. In accordance with the terms of his employment agreement, Dr. Mills (1) received a stock option award to purchase 456,278 shares of Class A common stock of the Company (the "Option Grant") on June 21, 2022; three-fifths of such Option Grant is subject to time-based vesting (the "Time-Based Options") and two-fifths of such Option Grant is subject to performance-based vesting (the "Performance Based Options") and (2) received 224,734 restricted stock units (the "RSU Grant"); three-fifths of such RSU Grant is subject to time-based vesting (the "Time-Based RSUs") and two-fifths of such RSU Grant is subject to performance-based vesting (the "Performance-Based RSUs"). One-third of the Time-Based Options vested on August 9, 2022 (end of the Interim Period), and two-thirds of the Time-Based Options vest over a four-year vesting schedule with 25% vesting on the first anniversary of June 21, 2022 and the remaining portion vesting in twelve equal quarterly installments. One-third of the Time-Based RSUs vest on the grant date, and two-thirds of the Time-Based RSUs vest over a four-year vesting schedule in equal annual installments. The Performance-Based Options and Performance-Based RSUs each vest in equal installments upon the achievement of certain share price thresholds for twenty consecutive days of trading at each respective threshold. Pursuant to the terms of the employment agreement, all of these awards were deemed granted on June 21, 2022, for purposes of and in accordance with ASC 718, *Accounting for Stock Based Compensation*; however, the RSUs were not legally granted until April 2023 and the vested shares underlying the award were not deemed outstanding until such time.

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 four-year period from the date of grant.

A summary of stock option activity under the Company's 2015 Plan and 2020 Plan for the nine months ended September 30, 2023 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2022	1,864,739	$ 9.41	7.5	$ 8
Granted	157,500	$ 2.64		
Exercised	—	$ —		
Forfeited	(374,049)	$ 9.92		
Outstanding, September 30, 2023	1,648,190	$ 8.63	8.1	$ -
Vested and exercisable, September 30, 2023	730,180	$ 9.80	7.4	$ -

The weighted average grant date fair value of options granted during the nine months ended September 30, 2023 was $1.63. As of September 30, 2023, there was approximately $2.4 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted-average period of approximately two years.

The Company uses the Black-Scholes model to value its time-based stock option grants 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 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 primarily 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 nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,	
	2023	2022
Expected term (years)	6.0	6.2
Risk-free interest rate	3.9 %	2.0 %
Volatility factor	63.8 %	53.0 %
Dividend yield	—	—

For the Performance-Based Options with a market condition granted as described above, the Company 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.

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. The Company's RSUs generally vest over a three to four year period from the date of grant.

A summary of the RSU activity under the Company's 2020 Plan for the nine months ended September 30, 2023 is as follows:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2022	372,307	$ 5.90
Granted	72,000	$ 2.24
Vested	(35,044)	$ 9.23
Forfeited	(39,738)	$ 4.54
Unvested, September 30, 2023	369,525	$ 4.96

For the Performance-Based RSUs, including those granted to Dr. Mills as described above, 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 two to three years using the graded vesting method.

As of September 30, 2023, $0.9 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of approximately two years.

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 September 30, 2023, the total shares of Class A common stock authorized for issuance under the ESPP was 542,365, of which 335,808 remained available for future issuance. During the three and nine months ended September 30, 2023, 63,628 and 104,905 shares, respectively, of Class A common stock were issued under the ESPP.

Stock-Based Compensation Expense

Stock-based compensation expense recognized during the three and nine months ended September 30, 2023 and 2022 was comprised of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Sales and marketing	$ 164	$ 330	$ 466	$ 819
General and administrative	373	(124)	1,264	1,460
Research and development	15	(14)	102	414
Cost of goods sold	14	27	40	61
Total stock-based compensation expense	$ 566	$ 219	$ 1,872	$ 2,754

Stock-based compensation expense included within Discontinued Operations totaled $0.1 million for both the three and nine months ended September 30, 2023 and 2022.

Note 6. Inventory

Inventory was comprised of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	$ 1,107	$ 652
Work in process	781	541
Finished goods	4,615	3,047
Total	$ 6,503	$ 4,240

See Note 4 for inventory attributable to the divested Orthobiologics Business.

The VBM recall and market withdrawal, as described in Note 10, necessitated the establishment of a product returns reserve and reversal of revenue totaling $3.0 million during the three months ended June 30, 2023. Based on the timing of the market withdrawal and additional information received from our customers, the Company recorded an additional reversal of revenue totaling $0.3 million during the three months ended September 30, 2023. As of September 30, 2023, the remaining product returns reserve was $2.7 million, which is included in accrued expenses and other current liabilities in the condensed consolidated balance sheet as of September 30, 2023. Furthermore, the Company wrote off the full value of its VBM inventory on-hand at June 30, 2023 resulting in a $2.0 million charge to cost of goods sold in the condensed consolidated income statement for the nine months ended September 30, 2023. Such write-down was deemed necessary due to the limited shelf-life of the inventory and the inability to sell the VBM inventory until a valid MTB test can be identified or developed, both of which continue to be uncertain at this time.

Note 7. Long-Term Debt

On August 10, 2022 (the “Closing Date”), the Company entered into a senior secured term loan facility with SWK Funding LLC (“SWK”), as agent, and other lenders party thereto (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 had not been entered into as of September 30, 2023. 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 September 30, 2023, 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. The SWK Loan Facility also includes both revenue and minimum liquidity covenants, restrictions as to payment of dividends, and is secured by all assets of the Company, subject to certain customary exceptions. On May 12, 2023, the Company entered into that certain First Amendment to the SWK Loan Facility Agreement with SWK, as agent, and the other lenders party thereto (the “Amendment”). The Amendment modified the minimum liquidity covenant applicable to the Company under the SWK Loan Facility Agreement, such that the Company must maintain a minimum liquidity of at least $5.0 million until August 15, 2023. After such date, a minimum liquidity of at least the greater of (i) $5.0 million, and (ii) the sum of the operating cash burn (as defined in the SWK Loan Facility Agreement) for the two prior consecutive fiscal quarters then ended. As of September 30, 2023, Elutia was in compliance with its financial covenants under the agreement governing the SWK Loan Facility (the “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 the conditions to draw the Additional Term Loan have not been met, or (y) if such conditions to draw the Additional Term Loan have been satisfied, until November 17, 2025. The “Term SOFR Rate” is subject to a floor of 2.75%. 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. The weighted average interest rate on the SWK Loan Facility was 13.5% and 13.1% for the three and nine months ended September 30, 2023, respectively.

On August 10, 2022, the Company issued to SWK Funding LLC a warrant (the "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 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 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 Warrant will expire on the seventh anniversary of the Closing Date. Upon issuance, the Company valued the Warrant at approximately $0.6 million using the Black-Scholes model. The recognition of the Warrant as well as deferred financing costs of approximately $0.5 million incurred in securing the SWK Loan Facility resulted in a reduction in 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 nine months ended September 30, 2023; however, the closing of the divestiture of the Orthobiologics Business 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 is to be paid by the earlier of (i) February 15, 2024 and (ii) two business days following written request by SWK based on mutual agreement between the parties.

In connection with the August 2022 debt refinancing, the Company used $16 million of the proceeds of the SWK Loan Facility to repay all outstanding obligations on its former MidCap term loan ("MidCap Loan Facility") and former asset-backed revolving line of credit ("MidCap Credit Facility"). Borrowings under the MidCap Loan Facility bore interest at a rate per annum equal to the sum of (x) the greater of (i) 2.25% and (ii) the applicable London Interbank Offered Rate for U.S. dollar deposits divided by 1.00 minus the maximum effective reserve percentage for Eurocurrency funding ("LIBOR") plus (y) 7.25%. The weighted average interest rate on MidCap Loan Facility was 9.5% for the three and nine months ended September 30, 2022. Borrowings under the MidCap Credit Facility bore interest at a rate per annum equal to the sum of (x) the greater of (i) 2.25% and (ii) LIBOR plus (y) 4.95%. The weighted average interest rate on MidCap Credit Facility was 7.2% for the three and nine months ended September 30, 2022.

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

	September 30, 2023	December 31, 2022
Term Loan Facility, net of unamortized discount and deferred financing costs	$ 25,278	$ 24,260
Current Portion	—	—
Long-Term Debt	$ 25,278	$ 24,260

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 September 30, 2023 and December 31, 2022.

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 ("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 require 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 version of CanGaroo Elutia is currently developing that is designed to include antibiotics.

Furthermore, a $5.0 million payment is 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. The initial $5.0 million milestone payment became due in the second quarter of 2023.

The Company recorded the present value of the estimated total future payments under the Revenue Interest Obligation as a long-term obligation, with the annual minimum payments, along with the expected payment timing of the first $5.0 million sales milestone payment noted above, serving to establish the short-term portion. 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. There was no change to estimated future payments during the three and nine months ended September 30, 2023 and 2022, and thus, no re-measurement gain or loss was recognized. Interest expense related to the Revenue Interest Obligation of approximately $0.6 million and $0.7 million was recorded for the three months ended September 30, 2023 and 2022, respectively and approximately $1.6 million and $2.0 million was recorded for the nine months ended September 30, 2023 and 2022, respectively.

Note 9: Common Stock and Warrants

Private Placement of Common Stock and Warrants

On September 21, 2023, the Company sold, in a private offering exempt from the registration provisions of the Securities Act of 1933, as amended, an aggregate of (i) 6,852,811 units (the "Common Units") to certain purchasers, each comprised of (a) one share of the Company's Class A common stock, par value $0.001 per share ("Class A Common Stock") and (b) a warrant (a "Common Warrant") to purchase one and one half shares of Class A Common Stock, and (ii) 503,058 units (the "Prefunded Units") to certain purchasers, each comprised of (a) a prefunded warrant (a "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 (the "Offering"). Each Common Warrant is exercisable at any time until the earlier of (a) 30 trading days after the clearance by the U.S. Food & Drug Administration of the Company's 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 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 $0.9 million in connection with the private placement, of which $0.2 million were allocated to the issuance of the common stock. See below for discussion of the accounting for warrants and the allocation of the remainder of the transaction fees.

Warrant Liabilities

The Company has concluded that the Common Warrants and the Prefunded Warrants (collectively, the "Offering Warrants") 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, as of the September 21, 2023 issuance date, the Company allocated $8.6 million of the gross proceeds from the offering to the Offering Warrants based on their fair value, and the remaining $1.9 million was allocated to the common shares and recorded as permanent equity. The warrant liability is included within Warrants and other long-term liabilities in the accompanying condensed consolidated balance sheet as of September 30, 2023.

The valuation of the Offering Warrants is adjusted to fair value (Level 3) at each subsequent balance sheet date until the warrants are settled. To this end, due primarily to fluctuations in the Company's underlying common stock price between the issuance date of the Offering Warrants and September 30, 2023, the warrant liability was revalued to $7.6 million as of September 30, 2023. The change in fair value of $1.1 million has been recorded as other income, net in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2023.

The Company also allocated a portion of the transaction fees noted above to the Offering Warrants and expensed within other expense, net, approximately $0.7 million of these fees.

The Company calculated the fair value of the Common Warrants and Prefunded Warrants using the Black-Scholes option pricing model with the following inputs:

	Common Warrants		Prefunded Warrants	
	September 21, 2023	September 30, 2023	September 21, 2023	September 30, 2023
Common stock price	$ 1.53	$ 1.43	$ 1.53	$ 1.43
Expected term (years)	0.9	0.9	0.9	0.9
Risk-free interest rate	5.5 %	5.5 %	5.5 %	5.5 %
Volatility factor	117.4 %	114.9 %	117.4 %	114.9 %
Dividend yield	— %	— %	— %	— %

The expected term of the Common Warrants and Prefunded Warrants is based on a significant unobservable input, the Company's probability-weighted expectations relative to the timing of the clearance by the U.S. Food & Drug Administration of the Company's CanGarooRM antibiotic-eluting biologic envelope.

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 nine months ended September 30, 2023 or 2022. 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

In June 2021, the Company announced a voluntary recall of a single lot of FiberCel fiber viable bone matrix. Since September 2021, 76 lawsuits (78 plaintiffs) in Indiana, Delaware, Florida, Maryland, Colorado, Michigan, Ohio, Kentucky, Oregon, North Carolina, Louisiana, Illinois, Virginia, California, Pennsylvania, and Arizona have been filed against Elutia Inc., certain Medtronic entities, and others alleging 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 Indiana state court (collectively, the “Indiana State Complaints”); the Superior Court of the State of Delaware (collectively, the “Delaware State Complaints”); the Circuit Court of Maryland (collectively, the “Maryland State Complaints”); the Court of Common Pleas of Ohio and the U.S. District Court of the Southern District of Ohio (collectively, the “Ohio Complaints”); the U.S. District Court for the Western District of North Carolina (“North Carolina Federal Complaint”); the U.S. District Court for the Northern District of Florida and the U.S. District Court for the Southern District of Florida (collectively, the “Florida Federal Complaints”); the U.S. District Court for the Eastern District of Michigan (collectively “the Michigan Federal Complaints”); the U.S. District Court for the District of Colorado (“Colorado Federal Complaint”); the U.S. District Court for the District of Oregon (“Oregon Federal Complaint”); the Fayette, Kentucky Circuit Court and the U.S. District Court for the Eastern District of Kentucky (collectively, the “Kentucky Complaints”); the U.S. District Court for the Western District of Louisiana (“Louisiana Federal Complaint”) the Illinois Circuit Court (collectively, the “Illinois State Complaints”); the U.S. District Court for the Eastern District of Virginia (“Virginia Federal Complaint”); the U.S. District Court for the Eastern District of Pennsylvania (“Pennsylvania Federal Complaint”); Philadelphia County Court of Common Pleas (“Pennsylvania State Complaint”); the U.S. District Court for the Central District of California (“California Federal Complaint”) and the U.S. District Court for the District of Arizona (“Arizona Federal Complaint.”).

Plaintiffs in the Indiana State Complaints allege a cause of action under Indiana’s Product Liability Act, citing manufacturing defects, defective design and failure to properly warn and instruct, and several of the complaints allege loss of consortium. Plaintiffs in these actions 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 FiberCel and are seeking various types of damages, including economic damages, non-economic damages and loss of consortium. Plaintiffs in one of the Indiana State Complaints allege causes of action for product liability, negligence, breach of express and implied warranties, and punitive damages. Each of the plaintiffs in the Delaware State Complaints alleges negligence, breach of implied warranty, breach of express warranty, medical monitoring and punitive damages, and two also allege loss of consortium. Plaintiffs in the Delaware State Complaints are seeking economic, consequential, and punitive damages. The Maryland State Complaints assert claims of negligence, breach of implied warranty, breach of express warranty, medical monitoring, and loss of consortium. The Florida Federal Complaints contain three strict liability claims for defective design, defective manufacture, and failure to warn. A claim for punitive damages is also pleaded. The Ohio State Complaints allege causes of action for product liability and negligence and seeks compensatory damages. The Colorado Federal Complaint asserts causes of action for strict product liability, misrepresentation, negligence, breach of express warranty, and breach of implied warranty of merchantability. The Michigan Federal Complaints assert causes of action for negligence, gross negligence breach of implied warranty, breach of express warranty, intentional infliction of emotional distress, and liability under the res ipsa loquitur doctrine. The Michigan Federal Complaints seek compensatory damages and punitive damages. The North Carolina Federal Complaint alleges causes of action for negligence, defective design, breach of implied warranty, breach of express warranty, and loss of consortium, and seeks both compensatory and punitive damages. The Oregon Federal Complaint asserts strict liability claims for defective design, defective manufacture, and failure to warn, and seeks compensatory damages. The Ohio Federal Complaint asserts strict liability claims for defective manufacturing, inadequate warning, nonconformance with representations, and also alleges loss of consortium and seeks compensatory damages. The Kentucky Complaints assert strict liability claims based on manufacturing defect, design defect, failure to warn, negligence, breach of implied warranty, breach of express warranty, and seek recovery for

medical monitoring, loss of consortium, compensatory damages, and punitive damages. The Louisiana Federal Complaint asserts claims of violation of the Louisiana products liability act, negligence and gross negligence, breach of implied warranty, breach of express warranty and seek recovery for medical monitoring. The Illinois State Complaints contain claims of strict liability- defective design and manufacturing, breach of express warranty, breach of implied warranty and negligence and seek compensatory damages. The Virginia Federal Complaint asserts causes of action for negligent failure to warn, negligence, breach of implied warranty and breach of express warranty and seeks recovery for medical monitoring, compensatory damages and punitive damages. The California Federal Complaint advances claims of strict liability (defective design and manufacture), negligence and breach of implied warranty and seeks compensatory damages and recovery for medical monitoring. The Arizona Federal Complaint asserts strict product liability claims for defective design, manufacture and failure to warn, negligence, breach of implied warranty and breach of express warranty and seeks recovery for medical monitoring, loss of consortium, compensatory damages, and punitive damages. Plaintiff in the Pennsylvania State Complaint, which was removed to the Eastern District of Pennsylvania, asserts claims for strict liability, negligence, breach of implied warranty, and breach of express warranty, as well as claims under the Wrongful Death Act and the Survival Act and seeks compensatory and punitive damages. Plaintiff in the Tennessee Federal Complaint asserts claims for indemnity and breach of contract.

In addition to the above, there are 31 claims related to the FiberCel recall that have not yet resulted in a lawsuit. The Company refers to all of the aforementioned litigation, or claim notices, collectively as the “FiberCel Litigation.”

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 27 of the cases was settled and paid for a total of approximately $7.5 million as of September 30, 2023. For the remaining 82 cases for which settlements have not been reached, the Company estimated a probable loss related to each case and has recorded a liability at an estimated amount of $15.7 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying consolidated balance sheets. In order to reasonably estimate the liability for the unsettled FiberCel Litigation cases, the Company, along with outside legal counsel and medical professionals, 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 turn on a case-by-case analysis of the relevant facts. As more information is learned about asserted claims and potential future trends, adjustments may be made to this Contingent Liability for FiberCel Litigation 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 results of operations and the 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 are recognized in the accompanying consolidated statements of operations as incurred.

The Company has purchased insurance coverage that, subject to common contract exclusions, provided coverage for the FiberCel 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 FiberCel Litigation, 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 September 30, 2023 totaled $7.5 million and are recorded as Receivables of FiberCel Litigation Costs in the accompanying consolidated balance sheets.

The indemnity and contribution receivables amount at September 30, 2023 represents amounts that are not believed to be subject to any current dispute. At September 30, 2023, the Company continues to pursue up to $3.8 million or more in additional amounts in respect of such indemnity and contribution claims and as such, has not been reflected as part of this receivable. The Company will vigorously pursue its position with respect to this amount.

Viable Bone Matrix Recall

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 Matter"). Such VBM products are within the Company's Orthobiologics Business. 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.

At present, one lawsuit has been filed, and twelve claims have been asserted as a result of the VBM Matter. Management has determined that there is a reasonably possible likelihood of material claims due to the recall and market withdrawal but does not believe that the claims are estimable. Consequently, management has determined that no liability for such possible claims would be recognized for the VBM recall and market withdrawal as of September 30, 2023. While unknown at this time, possible losses in connection with the VBM Matter could have a material effect on the Company's financial position and results of operations. Consistent with the FiberCel Litigation above, the Company has purchased insurance coverage that, subject to common contract exclusions, provide coverage for the possible claims associated with the VBM Matter as well as legal defense costs.

Liabilities recognized for the FiberCel Litigation and potential liabilities in connection with the VBM Matter are excluded from the liabilities assumed by Berkeley in connection with their purchase of the Orthobiologics Business described in Note 4.

As of both September 30, 2023 and 2022, the Company was not a party to, or aware of, any legal matters or claims with material financial exposure, except for the FiberCel Litigation and VBM Matter.

Note 11. Net Loss Per Share

(in thousands, except share and per share data)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net loss from continuing operations	$ (8,519)	$ (11,029)	$ (26,027)	$ (30,167)
Income (loss) from discontinued operations	$ (1,228)	$ 1,119	$ (2,315)	$ 2,710
Net loss	$ (9,747)	$ (9,910)	$ (28,342)	$ (27,457)
Denominator:				
Weighted average number of common shares - basic and diluted	17,017,610	13,660,555	16,464,262	13,618,580
Net loss from continuing operations per share - basic and diluted	$ (0.50)	$ (0.81)	$ (1.58)	$ (2.22)
Net income (loss) from discontinued operations per share - basic and diluted	$ (0.07)	$ 0.08	$ (0.14)	$ 0.20
Net loss per share - basic and diluted	$ (0.57)	$ (0.73)	$ (1.72)	$ (2.02)

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:

	September 30,	
	2023	2022
Options to purchase common stock	1,648,190	1,755,447
Restricted stock units	369,525	373,332
Class A common stock warrants	187,969	187,969
Common Warrants	11,033,804	—
Prefunded Warrants	503,058	—
Total	13,742,546	2,316,748

Note 12. Segment Information

With the divestiture 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net sales:				
Device protection	$ 2,575	2,319	$ 7,147	$ 6,617
Women's health	2,614	1,812	7,309	5,270
Cardiovascular	938	1,718	4,414	5,375
Total Net Sales	$ 6,127	$ 5,849	$ 18,870	$ 17,262

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Gross profit:				
Device protection	$ 1,704	$ 1,670	$ 4,998	$ 4,419
Women's health	1,417	765	3,376	2,443
Cardiovascular	569	1,353	3,100	4,258
Gross profit, excluding intangible asset amortization	$ 3,690	3,788	11,474	11,120
Intangible asset amortization expense	849	849	2,547	2,547
Gross profit	$ 2,841	$ 2,939	$ 8,927	$ 8,573

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Gross profit, excluding intangible asset amortization	$ 3,690	$ 3,788	$ 11,474	$ 11,120
Adjustments:				
Intangible asset amortization expense	(849)	(849)	(2,547)	(2,547)
Sales and marketing	(2,802)	(4,379)	(10,514)	(13,672)
General and administrative	(2,757)	(4,330)	(10,137)	(12,788)
Research and development	(557)	(1,723)	(3,016)	(5,867)
FiberCel litigation costs	(4,096)	(1,474)	(7,278)	(1,908)
Loss from operations	(7,371)	(8,967)	(22,018)	(25,662)
Interest expense	1,448	1,247	4,285	3,666
Other income, net	(312)	803	(312)	803
Loss before provision for income taxes	$ (8,507)	$ (11,017)	$ (25,991)	$ (30,131)

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 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 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 700,000 surgical procedures were perfomed per year 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.

We have leading products in 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 creates a secure pocket to hold the device and mitigates complications such as device migration and erosion. It is a biomatrix made 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. In addition, we offer the only envelope designed for subcutaneous implantable cardiac defibrillators, a growing market.

In Women's Health, we have developed both patented and proprietary technologies to preserve and protect natural extracellular matrix structure and biologic factors needed to support tissue remodeling. This results in undamaged human acellular dermal matrices with superior handling, designed to promote faster healing and reduce inflammation. This technology is the basis for our product, SimpliDerm. Dermal matrices are standard of care for breast reconstruction surgeries, and our largest market.

With respect to pipeline products, we are pioneering the drug-eluting biomatrix ("DEB"), which will solve problems unaddressed by available options. Our lead product is a version of CanGaroo known as CanGarooRM, a first-in-class biomatrix that combines the CanGaroo envelope with antibiotics. These antibiotics, rifampin and minocycline, have been shown to reduce the risk of infection following surgical implantation of an electronic device. We anticipate CanGarooRM will be the only drug-eluting biomatrix approved for use with implantable electronic devices, providing both acute and long-term benefits to the patient. CanGarooRM will require clearance of a U.S. Food and Drug Administration 510(k) submission to be marketed in the United States. We believe CanGarooRM has a market potential that exceeds $300 million in the established pacemaker and cardiac implant space. Furthermore, we 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. The current status of the CanGarooRM clearance is described below.

CanGaroo is sold through both our internal sales force and independent sales agents and marketing partners, which include Boston Scientific and Biotronik. SimpliDerm is sold through both independent sales agents and our distributor, Sientra.

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, 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, with the divestiture of the Orthobiologics Business described below, SimpliDerm will be provided to us on a go forward basis through a long-term supply agreement with the purchaser of the Orthobiologics Business, Berkeley Biologics, LLC, as described below.

Since inception, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities, sales of our products and, more recently, with proceeds from our initial public offering ("IPO"), a follow-on public offering and private placements of our common stock and warrants. We have devoted the majority of our resources to acquisitions and integration, manufacturing and administrative costs, general and administrative, research and development, clinical activity, purchase of property and equipment used in the production activities of our former Richmond, California facility 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 September 30, 2023, we had 107 full-time employees, and after the divestiture of the Orthobiologics Business described below, we had 53 full-time employees.

We have incurred significant operating losses since our inception. We incurred a net loss of $28.3 million for the nine months ended September 30, 2023. Our accumulated deficit as of September 30, 2023 was $166.3 million. 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 risks relating to our ability to obtain FDA clearance for the next generation of our flagship CanGaroo product, CanGarooRM, and our ability to successfully commercialize this 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 private placement which we closed in September 2023 described below, pursue asset sales or other transactions, such as the sale of the Orthobiologics Business described below, or restructure our Revenue Interest Obligation. 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.

Recent Developments

Sale of Common Stock and Warrants in Private Placement

On September 18, 2023, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the Purchase Agreement, on September 21, 2023, we sold, in a

private offering exempt from the registration provisions of the Securities Act of 1933, as amended, an aggregate of (i) 6,852,811 units (the "Common Units") to certain of the Investors, each comprised of (a) one share of Elutia's Class A common stock, par value $0.001 per share ("Class A Common Stock") and (b) a warrant (a "Common Warrant") to purchase one and one half shares of Class A Common Stock, and (ii) 503,058 units (the "Prefunded Units") to certain of the Investors, each comprised of (a) a prefunded warrant (a "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 U.S. Food & Drug Administration of the Company's CanGaroo®RM antibiotic-eluting biologic envelope or (b) five years from the date of the offering, at an exercise price per share of $1.4275. Each 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).

Sale of Orthobiologics Business

On September 17, 2023, we executed an Asset Purchase Agreement (the "Purchase Agreement") with Berkeley Biologics, LLC ("Berkeley"), a Delaware limited liability company and wholly owned subsidiary of GNI Group, Ltd. (Tokyo Stock Exchange: 2160.T). On November 8, 2023, at the closing (the "Closing") of the transactions contemplated by the Purchase Agreement (the "Asset Purchase"), Berkeley purchased from us substantially all of our assets that are related to (i) our business of researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing our Orthobiologics products identified in the Purchase Agreement (the "Products"), and (ii) the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products (but excluding the business of contract manufacturing of acellular dermis products for use in the field of breast reconstruction, other than as a supplier to Elutia). The assets sold represent the entirety of our Orthobiologics segment (the "Orthobiologics Business"). The Purchase Agreement provides for an aggregate purchase price, subject to certain adjustments pursuant to the terms of the Purchase Agreement, of up to $35 million in cash, with approximately $14.6 million, as adjusted, having been paid shortly after the Closing and up to $20 million after the Closing potentially payable in the form of earn-out payments (each an "Earn-Out Payment"). For each of the five years following the Closing, Berkeley would be required to pay to us an Earn-Out Payment equal to 10% of the actual revenue earned by Berkeley in the applicable year that is derived from sales of those Products defined as "Earn-Out Products" under the Purchase Agreement, and from any improvements, modifications, derivatives and enhancements related to the Earn-Out Products, with the aggregate amount of Earn-Out Payments capped at $20 million.

The Purchase Agreement contains customary representations, warranties and covenants of the parties. We, on the one hand, and Berkeley, on the other hand, have agreed to indemnify each other from and against losses the respective parties may incur arising out of breaches of the other party's representations, warranties and covenants contained in the Purchase Agreement, and Berkeley will indemnify us for losses relating to the Assumed Liabilities (as defined in the Purchase Agreement), and we will indemnify Berkeley for losses relating to the Excluded Assets, Excluded Liabilities, or Excluded Contracts (each as defined in the Purchase Agreement). We will also indemnify Berkeley for losses related to the operation of the Orthobiologics Business prior to Closing, actions initiated by stockholders or creditors of the Company relating to the Asset Purchase, non-compliance with any applicable bulk sales laws, and any third party action against Berkeley or its related indemnified parties if the facts alleged in the action would give the indemnified party a right to indemnification under the Purchase Agreement, among other indemnification requirements. Various of the indemnification obligations of the parties under the Purchase Agreement are subject to specified survival limitations and other customary exceptions and limitations.

Viable Bone Matrix Recall

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. (the "VBM Matter"). Such VBM products are within our Orthobiologics Business. Notice of the voluntary recall was issued to centers after we learned of post-surgical Mycobacterium tuberculosis ("MTB") infections in two patients treated with product from a single donor lot of our VBM product. 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. A total of 36 patients were treated with product from the single donor lot. At present, one lawsuit has been filed, and twelve claims have been asserted as a result of the VBM Matter. While unknown at this time, possible losses in connection with the VBM Matter could have a material effect on our financial position and results of operations. We have purchased insurance coverage that, subject to common contract exclusions, will provide coverage for the VBM Matter as well as legal defense costs.

CanGarooRM Status

As described above, we are developing a new version of CanGaroo known as CanGarooRM, a first-in-class biomatrix that combines the CanGaroo envelope with antibiotics. CanGarooRM will require clearance of a 510(k) submission to be marketed in the United States. We submitted the required 510(k) in April 2022 and, in March 2023, received a Not Substantially Equivalent ("NSE") letter from FDA requiring us to address questions relating to drug testing, primarily a request by FDA to modify an in vitro drug release assay employed as a manufacturing control. We intend to address the questions raised in the NSE letter and continue to work with FDA for potential clearance via the 510(k) pathway. We anticipate being able to complete our responses to outstanding questions from FDA in the 2023 calendar year and gain clearance from the FDA for CanGarooRM in the first half of 2024.

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 nine months ended September 30, 2023 and 2022. 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. During the three months ended September 30, 2023, our device protection and cardiovascular products were sold to hospitals and other healthcare facilities primarily through our direct sales force, commercial partners or independent sales agents; however, beginning in April 2023, our cardiovascular products have been sold domestically through our distribution agreement with LeMaitre Vascular and internationally through commercial partners. Our women's health product, SimpliDerm, is sold directly to hospitals and other healthcare facilities through independent sales agents or through our distribution agreement with Sientra.

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 as we expand our 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 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 have also historically contributed to sales and marketing expenses. Outside of our direct sales force, we incur significant expenses relating to commissions to our CanGaroo 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. Our product development efforts primarily relate to activities associated with the development of CanGarooRM, our CanGaroo Envelope with antibiotics. 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 amounts recoverable under insurance, indemnity and contribution agreements for such costs.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

	Three Months Ended September 30,					
	2023		2022		Change 2022 / 2023	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 6,127	100.0 %	$ 5,849	100.0 %	$ 278	4.8 %
Cost of goods sold	3,286	53.6 %	2,910	49.8 %	376	12.9 %
Gross profit	2,841	46.4 %	2,939	50.2 %	(98)	(3.3)%
Sales and marketing	2,802	45.7 %	4,379	74.9 %	(1,577)	(36.0)%
General and administrative	2,757	45.0 %	4,330	74.0 %	(1,573)	(36.3)%
Research and development	557	9.1 %	1,723	29.5 %	(1,166)	(67.7)%
FiberCel litigation costs	4,096	66.9 %	1,474	25.2 %	2,622	NM
Total operating expenses	10,212	166.7 %	11,906	203.6 %	(1,694)	(14.2)%
Loss from operations	(7,371)	(120.3)%	(8,967)	(153.3)%	1,596	(17.8)%
Interest expense	1,448	23.6 %	1,247	21.3 %	201	16.1 %
Other (income) expense, net	(312)	(5.1)%	803	13.7 %	(1,115)	NM
Loss before provision of income taxes	(8,507)	(138.8)%	(11,017)	(188.4)%	2,510	(22.8)%
Income tax expense	12	0.2 %	12	0.2 %	—	— %
Net loss from continuing operations	(8,519)	(139.0)%	(11,029)	(188.6)%	2,510	(22.8)%
Discontinued operations	(1,228)	(20.0)%	1,119	19.1 %	(2,347)	(209.7)%
Net loss	**$ (9,747)**	**(159.1)%**	**$ (9,910)**	**(169.4)%**	**$ 163**	**1.6 %**

Net Sales

Net sales information for our products is summarized as follows:

	Three Months Ended September 30,					
	2023		2022		Change 2022 / 2023	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Products:						
Device protection	$ 2,575	42.0 %	$ 2,319	39.6 %	$ 256	11.0 %
Women's health	2,614	42.7 %	1,812	31.0 %	802	44.3 %
Cardiovascular	938	15.3 %	1,718	29.4 %	$ (780)	(45.4)%
Total Net Sales	**$ 6,127**	**100.0 %**	**$ 5,849**	**100.0 %**	**$ 278**	**4.8 %**

Total net sales increased $0.3 million, or 4.8%, to $6.1 million in the three months ended September 30, 2023 compared to $5.8 million in the three months ended September 30, 2022. Revenues from Device Protection and Women's Health increased compared to the prior year's third quarter due 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 transfer 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 September 30,					
	2023		2022			
(in thousands, except percentages)	Amount	Gross Margin %	Amount	Gross Margin %	Change 2022 / 2023 $	Change 2022 / 2023 %
Products:						
Device protection	$ 871	66.2 %	$ 649	72.0 %	$ 222	34.2 %
Women's health	1,197	54.2 %	1,047	42.2 %	150	14.3 %
Cardiovascular	369	60.7 %	365	78.8 %	4	1.1 %
Cost of goods sold, excluding intangible asset amortization	2,437	60.2 %	2,061	64.8 %	376	18.2 %
Intangible asset amortization expense	849	(13.9)%	849	(14.5)%	—	— %
Total Cost of Goods Sold	**$ 3,286**	**46.4 %**	**$ 2,910**	**50.2 %**	**$ 376**	**12.9 %**

Total cost of goods sold increased $0.4 million to $3.3 million in the three months ended September 30, 2023 compared to $2.9 million in the three months ended September 30, 2022. Gross margin was 46.4% in the three months ended September 30, 2023 compared to 50.2% in the three months ended September 30, 2022. Gross margin, excluding intangible asset amortization, was 60.2% in the three months ended September 30, 2023 compared to 64.8% in the three months ended September 30, 2022. The decline in gross margin was primarily due to the Cardiovascular business which declined due to the commencement of the LeMaitre Vascular distribution agreement described above.

Operating Expenses

Sales and Marketing

Sales and marketing expenses decreased $1.6 million, or 36.0%, to $2.8 million in the three months ended September 30, 2023 compared to $4.4 million in the three months ended September 30, 2022. As a percentage of sales, sales and marketing expenses decreased to 45.7% in the three months ended September 30, 2023 from 74.9% in the three months ended September 30, 2022. The decrease in expense was largely attributable to the previously announced reduction in force which occurred in the first quarter of 2023 and primarily impacted certain members of sales and marketing management.

General and Administrative

G&A expenses decreased $1.5 million, or 36.3%, to $2.8 million in the three months ended September 30, 2023 compared to $4.3 million in the three months ended September 30, 2022. As a percentage of net sales, G&A expenses decreased to 45.0% in the three months ended September 30, 2023 from 74.0% in the three months ended September 30, 2022. The decrease in expense was primarily due to certain non-recurring legal and severance costs incurred in the third quarter of 2022.

Research and Development

R&D expenses decreased to $0.6 million in the three months ended September 30, 2023 compared to $1.7 million in the three months ended September 30, 2022. We continue to focus our R&D efforts primarily on the development of our CanGarooRM Antibacterial Envelope. Such related costs were less in the third quarter of 2023 versus the prior year’s comparable period due to the reduction of efforts needed and expenses incurred as the development progresses toward anticipated completion.

FiberCel Litigation Costs

FiberCel litigation costs increased to $4.1 million in the three months ended September 30, 2023 compared to $1.5 million in the three months ended September 30, 2022. The increase in expense was primarily due to the continued evaluation of the contingent FiberCel liability and higher legal defense costs as the FiberCel cases progress. See further discussion in Note 10 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest Expense

Interest expense was approximately $1.6 million in the three months ended September 30, 2023 compared to $1.3 million in the three months ended September 30, 2022. The increase was due to the higher principal outstanding and interest rates incurred by us on our existing debt, the SWK Loan Facility, as compared to the debt outstanding in the three months ending September 30, 2022, which consisted primarily of the MidCap Loan Facility and MidCap Credit Facility. See " - Liquidity and Capital Resources - Credit Facilities" below for a further discussion of these debt agreements and Note 7 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Discontinued Operations

Net loss from discontinued operations for the three months ended September 30, 2023 was $1.1 million and net income from discontinued operations for the three months ended September 30, 2022 was $1.2 million. The decrease was largely due to revenue reduction and overall financial impact to the Orthobiologics Business caused by the viable bone matrix recall and market withdrawal in July 2023. Also contributing to the decrease were the legal fees incurred in connection with the Orthobiologics disposition.

Comparison of the Nine Months Ended September 30, 2023 and 2022

	Nine Months Ended September 30,				Change 2022 / 2023	
	2023		2022			
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 18,870	100.0 %	$ 17,262	100.0 %	$ 1,608	9.3 %
Cost of goods sold	9,943	52.7 %	8,689	50.3 %	1,254	14.4 %
Gross profit	8,927	47.3 %	8,573	49.7 %	354	4.1 %
Sales and marketing	10,514	55.7 %	13,672	79.2 %	(3,158)	(23.1)%
General and administrative	10,137	53.7 %	12,788	74.1 %	(2,651)	(20.7)%
Research and development	3,016	16.0 %	5,867	34.0 %	(2,851)	(48.6)%
FiberCel litigation costs	7,278	38.6 %	1,908	11.1 %	5,370	NM
Total operating expenses	30,945	164.0 %	34,235	198.3 %	(3,290)	(9.6)%
Loss from operations	(22,018)	(116.7)%	(25,662)	(148.7)%	3,644	14.2 %
Interest expense	4,285	22.7 %	3,666	21.2 %	619	16.9 %
Other income, net	(312)	(1.7)%	803	4.7 %	(1,115)	NM
Loss before provision of income taxes	(25,991)	(137.7)%	(30,131)	(174.6)%	4,140	13.7 %
Income tax expense	36	0.2 %	36	0.2 %	—	— %
Net loss from continuing operations	(26,027)	(137.9)%	(30,167)	(174.8)%	4,140	13.7 %
Discontinued operations	(2,315)	(12.3)%	2,710	15.7 %	(5,025)	(185.4)%
Net loss	**$ (28,342)**	**(150.2)%**	**$ (27,457)**	**(159.1)%**	**$ (885)**	**(3.2)%**

Net Sales

Net sales information for our products is summarized as follows:

	Nine Months Ended September 30,					
	2023		2022			
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	Change 2022 / 2023 $	Change 2022 / 2023 %
Products:						
Device protection	$ 7,147	37.9 %	$ 6,617	38.3 %	$ 530	8.0 %
Women's health	7,309	38.7 %	5,270	30.5 %	2,039	38.7 %
Cardiovascular	4,414	23.4 %	5,375	31.1 %	$ (961)	(17.9)%
Total Net Sales	**$ 18,870**	**100.0 %**	**$ 17,262**	**100.0 %**	**$ 1,608**	**9.3 %**

Total net sales increased $1,6 million, or 9.3%, to $18.9 million in the nine months ended September 30, 2023 compared to $17.2 million in the nine months ended September 30, 2022. Revenues from Device Protection and Women's Health increased compared to the corresponding period of the prior year due to volume growth and revenues from Cardiovascular decreased due to the commencement of our distribution agreement with LeMaitre Vascular which provides for sales at a transfer 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:

	Nine Months Ended September 30,					
	2023		2022			
(in thousands, except percentages)	Amount	Gross Margin %	Amount	Gross Margin %	Change 2022 / 2023 $	Change 2022 / 2023 %
Products:						
Device protection	$ 2,149	69.9 %	$ 2,198	66.8 %	$ (49)	(2.2)%
Women's health	3,933	46.2 %	2,827	46.4 %	1,106	39.1 %
Cardiovascular	1,314	70.2 %	1,117	79.2 %	197	17.6 %
Cost of goods sold, excluding intangible asset amortization	7,396	60.8 %	6,142	64.4 %	1,254	20.4 %
Intangible asset amortization expense	2,547	(13.5)%	2,547	(14.8)%	—	— %
Total Cost of Goods Sold	**$ 9,943**	**47.3 %**	**$ 8,689**	**49.7 %**	**$ 1,254**	**14.4 %**

Total cost of goods sold increased $1.3 million to $9.9 million in the nine months ended September 30, 2023 compared to $8.7 million in the nine months ended September 30, 2022. Gross margin was 47.3% in the nine months ended September 30, 2023 compared to 49.7% in the nine months ended September 30, 2022. Gross margin, excluding intangible asset amortization, was 60.8% in the nine months ended September 30, 2023 compared to 64.4% in the nine months ended September 30, 2022. The slight decline in gross margin was due to the commencement of the LeMaitre Vascular distribution agreement described above.

Operating Expenses

Sales and Marketing

Sales and marketing expenses decreased $3.2 million, or 23.1%, to $10.5 million in the nine months ended September 30, 2023 compared to $13.7 million in the nine months ended September 30, 2022. As a percentage of sales, sales and marketing expenses decreased to 55.7% in the nine months ended September 30, 2023 from 79.2% in the nine months ended September 30, 2022. The decrease in expense was largely attributable to the previously announced reduction in force which occurred in the first quarter of 2023 and primarily impacted certain members of sales and marketing management.

General and Administrative

G&A expenses decreased $2.7 million, or 20.7%, to $10.1 million in the nine months ended September 30, 2023 compared to $12.8 million in the nine months ended September 30, 2022. As a percentage of net sales, G&A expenses decreased to 53.7% in the nine months ended September 30, 2023 from 74.1% in the nine months ended September 30, 2022. The decrease in expense was primarily due to declines in the cost of insurance and certain non-recurring legal and severance costs incurred in the 2022 period.

Research and Development

R&D expenses decreased to $3.0 million in the nine months ended September 30, 2023 compared to $5.9 million in the nine months ended September 30, 2022. We continue to focus our R&D efforts primarily on the development of our CanGarooRM Antibacterial Envelope. Such related costs were less in the first nine months of 2023 versus the prior year's comparable period due to the reduction of efforts needed and expenses incurred as the development progresses toward anticipated completion.

FiberCel Litigation Costs

FiberCel litigation costs increased to $7.3 million in the nine months ended September 30, 2023 compared to $1.9 million in the nine months ended September 30, 2022. The increase in expense was primarily due to the continued evaluation of the contingent FiberCel liability and higher legal defense costs incurred as the FiberCel cases progress. See further discussion in Note 10 to condensed consolidated financial statements included elsewhere in this Quarterly Report.

Interest Expense

Interest expense was approximately $4.6 million in the nine months ended September 30, 2023 compared to $3.7 million in the nine months ended September 30, 2022. The increase was due to the higher principal outstanding and interest rates incurred by us on our existing debt, the SWK Loan Facility, as compared to the debt outstanding in the nine months ending September 30, 2022, which consisted primarily of the MidCap Loan Facility and MidCap Credit Facility. See " - Liquidity and Capital Resources - Credit Facilities" below for a further discussion of these debt agreements and Note 7 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Discontinued Operations

Net loss from discontinued operations for the nine months ended September 30, 2023 was $2.0 million and net income from discontinued operations for the three months ended September 30, 2022 was $2.8 million. The decrease was largely due to revenue reduction, inventory write-downs and overall financial impact to the Orthobiologics Business caused by the viable bone matrix recall and market withdrawal in July 2023. Also contributing to the decrease were the legal fees incurred in connection with the Orthobiologics disposition.

Non-GAAP Financial Measures

This Quarterly Report presents our gross margin, excluding intangible asset amortization, for the three and nine months ended September 30, 2023 and 2022. 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 nine months ended September 30, 2023 and 2022 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net sales	$ 6,127	$ 5,849	$ 18,870	$ 17,262
Cost of goods sold	3,286	2,910	9,943	8,689
Gross profit	2,841	2,939	8,927	8,573
Intangible asset amortization expense	849	849	2,547	2,547
Gross profit, excluding intangible asset amortization	$ 3,690	$ 3,788	$ 11,474	$ 11,120
Gross margin	46.4 %	50.2 %	47.3 %	49.7 %
Gross margin, excluding intangible asset amortization	60.2 %	64.8 %	60.8 %	64.4 %

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 September 30, 2023, we had cash of approximately $14.5 million. Since inception, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities, sales of our products and more recently, proceeds from our IPO, a follow-on offering and a private placement 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 the production activities of our Richmond, California facility 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 September 30, 2023, our accumulated deficit was $166.3 million.

On September 21, 2023, we sold, in a private offering exempt from the registration provisions of the Securities Act of 1933, as amended, an aggregate of (i) 6,852,811 units (the "Common Units") to certain of the Investors, each comprised of (a) one share of the Company's Class A common stock, par value $0.001 per share ("Class A Common Stock") and (b) a warrant (a "Common Warrant") to purchase one and one half shares of Class A Common Stock, and (ii) 503,058 units (the "Prefunded Units") to certain of the Investors, each comprised of (a) a prefunded warrant (a "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 (the "Offering"). Each Common Warrant is exercisable at any time until the earlier of (a) 30 trading days after the clearance by the U.S. Food & Drug Administration of the Company's 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 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).

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, 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 private placement which we closed in September 2023 described above, pursue asset sale or other transactions, such as the sale of the Orthobiologics Business described below, or restructure our Revenue Interest Obligation. 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 Nine Months Ended September 30, 2023 and 2022

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash used in:		
Operating activities	$ (12,678)	$ (16,189)
Investing activities	(329)	(406)
Financing activities	10,535	(5,732)
Net decrease in cash	**$ (2,472)**	**$ (22,327)**

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2023 was $12.7 million compared to $16.2 million for the nine months ended September 30, 2022. The year-over-year decrease was primarily due to a lower net loss as well as the receipt of insurance proceeds, and a corresponding decrease in insurance receivables, in connection with our FiberCel litigation.

Net Cash Used in Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2023 was $0.3 million compared to $0.4 million for the nine months ended September 30, 2022. In both periods, the use of cash related to the purchase of property and equipment, the majority of which were used in the production activities of our Richmond, California facility.

Net Cash Used in Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was $10.5 million compared to net cash used in financing activities of $5.7 million for the nine months ended September 30, 2022. The year-over-year net increase was caused primarily by the private placement in September 2023 which yielded $10.5 million in gross proceeds through the issuance of common stock and warrants. Further contributing to the increase were payments made in the 2022 period related to our Revenue Interest Obligation with no such payments having been made in the 2023 period due to ongoing restructuring discussions with Ligand (as defined below).

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. In connection with the August 2022 debt refinancing, we used $16 million of the proceeds of the SWK Loan Facility to pay all outstanding obligations on the formerly outstanding MidCap Loan Facility and MidCap Credit Facility. Such payment included (i) $12.8 million to repay all outstanding principal and accrued interest on the MidCap Loan Facility, (ii) $1.7 million to pay the prepayment and exit fees on the MidCap Loan Facility and (iii) $1.5 million to repay the outstanding balance, accrued interest and exit fees on the MidCap Credit Facility. As of September 30, 2023, we had $25.3 million of indebtedness outstanding under our SWK Loan Facility, with such balance being net of $0.8 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 will 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 profitability and regulatory conditions ("Extension Conditions") have not been met, or until November 17, 2025 if such conditions have been satisfied. 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 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 months ended September 30, 2023; however, the closing of the divestiture of the Orthobiologics Business 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 is to be paid by the earlier of (i) February 15, 2024 and (ii) two business days following written request by SWK based on mutual agreement between the parties.

Optional Prepayment

The SWK Loan Facility Agreement also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination, and prepayment penalties that are equal to: (i) 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 if such prepayment occurs prior to the first anniversary of the Closing Date, or (ii) 2% of the aggregate principal amount funded prior to termination if such prepayment occurs after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date.

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 September 30, 2023, 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 their assets;
- make investments, loans, advances, guarantees and acquisitions;
- enter into transactions with affiliates;
- amend or modify their governing documents;
- amend or modify certain material agreements; and
- alter the business conducted by them and their 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 Agreement) for the preceding 12-month period or, alternatively, to maintain Consolidated Unencumbered Liquid Assets (as defined in the SWK Loan Facility Agreement) 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 Agreement) for the preceding 12-month period. The second covenant requires us to maintain a minimum liquidity (as defined in the SWK Loan Facility Agreement) 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”).

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 September 30, 2023, we were in compliance with the financial covenant and all other covenants.

On May 12, 2023, we entered into a first amendment to the SWK Loan Facility Agreement with SWK and the other lenders party thereto. The amendment is described in further detail in Note 6 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Supplier Promissory Note

During 2017, we restructured certain of our liabilities with a tissue supplier and entered into an unsecured promissory note bearing interest at 5%. In connection with the August 2022 debt refinancing, we used $1.4 million of the proceeds from the SWK Loan Facility to repay the remaining balance on the promissory note, and as of September 30, 2023, we had no balance remaining on the promissory note.

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 September 30, 2023, we had $25.3 million of indebtedness outstanding, consisting of $26.1 million outstanding under our SWK Loan Facility (net of $0.8 million of unamortized discount and deferred financing costs). In addition, as further described in Note 8 to these condensed consolidated financial statements included elsewhere in this Quarterly Report, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated ("Ligand") pursuant to which we assumed a restructured, long-term obligation to Ligand (the "Revenue Interest Obligation"), that requires us to pay Ligand 5.0% of future sales of the products we acquired from CorMatrix (as well as products substantially similar to those products), subject to annual minimum payments of $2.75 million. Furthermore, a $5.0 million payment is 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. The initial $5.0 million milestone payment became due in the second quarter of 2023.

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 of the COVID-19 pandemic or any other 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 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 nine months ended September 30, 2023, 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 September 30, 2023 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 September 30, 2023, our cash was maintained with three 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 September 30, 2023.

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 September 30, 2023 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 the 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. Except as set forth below, there have been no material changes in our risk factors to those included in our Annual Report.

We may not realize the anticipated benefits of our sale of our Orthobiologics business .

On November 8, 2023, pursuant to the Asset Purchase Agreement with Berkeley Biologics, LLC (the "Purchase Agreement"), we completed the previously announced sale of our Orthobiologics Business. We received an up-front payment of approximately $14.6 million, as adjusted, shortly after the closing, and for each of the five years following the closing, Berkeley would be required to pay to the Company an earn-out payment (each, an "Earn-Out Payment") equal to 10% of the actual revenue earned by Berkeley in the applicable year that is derived from sales of those sold products defined as "Earn-Out Products" under the Purchase Agreement, and from any improvements, modifications, derivatives and enhancements related to the Earn-Out Products, with the aggregate amount of Earn-Out Payments capped at $20 million.

There can be no assurance that we will be able to realize the expected benefits of the transaction, or that we will receive all of the potential consideration associated with the Earn-Out Payments. If we are unable to or do not realize the expected strategic, economic, or other benefits of the transaction, it could adversely affect our business and financial position.

The processing of human and porcine tissue for our products is technically complex, requiring high levels of quality control and precision, which subjects us to increased production risks.

We manufacture our human and porcine tissue products using technically complex processes requiring specialized facilities, highly specific raw materials, skill and diligence by our personnel and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subject us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non-compliance with regulatory requirements, including stability requirements or specifications. The occurrence of this or any other actual or suspected production or distribution problem can lead to lost inventory, customer returns and, in some cases, recalls, with consequential damage to our reputation and customer relationships and the risk of product liability.

For example, in July 2023, we announced a voluntary recall of a single lot of a certain viable bone matrix product and the market withdrawal of all of our viable bone matrix ("VBM") products produced after a specified date ("VBM Matter"). 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.

Furthermore, 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 made from human tissue that is used in various orthopedic and spinal procedures. Notice of the voluntary recall was issued to hospitals that received product from this specific lot following our learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. The lot consisted of 154 units of FiberCel, all derived from a single donor, which were shipped to facilities in 20 states. We have investigated the source of the infections in coordination with our distributor, the FDA and the U.S. Centers for Disease Control and Prevention ("CDC"). Additionally, multiple product liability lawsuits have been filed against us in connection with FiberCel. See *"We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance"* for additional information about these product liability lawsuits.

These product recalls and investigations, as well as others that may occur in the future, and the remediation of any potential or identified problems can cause production delays and result in substantial additional expenses and lost revenue. In addition, we may experience difficulties in scaling up processing and production of our human and porcine tissue products, including problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures and availability of skilled personnel. Furthermore, developing and maintaining our production capabilities has required, and will continue to require, the investment of significant resources, and we cannot guarantee that we will be able to achieve economies of scale. If we are unable to process and produce our human tissue products on a timely basis, at acceptable quality and costs and in sufficient quantities, or if we experience technological problems, delays in production, failure in the storage of our products or other loss of supply, our business would be materially and adversely affected.

We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing, investigating and marketing of medical devices and human and animal tissue products. For example, since the voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix was issued, and since September 2021, we have received notice of 109 separate lawsuits or claims alleging that the plaintiffs contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. We have settled 27 of these lawsuits for a total of approximately $7.5 million as of September 30, 2023. For the remaining 82 cases for which settlements have not been reached, we estimated a probable loss related to each case and have recorded a liability at an estimated amount of $15.7 at September 30, 2023, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying condensed consolidated balance sheets included in this Quarterly Report. See Part II, Item 1, "Legal Proceedings" and Note 10 to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

We are, and may in the future be, subject to product liability claims and lawsuits, including claims that may result from the VBM Matter noted above, and potential class actions or mass tort claims, alleging that our products have resulted or could result in an unsafe condition or injury. Product liability claims may be made by patients and their families, healthcare providers or others selling our products. Product liability claims may include, among other things, allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties.

Additionally, we may be subject to product liability claims, proceedings and lawsuits, even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians and other healthcare providers to properly and correctly use our products. If these physicians or other healthcare providers are not properly trained or are negligent in using our products, the capabilities of our products may be diminished, or the patient may suffer critical injury. In addition, we may be subject to product liability claims, as well as a number of other risks, as a result of physicians and other healthcare providers using our products "off-label." See the risk factor entitled "*The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business*" included in the Annual Report.

Defending any current or future claims, proceedings or lawsuits, regardless of merit, could be costly, divert management attention and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- harm to our business reputation;
- investigations by regulators;
- significant legal costs;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- decreased demand for our products.

Our product liability insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance. As of September 30, 2023, we have recorded insurance receivables of $7.5 million on our balance sheet in respect of our insurance coverage for the FiberCel Litigation product liability losses. However, it is possible that future claims related to the FiberCel Litigation or other product liability claims could exceed the limits of, or be excluded from, coverage under our policies, and claims against us could also increase the cost of maintaining our coverage. If these or other claims are excluded from our coverages, or if we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims, or if we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. One or more product liability claims could have a significant adverse effect on our business, financial condition and results of operations.

Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, litigation, including product liability claims, and negative publicity, any of which may erode our competitive advantage and market share and have a material adverse effect on our reputation, business, financial condition and results of operations.

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Quality and safety issues may occur with respect to any of our products, and our future operating results will depend on our ability to maintain an effective quality control system and effectively train and manage our workforce with respect to our quality system. The development, manufacture and control of our products are subject to extensive and rigorous regulation by numerous government agencies, including the FDA, the competent authorities of the EU member states and similar foreign agencies. Compliance with these regulatory requirements, including but not limited to the FDA's Quality System Regulation ("QSR"), current Good Manufacturing Practices ("GMPs") and adverse events/recall reporting requirements in the United States and other applicable regulations worldwide, is subject to continual review and is monitored rigorously through periodic inspections by the FDA and foreign regulatory authorities. If we fail to comply with our reporting obligations, the FDA, the competent authorities of the EU member states or other regulatory authority could take action, including issuance of warning letters and/or untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in the clearance of future products.

The FDA and foreign regulatory authorities may also require post-market testing and surveillance to monitor the performance of approved or certified products. Our facilities and those of our suppliers, commercial partners and independent sales agents are also subject to periodic regulatory inspections. If the FDA or a foreign authority were to conclude that we have failed to comply with any of these requirements, it could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions, such as product recalls or seizures, withdrawals, monetary penalties, consent decrees, injunctive actions to halt the manufacture or distribution of products, import detentions of products made outside the United States, export restrictions, restrictions on operations or other civil or criminal sanctions. Civil or criminal sanctions could be assessed against our officers, employees, or us. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products.

If our products do not function as designed, or are designed improperly, we or the third-party manufacturer of such products may withdraw such products from the market, whether by choice or as a result of regulatory requirements. 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 made from human tissue that is used in various orthopedic and spinal procedures, following our learning of post-surgical infections in patients treated with FiberCel, including some patients that tested positive for tuberculosis. This recall had a negative effect on our business, financial condition and results of operations and resulted in a number of lawsuits filed against us as discussed under the risk factor " *We face significant litigation related to FiberCel*" included in our Annual Report. Furthermore, in July 2023, we announced a voluntary recall of a single lot of a certain viable bone matrix product and the market withdrawal of all of our viable bone matrix ("VBM") products produced after a specified date ("VBM Matter"). Notice of the voluntary recall was issued to centers after we 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. The VBM Matter product recall has had and may continue to have, and any product recall we or a third-party manufacturer may conduct in the future, whether voluntary or required, could also have, a negative impact on our business, financial condition and results of operations, and this effect may be material.

In addition, we cannot predict the results of future legislative activity or future court decisions, any of which could increase regulatory requirements, subject us to government investigations or expose us to unexpected litigation. Any regulatory action or litigation, regardless of the merits, may result in substantial costs, divert management's attention from other business concerns and place additional restrictions on our sales or the use of our products. In addition, negative publicity, including regarding a quality or safety issue, could damage our reputation, reduce market acceptance of our products, cause us to lose customers and decrease demand for our products. Any actual or perceived quality issues may also result in issuances of physician's advisories against our products or cause us to conduct voluntary recalls. Any product

defects or problems, regulatory action, litigation, negative publicity or recalls could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

We recently received a Nasdaq delisting determination letter and there is no assurance that we will be successful in our appeal of the delisting determination, that we will regain compliance with Nasdaq continued listing standards, or that we will maintain our Nasdaq listing.

On May 4, 2023, we received a letter from the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") notifying us that we did not meet the Market Value of Listed Securities ("MVLS") requirement for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2) (the "Market Value Standard"), and noting that the Company did not meet the requirements under Nasdaq Listing Rules 5550(b)(1) (Equity Standard) and 5550(b)(3) (Net Income Standard). The Original Notice provided that, in accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company would have a period of 180 calendar days from the date of the Original Notice, or until October 31, 2023 (the "Compliance Date"), to regain compliance with the Market Value Standard by having the Company's MVLS close at or above $35 million for a minimum of 10 consecutive business days prior to the Compliance Date.

On November 1, 2023, we received a delisting determination letter (the "Letter") from the Staff advising the Company that the Staff had determined that the Company did not regain compliance with the Market Value Standard by the Compliance Date. As a result, if not for our appeal of the Staff's determination, trading of our common stock on the Nasdaq Capital Market would have been suspended at the opening of business on November 10, 2023, and Form 25-NSE would have been filed with the Securities and Exchange Commission to remove the Company's securities from listing and registration on the Nasdaq Capital Market. However, we timely submitted a hearing request to Nasdaq's Hearings Panel (the "Panel"), which stayed the suspension of our common stock pending the panel's conclusion of the hearing process.

Our hearing has been scheduled for February 15, 2024. At the hearing, we intend to present a plan to regain compliance with the Market Value Standard, and in the interim, our common stock will continue to trade on the Nasdaq Capital Market under the symbol "ELUT" at least pending the ultimate conclusion of the hearing.

There can be no assurance that our plan will be accepted by the Panel or that, if it is, we will be able to regain compliance with the applicable Nasdaq listing requirements. If we cannot regain compliance with the Market Value Standard or under Nasdaq's alternative continued listing requirements, and if our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our collaborators, vendors, suppliers and employees, which could harm our business and future prospects.

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

Private Placement of Common Stock and Warrants

On September 18, 2023, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the Purchase Agreement, on September 21, 2023, we sold an aggregate of (i) 6,852,811 units (the "Common Units") to certain of the Investors, each comprised of (a) one share of Elutia's Class A common stock, par value $0.001 per share ("Class A Common Stock") and (b) a warrant (a "Common Warrant") to purchase one and one half shares of Class A Common Stock, and (ii) 503,058 units (the "Prefunded Units") to certain of the Investors, each comprised of (a) a prefunded warrant (a "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. Commissions to the placement agent were approximately $0.7 million.

Each Common Warrant is exercisable at any time until the earlier of (a) 30 trading days after the clearance by the U.S. Food & Drug Administration of the Company's 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 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 securities were sold solely to "accredited investors" pursuant to the exemptions from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

The summaries of the terms of the Purchase Agreement, Common Warrant and Prefunded Warrant appearing above are qualified in its entirety by the full text of the Purchase Agreement, Form of Common Warrant and Form of Prefunded Warrant filed as Exhibits 10.1, 4.5 and 4.6 hereto, respectively.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the three months ended September 30, 2023, 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
2.1	Asset Purchase Agreement, dated September 17, 2023, by and among Elutia Inc., Berkeley Biologics, LLC, and GNI Group, Ltd. (solely with respect to Section 11.18)	8-K	001-39577	10.1	9/19/23	
3.1	Restated Certificate of Incorporation of Elutia Inc.	8-K	001-39577	3.1	10/13/2020	
3.2	Amended and Restated Bylaws of Elutia Inc.	8-K	001-39577	3.2	10/13/2020	
4.1	Second Amended and Restated Investor Rights Agreement, dated as of March 14, 2020, among the Registrant and the investors named therein	S-1	333-248788	4.1	09/14/2020	
4.2	Specimen stock certificate evidencing the shares of Class A common stock	S-1	333-248788	4.2	09/14/2020	
4.3	Specimen stock certificate evidencing the shares of Class B common stock	S-1/A	333-248788	4.3	09/30/2020	
4.4	Warrant to Purchase Stock, issued on August 10, 2022, by Elutia Inc.to SWK Funding LLC.	8-K	001-39577	4.1	08/15/2022	
4.5	Form of Common Warrant	8-K	001-39577	4.1	9/21/23	
4.6	Form of Prefunded Warrant	8-K	001-39577	4.2	9/21/23	
4.7	Registration Rights Agreement, dated September 21, 2023, by and among Elutia Inc. and the Investors named therein	8-K	001-39577	10.2	9/21/23	
10.1	Securities Purchase Agreement, dated September 18, 2023, by and among Elutia Inc. and the Investors named therein.	8-K	001-39577	10.1	9/21/23	
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.

Annexes, schedules and exhibits have been omitted pursuant to Item 601(a)(5)(b)(2) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.

† Denotes a management contract or compensation plan or arrangement.

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: November 14, 2023

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

Date: November 14, 2023

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

Exhibit 31.1

CERTIFICATIONS

I, C. Randal Mills, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023 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: November 14, 2023

By: /s/ C. Randal Mills
C. Randal Mills
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 September 30, 2023 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: November 14, 2023

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 September 30, 2023 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: November 14, 2023

By: /s/ C. Randal Mills
C. Randal Mills
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 September 30, 2023 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: November 14, 2023

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.