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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K  
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 20, 2023

ELUTIA INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-39577</u> (Commission File Number)	<u>47-4790334</u> (IRS Employer Identification No.)
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12510 Prosperity Drive, Suite 370, Silver Spring, MD 20904

(Address of principal executive offices) (Zip Code)

(240) 247-1170

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Class A Common Stock, \$0.001 par value per share	ELUT	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 8.01. Other Events.**

Elutia Inc. (the “Company” or “Elutia”) is filing this Current Report on Form 8-K, including Exhibit 99.1, solely to recast certain financial information and related disclosures included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022 originally filed with the U.S. Securities and Exchange Commission (the “SEC”) on March 23, 2023 (the “2022 Form 10-K”).

As previously reported in its Current Report on Form 8-K filed November 14, 2023, on November 8, 2023, Elutia completed the sale of substantially all of the assets of its Orthobiologics business to Berkeley Biologics, LLC (“Berkeley”) pursuant to an Asset Purchase Agreement with Berkeley dated September 17, 2023. The Orthobiologics business met the criteria within Accounting Standard Codification 205-20, *Discontinued Operations*, to be reported as discontinued operations. Therefore, the Company is reporting the historical results of the Orthobiologics business, including the results of operations and cash flows, as, and related assets and liabilities were retrospectively reclassified as assets and liabilities of, discontinued operations for all periods presented in Exhibit 99.1 to this Current Report on Form 8-K (this “Form 8-K”). Unless otherwise noted, applicable amounts in the prior years have been recast to conform to this discontinued operations presentation.

Prior to the sale of the Orthobiologics business, the Company operated four reportable segments—Device Protection, Women’s Health, Orthobiologics and Cardiovascular. Subsequent to the sale of the Orthobiologics business, the Company eliminated the Orthobiologics reportable segment and currently operates the three remaining segments—Device Protection, Women’s Health and Cardiovascular.

In order to preserve the nature and character of the disclosures set forth in the 2022 Form 10-K, the items included in Exhibit 99.1 to this Form 8-K have been updated solely for matters relating specifically to the Orthobiologics business as discontinued operations. This Form 8-K does not reflect other events occurring after the filing date of the 2022 Form 10-K, except as otherwise reflected in Exhibit 99.1. This Form 8-K should be read in conjunction with the 2022 Form 10-K and the SEC filings made by the Company after the filing of the 2022 Form 10-K, including the Company’s Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2023, June 30, 2023 and September 30, 2023, and its Current Report on Form 8-K filed on November 15, 2023.

The following items of the 2022 Form 10-K are being recast to reflect the sale of the Orthobiologics business as shown in Exhibit 99.1 to this Form 8-K:

- Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations
- Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk; and
- Part II, Item 8. Financial Statements and Supplementary Data.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
23.1*	<a href="#">Consent of PricewaterhouseCoopers LLP</a>
99.1*	<a href="#">Revised Sections of the 2022 Form 10-K</a>
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 document)

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\* Filed herewith.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**ELUTIA INC.**  
*(Registrant)*

Date: November 20, 2023

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

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-249391) and Forms S-3 (Nos. 333-267197 and 333-262295) of Elutia Inc. of our report dated March 23, 2023, except for the effects of discontinued operations discussed in Note 4 to the consolidated financial statements, as to which the date is November 20, 2023 relating to the financial statements, which appears in this Current Report on Form 8-K.

/s/ PricewaterhouseCoopers LLP  
Baltimore, Maryland  
November 20, 2023

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**Management's Discussion and Analysis of Financial Condition and Results of Operations with Retrospective Segment Changes of the 2022 Form 10-K.**

*The following discussion and analysis should be read in conjunction with our consolidated financial statements and the related notes included. 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," "Risk Factors Summary" and in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 originally filed with the U.S. Securities and Exchange Commission on March 23, 2023 and Part II, Item 1A. "Risk Factors" of our Quarterly Reports on Forms 10-Q for the quarters ended March 31, 2023, June 30, 2023 and September 30, 2023 filed on May 12, 2023, August 14, 2023 and November 14, 2023, respectively.*

*As described below, on November 8, 2023, we sold the Orthobiologics Business segment to a third party. As a result, the assets, liabilities, and results of Orthobiologics were classified to discontinued operations in our Form 10-Q for the quarter ended September 30, 2023. As such, we have retrospectively reclassified all assets, liabilities, and results of the Orthobiologics Business as discontinued operations in the following discussion and adjusted all references to the Orthobiologics Business assets, liabilities, and results accordingly.*

**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 performed 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.

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.

We have incurred significant operating losses since our inception. We incurred a net loss from continuing operations of \$36.2 million and \$30.3 million for the years ended December 31, 2022 and 2021, respectively and a net loss of \$32.9 million and \$24.8 million for the years ended December 31, 2022 and 2021, respectively. Our accumulated deficit as of December 31, 2022 was \$138.0 million.

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 additional costs and expenses associated with operating as a public company.

Our ability to achieve profitability will depend on our ability to generate sales from existing or new products sufficient to exceed our ongoing operating expenses and capital requirements. Because of the numerous risks and uncertainties affecting product sales and our ongoing commercialization and product development efforts, including our ability to obtain FDA clearance for the next generation of our flagship CanGaroo product, CanGaroo RM and successfully commercialize this product, we are unable to predict with any certainty whether we will be able to increase sales of our products or the timing or amount of ongoing expenditures we will be required to incur. Accordingly, even if we are able to increase sales of our products, we may not become profitable.

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, restructure our Revenue Interest Obligation, or pursue asset sale or other transactions. However, such transactions may not be successful and we may not be able to raise additional equity, refinance or restructure 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.

## Discontinued Operations

As noted below, on November 8, 2023, we sold substantially all of our assets that are related to our Orthobiologics segment (the “Orthobiologics Business”) to Berkeley Biologics, LLC (“Berkeley”). The Orthobiologics Business is comprised of our business of researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing our Orthobiologics products and the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products.

Our commercial approach to the Orthobiologics Business had been to leverage commercial partners with existing sales and marketing infrastructure in these areas, while we focused on research and development and the manufacturing of products. Under the terms of those agreements, these customers purchased products from us at specified prices and resold such products in the United States to the primary customers, which are hospitals and other healthcare facilities. We fulfilled most orders from our commercial partners by shipping these products directly to these hospitals and other healthcare facilities. In addition to our proprietary products, we fulfilled tissue processing contracts based on product specifications established by our customers through contract manufacturing services at our Richmond, California facility. The resulting processed materials, including particulate bone, precision milled bone, cellular bone matrix, acellular dermis and other soft tissue products, are sold to medical/surgical companies as finished products and as a subcomponent of their products. Additionally, we processed amniotic membrane as finished product for select customers.

As part of the divestiture, we assigned the lease to our 36,173 square feet of manufacturing, laboratory and office space in Richmond, California to Berkeley

### 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 nearly the entirety of our 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.



## Impact of COVID-19

As a result of the COVID-19 pandemic, the number of procedures performed using our products has intermittently decreased, as governmental authorities in the United States have recommended, and in certain cases required, that elective, specialty and other non-emergency procedures and appointments be suspended or canceled in order to avoid patient exposure to medical environments and the risk of potential infection with COVID-19, and to focus limited resources and personnel capacity on the treatment of COVID-19 patients. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and may reduce our net sales in the future and negatively impact our business, financial condition and results of operations while the pandemic continues. In addition, numerous state and local jurisdictions, including those where our facilities are located, imposed, and others in the future may impose or re-impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. The extent to which the COVID-19 pandemic impacts our future financial condition and results of operations will depend on future events and developments, which are highly uncertain and cannot be predicted, including the severity and spread of the disease and the effectiveness of actions to contain the disease or treat its impact, among others. As new information regarding COVID-19 continues to emerge, and, as variants of COVID-19 emerge, it is difficult to predict the degree to which this disease will continue to affect our business.

## FiberCel Recall

On June 2, 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix, a bone repair product formerly distributed by Medtronic, after learning of post-surgical infections reported in several patients treated with the product, including some patients that tested positive for tuberculosis. Since the voluntary recall, we have settled 26 lawsuits relating to FiberCel for a total of approximately \$7.3 million and settled and paid 11 of these lawsuits for a total cash outlay of \$3.6 million. For the remaining 81 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 \$13.7 million for a total estimated liability at December 31, 2022 of \$17.4 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying consolidated balance sheets. As of December 31, 2022, we have recorded insurance receivables of \$13.8 million on our balance sheet in respect of our insurance coverage for the FiberCel Litigation product liability losses.

For an update on the legal proceedings related to the FiberCel Recall, see Part I, Item 3, “Legal Proceedings” and Note 17 to the consolidated financial statements.

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. Additionally, following the public announcement of our voluntary recall, there has been various media coverage surrounding the recall and patients impacted. Such negative publicity related to the perceived quality and safety of our products could affect our brand image, decrease confidence in our products or have an adverse effect on our ability to retain existing and attract new customers, suppliers and distribution partners, any one of which could result in decreased revenue, having an adverse effect on our business, financial condition and operating results.

## Components of Our Results of Operations

### *Net Sales*

We recognize revenue on the sale of our products. Our device protection and cardiovascular products are sold to hospitals and other healthcare facilities primarily through our direct sales force, commercial partners or independent sales agents. Our women’s health product, SimpliDerm, is sold directly to hospitals and other healthcare facilities through independent sales agents. Gross to net sales adjustments include sales returns and prompt payment and volume discounts.

## *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:

### *Costs 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 Years Ended December 31, 2022 and 2021

(in thousands, except percentages)	Years Ended December 31,				Change	
	2022		2021			
	Amount	% of Net Sales	Amount	% of Net Sales	\$	%
Net sales	\$ 23,849	100.0 %	\$ 20,456	100.0 %	\$ 3,393	16.6 %
Cost of goods sold	12,210	51.2 %	11,176	54.6 %	1,034	9.3 %
Gross profit	11,639	48.8 %	9,280	45.4 %	2,359	25.4 %
Sales and marketing	17,850	74.8 %	16,655	81.4 %	1,195	7.2 %
General and administrative	16,051	67.3 %	13,124	64.2 %	2,927	22.3 %
Research and development	7,727	32.4 %	7,754	37.9 %	(27)	(0.3)%
FiberCel litigation costs	5,200	21.8 %	276	1.3 %	4,924	1,784.1 %
Total operating expenses	46,828	196.4 %	37,809	184.8 %	9,019	23.9 %
Loss from continuing operations	(35,189)	(147.5)%	(28,529)	(139.5)%	(6,660)	23.3 %
Interest expense	5,118	21.5 %	5,324	26.0 %	(206)	(3.9)%
Other income, net	(4,159)	(17.4)%	(3,579)	(17.5)%	(580)	NM %
Loss before provision of income taxes	(36,148)	(151.6)%	(30,274)	(148.0)%	(5,874)	19.4 %
Income tax expense	34	0.1 %	55	0.3 %	(21)	(38.2)%
Net loss from continuing operations	(36,182)	(151.7)%	(30,329)	(148.3)%	(5,853)	19.3 %
Net income from discontinued operations	3,285	13.8 %	5,497	26.9 %	(2,212)	(40.2)%
<b>Net loss</b>	<b>\$ (32,897)</b>	<b>(137.9)%</b>	<b>\$ (24,832)</b>	<b>(121.4)%</b>	<b>\$ (8,065)</b>	<b>32.5 %</b>

NM = not meaningful

### Net Sales

Net sales information for our products is summarized as follows:

(in thousands, except percentages)	Years Ended December 31,				Change	
	2022		2021			
	Amount	% of Net Sales	Amount	% of Net Sales	\$	%
Products:						
Device protection	\$ 9,093	38.1 %	\$ 7,902	38.6 %	\$ 1,191	15.1 %
Women's health	7,474	31.3 %	5,046	24.7 %	2,428	48.1 %
Cardiovascular	7,282	30.5 %	7,508	36.7 %	(226)	(3.0)%
<b>Total Net Sales</b>	<b>\$ 23,849</b>	<b>100.0 %</b>	<b>\$ 20,456</b>	<b>100.0 %</b>	<b>\$ 3,393</b>	<b>16.6 %</b>

Total net sales increased \$3.4 million, or 16.6%, to \$23.8 million in the year ended December 31, 2022 compared to \$20.5 million in the year ended December 31, 2021. With respect to the individual product segments, the increase in the net sales of both our device protection and women's health products were primarily attributable to volume growth in the respective segment. Net sales of our cardiovascular products were relatively flat between the years.

## Cost of Goods Sold

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

(in thousands, except percentages)	Year Ended December 31,					
	2022		2021		Change 2021 / 2022	
	Amount	Gross Margin %	Amount	Gross Margin %	\$	%
Products:						
Device protection	\$ 2,979	67.2 %	\$ 2,141	72.9 %	\$ 838	(5.7)%
Women's health	4,337	42.0 %	4,132	18.1 %	205	23.9 %
Cardiovascular	1,497	79.4 %	1,507	79.9 %	(10)	(0.5)%
Cost of goods sold, excluding intangible asset amortization	8,813	63.0 %	7,780	62.0 %	1,033	1.1 %
Intangible asset amortization expense	3,397	(14.2)%	3,396	(16.6)%	1	2.4 %
<b>Total Cost of Goods Sold</b>	<b>\$ 12,210</b>	<b>48.8 %</b>	<b>\$ 11,176</b>	<b>45.4 %</b>	<b>\$ 1,034</b>	<b>3.4 %</b>

Total cost of goods sold increased \$1.0 million to \$12.2 million in the year ended December 31, 2022 compared to \$11.2 million in the year ended December 31, 2021 primarily due to an increase in total net sales. Gross margin was 48.8% in the year ended December 31, 2022 compared to 45.4% in the year ended December 31, 2021. Gross margin, excluding intangible asset amortization, was 63.0% in the year ended December 31, 2022 compared to 62.0% in the year ended December 31, 2021. With respect to the individual product segments, the gross margin of device protection declined slightly in the year ended December 31, 2022 compared to the year ended December 31, 2021 due to operational inefficiencies in the current year causing minor increases to the cost of the product. The gross margin of women's health products increased significantly in the current year due to non-recurring inventory writedowns in the prior year on certain slow moving product sizes which caused reductions in the prior years' gross margin. Gross margin on our cardiovascular products was relatively flat between years.

### Operating Expenses

#### Sales and Marketing

Sales and marketing expenses increased \$1.2 million, or 7.2%, to \$17.9 million in the year ended December 31, 2022 compared to \$16.7 million in the year ended December 31, 2021. The increase was primarily the result of increases in commissions paid to independent sales agents due to sales growth in our women's health products and higher stock-based compensation. As a percentage of net sales, sales and marketing expenses decreased to 74.8% in the year ended December 31, 2022 from 81.4% in the year ended December 31, 2021.

#### General and Administrative

G&A expenses increased \$2.9 million, or 22.3%, to \$16.1 million in the year ended December 31, 2022 compared to \$13.1 million in the year ended December 31, 2021. The increase in G&A expenses was primarily due to certain non-recurring charges associated with legal fees on various corporate matters and the Chief Executive Officer transition described in Note 5 to the consolidated financial statements. As a percentage of net sales, G&A expenses rose to 67.3% in the year ended December 31, 2022 from 64.2% in the year ended December 31, 2021.

#### Research and Development

R&D expenses were \$7.7 million in the year ended December 31, 2022 compared to \$7.8 million in the year ended December 31, 2021. We continue to focus our R&D efforts primarily on the development of our CanGaroRM Antibacterial Envelope.

FiberCel litigation costs increased to \$5.2 million in the year ended December 31, 2022 compared to \$0.3 million in the year ended December 31, 2021. The increase in expense was primarily due to the settlements reached in a significant number of FiberCel Litigation cases in the year ended December 31, 2022 as well as the estimation of contingent liabilities for the unsettled cases. The total of such settlement and estimated settlement values was recorded (net of estimated insurance, indemnity and contribution agreement recoveries) in the year ended December 31, 2022. See further discussion in Note 17 to consolidated financial statements.

***Interest Expense***

Interest expense was approximately \$5.1 million in the year ended December 31, 2022 and \$5.3 million in the year ended December 31, 2021. The minor fluctuation between years was due to lower draws on our formerly outstanding MidCap Credit Facility and lower outstanding principal on our formerly outstanding MidCap Loan Facility, with such reductions in interest expense being offset by increased principal outstanding and higher interest rates on the SWK Credit Facility which commenced in August 2022 upon consummation of our debt refinancing. See “ - Liquidity and Capital Resources - Credit Facilities” below for a further discussion of these debt agreements and Note 9 to the consolidated financial statements.

***Discontinued Operations***

Net income from discontinued operations was \$3.3 million for the year ended December 31, 2022 compared to \$5.5 million for the year ended December 31, 2021. The decrease was largely due to the net sales in the Orthobiologics business decreased between the years as a result of the discontinuation of sales to Medtronic in June 2021 following our recall. Also contributing to the decrease was the shift in product mix as the contracted services component of the Orthobiologics business, which have lower margins than our other products, experienced sales growth in the year ended December 31, 2022.

***Other Income, net***

Other income, net was approximately \$4.2 million in the year ended December 31, 2022 and was primarily attributable to the \$5.0 million gain on the revaluation of our Revenue Interest Obligation to Ligand. See Note 12 to the consolidated financial statements for additional information. Such gain was offset by other expense related to our debt refinancing in August 2022 and the associated prepayment fees, payment of unaccrued exit fees and the write-off of unamortized deferred financing costs, which collectively resulted in a loss of \$1.2 million. Such loss was offset by other income of \$0.4 million related to the forgiveness of interest accrued on the promissory note to a tissue supplier upon repayment of such note in August 2022. See Note 10 to the accompanying consolidated financial statements for further discussion of these transactions.

Other income, net was approximately \$3.6 million in the year ended December 31, 2021. Such other income relates to the forgiveness of our promissory note with Silicon Valley Bank under the Paycheck Protection Program of the CARES Act in the amount of approximately \$3.0 million and our receipt of \$550,000 in satisfaction of a 2018 settlement with KeraLink. For further discussion on these items, see Notes 10 and 18 to the consolidated financial statements.

***Non-GAAP Financial Measures***

In this “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” we present our gross margin, excluding intangible asset amortization. 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 and the results of the segments 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.

Although we use gross margin, excluding intangible asset amortization, as described above, this metric has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with GAAP. 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 years ended December 31, 2022 and 2021 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Year Ended December 31,	
	2022	2021
Net sales	\$ 23,849	\$ 20,456
Cost of goods sold	12,210	11,176
Gross profit	11,639	9,280
Intangible asset amortization expense	3,397	3,396
Gross profit, excluding intangible asset amortization	<u>\$ 15,036</u>	<u>\$ 12,676</u>
Gross margin	48.8 %	45.4 %
Gross margin, excluding intangible asset amortization	63.0 %	62.0 %

### Seasonality

Historically, we have experienced seasonality in our first and fourth quarters, 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 December 31, 2022, we had cash and restricted cash of approximately \$17.0 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 sales of our common stock. Our historical cash outflows have primarily been associated with acquisition and integration, manufacturing and administrative costs, research and development, clinical activity 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 December 31, 2022, our accumulated deficit was \$138.0 million.

On October 13, 2020, in connection with our IPO, we issued and sold 2,941,176 shares of common stock, consisting of 2,205,882 shares of Class A common stock and 735,294 shares of Class B common stock, at a price to the public of \$17.00 per share, resulting in net proceeds to us of approximately \$43.0 million, after deducting the underwriting discount of approximately \$3.5 million and offering expenses of approximately \$3.5 million. Additionally, in December 2021, we closed on a private investment in public equity (PIPE) financing, thereby receiving net proceeds of approximately \$13.8 million, after deducting offering costs. The PIPE investors purchased an aggregate of 2,122,637 shares of the Company's Class A common stock and an aggregate of 1,179,244 shares of the Company's Class B common stock (which

are convertible on a one-for-one basis into shares of Class A common stock), in each case, at a price of \$4.24 per share. Furthermore, in December 2022, we issued and sold 2,350,000 shares our Class A common stock at a price to the public of \$4.75 per share in a registered underwritten offering, resulting in net proceeds to us of approximately \$10.2 million, after deducting underwriting discounts and offering expenses.

We expect our losses to continue for the foreseeable future and these losses will continue to have an adverse effect on our financial position. Because of the numerous risks and uncertainties associated with our commercialization and development efforts, including our ability to obtain FDA clearance for the next generation of our flagship CanGaroo product, CanGaroo RM and 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, restructure our Revenue Interest Obligation, or pursue asset sale or other transactions. 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, availability under the SWK Loan Facility (described below under “—Credit Facilities”), 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.

**Cash Flows for the Years Ended December 31, 2022 and 2021**

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(in thousands)</b>	
<b>Net cash used in:</b>		
Operating activities	\$ (21,434)	\$ (15,446)
Investing activities	(540)	(369)
Financing activities	8,535	6,711
<b>Net decrease in cash</b>	<b>\$ (13,439)</b>	<b>\$ (9,104)</b>

*Net Cash Used in Operating Activities*

Net cash used in operating activities for the year ended December 31 2022 was \$21.4 million compared to \$15.4 million for the year ended December 31, 2021. The year-over-year increase was primarily due to a gain on extinguishment of debt in the year ended December 31, 2021 versus a loss experienced in the year ended December 31, 2022. Additionally, due to timing, accounts payable increases in the current period increased cash and offset a portion of the cash used in operating cash activities when compared to the prior period.

*Net Cash Used in Investing Activities*

Net cash used in investing activities for the year ended December 31, 2022 was \$0.5 million and approximately \$0.4 million for the year ended December 31, 2021. In both periods, the use of cash related to the purchase of property and equipment, the majority of which are used in the production activities of our Richmond, California facility.

*Net Cash Provided by Financing Activities*

Net cash provided by financing activities for the year ended December 31, 2022 totaled \$8.5 million compared to \$6.7 million of cash provided by financing activities for the year ended December 31, 2021. The year-over-year net increase was caused primarily by the net cash infusion from the proceeds of the August 2022 debt refinancing, less all debt

repayments and refinancing costs incurred during the year ended December 31, 2022 offset by the lower equity raise in the year ended December 31, 2022 as compared to the year ended December 31, 2021.

## **Credit Facilities**

### *General*

On August 10, 2022 (the “Closing Date”), we entered into a senior secured term loan facility with SWK Funding LLC, 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 drawn 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 to date. 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 December 31, 2022, we had \$24.3 million of indebtedness outstanding under our SWK Loan Facility, with such balance being net of \$1.0 million of unamortized discount and deferred financing costs, but increased by capitalized PIK Interest (as defined below) in November 2022 of \$0.3 million.

### *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), 4.75% 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 year ended December 31, 2022, 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 or (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 December 31, 2022, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the Initial Term Loan 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 December 31, 2022, we were in compliance with the financial covenant and all other covenants.

### **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 both 2022 and 2021, no payments were made on the promissory note because the Company's senior lender restricted payment of the amounts due. The Company used \$1.4 million of the proceeds from the SWK Loan Facility to repay the remaining balance on the promissory note; however the accrued interest on the promissory note was forgiven by the lender. Such forgiveness resulted in a gain to the Company of approximately \$0.4 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2022.

### **PPP Loan**

In May 2020, we entered into a promissory note with Silicon Valley Bank, or SVB, under the Paycheck Protection Program of the CARES Act pursuant to which SVB agreed to make a loan to us in the amount of approximately \$3.0 million. The PPP Loan bears interest at a rate of 1.0% per annum with monthly principal and interest payments beginning in March 2021 and ending on the maturity date of May 7, 2022; however such repayment commencement was deferred by the U.S. Small Business Administration while they evaluated our forgiveness application. In June 2021, we were notified by the U.S. Small Business Administration that the entire balance of our PPP Loan and all related accrued interest was forgiven. Such forgiveness resulted in a gain to us of approximately \$3.0 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2021.

### **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 December 31, 2022, we had \$24.3 million of indebtedness outstanding, consisting of \$25.3 million outstanding under our SWK Loan Facility (net of \$1.0 million of unamortized discount and deferred financing costs). In addition, as further described in Note 11 to the consolidated financial statements, 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 will be due to Ligand if cumulative sales of these products exceed \$100 million and a second \$5.0 million will be due if cumulative sales exceed \$300 million during the ten-year term of the agreement which expires on May 31, 2027. The initial \$5.0 million milestone payment became payable in mid-2023.

If our available cash balances and cash flow from operations, if any, 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, although we 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 current 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 “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.

#### **Off-Balance Sheet Arrangements**

As of December 31, 2022, we did not have any off-balance sheet arrangements, as defined under SEC Regulation S-K Item 303(a)(4)(ii).

## Critical Accounting Policies and Significant Judgments and Estimates

The preparation of financial statements in conformity with U.S. GAAP requires that management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the amounts of revenues and expenses reported during the period. On an ongoing basis, management evaluates these estimates and judgments, including those related to revenue, inventory valuation, valuation of intangibles, revenue interest obligation and stock-based compensation. Actual results may differ from those estimates. We have identified the following critical accounting policies:

### *Revenue Recognition*

We enter into contracts to sell and distribute products to healthcare providers or commercial partners which are billed under ship and bill contract terms. Revenue is recognized when we have met our performance obligations pursuant to our contracts with our customers in an amount that we expect to be entitled to in exchange for the transfer of control of the products and services to our customers. For all net sales, we have no further performance obligations and revenue is recognized when 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 our product revenue is generated from consigned inventory maintained at hospitals, and from inventory physically held by our direct sales representatives. For these types of products sales, we retain control until the product has been used or implanted, at which time revenue is recognized.

We have 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 us 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 our contracts vary; however, as a common business practice, payment terms are typically due in full within 30 to 60 days of delivery. We, at times, extend volume discounts to customers. We permit returns of our products in accordance with the terms of contractual agreements with customers.

### *Inventory Valuation*

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost or net realizable value, with cost determined 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, we also evaluate inventories for excess quantities, obsolescence or shelf life expiration. This evaluation includes analysis of our 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 us to reasonably expect that we can sell those products prior to their expiration, we adjust the carrying value of the inventory to its estimated net realizable value.

Due to the judgmental nature of inventory valuation, we may from time to time be required to adjust our assumptions as processes change and as we gain better information. Although we continue to refine the assumptions, described above, on which we base our estimates, we cannot be sure that our estimates are accurate indicators of future events. Accordingly, future adjustments may result from refining these estimates. Such adjustments may be significant.

### *Valuation of Purchased Intangible 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. We periodically evaluate the period of

amortization for purchased intangible assets to determine whether current circumstances warrant revised estimates of useful lives. We review our purchased intangible assets for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount to the net undiscounted cash flows expected to be generated by the asset. Impairment exists when the carrying value of our 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. An impairment loss would be recorded for the excess of net carrying value over the fair value of the asset impaired. 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.

#### *Revenue Interest Obligation*

In 2017, we completed an asset purchase agreement with CorMatrix and acquired all of the CorMatrix commercial assets and related intellectual property. As part of this acquisition, we entered into a royalty agreement with Ligand pursuant to which we assumed the Revenue Interest Obligation, with an estimated present value on the acquisition date of \$27.7 million. The terms of the Revenue Interest Obligation require us to pay Ligand 5% of future sales of the products we acquired in the CorMatrix acquisition, subject to certain annual minimum payments. Furthermore, a \$5.0 million payment will be due to Ligand if cumulative sales of the acquired 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.

We have estimated the fair value of the Revenue Interest Obligation, including contingent milestone payments and estimated sales-based payments, based on assumptions related to future sales of the acquired products. At each reporting period, the value of the Revenue Interest Obligation is re-measured based on current estimates of the net present value of future payments, with changes to be recorded in the consolidated statements of operations. In connection with our estimation at December 31, 2022, it was determined that the estimated future payments, discounted at the original discount rate, had decreased since the prior estimates. Such decrease was primarily the result of anticipated changes to our strategic partnerships relative to sales of both our CanGaroo and cardiovascular product lines that will impact the timing and extent of such sales and, thereby, will reduce expected future payments to Ligand. The change to estimated future payments yielded a reduction to the total Revenue Interest Obligation of approximately \$5.0 million for the year ended December 31, 2022 with such amount recognized as a gain in Other income, net in our consolidated statement of operations. There was no change to estimated future payments during the year ended December 31, 2021 and thus, no re-measurement gain or loss was recognized. The estimation of future sales and the possible attainment of sales milestones is subject to significant judgment. Different judgments would yield different valuations of the Revenue Interest Obligation and these differences could be significant.

#### *Contingent Liability for FiberCel Litigation*

We review every lawsuit and claim and are in contact with outside counsel on an ongoing basis in determining our Contingent Liability for FiberCel Litigation. An accrual is established for each lawsuit and claim, when appropriate, based on the nature of each such lawsuit or claim. The provision for FiberCel Litigation claims are based upon many factors, which vary for each case. These factors include (i) the extent of the injuries incurred, (ii) recent experience on 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 estimated liability. While we believe our 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 such, actual settlement amounts may differ from our estimates and such differences may be material.

#### *Stock-Based Compensation*

Compensation costs associated with stock option awards and other forms of equity compensation are measured at the grant-date fair value of the awards and recognized over the requisite vesting period of the awards on a straight-line basis.

Our policy is to grant stock options at an exercise price equal to 100% of the market value of a share of common stock at closing on the date of the grant. Our stock options generally have seven to ten year contractual terms and vest over a four-year period from the date of grant. We use the Black-Scholes model to value our time-vested stock option grants. 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 our IPO, our board of directors determined the fair value of common stock considering the state of the business, input from management, third party valuations and other considerations. We use the simplified method for estimating the expected term used to determine the fair value of options. Until our IPO in October 2020, there had been no public market for our common stock and thus, we lacked company-specific historical and implied volatility information. As a result, we estimate the expected volatility primarily based on the historical volatility of comparable companies in the industry whose share prices are publicly available and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price. We use a zero-dividend yield assumption as we have not paid dividends since inception nor do we 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.

For our performance-based stock option grants which vest upon the achievement of specified market conditions, we used the Monte Carlo simulation model to calculate the grant-date fair value. This model simulates the probabilities of the potential outcomes of our future stock prices over the performance period to determine a fair value. Under this simulation model, our key assumptions relate to the risk-free interest rate and equity volatility based on consideration of our historical trading volatility as well as the observed equity volatility of other publicly-traded life sciences companies.

The period expense for all of our stock options is recognized on a straight-line basis over the requisite service period for the entire award. Different assumptions relative to the fair valuation of our stock options would result in a different period expense and such differences may be material.

### **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, and will be able to take advantage of the foregoing exemptions, 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.

### **Recently Issued Accounting Pronouncements**

See Note 3, “Recently Issued Accounting Standards,” to our audited consolidated financial statements regarding recently issued accounting pronouncements.

### **Item 7A. 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 bears 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 to our variable rate indebtedness outstanding during the years ended December 31, 2022 or 2021 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 December 31, 2022, our cash and cash equivalents were maintained with one financial institution 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. As of December 31, 2022 we maintained \$17.8 million in bank deposit accounts that are in excess of the federally insured limit in one federally insured financial institution. The Company has not experienced any losses in such accounts.

Our accounts receivable relate to sales to customers. To minimize credit risk, ongoing credit evaluations of all customers' financial condition are performed. Two customers represented 10% or more of our accounts receivable as of December 31, 2022.

### ***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.

### ***Inflation Risk***

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 years ended December 31, 2022 and 2021. 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.

## **Item 8. Financial Statements and Supplementary Data.**

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To the Board of Directors and Stockholders of Elutia Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of Elutia Inc. (formerly known as Aziyo Biologics, Inc.) and its subsidiaries (the “Company”) as of December 31, 2022 and 2021, and the related consolidated statements of operations, of changes in stockholders’ equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

***Substantial Doubt About the Company’s Ability to Continue as a Going Concern***

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has generated recurring losses from operations and is expected to incur cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***Change in Accounting Principle***

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2022.

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP  
Baltimore, Maryland

March 23, 2023 except for the effects of discontinued operations discussed in Note 4 to the consolidated financial statements, as to which the date is November 20, 2023

We have served as the Company’s auditor since 2015.

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

	December 31, 2022	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash	\$ 16,989	\$ 30,393
Restricted cash	—	35
Accounts receivable, net	3,774	3,358
Inventory	4,240	2,786
Receivables of FiberCel litigation costs	13,813	—
Prepaid expenses and other current assets	2,387	783
Current assets of discontinued operations	9,496	10,073
Total current assets	50,699	47,428
Property and equipment, net	245	214
Intangible assets, net	15,069	18,466
Operating lease right-of-use assets and other	320	76
Noncurrent assets of discontinued operations	2,508	986
<b>Total assets</b>	<b>\$ 68,841</b>	<b>\$ 67,170</b>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,374	\$ 613
Accrued expenses	8,830	4,991
Payables to tissue suppliers	900	344
Current portion of long-term debt	—	8,059
Current portion of revenue interest obligation	8,990	2,750
Revolving line of credit	—	4,763
Contingent liability for FiberCel litigation	17,360	—
Current operating lease liabilities and other	232	5
Current liabilities of discontinued operations	4,929	4,476
Total current liabilities	42,615	26,001
Long-term debt	24,260	10,410
Long-term revenue interest obligation	5,916	16,540
Long-term operating lease liabilities	—	—
Other long-term liabilities	127	698
Noncurrent liabilities of discontinued operations	956	—
Total liabilities	73,874	53,649
Commitments and contingencies (Note 18)		
Stockholders' equity (deficit):		
Class A Common stock, \$0.001 par value, 200,000,000 shares authorized as of December 31, 2022 and December 31, 2021, and 11,823,445 and 9,245,146 shares issued and outstanding, as of December 31, 2022 and December 31, 2021, respectively	12	9
Class B Common stock, \$0.001 par value, 20,000,000 shares authorized, as of December 31, 2022 and December 31, 2021 and 4,313,406 issued and outstanding as of December 31, 2022 and December 31, 2021	4	4
Additional paid-in capital	132,939	118,599
Accumulated deficit	(137,988)	(105,091)
Total stockholders' equity (deficit)	(5,033)	13,521
<b>Total liabilities and stockholders' equity (deficit)</b>	<b>\$ 68,841</b>	<b>\$ 67,170</b>

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

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

	Year Ended December 31,	
	2022	2021
Net sales	\$ 23,849	\$ 20,456
Cost of goods sold	12,210	11,176
Gross profit	11,639	9,280
Sales and marketing	17,850	16,655
General and administrative	16,051	13,124
Research and development	7,727	7,754
FiberCel litigation costs, net	5,200	276
Total operating expenses	46,828	37,809
Loss from continuing operations	(35,189)	(28,529)
Interest expense	5,118	5,324
Other income, net	(4,159)	(3,579)
Loss before provision for income taxes	(36,148)	(30,274)
Income tax expense	34	55
Net loss from continuing operations	(36,182)	(30,329)
Income from discontinued operations	3,285	5,497
<b>Net loss</b>	<b>\$ (32,897)</b>	<b>\$ (24,832)</b>
Net loss per share from continuing operations attributable to common stockholders - basic and diluted	<b>\$ (2.62)</b>	<b>\$ (2.90)</b>
Net income per share from discontinued operations attributable to common stockholders - basic and diluted	<b>\$ 0.24</b>	<b>\$ 0.53</b>
Net loss per share - basic and diluted	<b>\$ (2.38)</b>	<b>\$ (2.38)</b>
Weighted average common shares outstanding - basic and diluted	13,832,887	10,444,767

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

**ELUTIA INC.**  
**CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)**  
(In Thousands, Except Share and Per Share Data)

	Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount			
<b>Balance, December 31, 2020</b>	<b>7,091,960</b>	<b>\$ 7</b>	<b>3,134,162</b>	<b>\$ 3</b>	<b>\$ 101,080</b>	<b>\$ (80,259)</b>	<b>\$ 20,831</b>
Proceeds from stock option exercises	3,305	—	—	—	26	—	26
Proceeds from sale of common stock through Employee Stock Purchase Plan	27,244	—	—	—	208	—	208
Issuance of common stock through private placement, net of issuance costs of \$247	2,122,637	2	1,179,244	1	13,750	—	13,753
Stock-based compensation	—	—	—	—	3,535	—	3,535
Net loss	—	—	—	—	—	(24,832)	(24,832)
<b>Balance, December 31, 2021</b>	<b>9,245,146</b>	<b>\$ 9</b>	<b>4,313,406</b>	<b>\$ 4</b>	<b>\$ 118,599</b>	<b>\$ (105,091)</b>	<b>\$ 13,521</b>
Proceeds from stock option exercises	13,887	—	—	—	78	—	78
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
Proceeds from sale of common stock in secondary public offering, net of issuance costs of \$966	2,350,000	3	—	—	10,196	—	10,199
Vesting of restricted stock units, net of shares withheld and taxes paid	140,004	—	—	—	(395)	—	(395)
Issuance of warrants in connection with debt financing	—	—	—	—	607	—	607
Stock-based compensation	—	—	—	—	3,647	—	3,647
Net loss	—	—	—	—	—	(32,897)	(32,897)
<b>Balance, December 31, 2022</b>	<b>11,823,445</b>	<b>\$ 12</b>	<b>4,313,406</b>	<b>\$ 4</b>	<b>\$ 132,939</b>	<b>\$ (137,988)</b>	<b>\$ (5,033)</b>

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

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

	Year Ended December 31,	
	2022	2021
Net loss	\$ (32,897)	\$ (24,832)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,733	3,730
(Gain) loss on extinguishment of debt	311	(3,029)
(Gain) on revaluation of revenue interest obligation	(4,962)	—
Amortization of deferred financing costs and debt discount	115	121
Interest expense recorded as additional revenue interest obligation or long-term debt	2,908	2,654
Stock-based compensation	3,647	3,535
Changes in operating assets and liabilities:		
Accounts receivable	(834)	1,170
Inventory	(498)	563
Receivables of FiberCel litigation costs	(13,813)	—
Prepaid expenses and other	(1,526)	1,442
Accounts payable and accrued expenses	4,908	(420)
Obligations to tissue suppliers	685	172
Contingent liability for FiberCel litigation	17,360	—
Deferred revenue and other liabilities	(571)	(552)
<b>Net cash used in operating activities</b>	<b>(21,434)</b>	<b>(15,446)</b>
<b>INVESTING ACTIVITIES:</b>		
Expenditures for property, plant and equipment	(540)	(369)
<b>Net cash used in investing activities</b>	<b>(540)</b>	<b>(369)</b>
<b>FINANCING ACTIVITIES:</b>		
Proceeds from public offering or private placement, net of offering costs	10,089	13,753
Net borrowings (repayments) under revolving line of credit	(4,763)	(1,751)
Proceeds from stock option exercises	78	26
Proceeds from long-term debt	25,000	—
Deferred financing costs	(468)	—
Repayments of long-term debt	(18,615)	(2,778)
Costs related to the extinguishment of debt	(633)	—
Payments on revenue interest obligation	(2,075)	(2,747)
Payments for taxes upon vesting of restricted stock units	(395)	—
Proceeds from sales of common stock through Employee Stock Purchase Plan	317	208
<b>Net cash provided by financing activities</b>	<b>8,535</b>	<b>6,711</b>
<b>Net decrease in cash and restricted cash</b>	<b>(13,439)</b>	<b>(9,104)</b>
<b>Cash and restricted cash, beginning of period</b>	<b>30,428</b>	<b>39,532</b>
<b>Cash and restricted cash, end of period</b>	<b>\$ 16,989</b>	<b>\$ 30,428</b>
<b>Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:</b>		
Cash paid for interest	\$ 5,480	\$ 4,984
Fair value of warrants issued	\$ 607	\$ —
Forgiveness of SBA PPP loan	\$ -	\$ 3,029

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**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, whose name was changed on September 6, 2023, 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.

**Note 2. Summary of Significant Accounting Policies*****Basis of Presentation and Liquidity***

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

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

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.

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 year ended December 31, 2022, the Company incurred a net loss of \$32.9 million, and as of December 31, 2022, the Company had an accumulated deficit of \$138.0 million. In addition, during the year ended December 31, 2022, the Company used \$21.4 million of cash in operating activities, and expects to continue to incur cash outflows in 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 flows.

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 or debt, restructure its Revenue Interest Obligation (as such term is defined, and further described, in Note 11), or pursue asset sale or other transactions. However, such transactions may not be successful and the Company may not be able to raise additional equity or debt, restructure its Revenue Interest Obligation, or sell or license assets on acceptable terms, or at all. As such, based on its current operating plans, the Company believes there is uncertainty as to whether its future cash flows along with its existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet the Company's anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about the Company's 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***

Certain reclassifications have been made to prior year amounts to conform to current year financial statement presentation. The reclassifications relate to the separate presentation of prior year costs related to the FiberCel Litigation. Such costs were formerly shown as a component of general and administrative expenses in the accompanying consolidated statements of operations.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions relating to inventories, receivables, long-lived assets, the valuation of stock-based awards, the valuation of the revenue interest obligation, the 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.

### ***Impact of COVID-19***

The Company continues to closely monitor the impact of the COVID-19 pandemic and its variants on its business. In March 2020, the World Health Organization declared COVID-19 a global pandemic and recommended various containment and mitigation measures worldwide. Since that time, the number of procedures performed using the Company's products has intermittently decreased, as governmental authorities in the United States have recommended, and in certain cases required, that elective, specialty and other non-emergency procedures and appointments be suspended or canceled in order to avoid patient exposure to medical environments and the risk of potential infection with COVID-19, and to focus limited resources and personnel capacity on the treatment of COVID-19 patients. As a result, beginning in March 2020, a significant number of procedures using the Company's products have intermittently been postponed or cancelled, which has negatively impacted sales of its products. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and may reduce the Company's net sales in the future and negatively impact its business, financial condition and results of operations while the pandemic continues.

## **Net Loss per Share**

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

## **Fair Value of Financial Instruments**

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

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

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

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

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

## **Cash and Restricted 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.

Under the provisions of the Company’s former revolving credit facility, the MidCap Credit Facility (as such term is defined, and further described in Note 10), the Company had a lockbox arrangement with the banking institution whereby daily lockbox receipts were contractually utilized to pay down outstanding balances on the MidCap Credit Facility debt. Lockbox receipts that had not yet been applied to the MidCap Credit Facility were classified as restricted cash in the accompanying consolidated balance sheets. The following table provides a reconciliation of cash and restricted cash included in the consolidated balance sheets to the amounts included in the statements of cash flows (in thousands).

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Cash	\$ 16,989	\$ 30,393
Restricted cash	—	35
<b>Total cash and restricted cash shown in statements of cash flows</b>	<b>\$ 16,989</b>	<b>\$ 30,428</b>



## **Accounts Receivable and Allowances**

Accounts receivable in the accompanying balance sheets are presented net of allowances for doubtful accounts and other credits. 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 doubtful accounts 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. The Company's allowance for doubtful accounts was approximately \$0.1 million as of December 31, 2022 and 2021.

## **Inventories**

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are 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 inventories 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 FASB issued ASU No 2016-02 "Leases" to increase the transparency and comparability about leases among entities. Additional ASUs have been issued subsequent to ASU 2016-02 to provide supplementary clarification and implementation guidance for leases related to, among other things, the application of certain practical expedients, the rate implicit in the lease, lessee reassessment of lease classification, lessor reassessment of lease term and purchase options, variable payments that depend on an index or rate and certain transition adjustments. ASU 2016-02 and these additional ASUs are now codified as Accounting Standards Codification Standard 842 - "Leases" ("ASC 842"). ASC 842 supersedes the lease accounting guidance in Accounting Standards Codification 840 "Leases" ("ASC 840") and requires lessees to recognize a lease liability and a corresponding lease asset for virtually all lease contracts. It also requires additional disclosures about leasing arrangements. The Company elected to utilize the "package" of expedients, as defined

in ASC 842, which retain the lease classification and initial direct costs for any leases that existed prior to adoption of the standard. Accordingly, previously reported financial information has not been restated to reflect the application of the new standard to the comparative periods presented. Elutia adopted the standard in the fourth quarter of 2022 for the full 2022 year resulting in the recognition of a Right-of-use (“ROU”) asset and operating lease liability on the Company’s consolidated balance sheet of approximately \$0.6 million as of January 1, 2022. As the ROU asset and the lease payable obligation were essentially the same upon adoption of ASC 842, there was no cumulative effect impact on the Company’s accumulated deficit.

The Company determines if an arrangement contains a lease at inception. 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 years ended December 31, 2022 and 2021.

### ***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 which are billed under ship and bill contract terms. 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 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. Shipping and handling costs were approximately \$0.3 million for both the years ended December 31, 2022 and 2021.

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.

#### ***Deferred Rent***

Prior to the adoption of ASU 2016-02 (as noted above) in the year ended December 31, 2022, the Company recognized rent expense by the straight-line method over the lease term. Funds received from the lessor used to reimburse the Company for the cost of leasehold improvements are recorded as a deferred credit resulting from a lease incentive and are amortized over the lease term as a reduction of rent expense.

#### ***Stock-Based Compensation Plans***

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

#### ***Research and Development Costs***

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

#### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash. At December 31, 2022 and 2021, the Company maintained \$17.8 million and \$30.9 million, respectively, in bank deposit accounts that are in excess of the \$0.25 million insurance provided by the Federal Deposit Insurance Corporation in one federally insured financial institution. The Company has not experienced any losses in such accounts.

#### ***Comprehensive Income (Loss)***

Comprehensive income (loss) comprises net income (loss) and other changes in equity that are excluded from net income (loss). For the years ended December 31, 2022 and 2021, 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.

## **Segment Reporting**

Operating segments are components of an entity that engage in business activities with discrete financial information available that is regularly reviewed by the chief operating decision maker ("CODM") in order to assess performance and allocate resources. The Company's CODM is its President and Chief Executive Officer. As discussed further in Note 19, the Company has 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 in November 2023. Segment results for the year ended December 31, 2021 have been restated to conform to the new segment presentation. See Note 19 for further discussion.

## **Note 3. Recently Issued Accounting Standards**

In June 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 will be 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. The Company is currently evaluating the impact of adopting this new guidance on its consolidated financial statements and timing of adoption.

## **Note 4. Divestiture of Orthobiologics Business**

As described in Note 2, on September 17, 2023, the Company executed the Purchase Agreement for the sale of substantially all of its Orthobiologics Business. Accordingly, as initially presented in the Company's Form 10-Q for the quarter ended September 30, 2023, the Orthobiologics Business is reported herein 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 December 31, 2022 and 2021 in the consolidated balance sheets and the results of operations from the Orthobiologics Business are reported as discontinued operations in the consolidated statements of operations for the years ended December 31, 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:

	Year Ended December 31,	
	2022	2021
<b>Carrying amounts of the major classes of assets included in discontinued operations:</b>		
Accounts receivable, net	\$ 3,056	\$ 2,638
Inventory	5,812	6,768
Prepaid expenses and other current assets	628	667
Total current assets	9,496	10,073
Property and equipment, net	1,158	986
Operating lease right-of-use assets and other	1,350	—
Total non-current assets	2,508	986
<b>Total assets of discontinued operations</b>	<b>\$ 12,004</b>	<b>\$ 11,059</b>
<b>Carrying amounts of the major classes of liabilities included in discontinued operations:</b>		
Accounts payable	\$ 954	\$ 971
Accrued expenses and other current liabilities	1,273	1,383
Payables to tissue suppliers	2,252	2,122
Current operating lease liabilities	450	—
Total current liabilities	4,929	4,476
Long-term operating lease liabilities	956	—
<b>Total liabilities of discontinued operations</b>	<b>\$ 5,885</b>	<b>\$ 4,476</b>

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:

	As of December 31,	
	2022	2021
Net sales	\$ 25,338	\$ 26,934
Cost of goods sold	17,755	17,192
Gross profit	7,583	9,742
Sales and marketing	2,345	2,170
General and administrative	576	563
Research and development	1,213	1,512
Total operating expenses	4,134	4,245
Interest Expense	164	—
Net income (loss)	<b>\$ 3,285</b>	<b>\$ 5,497</b>

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

	Twelve Months Ended December 31,	
	2022	2021
<b>Significant operating non-cash reconciliation items</b>		
Depreciation	\$ 167	\$ 120
Stock-based compensation	144	148
Changes in operating assets and liabilities:		
Accounts receivable	(417)	1,832
Inventory	956	(1,048)
Prepaid expenses and other	39	(636)
Accounts payable and accrued expenses and other current liabilities	(127)	725
Obligations to tissue suppliers	130	305
<b>Significant investing items</b>		
Expenditures for property, plant and equipment	378	255

#### Note 5. Stock-Based Compensation

In 2015, the Company established the Elutia Inc. 2015 Stock Option/Stock Issuance Plan, as amended (the “2015 Plan”) which provided for the granting of incentive and non-qualified stock options to employees, directors and consultants of the Company. On October 7, 2020, in connection with the Company’s IPO, the Company adopted the Elutia Inc. 2020 Incentive Award Plan (the “2020 Plan”), which authorizes the grant of incentive and non-qualified stock options, restricted stock, restricted stock units and stock appreciation rights to employees, directors and consultants. Shares of Class A common stock totaling 1,636,000 were initially reserved for issuance pursuant to the 2020 Plan. In addition, the shares reserved for issuance under the 2020 Plan will 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 December 31, 2022, the Company had 656,689 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) is eligible to receive 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 had not been legally granted as of December 31, 2022. It is anticipated that such RSUs will be legally granted prior to June 30, 2023, and the vested shares underlying the award will be deemed outstanding as of such time.

In connection with his resignation as President and Chief Executive Officer, Mr. Lloyd and the Company entered into a separation agreement, pursuant to which Mr. Lloyd remained a full-time, non-officer employee of the Company through September 30, 2022 to assist with the transition of his duties to his successor. On September 30, 2022, Mr. Lloyd received: (i) cash severance in an amount equal to his base salary for a period of 12 months and 100% of his annual target bonus and (ii) the COBRA benefits, during the 12-month period following September 30, 2022. The Company recognized Mr. Lloyd's severance costs totaling approximately \$1.0 million over the period from June 21, 2022 through September 30, 2022, and as of December 31, 2022, all such expenses remaining to be paid were included in Accrued Expenses in the accompanying consolidated balance sheets.

### 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 have contractual terms of seven to 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 years ended December 31, 2022 and 2021 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2021	1,386,811	\$ 13.28	7.8	\$ 179
Granted	1,246,904	\$ 5.91		
Exercised	(13,887)	\$ 5.57		
Forfeited	(755,089)	\$ 10.83		
Outstanding, December 31, 2022	<u>1,864,739</u>	\$ 9.41	7.5	\$ 8
Vested and exercisable, December 31, 2022	<u>723,793</u>	\$ 11.25	5.0	-

As of December 31, 2022, there was approximately \$4.1 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted-average period of 2.5 years. The weighted average grant date fair value of options granted during the years ended December 31, 2022 and 2021 were \$3.30 and \$7.26, respectively. The total intrinsic value of options exercised was not material for both the years ended December 31, 2022 and 2021.

The Company uses the Black-Scholes model to value its 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 of Directors determined the fair value of common stock considering the state of the business, input from management, third party valuations and other considerations. The Company uses the simplified method for estimating the expected term used to determine the fair value of options. The expected volatility of the Class A common stock is 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 options during the years ended December 31, 2022 and 2021:

	<u>Year Ended</u> <u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
Expected term (years)	6.2	5.9
Risk-free interest rate	2.3 %	1.0 %
Volatility factor	63.8 %	63.6 %
Dividend yield	—	—

For the Performance-Based Options granted 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 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.

A summary of the RSU activity under the Company’s 2020 Plan for the year ended December 31, 2022 is as follows:

	<u>Number of Shares</u> <u>Underlying RSUs</u>	<u>Weighted-</u> <u>Average</u> <u>Grant Date</u> <u>Fair Value</u>
Unvested, December 31, 2021	235,985	\$ 15.98
Granted	586,083	\$ 4.08
Vested	(238,617)	\$ 6.64
Forfeited	(211,144)	\$ 11.40
Unvested, December 31, 2022	<u>372,307</u>	<u>\$ 5.90</u>

The total fair value of the RSUs granted during the year ended December 31, 2022 and 2021 of \$2.4 million and \$1.3 million, respectively was based on the fair market value of the Company’s Class A common stock on the date of grant. The fair value at the time of the grant is amortized to expense on a straight-line basis over the vesting period of three to four years.

During the year ended December 31, 2022, the Company granted 289,282 Performance-Based RSUs, with 209,054 still outstanding at December 31, 2022. All such RSUs, including those granted to Dr. Mills and described above, vest only if or when the Company’s Class A common stock closing price is at or exceeds a defined share price for a defined period of time. As such, all of these awards have been accounted for as market condition awards. Given the nature of these market condition arrangements, an option pricing model, the Monte Carlo model, was used to determine the fair value of these RSUs as well as the expense recognition term of two to three years using the graded vesting method.

As of December 31, 2022, \$1.4 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of two years.

### **Employee Stock Purchase Plan**

The Company makes shares of its Class A common stock available for purchase under the Elutia Inc. 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 equal to the lesser of (i) 1% of the total shares of Class A common stock outstanding on the final day of the immediately preceding calendar year; or (ii) a lesser number of shares determined by the Company's board of directors. As of December 31, 2022, the total shares of Class A common stock authorized for issuance under the ESPP was 380,997, of which 279,345 remained available for future issuance. During the year ended December 31, 2022, 74,408 shares of Class A common stock were issued under the ESPP.

### **Stock-Based Compensation Expense**

Stock-based compensation expense recognized during the years ended December 31, 2022 and 2021 comprised of the following (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Sales and marketing	\$ 1,041	\$ 652
General and administrative	1,922	2,179
Research and development	466	521
Cost of goods sold	74	36
<b>Total stock-based compensation expense</b>	<b>\$ 3,503</b>	<b>\$ 3,388</b>

Stock-based compensation expense included within Discontinued Operations totaled \$0.1 million for both the year ended December 31, 2022 and 2021.

### **Note 6. Inventory**

Inventory as of December 31, 2022 and 2021 was comprised of the following (in thousands):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Raw materials	\$ 652	\$ 434
Work in process	541	497
Finished goods	3,047	1,855
<b>Total</b>	<b>\$ 4,240</b>	<b>\$ 2,786</b>

### **Note 7. Property and Equipment**

Property and equipment as of December 31, 2022 and 2021 were comprised of the following (in thousands):

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Processing and research equipment	\$ (1,000)	\$ (985)
Leasehold improvements	613	606
Office equipment and furniture	188	187
Computer hardware and software	1,029	994
	830	802
Less: accumulated depreciation and amortization	(585)	(588)
<b>Property and equipment, net</b>	<b>\$ 245</b>	<b>\$ 214</b>

Depreciation and amortization expense on property and equipment totaled approximately \$0.1 million in both the years ended December 31, 2022 and 2021. Amounts included within cost of goods sold is not material.

## Note 8. Leases

The Company leases one production facility, one administrative and research facility and one administrative facility under non-cancelable operating lease arrangements that expire through July 2023. All leases contain renewal options and escalation clauses based upon increases in the lessors' operating expenses and other charges.

The following is a summary of the Company's ROU assets and operating lease liabilities as of December 31, 2022 (in thousands):

	Classification on the Balance Sheet	December 31, 2022
<b>Assets</b>		
Operating leases assets	Operating lease right-of-use assets and other	\$ 226
<b>Liabilities</b>		
Operating leases current liabilities	Current operating lease liabilities and other	232
Operating leases non-current liabilities	Long-term operating lease liabilities	—
Total lease liabilities		<u>\$ 232</u>
Weighted average remaining lease term		0.6
Weighted average discount rate		7.2%

For the year ended December 31, 2022, the Company recognized operating lease cost of approximately \$0.4 million and expenses related to non-lease elements such as building maintenance and utilities of \$0.4 million. Cash paid for amounts included in the measurement of operating lease liabilities are included in operating cash flows and were approximately \$0.4 million for the year ended December 31, 2022.

For the year ended December 31, 2021, the Company recorded rent expense on a straight-line basis over the life of the lease and the difference between the average rent expense and cash payments for rent was recorded as deferred rent and included in accrued liabilities on the balance sheet as of December 31, 2021. Rent expense for the year ended December 31, 2021 was approximately \$0.4 million and is included as a component of either cost of goods sold or general and administrative expenses.

The table below reconciles the Company's future cash obligations to the operating lease liabilities recorded on the balance sheet as of December 31, 2022 (in thousands):

<b>Years ending December 31,</b>		
2023	\$	237
2024		—
2025		—
Total minimum lease payments		237
Less: amount of lease payments representing interest		(5)
Present value of future minimum lease payments		232
Less: current operating lease liabilities		(232)
Long-term operating lease liabilities	\$	<u>—</u>

## Note 9. Intangible Assets

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. A substantial portion of the assets acquired consisted of intangible assets related to the acquired products and customer relationships. Management determined that the estimated acquisition-date fair values of the intangible assets related to acquired products and customer relationships were \$29.3 million and \$4.7 million, respectively.

The components of identified intangible assets as of December 31, 2022 and 2021 are as follows (in thousands):

	December 31, 2022			December 31, 2021		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Acquired products	\$ 29,317	\$ (16,334)	\$ 12,983	\$ 29,317	\$ (13,409)	\$ 15,908
Customer relationships	4,723	(2,637)	2,086	4,723	(2,165)	2,558
Total	<u>\$ 34,040</u>	<u>\$ (18,971)</u>	<u>\$ 15,069</u>	<u>\$ 34,040</u>	<u>\$ (15,574)</u>	<u>\$ 18,466</u>

Acquired products and customer relationships are both amortized over a ten-year period. Amortization expense totaled approximately \$3.4 million for each of the years ended December 31, 2022 and 2021, which is included in cost of goods sold in the accompanying consolidated statements of operations. Annual amortization expense is expected to be approximately \$3.4 million during the years ended December 31, 2023 through 2026 and approximately \$1.5 million during the year ended December 31, 2027.

#### Note 10. Long-Term Debt

On May 31, 2017, Elutia entered into a \$12 million term loan facility (the “MidCap Loan Facility”) and an \$8.0 million asset-backed revolving line of credit (the “MidCap Credit Facility”), under which the Company’s borrowing capacity was limited by certain qualifying assets, with a financial institution (the “May 2017 Financing”). The MidCap Loan Facility was amended in December 2017, February 2018 and July 2019 (all amendments being considered modifications) such that an additional \$1.5 million, \$3.0 million, and \$3.5 million, respectively were received by the Company bringing the total aggregate principal amount outstanding under the MidCap Loan Facility to \$20 million. The borrowings under the MidCap Loan Facility and the MidCap Credit Facility were fully repaid with a portion of the proceeds from the SWK Loan Facility (as defined below) as more fully described below.

On August 10, 2022 (the “Closing Date”), the Company entered into a senior secured term loan facility with SWK Funding LLC, 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 drawn 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 December 31, 2022. 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 December 31, 2022, quarterly principal payments are scheduled to begin on November 15, 2024, in an amount equal to 5% of the Initial Term Loan with the balance paid at maturity. The SWK Loan Facility also includes both revenue and liquidity covenants, restrictions as to payment of dividends, and is secured by all assets of the Company, subject to certain customary exceptions. As of December 31, 2022, 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), 4.75% 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 governing the SWK Loan Facility also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination 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 12.6% for the period from August 10, 2022 through December 31, 2022.

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 served to reduce the recorded value of the associated debt. The debt discount and deferred financing costs will be recognized as interest expense through the maturity of the loan.

The Company used \$16 million of the proceeds of the SWK Loan Facility to repay all outstanding obligations on the 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. The prepayment fees, payment of unaccrued exit fees and the write-off of unamortized deferred financing costs resulted in a loss to the Company of approximately \$1.2 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2022.

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 year ended December 31, 2022.; however, the closing of the divestiture of the Orthobiologics Business on November 8, 2023 triggered the mandatory prepayment of \$4.0 million. Of such amount, \$2.0 million was paid shortly after closing of the divestiture of the Orthobiologics Business and the remainder is to be paid by the earlier of (i) February 15, 2024 or (ii) two business days following written request by SWK based on mutual agreement between the parties.

Borrowings under the MidCap Loan Facility, as amended, 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% from January 1, 2022 through August 10, 2022 (the “Repayment Date”) and for the year ended December 31, 2021.

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% from January 1, 2022 through the Repayment Date and for the year ended December 31, 2021.

During 2017, the Company restructured certain of its liabilities with a tissue supplier and entered into an unsecured promissory note totaling \$2.1 million. The note bears interest at 5% and includes quarterly interest-only payments in 2017 and quarterly interest and principal payments from March 31, 2018 through August 31, 2021. The Company used \$1.4 million of the proceeds from the SWK Loan Facility to repay the remaining balance on the promissory note; however the accrued interest on the promissory note was forgiven by the lender. Such forgiveness resulted in a gain to the Company of approximately \$0.4 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2022.

In May 2020, Elutia entered into a promissory note with Silicon Valley Bank that provided for the receipt by the Company of loan proceeds totaling approximately \$3.0 million (the “PPP Loan”) pursuant to the Paycheck Protection

Program under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”). In September 2021, Elutia was notified by the U.S. Small Business Administration that the entire balance of the Company’s PPP Loan and all related accrued interest was forgiven. Such forgiveness resulted in a gain to the Company of approximately \$3.0 million which has been recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2021.

As of December 31, 2022, the contractual maturities of the long-term debt are as follows (in thousands):

Years ending December 31,	Term Loan
2023	\$ —
2024	1,263
2025	5,051
2026	5,051
2027	13,890
Total	25,255
Debt Discount	(562)
Deferred Financing Costs	(433)
Total, net	24,260
Current Portion	—
Long-term Debt	\$ 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 December 31, 2022 and 2021.

#### **Note 11. Revenue Interest Obligation**

As part of the CorMatrix asset acquisition described in Note 8, 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 that Elutia is currently developing that is designed to include antibiotics.

Furthermore, a \$5.0 million payment will be due to Ligand if cumulative sales of these products exceed \$100 million and a second \$5.0 million will be due if cumulative sales exceed \$300 million during the ten-year term of the agreement which expires on May 31, 2027.

The Company recorded the present value of the estimated total future payments under the Revenue Interest Obligation as a long-term obligation, with the short-term portion as of December 31, 2022 comprised of (i) the 2023 minimum payments, (ii) the first \$5.0 million sales milestone payment noted above and (iii) the unpaid portion of the 2022 minimum payments. The short-term portion as of December 31, 2021 was comprised of the 2022 minimum payments. Interest expense related to the Revenue Interest Obligation of approximately \$2.7 million was recorded for both the years ended December 31, 2022 and 2021. See Note 12 for discussion of the value of this obligation.

## Note 12. Fair Value Measurements

The following table sets forth by level, within the fair value hierarchy, the liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Revenue Interest Obligation*	—	—	19,290	19,290
Total	\$ —	\$ —	\$ 19,290	\$ 19,290

	Fair Value Measurements at December 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Revenue Interest Obligation*	—	—	14,906	14,906
Total	\$ —	\$ —	\$ 14,906	\$ 14,906

\*Net Present Value; see discussion of value below

The Company has estimated the value of the Revenue Interest Obligation, including contingent milestone payments and estimated sales-based payments, based on assumptions related to future sales of the acquired products. At each reporting period, the value of the Revenue Interest Obligation is re-measured based on current estimates of future payments, with changes to be recorded in the consolidated statements of operations using the catch-up method. In connection with our estimation at December 31, 2022, it was determined that the estimated future payments, discounted at the original discount rate, had decreased since the prior estimates. Such decrease was primarily the result of anticipated changes to our strategic partnerships relative to sales of both our CanGaroo and cardiovascular product lines that will impact the timing and extent of such sales and, thereby, will reduce expected future payments to Ligand. The change to estimated future payments yielded a reduction to the total Revenue Interest Obligation of approximately \$5.0 million for the year ended December 31, 2022 with such amount recognized as a gain in Other income, net in our consolidated statement of operations. There was no change to estimated future payments during the year ended December 31, 2021 and thus, no re-measurement gain or loss was recognized.

The following table provides a rollforward of the aggregate fair value of the Revenue Interest Obligation categorized with Level 3 inputs for the years ended December 31, 2022 and 2021 (in thousands):

Balance as of January 1, 2021	\$ 19,383
Payments on Revenue Interest Obligation	(2,747)
Interest accrued to Revenue Interest Obligation	2,654
Balance as of December 31, 2021	\$ 19,290
Payments on Revenue Interest Obligation	(2,075)
Interest accrued to Revenue Interest Obligation	2,653
Gain on revaluation of revenue interest obligation	(4,962)
Balance as of December 31, 2022	\$ 14,906

## Note 13. Income Taxes

The Company is subject to income taxes in the United States. Income taxes are accounted for under the asset and liability method. Deferred income tax assets and liabilities are calculated based on the difference between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using the enacted income tax rates expected to be in effect during the years in which the temporary differences are expected to reverse.

The reconciliation of the U.S. federal statutory rate to the consolidated effective tax rate is as follows:

	Years Ended December 31,	
	2022	2021
Tax benefit at U.S. statutory rate	21.0 %	21.0 %
State income tax benefit, net of federal benefit	1.9 %	1.6 %
Nondeductible expenses	(0.3)%	1.6 %
State law changes	0.5 %	0.4 %
Other	0.1 %	0.3 %
Change in valuation allowance	(23.3)%	(25.1)%
Income tax expense	<u>(0.1)%</u>	<u>(0.2)%</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes as well as net operating loss carryforwards. As of December 31, 2022 and 2021, significant components of the Company's net deferred income taxes are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Tax goodwill	\$ 2,947	\$ 3,267
Net operating loss carryforwards	19,743	14,794
Inventory	491	647
Acquired intangibles	1,452	1,174
Revenue interest obligation	774	1,347
Interest expense	2,533	1,866
Research and development costs	1,749	-
Operating lease liability	364	-
FiberCel litigation costs	669	-
Other	2,045	1,314
Total assets	<u>32,767</u>	<u>24,409</u>
Deferred tax liabilities:		
Operating lease right-to-use assets	(350)	-
Prepaid expenses	(562)	(200)
Total liabilities	<u>(912)</u>	<u>(200)</u>
Total net deferred tax asset	31,855	24,209
Valuation allowance	(31,855)	(24,209)
Net deferred tax asset, net of valuation allowance	<u>\$ —</u>	<u>\$ —</u>

The Company did not recognize any deferred benefit for income taxes for the years ended December 31, 2022 and 2021, as the increases to the respective net deferred tax assets of \$7.6 million and \$6.2 million, respectively, were offset by corresponding increases to the Company's deferred tax asset valuation allowance due to uncertainty of realizing the deferred tax assets.

The Company evaluates the need for deferred tax asset valuation allowances based on a more likely than not standard. The ability to realize deferred tax assets depends on the ability to generate sufficient taxable income within the carryback or carryforward periods provided for in the tax law for each applicable tax jurisdiction. Valuation allowances are established when necessary to reduce deferred tax assets to amounts that are more likely than not to be realized. Based on the uncertainty of future taxable income generation, as of December 31, 2022 and 2021, the Company has provided valuation allowances against all deferred tax assets.

The Company regularly assesses the realizability of its deferred tax assets. Changes in historical earnings performance and future earnings projections, among other factors, may cause the Company to adjust its valuation

allowance, which would impact the Company's income tax expense in the period the Company determines that these factors have changed.

The income tax expense for the years ended December 31, 2022 and 2021 relates to current amounts due on certain state tax obligations.

As of December 31, 2022, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$86.9 million, comprised of \$17.7 million that will expire beginning in 2036 and \$69.3 million that have no expiration date. The Company also had state net operating loss carryforwards of approximately \$26.4 million that will expire beginning in 2030. Utilization of the net operating loss carryforwards may be subject to an annual limitation under Section 382 of the Code, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the net operating loss carryforwards before utilization.

As of December 31, 2022, the Company had no unrecognized tax benefits.

#### **Note 14. Stockholders' Equity**

##### *Public Offering of Common Stock*

On December 1, 2022, the Company issued and sold 2,350,000 shares of its Class A common stock at a price to the public of \$4.75 per share in a registered underwritten public offering, resulting in net proceeds to the Company of approximately \$10.2 million, after deducting underwriting discounts and offering expense.

##### *Private Placement of Common Stock*

On December 8, 2021, the Company closed on a private investment in public equity (PIPE) financing, thereby receiving net proceeds of approximately \$13.8 million, after deducting offering costs. The PIPE investors purchased an aggregate of 2,122,637 shares of the Company's Class A common stock and an aggregate of 1,179,244 shares of the Company's Class B common stock (which are convertible on a one-for-one basis into shares of Class A common stock), in each case, at a price of \$4.24 per share.

#### **Note 15. Retirement Plan**

The Company has a defined contribution savings plan under section 401(k) of the Internal Revenue Code. The plan covers substantially all employees. The Company matches employee contributions made to the plan according to a specified formula. The Company's matching contributions totaled approximately \$0.3 million and \$0.4 million for the years ended December 31, 2022 and 2021, respectively.



**Note 16. Net Loss Per Share**

(in thousands, except share and per share data)	Year Ended December 31,	
	2022	2021
<b>Numerator:</b>		
Net loss from continuing operations	\$ (36,182)	\$ (30,329)
Net income from discontinued operations	\$ 3,285	\$ 5,497
Net loss	\$ (32,897)	\$ (24,832)
<b>Denominator:</b>		
Weighted average number of common shares - basic and diluted	13,832,887	10,444,767
Net loss per share from continuing operations attributable to common stockholders - basic and diluted	\$ (2.62)	\$ (2.90)
Net income per share from discontinued operations attributable to common stockholders - basic and diluted	\$ 0.24	\$ 0.53
Net loss per share - basic and diluted	\$ (2.38)	\$ (2.38)

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:

	December 31,	
	2022	2021
Options to purchase common stock	1,864,739	1,386,811
Restricted stock units	372,307	235,985
Class A common stock warrants	187,969	—
Total	2,425,015	1,622,796

**Note 17. Commitment and Contingencies*****ViBone Exclusivity Agreement***

In August 2018, the Company entered into an agreement with Surgalign Holdings, Inc. (formerly RTI Surgical, Inc.) ("Surgalign Holdings") for the exclusive distribution in the United States of the Company's ViBone® cellular bone product. Such agreement includes requirements that Surgalign Holdings purchase certain annual minimum quantities for years 2019 through 2021 and also included an upfront payment of \$2.0 million for the exclusivity. As of December 31, 2022 and 2021, the Company's net accounts receivable from Surgalign totaled \$0.8 million and \$0.7 million, representing 22% and 21% of total accounts receivable at such dates.

***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 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 the 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 years ended December 31, 2022 and 2021. 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, occurs within Elutia. The Company, in its sole discretion, can terminate the 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. These accruals are adjusted periodically as assessments change or additional information becomes available.

#### *FiberCel Litigation*

In June 2021, the Company announced a voluntary recall of a single lot of FiberCel fiber viable bone matrix. Since September 2021, 58 lawsuits (60 plaintiffs) in Indiana, Delaware, Florida, Maryland, Colorado, Michigan, Ohio, Kentucky, Oregon, North Carolina, Louisiana and Illinois 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 spinal 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 ("Ohio State Complaint"); the Northern District of Ohio ("Ohio Federal Complaint"); 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 ("Florida Federal Complaint"); U.S. District Court for the Eastern District of Michigan and the Eastern District of Michigan (collectively "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, "Kentucky Complaints."); the U.S. District Court for the Western District of Louisiana ("Louisiana Federal Complaint") and the Circuit Court of Cook County, Illinois ("Illinois State 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, and 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 Complaint contains three strict liability claims for defective design, defective manufacture, and failure to warn. A claim for punitive damages is also pled. The Ohio State Complaint alleges 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.

In addition to the above, there are 47 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 26 of the cases was settled for a total of approximately \$7.3 million. Settlement agreements have been executed in 20 of those cases and settlements of the remaining six cases are pending finalization of the related settlement agreements. Of these settled matters, 11 cases were both settled and paid as of December 31, 2022 for a total cash outlay of \$3.6 million. For the remaining 81 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 \$13.7 million bringing the total estimated liability at December 31, 2022 to \$17.4 million, which is recorded as Contingent Liability for FiberCel Litigation in the accompanying consolidated balance sheets. Although the Company believes there is a possibility that a loss in excess of the amount recognized exists, the Company is unable to estimate the possible loss or range of loss in excess of the amount recognized at this time. In order to reasonably estimate the liability for the unsettled FiberCel Litigation cases, the Company, along with outside legal counsel, has assessed a variety of factors, including (i) the extent of the injuries incurred, (ii) recent experience on the settled claims, (iii) settlement offers made to the other parties to the litigation and (iv) any other factors that may have a material effect on the FiberCel Litigation. While the Company believes its estimated liability to be reasonable, the actual loss amounts are highly variable and 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.

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 December 31, 2022 totaled \$13.8 million and are recorded as Receivables of FiberCel Litigation Costs in the accompanying consolidated balance sheets.

The indemnity and contribution receivables amount at December 31, 2022 represents amounts that are not believed to be subject to any current dispute. At December 31, 2022, 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.

As of both December 31, 2022 and December 31, 2021, the Company was not a party to, or aware of, any legal matters or claims with material financial exposure, except for the FiberCel Litigation.

#### **Note 18. Related Party Transactions**

As part of the contribution of assets transacted from Tissue Banks International, now KeraLink International (“KeraLink”), to Elutia upon formation of the Company, a provision existed which guaranteed a certain level of working capital, as defined, on the opening balance sheet of Elutia. Such guarantee was largely finalized in 2016; however, an additional \$0.4 million was received by the Company in connection with a settlement reached in 2018. Furthermore, as part of the 2018 settlement, it was agreed that when KeraLink sells its Elutia common shares for net proceeds greater than

\$550,000, KeraLink is obligated to pay Elutia \$550,000 within three days of such cash being received. In May 2021, KeraLink sold Elutia common shares for proceeds in excess of \$550,000, and as such, remitted \$550,000 to Elutia in full satisfaction of the 2018 settlement. Amounts received in connection with this settlement were recorded as other income, net in the accompanying consolidated statements of operations for the year ended December 31, 2021.

#### Note 19. Segment Information

The Company operates in three segments. These segments are based on financial information that is utilized by the Company's CODM 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.

For the years ended December 31, 2022 and 2021, the Company's net sales disaggregated by segment were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Net sales:		
Device protection	\$ 9,093	\$ 7,902
Women's health	7,474	5,046
Cardiovascular	7,282	7,508
Total Net Sales	<u>\$ 23,849</u>	<u>\$ 20,456</u>

For the years ended December 31, 2022 and 2021, the Company's gross profit disaggregated by segment were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Gross profit:		
Device protection	\$ 6,114	\$ 5,761
Women's health	3,137	914
Cardiovascular	5,785	6,001
Gross profit, excluding intangible asset amortization	15,036	12,676
Intangible asset amortization expense	3,397	3,396
Gross profit	<u>\$ 11,639</u>	<u>\$ 9,280</u>

The following table is a reconciliation of segment gross profit to the consolidated loss before provision for income taxes for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,	
	2022	2021
Gross profit	\$ 11,639	\$ 9,280
Adjustments:		
Sales and marketing	(17,850)	(16,655)
General and administrative	(16,051)	(13,124)
Research and development	(7,727)	(7,754)
FiberCel litigation costs	(5,200)	(276)
Loss from operations	(35,189)	(28,529)
Interest expense	5,118	5,324
Other income, net	(4,159)	(3,579)
Loss before provision for income taxes	<u>\$ (36,148)</u>	<u>\$ (30,274)</u>

During the years ended December 31, 2022 and 2021, the Company did not have any international product sales to specific countries where such country-specific sales represented material product sales, and the Company did not own any long-lived assets outside the United States.