UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the fiscal year ended December 31, 2024
or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For transition period from to

Commission File Number: 001-39577

Elutia Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

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

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, as of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $105,147,253 based on the closing price of $4.96 of the registrant's Class A common stock as reported on the Nasdaq Capital Market on such date. Solely for the purposes of this disclosure, shares of common stock held by the registrant's executive officers, directors and certain of its stockholders as of such date have been excluded because such holders may be deemed to be affiliates.

As of March 3, 2025, there were 36,423,482 shares of the registrant's Class A common stock and 4,313,406 shares of the registrant's Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 annual meeting of stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report, including, without limitation, statements regarding our results of operations, financial position, and business strategy; expectations regarding our products and their targeted effects; plans for our sales and marketing growth; expectations regarding the potential payment of post-closing earnout payments from the sale of our former Orthobiologics segment (the "Orthobiologics Business") to Berkeley Biologics, LLC ("Berkeley"); our anticipated expansion of our product development and research activities; increases in expenses and seasonality; expectations regarding our competitive advantages, and overall clinical and commercial success; expectations regarding the pending lawsuits and claims related to our recall of a single lot of Fiber Viable Bone Matrix ("FiberCel") and a separate single lot of viable bone matrix ("VBM") and expectations regarding the litigation matter with Medtronic Sofamor Danek USA, Inc. ("Medtronic"), amounts recoverable under insurance, indemnity and contribution agreements and the impact of such lawsuits and claims on our future financial position, and our expectations and plans regarding pursuit of any strategic transactions are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

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

These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties, and other important factors that may cause our actual results, performance or achievements to be materially different from and actual results, performance or achievements to be materially different from any future results, performance or achievements due to various factors, including, but not limited to those identified in Part I, Item 1A. "Risk Factors" and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report and in our other filings with the Securities and Exchange Commission (the "SEC"), each of which filings are accessible on the SEC's website at www.sec.gov and the Investor Relations page of our website at https://investors.Elutia.com/financials/sec-filings.

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

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

As used in this Annual Report, unless otherwise specified or the context otherwise requires, references to "we," "us," "our," the "Company" and "Elutia" refer to the operations of Elutia Inc. (formerly known as Aziyo Biologics, Inc.) and its consolidated subsidiaries.

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This Annual Report includes our trademarks, trade names and service marks, including, without limitation, "Elutia®," "CanGaroo®," "EluPro®," "CanGarooRM®," "ProxiCor®," "Tyke®," "VasCure®," "SimpliDerm®,"

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

INDUSTRY AND OTHER DATA

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

RISK FACTORS SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- our future results depend upon our ability to successfully commercialize, market and sell our newly approved EluPro antibacterial envelope device and the success of a smaller suite of established products than has historically been the case;
- we have incurred operating losses and may continue to do so for the near-term future, and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability;
- we have identified conditions and events that raise substantial doubt regarding our ability to continue as going concern;
- we face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance;
- we face significant litigation related to our FiberCel and Viable Bone Matrix recalls and have no more insurance coverage on the FiberCel recall;
- 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;
- our success depends on the continued and future acceptance of our products by the medical community;
- our long-term growth depends on our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings;

- a substantial portion of our net sales is generated through our commercial partners and independent sales agents, which subjects us to various risks;

- because we depend upon a limited number of third-party suppliers and manufacturers and, in certain cases, exclusive suppliers for products essential to our business, we may incur significant product development costs and experience material delivery delays if we lose any significant supplier, which could materially and adversely affect our business, financial condition and results of operations;

- our ability to successfully realize the anticipated benefits of the sale of our Orthobiologics Business;

- our future growth depends on physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products;

- we face significant and continuing competition from other companies, most of which have longer operating histories, more established products and/or greater resources than we do, which could adversely affect our business, financial condition and results of operations;

- pricing pressure as a result of cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could adversely affect our sales and profitability; and

- if we are unable to obtain, maintain and adequately protect our intellectual property rights, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

PART I

Item 1. Business.

Overview

At Elutia, our mission is to humanize medicine so that patients can thrive without compromise. As a commercial-stage company, we seek to leverage our unique understanding of biologics combined with local drug delivery to improve the interaction between implanted medical devices and patients by reducing complications associated with these surgeries. These complications include infection, device migration, erosion, implant rejection, non-union of implants, fibrosis and scar formation.

We estimate that more than 700,000 surgical procedures were performed annually in the United States involving the implantation of medical devices such as pacemakers, defibrillators, neurostimulators or tissue expanders for breast reconstruction. This number has been driven by advances in medical device technologies, reimbursement models focused on patient outcomes, and an aging population with a growing incidence of comorbidities, including diabetes, obesity and cardiovascular and peripheral vascular diseases. These comorbidities can exacerbate various immune responses and contribute to other complications upon device implant.

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

In Device Protection, we sell EluPro, a unique bioenvelope designed to mitigate complications associated with the implantation of electronic medical devices such as pacemakers, internal defibrillators and neurostimulation devices. Complications addressed by EluPro include infection, device migration and erosion. The bioenvelope features a biomatrix comprised of extracellular matrix ("ECM"), which supports healthy wound healing and may facilitate re-operative procedures by reducing scar formation and fibrosis. Additionally, EluPro is embedded with the powerful antibiotics rifampin and minocycline, which are gradually released into the surrounding tissue over several weeks post-implantation

to provide antimicrobial protection. EluPro is the only drug-eluting biomatrix ("DEB") offering in the U.S. implantable electronic device protection market. Alongside EluPro, we market the CanGaroo bioenvelope, our first generation product, which uses the same biomatrix but does not contain antibiotics.

In Women's Health, we have developed both patented and proprietary technologies, culminating in the creation of SimpliDerm—a novel biological matrix that leverages the inherent science of natural healing processes. SimpliDerm's design uses human-based hydrated acellular dermal matrix ("HADM") with heightened structural integrity and superior handling capabilities, which may mitigate inflammation and enhance tissue incorporation, leading to a better healing experience as compared to other human acellular dermal matrices ("ADM"), both lyophilized and pre-hydrated. We believe that these acellular dermal matrices represent an ideal choice for tissue repair and reconstruction, finding applications in fields such as breast reconstruction, sports medicine, hernia repair and trauma reconstruction.

We also sell legacy products into the Cardiovascular market. In Cardiovascular, we sell our specialized porcine small intestine submucosa, which is based on the same biomatrix used in EluPro and 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 distribution agreement with LeMaitre Vascular. This agreement also provided LeMaitre with an option to acquire the Cardiovascular product line through March 2026.

Our growth strategy is focused on increasing penetration in the Device Protection and Women's Health markets. We believe we can grow our business by increasing our commercial footprint, developing clinically exceptional products and, when possible and appropriate, through inorganic opportunities.

Our go-to-market strategy includes a combination of a direct sales force, commercial partners and independent sales agents. EluPro and CanGaroo are sold through both our internal sales force and independent sales agents and our commercial partner, Boston Scientific Corporation ("Boston Scientific"). As of December 31, 2024, we had 11 direct sales representatives and 31 independent sales agents focused on expanding market access and driving market penetration, not only by selling our products, but also, where appropriate, by managing commercial partners and providing technical expertise. SimpliDerm is sold through both independent sales agents and our distributor, Tiger Aesthetics Medical ("Tiger"). Through our direct sales force and leveraging our existing commercial partners and sales agents, we believe we can expand our customer base and further strengthen our existing customer relationships and increase penetration in our priority markets.

We have a well-established and scalable internal manufacturing facility along with our corporate headquarters and other administrative location. Our Roswell, Georgia location is our processing, production and distribution facility for all of our implantable electronic Device Protection and Cardiovascular products. Our Silver Spring, Maryland location is our headquarters and functions as a research and development and corporate support center. Our San Diego, California location provides additional administrative oversight and support. With the sale of our Orthobiologics Business in November 2023 to Berkeley as described in further detail below, we no longer operate our former Richmond, California human tissue processing and distribution facility; however, we continue to have a contract manufacturing relationship with Berkeley under which we receive SimpliDerm.

Discontinued Operations - Sale of Orthobiologics Business

On November 8, 2023, we completed the sale of substantially all of the assets relating to our former Orthobiologics Business to Berkeley. The Orthobiologics Business was comprised of assets relating to researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing our Orthobiologics products, and the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products. The assets sold represent the entirety of our Orthobiologics segment. In the sale, we received approximately $14.6 million, and we may earn up to an additional $20 million, in the aggregate, in the form of earn-out payments. The earn-out payments are equal to 10% of the actual revenue earned by Berkeley in each of the five years after the closing of the sale from sales of specified Orthobiologics products under the purchase agreement (including improvements, modifications, derivatives and enhancements related to those products). There have been no earn-out payments made to date. Additionally, the purchase agreement provides for a customary indemnity holdback in

the amount of $1.5 million to be retained by Berkeley for 24 months after close. In the purchase agreement, the Company has retained the liabilities arising out of the VBM and FiberCel matters, as described in Note 17, both of which products were part of the Orthobiologics Business. We recognized a gain of $6.0 million on the sale of the Orthobiologics Business in 2023 and an additional gain of $0.2 million in 2024 from an adjustment payment related to the final working capital received by Berkeley at the sale date. The indemnity holdback is available as a source of recovery for Berkeley for claims of indemnification under the purchase agreement, and some or all of the holdback may be retained by Berkeley if Berkeley is successful in asserting a claim or claims for indemnification against us. Should we receive incremental proceeds in the future through an earn-out payment or payment of the holdback amount, an additional gain will be recorded upon the receipt of such amounts.

Our Competitive Strengths

Our mission is to provide advanced regenerative care products that improve the outcomes in patients primarily undergoing implantable device-related surgery. To accomplish this mission, we intend to establish our products as the standard of care for treating patients undergoing such procedures. We believe our key competitive strengths position us well to execute on our growth strategy. Our key competitive strengths are:

Pioneering Technology. We are developing and commercializing products in the unique and innovative category of DEB. Our commercial DEB offering, EluPro, is the world's first and only antibiotic-eluting biologic envelope cleared by the U.S. Food and Drug Administration, and represents a breakthrough for implantable electronic device procedures. Through advanced tissue engineering, EluPro integrates clinically proven antibiotics with natural ECM to create a soft, conforming bioenvelope that provides optimal device stability and protection against infection. We believe that our DEB technology will redefine patient outcomes and procedural success.

Our Integrated Company. Our end-to-end capabilities spanning research and development ("R&D"), manufacturing and commercialization enable us to continually advance our product portfolio and drive commercial growth. For example, our integrated structure allows us to receive market feedback from our sales team on unmet physician and patient needs, providing us with invaluable direction on our innovation priorities. It is this feedback, for example, that allowed us to refine our SimpliDerm product to have, what we believe to be, industry-leading handling properties.

Well-positioned in Large, Attractive and Growing Markets. We believe that the Device Protection, Women's Health and Cardiovascular markets, which we believe currently represent a combined market opportunity of greater than $1 billion in the United States, will continue to experience significant growth, given advancements in implantable medical device technologies and surgical techniques; shifting global demographics that include an aging population with a greater incidence of comorbidities, and increasing procedure volumes. We believe there is growing adoption of regenerative medicine products by the medical community as physicians become aware of the benefits of natural products, including improved healing and reduced inflammation, scar-tissue formation and foreign body response.

Large and Growing Body of Clinical Data. We have and continue to develop a body of pre-clinical, clinical and patient outcomes data, including third-party publications and patient registries that provide evidence supporting the technical and clinical attributes of our products. We believe that our extensive in vivo and clinical data give us a competitive advantage.

Commercial Relationships with Major Medical Device Companies. We have commercial agreements with major medical device companies, including our strategic relationships with Boston Scientific, Tiger and LeMaitre Vascular, which we collectively refer to as our commercial partners, to promote or commercialize some of our products. These commercial partners use their own network of approximately 1,100 sales representatives, clinical specialists and independent sales agents, including approximately 1,000 of which are focused on our CanGaroo product. We leverage this additional presence in targeted markets to significantly increase our opportunity to cost-effectively penetrate these large markets.

Executive Management Team with Extensive Experience in Regenerative Medicine. Our executive management team has extensive experience in the regenerative medicine and medical device industries, spanning R&D,

operations, manufacturing and commercial. This experience allows us to operate with a deep understanding of the underlying trends in this industry and the intertwined scientific, clinical, regulatory, commercial and manufacturing functions that drive success. We believe our team has the necessary experience to lead us through our continued commercial expansion and the development and launch of our pipeline products.

Our Growth Strategy

The key elements of our growth strategy are:

Increase Penetration in Our Target Markets. We believe that the potential for growth in our target market segments presents a long-term opportunity to increase the use of our products. We plan to continue our growth and accelerate our penetration into our target markets through our direct sales force and by leveraging our relationships with our commercial partners, Boston Scientific, Tiger and LeMaitre Vascular, each of which have well-established and significant infrastructure and experience in our target markets.

Pipeline of Innovative Drug-Eluting Biologics Products. In June 2024, EluPro was cleared for marketing by the FDA and is the only DEB offering in the U.S. for use with cardiac implantable electronic devices ("CIED"), such as pacemakers and internal defibrillators. We are pioneering DEBs to help solve problems unaddressed by available options. We intend to leverage our DEB platform technology by developing and commercializing products for markets with similar unmet needs, including breast reconstruction and neurostimulation.

Our Proprietary Products/Solutions

Our portfolio of regenerative medicine products has been developed to address the following specific markets:

Device Protection and Cardiovascular Markets

Market Opportunity

We estimate, based on industry sources and other third-party estimates, that there were more than 600,000 procedures in the United States to install or replace implantable electronic devices ("IED"), such as pacemakers, pulse generators and defibrillators, as well as spinal cord neuromodulators and vagus nerve, deep brain and sacral nerve stimulators, which represents an estimated $600 million opportunity.

Limitations of Existing Solutions

CIEDs are used extensively to treat cardiac arrhythmias as well as heart failure. While these devices are generally well tolerated, they are not free from complications.

In 2015, a group of third-party researchers published a systematic review and meta-analysis of 60 published reports, consisting of 21 prospective, nine case-control and 30 retrospective cohort studies published between 1981 and 2013, each of which examined the rate of infection associated with the implantation of electronic devices. The average rate of infection was between 1.0 and 1.3% and the reported rates of infection ranged from 0.3% to 16.4%. In 2019, a different group of third-party researchers published the results of a global, prospective randomized clinical study focused on infection complications of implantable electronic cardiovascular devices which identified a 1.2% infection rate during 12-month follow-up in the control arm (3,488 patients), and this was later reported by other third-party researchers in 2020 to rise to 1.9% at the 36 months follow-up. However, infection is not the only significant complication associated with implantation. Data from third-party studies published in 2011 and 2016 indicated that migration occurred in 0.5% to 10.9% of such procedures, and data from third-party studies published in 2001 and 2007 indicated that erosion of the device through the skin occurred in 0.2% to 5.0% of such procedures. Thus, migration and erosion have been shown to be similarly frequent and can both result in infection or require replacement of the device. Other complications include those associated with Twiddler's syndrome, which is a malfunction of a pacemaker due to manipulation of the device by the patient, and discomfort at the implant site. Overall, we estimate the rate of complication for CIED placement ranges from 7% to 11%.

As patients with implants live longer, device reoperations are ever more common, including those to replace or upgrade the device, or to replace or revise the wire leads. Due to an inflammatory response upon device implant, some patients may experience the formation of dense fibrotic tissue surrounding their device. This dense, under-vascularized capsule surrounding a device and its wire leads makes replacement or revision more difficult, increases the time needed for the extraction and replacement procedure and progressively increases the risk of infection. For neurostimulator devices, the common location of these devices, which is in the soft tissue of the abdomen or back, increases the risk of migration and erosion and that of patient discomfort when sleeping or sitting. Fibrotic tissue and scar can also encapsulate these devices.

Device envelopes were originally designed to enhance stability and reduce migration of the implanted devices. To address the risk of infection, TyRx Pharma ("TyRx") launched an antibiotic coated, resorbable synthetic envelope in 2013. In 2014, Medtronic acquired TyRx and now sells this product under the name TYRX™.

The utilization of TYRX, a synthetic mesh, presents several challenges. Notably, the material's rigidity and limited sizes options require larger incisions during surgery or modification of the envelope, which may compromise its ability to stabilize the CIED. Furthermore, the foreign body response, which can lead to the formation of fibrous capsules around synthetic material, poses significant hurdles. Excessive scar tissue resulting from this response may extend surgery times and complicate future device replacement and revision surgeries.

Our Solutions

EluPro was created as a unique bioenvelope designed to secure implanted devices, mitigating complications such as migration and erosion. The bioenvelope features a biomatrix comprised of ECM, which supports healthy wound healing and may facilitate re-operative procedures by reducing scar formation and fibrosis. Additionally, EluPro is embedded with the powerful antibiotics rifampin and minocycline, which are gradually released into the surrounding tissue over several weeks post-implantation to provide antimicrobial protection. This unique combination of drug and biomatrix supports the regeneration of a healthy, vascularized pocket from the patient's own tissue, mitigating a long-term foreign body response.

Alongside EluPro, we continue to market CanGaroo which was designed to mitigate complications deriving from implantable electronic devices and the shortcomings of synthetic envelopes. Data supports that the biomatrix in our bioenvelope products forms a natural, systemically vascularized pocket that conforms to and securely holds implantable electronic devices. EluPro and CanGaroo are cleared for use with pacemaker pulse generators, defibrillators and other cardiac implantable electronic devices as well as vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators and sacral nerve stimulators.

EluPro and CanGaroo are both constructed from perforated, multi-laminate sheets of decellularized, non-crosslinked, lyophilized porcine small intestine submucosa ("SIS") ECM, a natural biomaterial, which is rich in natural growth factors, structural proteins and collagens. This creates a soft, conforming envelope with excellent handling features and optimal stability for implantable electronic devices. The ECM is designed to mitigate the biologic foreign body response that normally occurs around the electronic device. The biomatrix is remodeled into a surrounding layer of vital, vascularized tissue, potentially reducing the risk of thick capsule formation, migration and erosion of the implantable device through the skin, and complications associated with Twiddler's syndrome. Bioenvelopes may also enhance patient comfort and facilitate the process of implantation and of device removal during its replacement.

EluPro has a shelf life of nine months and CanGaroo has a shelf life of 30 months.

Development Pipeline

EluPro received clearance by the FDA in June 2024, and we are building on this marketing authorization with stability studies to support a Special 510(k) filing for additional sizes. We also have ongoing initiatives to extend shelf life and reduce the cost to manufacture EluPro as production volumes increase.

Commercial Approach

We sell EluPro and CanGaroo in the United States using our direct sales force and our commercial partner, Boston Scientific, which acts as a sales agent and gives us access to approximately 900 sales representatives and clinical specialists to further expand our footprint and accelerate our sales. Our primary customers are electrophysiologists, cardiac surgeons and neurosurgeons. Our direct sales force is focused on gaining additional market access and driving market penetration, not only by selling our products, but also, where appropriate, by managing our commercial partners and providing technical assistance for selling our products. Our sales team provides the critical knowledge of the advantages that EluPro and CanGaroo provide for patients over those of our competitors. We ship the product directly to hospitals.

Cardiovascular Products

We also sell additional cardiovascular products derived from our specialized SIS ECM, all of which received 510(k) regulatory clearance as medical devices:

- ProxiCor for Cardiac Tissue Repair ("CTR") is cleared for use as an intracardiac patch for repairs such as atrial and ventricular septal defects and suture-line buttressing, as well as for pledgets. ProxiCor CTR enables cardiac and congenital heart surgeons to reestablish the essential native anatomical structures of the heart by providing a natural bio-scaffold that allows the patient's own cells to form a new tissue layer versus a synthetic patch which may calcify over time.

- ProxiCor for Pericardial Closure ("PC") is used to reconstruct the pericardium after heart surgery. Data shows that post-operative complications associated with open-heart surgery are reduced in patients who have had their pericardium reconstructed. By providing a protective covering over the heart, ProxiCor PC may help protect the heart during repeat sternotomies.

- Tyke was developed based on a request by pediatric cardiovascular surgeons to deliver an ECM material that maintained the biomechanical properties found in our existing products, but was thinner, more pliable and better suited for intracardiac and branch pulmonary artery use in neonates and infants. Tyke is cleared for use in neonates and infants for the repair of pericardial structures; as an epicardial covering for damaged or repaired cardiac structures; and as a patch material for intracardiac defects, septal defect and annulus repair, suture-line buttressing and cardiac repair. Tyke is the only extracellular material that has been specifically cleared for use in neonates and infants to repair cardiac structures.

- VasCure is cleared for use, and is used by, cardiovascular, vascular and general surgeons as, a patch material to repair or reconstruct the peripheral vasculature, including the carotid, renal, iliac, femoral and tibial blood vessels, by modeling into site-specific tissue and conforming to repair defects easily. VasCure is also cleared and is used for the closure of vessels, as a pledget, or for suture line buttressing when repairing vessels. Unlike synthetic or cross-linked materials, VasCure approximates normal tissue and, we believe, is, therefore, less likely to provoke an immune response.

In April 2023, we entered into an agreement with LeMaitre Vascular, a provider of vascular devices, implants and services, granting LeMaitre Vascular the exclusive U.S. distribution rights for the products within our cardiovascular segment: ProxiCor PC, ProxiCor CTR, Tyke and VasCure. The term of the collaboration is three years, and LeMaitre Vascular has the exclusive option to acquire the product line through March 2026.

Clinical Data

We have accumulated a substantial body of clinical and pre-clinical data for our Device Protection products. We believe that the reported outcomes from our studies help to differentiate our products in the marketplace.

Pre-clinical Studies

Recently published data in *Frontiers in Drug Delivery* by Garrigos et al. demonstrated that EluPro, the first FDA-cleared antibiotic-eluting biologic envelope, effectively reduces bacterial colonization associated with CIEDs. Using a well-established rabbit model of CIED infection, the study showed that EluPro achieved complete eradication of methicillin-resistant *Staphylococcus aureus* ("MRSA") and other bacterial strains while providing sustained local antibiotic release for over a week with minimal systemic exposure. None of the animals receiving EluPro exhibited signs of infection, whereas the control group developed infections and associated complications. These findings highlight EluPro's potential to address bacterial contamination, a major concern in CIED procedures, and support its role in reducing infection risk for patients receiving implantable devices.

Earlier published pre-clinical data from a rabbit model showed that the CanGaroo Envelope was more successful in providing a barrier surrounding a CIED compared to a pacemaker canister alone. When implanted with a pacemaker, CanGaroo Envelopes promoted significantly greater stabilization of the device and more vascularized tissue ingrowth within the pocket compared to implantation with only standard fixation methods, such as sutures through the CIED header or no fixation at all. These data were initially presented as a live podium presentation at the American Society for Artificial Internal Organs ("ASAIO") 2022 annual conference and published in abstract form in ASAIO Journal.

Clinical Studies

To evaluate our CanGaroo Envelope, we have conducted multiple post-market studies and are currently conducting prospective studies that comprise over 2,000 patients in total. We believe the results from the completed studies provide evidence supporting the benefits of the biomatrix in EluPro and CanGaroo when used for the implantation of CIEDs in humans.

CARE Study and SECURE Study

The CARE Study, a retrospective, post-market investigation, gathered data from 96 consecutive patients who underwent simultaneous implantation of CIED and CanGaroo Envelope at a single institution. The SECURE Study, a prospective, single-arm, observational, post-market study, included 1,026 patients from 39 centers who underwent CIED implantation within a CanGaroo Envelope. Combining data from both studies resulted in a comprehensive analysis involving a total of 1,102 patients from 40 centers across the United States. The dataset, with an average of 2.3 infection risk factors per patient and a mean follow-up time of 223 days, was utilized to evaluate overall clinical outcomes and adverse events. Common risk factors among the enrolled patients encompassed oral systemic anticoagulants, obesity, diabetes, congestive heart failure, device replacement/revision, and renal insufficiency.

This real-world dataset revealed physician practice patterns for usage of the CanGaroo Envelope, and the type of hydration solutions that were chosen by the treating physician. Physicians demonstrated a preference for usage of an antibiotic hydration solution in higher infection risk patients ($p<.05$), particularly gentamicin, and those patients had an equivalent major infection rate to lower risk patients receiving a saline soaked CanGaroo (p=NS). Of the total sample population, 14 patients (1.3%) developed hematoma requiring intervention, and 12 patients (1.1%) developed a pocket infection - 10 of which (0.9%) came from the antibiotic without gentamicin hydration group. The use of gentamicin was associated with a threefold reduction in infection risk (OR 3.0, 95% CI, 1.0 – 10.0). A major contributing factor to pocket infection rate was whether the site also employed guideline recommended preoperative intravenous antibiotics (IV ABX) alongside use of an antibacterial envelope; sites utilizing IV ABX on ≥80% of their patients had significantly lower infection rates than sites that used it on <80% of their patients (0.8% vs. 5.6%, p=.008). There were no reports of device migration in the total dataset. These results were presented and published as separate sub-analyses of the dataset at multiple national conferences between 2017 – 2022, and collectively in a recent publication, and highlight the importance of evaluating real world evidence for CIED envelopes, and conjunctive use alongside other guideline recommendations for high infection risk patients. We believe the low rates of CanGaroo Envelope complications observed in the CARE and SECURE Studies support the safety of the product when used clinically in human CIED implantation.

CARE Plus Study

The CARE Plus Study, a single-center, post-market, retrospective cohort study, assessed outcomes in patients undergoing CIED implantation with either a biologic CanGaroo Envelope, Medtronic's non-biologic TYRX envelope, or

no envelope. The study, published in Cureus in May 2022, included results from 455 patients (165 CanGaroo, 219 TYRX, and 71 no envelope). Analysis of adverse patient outcomes and events occurring up to 12 months post-implantation revealed that most patients with at least two infection risk factors received an antibacterial envelope (77.9% any envelope vs. 52.1% no envelope, p<.001). The overall rate of adverse events was 9.2% (n = 42), with low rates of pocket infection (0.4%) and hematoma (2.6%), and no significant differences between groups in overall or individual adverse event rates. The findings suggest the potential benefit of antibiotic-eluting CIED envelopes in reducing infection risk for high-risk patients. The study also presented a decision tree to aid clinical decision-making regarding CIED envelope usage.

HEAL Study

The HEAL Study was a retrospective cohort study of CIED patients who were presenting for reoperation after a prior implantation. The study was designed to compare the characteristics of soft tissue healing surrounding CIED implants with or without an envelope. A total of 46 patients were enrolled, categorized into three cohorts based on whether a biologic CanGaroo Envelope, Medtronic's non-biologic TYRX Envelope, or no envelope was employed during their prior implantation. During reoperation, the current implant pockets of the patients were examined and compared using both a blinded histological biopsy and visual assessment through photographs.

Positive outcomes from the HEAL Study, were presented at Heart Rhythm Society (HRS 2023). The study assessed patients who underwent CIED implantation with CanGaroo Envelope, Medtronic's TYRX non-biologic envelope, or no envelope, returning for a revision procedure at least four months post-implantation. In the interim analysis of 43 patients, CanGaroo demonstrated statistically significant advantages, with reoperations scoring 46% easier in generator mobilization (p=.02), 41% easier in lead mobilization (p=.01), and 43% less overall procedural difficulty (p=.04) compared to the no-envelope group. CanGaroo required significantly fewer capsulectomy procedures (83% less, p=.04), and histologic evaluation revealed 30% thinner capsules compared to no envelope (p=0.12) and 32% thinner capsules compared to TYRX (p=.09). The study findings underscore the potential of CanGaroo to enhance CIED implantation outcomes and streamline subsequent reoperative procedures.

CanGaroo S-ICD Pilot Study

A retrospective, single-center, post-market pilot study was designed to evaluate whether low voltage lead impedance ("LVZ"), as routinely measured by subcutaneous implantable cardioverter defibrillators ("S-ICDs"), could be a clinically relevant assessment. These devices sense changes in impedance, which could be influenced by fibrotic tissue surrounding the S-ICD. Such encapsulation could complicate future procedures for patients.

LVZ changes from 0 to 4 years post implantation of an S-ICD were analyzed in 24 patients, half of whom received CanGaroo Envelope and half received no envelope. LVZ measurements reliably detected changes in impedance over time and between groups. After an initial decrease in both groups in the first month, impedance changes appeared to increase more slowly in the CanGaroo cohort compared to patients in the no envelope cohort out to 30 months. The data, presented at the European Society of Cardiology 2022 Congress and published in *European Heart Journal*, suggest that LVZ may provide a non-invasive assessment of surrounding tissue quality. Further study is needed to determine whether use of a CanGaroo Envelope may stabilize impedance changes long-term.

CanGaroo Registry Study

The CanGaroo Registry Study is a prospective, multi-center registry that completed enrollment at 500 patients (329 CanGaroo and 171 no envelope) in December, 2022. The objective is to explore clinical profiles, procedural details, and post-implant outcomes of patients who received the CanGaroo Envelope or no envelope at time of initial (*de novo*) CIED implantation. All patients will be followed for three months postoperatively, and a subgroup of patients aged 65 years or younger at time of enrollment will undergo extended follow-up for up to five years.

EluPro Registry Study

The EluPro Registry Study is a prospective, multi-center, post-market study enrolling up to 100 participants undergoing CIED procedures utilizing the EluPro Antibiotic-Eluting BioEnvelope. The primary objective is to evaluate

the real-world safety and performance of the bioenvelope. Data on rates of complications —including infection, hematoma, lead dislodgement, device migration or erosion, and implant site complications—over a 12-month follow-up period will be collected and analyzed. In addition to standard clinical endpoints, the study incorporates novel patient-centric measures, including post-implant pain and satisfaction, to provide a more comprehensive assessment of patient experience and quality of life following CIED implantation. By integrating both clinical and patient-reported outcomes, this registry aims to generate real-world evidence on the impact of the EluPro Antibiotic-Eluting BioEnvelope in routine clinical practice, and will offer insights into both safety and patient well-being.

Women's Health Market

Market Opportunity

According to certain third-party estimates, the use of acellular dermal matrices in breast construction surgery in the United States grew 29% in 2022 versus 2020, with such surgeries now constituting an approximately $500 million market. Such surgery is performed to treat structures of the human body that are affected aesthetically or functionally due to defects, abnormalities, trauma, infection, burns, tumors or disease. Plastic and reconstructive surgery is generally performed to improve function and ability, but it may also be performed to achieve a natural appearing restoration of the affected anatomical structure. Clinical practice of plastic and reconstructive surgery includes excision of tumors of the skin, vasculature, chest, oral and oropharyngeal cavities and extremities and reconstructions of the same; debridement, skin grafting and skin flaps for burn reconstructions; trauma surgery for the hands, upper and lower limbs and facial region; congenital or acquired malformations related to the hands, face, skull and jaw; surgical removal of vascular abnormalities; a range of aesthetic surgeries; and reconstructions of the breast.

One of the most common applications of biologic matrices in plastic and reconstructive surgery is breast reconstruction surgery after mastectomy. Mastectomy is surgical removal of the breast tissue, including the tumor, to treat breast cancer. It is estimated that more than 10% of women will develop invasive breast cancer in their lifetimes, which in 2022, led to approximately 150,000 post-mastectomy breast reconstructions in the U.S. Breast reconstruction surgery restores a breast to near normal shape and appearance and can be performed using either a prosthetic breast implant, referred to as implant-based reconstruction, or the patient's own tissue, referred to as autologous reconstruction.

In 2022, plastic surgeons used ADMs in approximately 76,000 women, reconstructing approximately 125,000 breasts. About two-thirds of these procedures involved reconstruction of both breasts. The use of these materials is well-characterized in the clinical literature and recommended by recent U.S. and European consensus guidelines for certain surgical techniques. As of January 2025, no biologic matrix or any other soft tissue reinforcement material, including our product, has been approved or cleared by the FDA specifically for use in breast reconstruction surgery.

Limitations of Existing Solutions

Autologous tissue repair procedures are options for stabilizing soft tissue defects in various applications. However, these methods have limitations. The procedure may not be surgically feasible or the patient may decline its use. In addition, autologous tissue reconstruction may cause complications, such as infection, extended recovery and healing time, loss of sensation or weakness at the donor site and prolonged time under anesthesia during surgery.

Synthetic products provide a substitute when autologous reconstruction is not feasible or desired. Yet, they too have their limitations. Implantation of products not recognized by the body as "self" may trigger a foreign body reaction. The result of this signaling cascade is encapsulation of the foreign body in fibrotic tissue, which may impede tissue healing and lead to capsular contracture which occurs when scar tissue, or capsule, around the device tightens and squeezes the implant. This can cause both visible deformity as well as severe pain. Other major issues are damage to the surrounding soft tissue, altering of the mechanical properties or appearance of the original tissue and increased risk of infection.

ADM products offer an "off the shelf" biologic choice for reconstructive procedures, but they have their own limitations. The use of harsh chemicals to remove the cells can damage the extracellular matrix. The products can lack uniformity as determined by pliability in each direction, elasticity and non-uniform thickness. Such issues can affect how

rapidly, and the extent to which the implant is integrated, as well as the resulting tissue strength. In addition, there is a limited availability in larger sizes for some of these products.

Our Solution

We designed SimpliDerm to offer improved biocompatibility and better tissue integration in the patient. It is marketed for use for the repair or replacement of damaged or insufficient integumental tissue or for the repair, reinforcement or supplemental support of soft tissue defects or any other homologous use of human integument. SimpliDerm is a pre-hydrated, human ADM manufactured with our patented cell removal technology, a process that maintains the biological and structural integrity of the tissue's extracellular matrix components and is designed to allow for rapid integration, cellular repopulation and revascularization at the surgical site. Its structurally intact extracellular matrix is designed to closely resemble natural, healthy tissue.

Development Pipeline

Elutia is leveraging its DEB technology, first developed for EluPro, to create SimpliDermRM, a novel, next generation biomatrix for breast reconstruction. Clinical literature suggests that more than 10% of breast reconstruction patients experience post-operative infections, often requiring a major surgical procedure to remove the implant. SimpliDermRM is being developed to address this and other surgical complications by combining the structural benefits of porcine acellular dermis with antibiotic protection. As a Class III medical device, it will require FDA premarket approval ("PMA") before commercialization. To advance this program, Elutia is preparing for an investigational device exemption ("IDE") which we anticipate submitting by the end of 2025 to initiate a pilot clinical study.

SimpliDermRM is designed to provide soft tissue reinforcement while targeting the high complication rates associated with implant-based breast reconstruction, which range from 26% to 31%. These complications include capsular contracture, delayed healing, and surgical site infections, some of which may lead to life-threatening sepsis. While biomaterial matrices are commonly used in reconstructive procedures, no FDA-approved medical device specifically addresses these risks. Existing options have not sufficiently reduced complication rates, leading to additional surgical interventions and negatively impacting patient quality of life. By integrating antibiotics within its biologically derived matrix, SimpliDermRM aims to mitigate bacterial colonization, enhance tissue integration, and improve long-term surgical outcomes for breast reconstruction patients.

Commercial Approach

We sell SimpliDerm through independent sales agents to plastic and reconstructive surgeons. Additionally, in March 2023, we entered into an agreement with Sientra, a medical aesthetics company uniquely focused on plastic surgery, to expand the distribution of SimpliDerm. In April 2024, such agreement was acquired by Tiger in connection with their asset acquisition of Sientra. Under the agreement terms, Elutia has granted Tiger certain non-exclusive rights in the United States to market, sell and distribute SimpliDerm. This agreement with Tiger gives us access to approximately 50 sales representatives to further expand our footprint and accelerate our sales.

Clinical Data

We have accumulated a substantial body of clinical and pre-clinical data for our Women's Health products. We believe that the reported outcomes from our studies help to differentiate our products in the marketplace.

Pre-clinical Studies

In vitro studies were conducted to evaluate and compare SimpliDerm to native human dermis and two other commercially available HADMs, in terms of morphological structure, composition, physical characteristics and chemical and thermal stability. Histology slides of SimpliDerm and native dermal matrix were examined microscopically, using three different stains. Stained samples of SimpliDerm retained the collagen structure (density and orientation), elastin, blood vessels and basement membrane complex that was observed in the native dermal matrix. Transmission electron microscopy demonstrated intact collagen fibril structures in native dermis and SimpliDerm, supporting the conclusion that

the decellularization process used to produce SimpliDerm did not damage the ultrastructural architecture of the collagen matrix.

Additional testing was performed that compared the properties of SimpliDerm and alternative HADMs, AlloDerm RTU and DermACELL, to native dermis. These tests included glycosaminoglycan content, matrix protein stability and differential scanning calorimetry. The glycosaminoglycan content of SimpliDerm and AlloDerm RTU was similar, with a substantial reduction in the amount of glycosaminoglycans observed in DermACELL. Matrix protein stability was evaluated by determining acid-soluble collagen content and by performing collagenase degradation on the product samples. SimpliDerm was closest to native dermal matrix in both acid-soluble collagen content and collagenase degradation. Differential scanning calorimetry was performed on the samples, and SimpliDerm and AlloDerm RTU were equivalently close to native dermis, while DermACELL showed the largest difference. The combined testing indicates that SimpliDerm had a structurally intact matrix that was closest overall to native human dermis among the HADMs evaluated.

In addition, a non-human primate study was conducted evaluating the ability of SimpliDerm and AlloDerm RTU to regenerate host tissue two weeks, four weeks and three months after implantation. Explanted samples were subjected to analysis that included histology, growth factor analysis and gene expression characterization. H&E and VVG stains and staining for macrosialin ("CD68") were used to prepare tissue samples for microscopic observation. AlloDerm RTU samples demonstrated faster implant degradation and cell infiltration, and more inflammatory cells than SimpliDerm. Growth factor analysis of samples for tumor necrosis factor, an indicator for an inflammatory environment, was higher for AlloDerm RTU than SimpliDerm at three months. Gene expression analysis was performed for samples at all time points. Markers for evidence of an inflammatory response to the implants, including collagen synthesis, vascularization, fibrosis, myofibroblast presence and collagen crosslinking, were analyzed and compared. AlloDerm RTU was found to exhibit higher amounts of these inflammatory response markers. The histology, growth factor testing and gene expression data support the conclusion that compared to AlloDerm RTU, SimpliDerm showed less acute and chronic inflammation and less fibrosis, leading to a pro-remodeling microenvironment that promoted tissue repair and regeneration by three months post-implantation.

Clinical Studies

A retrospective, multi-center study evaluating patients who have undergone breast reconstruction post-mastectomy with SimpliDerm and patients receiving other HADMs has been published. A total of 107 patients (181 breasts) who underwent immediate, 2-stage breast reconstruction with tissue expanders and either SimpliDerm (n=38) or AlloDerm RTU (n=69) after mastectomy, were followed to exchange to permanent implant(s) or tissue expander(s) explant. Reconstructions were predominantly prepectoral (82.3%). Patients were followed for a median of 134 days. A total of 35 adverse events ("AEs") occurred in 27 (25.2%) patients, with no difference in AE type or rates between ADM groups, and no AEs deemed related. The observed AE profiles and rates were similar to those published for other ADMs in breast reconstruction. These results demonstrate comparable clinical outcomes of SimpliDerm and AlloDerm RTU following 2-stage breast reconstruction.

Competition

We operate in highly competitive markets that are subject to rapid technological change. Success in these markets depends on product efficacy, ease of product use, product price, availability of payor coverage and adequate third-party reimbursement, customer support services for technical, clinical and reimbursement support and customer preference for, and loyalty to, the products.

We believe that the demonstrated clinical efficacy of our products, the breadth of our product portfolio, our in-house customer support services, our customer relationships and our reputation offer us advantages over our competitors.

Our products compete primarily with implantable electronic device envelopes and other cardiovascular repair and human-derived acellular dermis products. The EluPro and CanGaroo Envelopes compete with the synthetic envelope TYRX from Medtronic. ProxiCor, Tyke and VasCure compete with bovine pericardium and synthetic patch materials produced by numerous companies, including Gore's Gore-tex and Terumo's Vascutek. SimpliDerm competes primarily against human-derived acellular dermis matrix meshes, including AbbVie's AlloDerm, MTF's FlexHD, Stryker's

DermACELL and Evergen's (formerly RTI Surgical) Cortiva. SimpliDerm also competes against animal-derived biological mesh products, such as AbbVie's Strattice and Integra's SurgiMend, as well as various synthetic mesh products.

We also compete in the marketplace to recruit and retain qualified scientific, management and sales personnel, as well as to acquire technologies and technology licenses complementary to our products or advantageous to our business.

Our competitors' products in the soft tissue repair market have been available for use for multiple years. During this time, private payors have developed policies for coverage based on available data and literature. While there are certain national and regional third-party payors who cover SimpliDerm or procedures using SimpliDerm, the majority do not.

We are aware of several companies that compete, or are developing technologies, in our current and future product areas. As a result, we expect competition to remain intense. Our ability to compete successfully will depend primarily on our ability to develop proprietary products that reach the market in a timely manner, are used in procedures that receive adequate payor coverage and reimbursement, are cost-effective, and are safe and effective, as well as our reputation in the market and success of our sales strategy. See Part I, Item 1A. "Risk Factors - Risks Related to Our Business - *We face significant and continuing competition from other companies, some of which have longer operating histories, more established products and/or greater resources than we do, which could adversely affect our business, financial condition and results of operations."*

Sales and Marketing

We have dedicated substantial resources to establishing a multi-faceted sales and marketing organization in the United States. We sell EluPro and CanGaroo in the United States using our direct sales force, which as of December 31, 2024, totaled 11 sales representatives and a network of 31 independent sales agents, and through our commercial partner, Boston Scientific, which acts as a sales agent, marketing EluPro and CanGaroo and obtaining orders, and gives us access to approximately 900 sales representatives and clinical specialists. Under the terms of this agreement, Boston Scientific receives a commission equal to a specified percentage of the end-user selling price for units they sell. Our direct sales representatives and distributors focus on gaining additional market access and driving market penetration, not only by selling our products, but also, by managing partnerships and providing technical expertise. These sales representatives and agents are supported by teams of professionals focused on sales management, sales operations, ongoing training, analytics and marketing.

SimpliDerm, our Women's Health product, is sold using independent sales agents and a partnership with Tiger, who Elutia has granted certain non-exclusive rights in the United States to market, sell and distribute SimpliDerm for select use in reconstruction surgery. This agreement with Tiger gives us access to approximately 50 sales representatives to further expand our footprint and accelerate our sales. Under the terms of this agreement, Tiger purchases SimpliDerm through a transfer fee and sells it to the end user hospital or healthcare facility.

Our cardiovascular products, ProxiCor, Tyke and VasCure, are sold in the U.S. through LeMaitre Vascular. In April 2023, we entered into an agreement with LeMaitre Vascular granting them the exclusive U.S. distribution rights for our cardiovascular products. The term of the collaboration is three years, and LeMaitre Vascular has the exclusive option to acquire the product line following the first year or under certain other circumstances.

We have historically focused our market development and commercial activities primarily in the United States. Sales generated in the United States represented greater than 96% of our net sales in 2024. Sales of our products outside of the United States ceased after May 2024 due to changes in certain international regulatory rules which required investment by us not warranted by the current level of sales in these markets.

Research and Development

Our research and development team has extensive experience in developing regenerative medicine and DEB products and works to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times, and, as a result, reduce costs. We have recruited and retained staff with significant experience and skills, gained through both industry experience and training at leading colleges and

universities. In addition to our internal staff, our external network of development laboratories, testing laboratories and physicians aids us in our research and development process.

Manufacturing and Suppliers

We manufacture CanGaroo and our cardiovascular products in our Roswell, Georgia facility and use Cook Biotech Incorporated ("Cook"), now owned by Evergen, as our sole porcine tissue supplier for these products. We have significant expansion capabilities in our in-house manufacturing facility. Cook has previously successfully expanded and, we believe, is well-positioned to support future expansion. However, they are our sole source, and we cannot guarantee that an interruption in supply will not occur. If necessary, we could engage an alternate supplier or set-up, validate and gain regulatory authorization to manufacture these products in our own facilities, although it would require significant time and expense.

We have robust internal compliance processes to maintain the high quality and reliability of our products. We use annual internal audits, combined with external audits by regulatory agencies and commercial partners to monitor our quality control practices. Our Roswell, Georgia facility is registered with the FDA as a medical device manufacturing establishment. In addition to Cook, we use other third-party suppliers to support our internal manufacturing processes. We select our suppliers through a rigorous process to ensure high quality and reliability with the capacity to support our expanding production levels. To date, we have not experienced any significant difficulty locating and obtaining the suppliers or materials necessary to fulfill our production requirements.

With the sale of our Orthobiologics Business in November 2023 to Berkeley, we no longer operate our former Richmond, California human tissue processing and distribution facility; however, we continue to have a contract manufacturing relationship with Berkeley under which we receive SimpliDerm. At present, Berkeley is our single source of supply for SimpliDerm, but we intend to develop our own in-house capability for the production of SimpliDerm. To this end, in March 2025, we signed a lease for 26,598 square feet in Gaithersburg, Maryland for purposes of, among other things, the internal production of SimpliDerm. We expect to be able to internally produce SimpliDerm by the third quarter of 2025. No contracted minimum purchase commitments are defined in the Berkeley agreement and Berkeley must comply with FDA current Good Tissue Practice (cGTP), American Association of Tissue Banks Standards and all applicable state and local regulations.

Intellectual Property

We rely on a combination of patents, trademarks, confidentiality agreements and security procedures to protect our proprietary products, preservation technology, trade secrets and know-how. We believe that our patents, trade secrets, trademarks and technology licensing rights provide us with important competitive advantages. We have also obtained additional rights through license agreements for additional products and technologies. As of December 31, 2024, we owned approximately 16 U.S. patents, eight U.S. patent applications, six foreign patents (in Australia, Germany, Spain, France, Great Britain and Italy), four foreign patent applications (in Australia, Canada, and Europe) and one Patent Cooperation Treaty application; and we in-licensed three U.S. patents, 12 foreign patents (in Australia, Canada, Japan, Denmark, Germany, Great Britain, Ireland, Italy and the Netherlands), and two U.S. and five foreign patent applications (in Brazil China and Japan, as well as an application with the European Patent Office). Our owned patent portfolio includes 15 U.S. patents and six U.S. patent applications that relate to our technology for EluPro and CanGaroo, including issued claims covering biological envelopes and pending claims covering their use. In addition, we own one U.S. patent that relates to our technology for SimpliDerm that claims a method of preparing an acellular dermal matrix. Excluding any patent term extension, our issued patents relating to our technology for EluPro and CanGaroo are anticipated to expire starting in 2027, and our issued patent that relates to our technology for SimpliDerm is anticipated to expire in 2033. There can be no assurance that any pending patent applications will ultimately be issued as patents. We do not own or in-license any patents or patent applications covering our other products.

As with other medical device and regenerative medicine companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates will depend on our success in obtaining effective patent claims and maintaining and enforcing claims that are granted. However, our owned and licensed patents could be invalidated or narrowed or otherwise fail to adequately protect our proprietary and intellectual property position and our

pending owned and licensed patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents.

In addition, the term of individual issued patents depends upon the legal term for patents in the countries in which they are obtained. In most countries in which we have filed, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. The life of a patent, and the protection it affords, is therefore limited and once the patent lives of our issued patents have expired, we may face competition, including from other competing technologies. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. Any such patent term extension can be for no more than five years, only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug or biological product, a method for using it or a method for manufacturing it may be extended. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. In the future, we expect to apply for patent term extensions on certain issued patents covering our products, depending upon the length of the clinical studies for each product and other factors. There can be no assurance that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For more information, see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property."

As of December 31, 2024, we had nine registered trademarks and ten pending trademark applications worldwide, including trademark registrations for "CanGaroo," "ProxiCor," "Tyke," "VasCure," "SimpliDerm," and "SimpliDerm Ellipse," in the United States, and for "CanGaroo" in the European Union, United Kingdom and Japan. Trademark applications have been filed for "Elutia" and "EluPro" in the United States, the European Union, United Kingdom and Japan, and for "Elutia" in Jamaica.

We have confidentiality agreements with our employees, consultants, independent sales agents and third-party vendors to maintain the confidentiality of our trade secrets and proprietary information. There can be no assurance that the obligations of our employees, consultants, independent sales agents and third parties, with whom we have entered into confidentiality agreements, will effectively prevent disclosure of our confidential information or provide meaningful protection for our confidential information if there is unauthorized use or disclosure, or that our trade secrets or proprietary information will not be independently developed by our competitors. See Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property" for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

License Agreement with Cook

On May 31, 2017, we entered into a license agreement, which we refer to as the Cook License Agreement, with Cook under which Cook granted to us an exclusive worldwide sublicensable license under certain licensed patents to make, have made, use, offer for sale, sell and import CorMatrix ECM for Pericardial Closure, CorMatrix ECM for Cardiac Tissue Repair, CorMatrix ECM for Carotid Repair, CorMatrix ECM for Vascular Repair, TYKE Patch, Pledget and Intracardiac, and CanGaroo ECM Envelope (into which implantable cardiac pacemaker or defibrillator devices are to be inserted). Cook retained certain co-exclusive rights to the CorMatrix ECM for Vascular Repair. The Cook License Agreement was amended on December 21, 2017 to expand our field of use for SIS pouch devices to include other implantable electronic cardiac stimulation devices, electronic neurostimulation devices for deep brain stimulation, spinal nerve and sacral nerve stimulation to relieve chronic pain and nerve stimulation to control bladder, digestive, abdomen and bowel movements, and also add additional payment requirements.

Under the Cook License Agreement, we agree to use commercially reasonable efforts to promote, solicit and expand the licensed products in certain fields of use. We are subject to a minimum purchase requirement for the SIS ECM for the fields of use added in connection with the December 21, 2017 amendment, or the Subfields, and certain diligence obligations for commercial sales in the Subfields. The license requires that we order and pay for a minimum of at least

$500,000 of SIS ECM per calendar year for use in the Subfields. Cook has the right to terminate the license granted to us in the Subfields or convert such license to a non-exclusive license, if we fail to comply with such minimum purchase requirement or diligence obligations. We have the first right, but not the obligation to initiate legal proceedings against any patent infringement in our fields of use by a third-party product that is the same as one of the licensed products.

Under the Cook License Agreement and SIS Material Supply Agreement, Cook is the exclusive supplier of the SIS ECM used in the licensed products. Under certain circumstances we will have the right to manufacture the SIS ECM used in the licensed products, provided that in such cases we are required to pay Cook a low single digit royalty on net sales of the licensed products that include the SIS ECM material manufactured by us and that are covered by a valid enforceable claim of a licensed patent.

As consideration for the license, we paid Cook a $200,000 license fee in 2018 and are responsible for a yearly license fee of $100,000 until 2026. Upon a change in control transaction, which includes an acquisition of 50% or more of our then outstanding capital stock, we will be obligated to pay Cook the total amount of all license fees that have not yet been paid within a specified period after the consummation of such change in control transaction.

The Cook License Agreement continues in effect until the date of expiration of the last to expire of the licensed patents, including any renewals or extensions. The expiration date for the last to expire of the licensed patents is currently expected to be 2031 (excluding any patent term adjustments or extensions). Either party may terminate the Cook License Agreement for any material breach by the other party uncured within a specified period. In addition, the Cook License Agreement terminates automatically if we no longer possess the rights to the licensed products sold by CorMatrix related to our acquisition of all of the commercial assets and related intellectual property of CorMatrix Cardiovascular, Inc. in 2017 (the "CorMatrix Acquisition"). Cook has the right to terminate the Cook License Agreement in its entirety, or convert the exclusive license of any field of use to a non-exclusive license if we fail to make any license fee when due.

Regulatory Matters

Government Regulation

Our products are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in any foreign jurisdictions in which we market our products. In the United States, they fall under the regulations of the Federal Food, Drug, and Cosmetic Act ("FDCA") as medical devices or as biological products under the Public Health Service Act ("PHSA"), enforced by the FDA. The FDA and other United States and foreign governmental agencies regulate, among other things, the development, design, nonclinical and clinical research, manufacturing, safety, efficacy, labeling, recordkeeping, premarket clearance or approval, promotion, marketing and distribution, and import and export of medical devices and biological products to ensure that such products distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA or PHSA.

FDA Premarket Clearance and Approval Requirements

In the United States, medical devices fall under the regulatory purview of the FDCA with classification into three categories based on risk. Class I devices, considered low-risk, are usually exempt from the 510(k) premarket notification. Class II devices, of moderate risk, require FDA clearance through a 510(k) submission, involving compliance with general controls and potential imposition of special controls, such as performance standards and post-market surveillance. The Quality System Regulation ("QSR") is a key aspect of general controls, ensuring adherence to quality standards in manufacturing processes. For the highest-risk Class III devices, PMA is required, encompassing life-sustaining devices, those with new intended uses, or utilizing advanced technology not substantially equivalent to existing devices. This comprehensive regulatory framework aims to ensure safety and effectiveness based on the specific risk levels of each device class.

510(k) Clearance Marketing Pathway

Certain of our ECM products are subject to premarket notification and clearance under Section 510(k) of the FDCA. To obtain 510(k) clearance, a product sponsor must submit to the FDA a premarket notification submission

demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process.

The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the De Novo process, which is a route to market for medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

Following 510(k) marketing clearance, significant modifications to a device, impacting safety or effectiveness or constituting a major change in intended use, necessitate a new 510(k) clearance, PMA approval, or de novo reclassification. Manufacturers initially determine the submission pathway, but the FDA can disagree and enforce marketing cessation or device recall until proper clearance or approval is obtained. Non-compliance may lead to regulatory fines or penalties.

PMA Approval Pathway

Class III devices necessitate PMA approval before marketing, although certain pre-amendment Class III devices without mandated PMAs are cleared through the 510(k) process. The PMA process, more rigorous than 510(k), requires manufacturers to demonstrate safety and efficacy with extensive pre-clinical and human clinical data, a full device description, manufacturing details, and proposed labeling. FDA has 180 days for PMA review, often extending beyond, with the possibility of convening an expert advisory panel for recommendations. A pre-approval inspection ensures compliance with the QSR. FDA approves the device for commercial distribution if it deems PMA data as valid scientific evidence, ensuring reasonable assurance of safety and effectiveness. Post-approval conditions, including labeling restrictions and additional clinical studies, may accompany PMA approval. Post-market surveillance may be required as well. Non-compliance with approval conditions may lead to adverse enforcement actions, such as withdrawal of approval.

None of our products are currently marketed pursuant to a PMA.

Clinical Studies

Clinical studies are typically required to support a PMA and may be necessary for a 510(k) submission. In the United States, all device-related clinical investigations to determine safety and effectiveness must adhere to FDA's IDE regulations. IDE regulations govern investigational device labeling, restrict promotion, and outline recordkeeping, reporting, and monitoring responsibilities for sponsors and investigators. If a device presents a "significant risk" as defined by the FDA, an IDE application must be submitted and approved before initiating human clinical studies. An IDE application must be supported by relevant data, such as animal and laboratory test results, demonstrating safety for human testing and a scientifically sound protocol. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the studies support the safety and effectiveness of the device. The IDE becomes effective 30 days after FDA receipt unless modifications are required.

Regardless of the device's risk level, clinical studies require approval and oversight from an Institutional Review Board ("IRB") at each site. The IRB conducts initial and ongoing reviews of the IDE, setting additional study requirements. If FDA and IRBs approve the IDE application, human clinical studies may commence.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, study monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, follow

the investigational plan and study protocol, and comply with all reporting and recordkeeping requirements. After a study begins, we, the FDA or the IRB could suspend or terminate a clinical study at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures;
- labeling and promotional regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which mandate manufacturers to report to the FDA if a marketed device may have caused or contributed to a death or serious injury, or if it has malfunctioned and the device or a similar one in the market could likely cause serious harm if the malfunction were to recur.
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

FDA Regulation of Combination Products

Certain products may be comprised of components, such as drug components and device components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA center for combination products. The determination of lead center is based on the "primary mode of action" of the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products. In reviewing the application for a combination product, FDA reviewers in the lead center will generally consult with their counterparts in other centers to ensure that each component meets applicable requirements regarding safety, effectiveness, durability and performance.

FDA Regulation of HCT/Ps

Certain of our products fall under FDA regulation as Human Cells, Tissues, and Cellular and Tissue-Based Products ("HCT/Ps") and may be categorized under Section 361 of the PHSA. This section allows the FDA to issue regulations preventing the spread of communicable diseases. These HCT/Ps must comply with various requirements, including facility registration, product listing, donor eligibility screening, and Good Tissue Practice for processing, storage, labeling, and distribution. These products, considered "minimally manipulated" and intended for "homologous use," do not require premarket authorization from the FDA for legal marketing in the U.S. "Homologous use" refers to use in the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. The HCT/P must also have no systemic effect and not depend upon the metabolic activity of living cells for its primary function. HCT/Ps failing to meet Section 361 criteria are regulated under Section 351 of the PHSA, requiring FDA premarket review and approval.

International Requirements

Sales of medical devices and shipments of human tissues outside the United States are subject to international regulatory requirements that vary widely from country to country. Approval or certification of a product by comparable regulatory authorities of other countries or notified bodies must be obtained and compliance with applicable regulations for tissues must be met prior to commercial distribution of the products or human tissues in those countries. The time required to obtain these approvals or certifications may be longer or shorter than that required for FDA approval. Countries, in which we distribute products and tissue, may perform inspections or audits of our facilities to ensure compliance with local country regulations.

Regulation of Medical Devices in the European Union

The European Union ("EU") has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices. We formerly had a CE mark for four of our cardiovascular products in the EU and had certification for updated labeling of our CanGaroo Envelope to allow for the addition of the antibiotic gentamicin. However, with the expiration of our CE mark on May 23, 2024, we no longer maintain our CE mark and do not market our products in the EU. We will maintain compliance with the transitional Medical Devices Regulation, or MDR, requirements as applicable, including post-market surveillance and vigilance requirements.

Regulation of Medical Devices in the United Kingdom

In the aftermath of Brexit, the Medicines and Healthcare products Regulatory Agency ("MHRA") has become the sole regulator for medical devices in the UK. The MHRA's proposed amendments to the UK Medical Devices Regulations 2002 aim to foster innovation, regulate software and artificial intelligence in medical devices, reform in vitro diagnostic regulation, and promote sustainability. Manufacturers with valid EU certifications can market their devices in the UK under the CE mark during transitional periods. However, from July 2024, the UK Conformity Assessment (UKCA)

mark will be required for medical devices sold in Great Britain. We do not intend to apply for the UKCA for our Cardiovascular and Device Protection products in the near future.

Regulations Governing Fraud and Abuse

Within the United States, our products and our customers are subject to extensive regulation by a wide range of federal and state agencies that govern business practices in the medical device and healthcare industry. These laws include federal and state anti-kickback, false claims, physician payment transparency, anti-corruption, and other fraud and abuse statutes and regulations. Internationally, other governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services.

In the United States, federal healthcare fraud and abuse laws generally apply to our activities because procedures using our products are covered under federal healthcare programs including Medicare and Medicaid. The Anti-Kickback Statute is particularly relevant because of its broad applicability. Specifically, the Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. A person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent in order to violate it to have committed a violation.

The healthcare industry is facing a heightened enforcement environment related to the federal Civil False Claims Act, with specific attention on actions initiated through the Act's whistleblower or qui tam provisions. This legal framework holds entities or individuals accountable for knowingly presenting false or fraudulent claims for payment by federal healthcare programs. It is noteworthy that claims stemming from violations of the federal Anti-Kickback Statute may also trigger scrutiny under the False Claims Act. The qui tam provisions empower private individuals to initiate actions on behalf of the government, providing them the opportunity to participate in any resulting financial recovery. The surge in legal actions against healthcare providers by private individuals, along with the potential for insurance companies to pursue treble damages against manufacturers under the federal Racketeer Influenced and Corrupt Organizations Act (RICO) for inducing false claims, underscores the industry's increased regulatory scrutiny, emphasizing the necessity for stringent compliance measures.

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (the “HIPAA”), among other things, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The HIPAA healthcare fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment, and/or exclusion from government sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent in order to violate it to have committed a violation.

The federal Physician Payment Sunshine Act requires, among other things, manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

State, local, and foreign laws impact business practices in the medical device and pharmaceutical industries, including state anti-kickback and false claims laws affecting research, distribution, sales, and marketing. These laws also extend to claims involving healthcare items reimbursed by third-party payors or patients and may restrict payments to

healthcare providers and referral sources. Additional regulations mandate pharmaceutical companies to comply with industry guidelines and federal guidance, while requiring drug manufacturers to report pricing and marketing information. State and local laws also necessitate tracking gifts and remuneration provided to physicians and healthcare entities. Violations of these laws, carrying potential criminal and civil penalties such as fines, exclusion from federal healthcare programs, disgorgement, and corporate integrity agreements, may be imposed on executives and employees, including imprisonment.

Anti-Bribery Laws

Our international operations are subject to compliance with a variety of complex foreign and United States laws that increase our costs of doing business in internal jurisdictions and could expose us or our employees to fines and penalties in the United States and abroad. Among others, we are subject to the United States Foreign Corrupt Practices Act of 1977 (the "FCPA"), which prohibits us, our officers, directors, employees, shareholders and agents acting on our behalf from offering, promising, authorizing or making corrupt payments to foreign officials for the purpose of influencing official decisions or securing an improper advantage to obtain or retain business.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws, and consumer protection laws and regulations govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

Market acceptance and sales of our products to our customers, who primarily consist of hospitals, government facilities, and ambulatory surgery centers, will depend on the availability of payor coverage and the adequacy of reimbursement, for the procedures using our products, by government insurance programs and other third-party payors. Payor coverage and reimbursement for procedures using medical devices in the United States and international markets vary significantly by country.

In the United States, our currently approved products are commonly treated as general supplies utilized in surgical procedures and if covered by third-party payors, are paid for as part of the procedure. Outside of the United States, there are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures during which our products are used. Failure by physicians, hospitals, ambulatory surgery centers and other users of our products to obtain sufficient coverage and reimbursement from third-party payors for procedures in which our products are used, or adverse changes in government and private third-party payors' coverage and reimbursement policies.

In our experience, third-party payors typically reimburse for surgical procedures involving our products when patients meet established medical necessity criteria. A trend towards managed care systems has been observed among certain payors, where healthcare cost control involves restricting authorizations for surgical procedures, including those utilizing our devices. While there is no uniform coverage and reimbursement policy among U.S. payors, decisions often hinge on factors such as the payor's determination that product use is a covered benefit, medically necessary for the specific indication, cost-effective, and not experimental or investigational. Reimbursement landscape variations exist from payor to payor in the United States. Third-party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate

care settings. Some third-party payors must approve coverage for new or innovative devices or procedures before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution by the FDA, we may find limited demand for the product unless and until reimbursement approval has been obtained from governmental and private third-party payors.

The Centers for Medicare & Medicaid Services ("CMS") is responsible for administering the Medicare program and sets coverage and reimbursement policies for the Medicare program in the United States. CMS, in partnership with state governments, also administers the Medicaid program and Children's Health Insurance Program ("CHIP"). CMS policies may alter coverage and payment related to our product portfolio in the future. These changes may occur as the result of national coverage determinations issued by CMS or as the result of local coverage determinations by contractors under contract with CMS to review and make coverage and payment decisions. Medicaid programs are funded by both federal and state governments, and may vary from state to state and from year to year and will likely play an even larger role in healthcare funding pursuant to the Affordable Care Act.

A key component in ensuring whether the appropriate payment amount is received for physician and other services, including those procedures using our products, is the existence of a Current Procedural Terminology ("CPT") code, to describe the procedure in which the product is used. To receive payment, healthcare practitioners must submit claims to insurers using these codes for payment for medical services. CPT codes are assigned, maintained and annually updated by the American Medical Association and its CPT Editorial Board. If the CPT codes that apply to the procedures performed using our products are changed or deleted, reimbursement for performances of these procedures may be adversely affected.

In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita (patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

The escalating costs of medical products and services, covered by government and private health insurance, are compelling the healthcare and medical device industry to reduce expenses. Third-party reimbursement programs are employing sophisticated strategies like prospective reimbursement, capitation programs, and group purchasing, alongside measures such as benefit redesign and mandatory second opinions for major surgeries. Additionally, uncertainties in coverage policies and periodic changes to reimbursement levels, including routine updates for procedures using our products, pose challenges. The industry must adeptly navigate these complexities to align with evolving cost control measures in healthcare.

Healthcare Reform

Since its enactment, the Affordable Care Act ("ACA") has faced challenges in the judicial, executive, and Congressional arenas. On June 17, 2021, the U.S. Supreme Court dismissed a challenge asserting the ACA's unconstitutionality on procedural grounds, affirming its continuation. President Biden's executive order, preceding the Supreme Court ruling, initiated a special enrollment period for ACA marketplace health insurance coverage from February 15, 2021, through August 15, 2021, prompting a review of healthcare access policies. The impact of other healthcare reform measures under the Biden administration on our business remains uncertain. Legislative changes, including aggregate reductions in Medicare payments to providers, have occurred since the ACA's inception. Notably, heightened governmental scrutiny on product pricing has led to Congressional inquiries and legislation, emphasizing transparency, pricing relationships, and reforming reimbursement methodologies. States are increasingly implementing regulations controlling product pricing, while third-party payors and authorities show growing interest in reference pricing systems, discounts, and list price disclosures.

Human Capital

As of December 31, 2024, we had 51 employees, nearly 100% of whom were full-time employees. We believe our employee relations are good.

Recruiting and Retention

We believe that we have been successful in attracting and retaining qualified personnel with the appropriate background and skills to support our business and its growth. We monitor recruiting efforts using a variety of metrics such as internal placement rates, employee referrals, information on the retention of business critical hires, and the percentage of budgeted openings filled on time and on budget. We also track voluntary and involuntary turnover rates. Although we believe our recruiting efforts have been successful to date, headcount reductions taken as part of cost saving initiatives and as our business strategy evolves may negatively impact our ability to attract qualified personnel in the future. See Part I. Item 1A. Risk Factors - Risks Related to Our Business - *Our success depends on our ability to retain and motivate key management personnel and other employees and consultants, to attract, retain and motivate additional qualified personnel and to effectively navigate changes in our senior management team.*"

Compensation and Benefits

We strive to offer competitive pay and benefits designed to attract and retain exceptional talent and drive company performance. In setting appropriate compensation levels, we look at the average base pay rate for each position based on market data. We also offer an annual cash incentive program and long-term equity incentive plans designed to assist in attracting, retaining and motivating employees, to align their interests with our stockholders and to promote the creation of long-term value for our investors.

Our standard employee benefits include paid and unpaid leaves, medical, dental and vision insurance coverage, a 401(k) plan, short- and long-term disability, life insurance, flexible spending accounts and an employee stock purchase plan. We benchmark our benefits program against others in our industry to help us make decisions on the size and elements of our compensation program.

Product Recalls

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 PLC, after learning of post-surgical infections reported in several patients treated with the product, including some patients that tested positive for tuberculosis (the "FiberCel Recall"). After the recall, we worked with the FDA and the U.S. Centers for Disease Control and Prevention ("CDC") to identify and secure all unused product, ascertain the medical status of patients treated with the recalled product, understand whether there is any relationship between the post-surgical infections and the recalled product lot and determine the medical cause of these infections. We identified the 154 units comprising the single product lot in question. Based on information from the CDC, 136 units within this product lot were implanted into 113 patients and the remaining 18 units were returned to either us or the CDC. The CDC advised us that the CDC, working with state health agencies, contacted all patients treated with the recalled lot of FiberCel to help ensure they were directed to appropriate medical treatment and informed us that all patients were started on standard four-drug treatment for tuberculosis. Samples of the recalled product underwent polymerase chain reaction ("PCR") analysis by a lab contracted by the CDC and tested positive for the presence of Mycobacterium tuberculosis ("MTB"). Cell culture testing of the recalled product was also conducted by the same lab that showed the presence of MTB, and this testing corroborated the PCR testing results.

Viable Bone Matrix Recall

In July 2023, we announced a voluntary recall of a single lot of one of our viable bone matrix ("VBM") products and the market withdrawal of all of our VBM products produced after a specified date (the "VBM Recall"). Notice of the voluntary recall was issued to centers after we learned of post-surgical MTB infections in two patients treated with product from a single donor lot of our VBM product. Consistent with the FiberCel Recall, after the VBM Recall, we worked with the FDA and CDC to identify and secure all unused product, ascertain the medical status of patients treated with the recalled product, understand whether there is any relationship between the post-surgical infections and the recalled product lot and determine the medical cause of these infections. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically

detect the MTB organism. Additionally, in August and September 2023, cell culture testing of the recalled product was conducted by the same lab and showed no presence of MTB. In October 2023, the CDC received the results of several MTB tests on the recalled VBM lot. Three cultures and five nucleic acid tests resulted in no detection of MTB, and two other cultures of the recalled VBM lot detected MTB. Based on our discussions with the CDC, we believe that a total of 36 patients were treated with product from the single donor lot.

All VBM products, which includes FiberCel, were divested by us in connection with the sale of our Orthobiologics Business to Berkeley in November 2023. Berkeley did not assume any liabilities related to the FiberCel Recall or VBM Recall, our market withdrawal of all of our viable bone matrix products, or any claims or lawsuits related thereto.

The FiberCel Recall and VBM Recall are described in further detail in Part I, Item 3, "Legal Proceedings" and Note 17 to the consolidated financial statements, included elsewhere in this Annual Report.

Available Information

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov. Our SEC filings are also available free of charge under the Investor Relations section of our website at www.elutia.com as soon as reasonably practicable after they are filed with or furnished to the SEC. Our website and the information contained on or available through our website is not incorporated into this Annual Report.

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

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this Annual Report, including our consolidated financial statements and the related notes, as well as our other public filings with the SEC, before making an investment in our common stock. Our business, financial condition, results of operations and prospects could be materially and adversely affected if any of these risks occur, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This Annual Report also contains forward-looking statements that involve risks and uncertainties, and our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below. See "Forward-Looking Statements."

Risks Related to Our Business

Our future results depend upon our ability to successfully commercialize, market and sell our newly approved EluPro antibacterial envelope device and the success of a smaller suite of established products than has historically been the case.

The Company has focused much of its attention recently on EluPro, which was cleared for marketing by the U.S. Food and Drug Administration ("FDA") in June 2024 and is indicated for use with implantable electronic devices including cardiac and neurostimulator devices. We believe the Company's success is highly dependent on the successful commercialization, marketing and sale of EluPro, as well as the extension of our drug-eluting biomatrix ("DEB") technology into potential adjacent applications. Alongside EluPro, we continue to market the CanGaroo bioenvelope, our first generation product, which uses the same biomatrix but does not contain antibiotics. Our Device Protection products, EluPro and CanGaroo, are sold through both our internal sales force and independent sales agents and our commercial

partner, Boston Scientific Corporation. We believe the commercialization and marketing efforts with respect to EluPro will require significant investments in time and resources. However, there can be no assurance that we will have or be able to obtain sufficient resources to make the necessary investments in order to increase the sales and market penetration for EluPro, or that if made, such investments will yield the results sought. If we fail to successfully commercialize, market and sell EluPro, the Company's business and financial condition may be materially adversely affected.

On November 8, 2023, we sold our Orthobiologics Business for consideration of $14.6 million up front, as adjusted, and up to $20 million payable in the form of earn-out payments over the five years following the closing. The purchaser did not assume any liabilities related to the FiberCel or VBM Recalls, or any claims or lawsuits related thereto. Our former Orthobiologics segment accounted for 52% and 39% of our consolidated net sales and gross profit, respectively in the year ended December 31, 2022. Our future results depend on the success of our Device Protection, Women's Health and Cardiovascular businesses. There can be no guarantee, however, that we will be able to increase the sales or profitability of the remaining businesses sufficiently to replace or exceed the financial contribution from the Orthobiologics Business.

Our enhanced reliance in the wake of the disposition of the Orthobiologics Business on a smaller suite of existing products and on future products may pose risks to the Company's growth. If the financial contribution from remaining legacy products and other DEB products fail to replace lost contribution from the Orthobiologics Business, or otherwise fail to meet expectations, the Company's business and financial condition may be materially adversely affected.

We have incurred operating losses and may continue to do so in the near-term, and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability.

For the years ended December 31, 2024 and 2023, we had net losses of $53.9 million and $37.7 million, respectively. We expect our losses to continue for the foreseeable future, and these losses will continue to have an adverse effect on our financial position. 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 commercialize our flagship Device Protection product, EluPro, 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. Sales of our products, as well as meaningful reductions, suspensions or discontinuations of such sales, may not offset our operating expenses. As a result, we expect to continue to incur operating losses in the future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows, negatively affect the value of our securities and our ability to raise capital and continue operations**.**

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

We have incurred net losses since our inception in 2015. For the year ended December 31, 2024, we had a net loss of $53.9 million and as of December 31, 2024, we had an accumulated deficit of $229.6 million. To date, we have financed our operations primarily through amounts borrowed under our credit facilities, sales of our products, proceeds from offerings and sales of our common stock and more recently, through the sale of our Orthobiologics Business. We have devoted the majority of our resources to manufacturing costs, research and development, clinical and administrative activity and investing in our commercial infrastructure through our direct sales force and commercial partners in order to expand our presence and to promote awareness and adoption of our products.

As noted above, we cannot assure you that we will achieve profitability or sustain it if we do. Without sustained profitability, we may not be able to satisfy our obligations as they become due, including our indebtedness or our obligations related to the FiberCel Recall or VBM Recall, which are described in further detail in Part I, Item 3, "Legal Proceedings" and Note 17 to the consolidated financial statements, in this Annual Report. As a result, we anticipate that we will need additional funding to support our continuing operations and pursue our growth strategy. In order to mitigate the current and potential future liquidity issues caused by the matters noted above, we may seek to raise capital through

the issuance of common stock or pursue asset sales or other transactions, such as the sale of the Orthobiologics Business described above. However, such transactions may not be successful, and we may not be able to raise additional equity, refinance our debt instruments, or sell assets on acceptable terms, or at all. As such, there can be no assurance that we will be able to continue as a going concern.

Our indebtedness and our Revenue Interest Obligation to Ligand Pharmaceuticals Incorporated may limit our flexibility in operating our business and adversely affect our financial health and competitive position.

As of December 31, 2024, we had $23.9 million of indebtedness outstanding, consisting of $23.5 million outstanding under our SWK Loan Facility (as defined under Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Credit Facilities"), plus $0.9 million of exit fee liabilities, less $0.5 million of unamortized discount and deferred financing costs. In addition, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated ("Ligand") pursuant to a long-term obligation to Ligand, which we amended in January 2024 (the "Revenue Interest Obligation"). The Revenue Interest Obligation requires us to pay Ligand 5.0% of future sales of our CanGaroo, ProxiCor, Tyke and VasCure products, and substantially similar products, such as EluPro, through May 31, 2027, subject to annual minimum payments of $4.4 million. See Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgment and Estimates — Revenue Interest Obligation."

In order to service this indebtedness and our Revenue Interest Obligation, and any additional indebtedness or other long-term obligations we may incur in the future, we need to generate sufficient levels of cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient levels of cash from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness, satisfy our obligations under the Revenue Interest Obligation and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness and satisfy our obligations under the Revenue Interest Obligation instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This will place us at a competitive disadvantage compared to our competitors that have less indebtedness.

In addition, the agreements governing our SWK Loan Facility contains, and any agreements evidencing or governing other future indebtedness may also contain, certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests. Subject to certain limited exceptions, these covenants limit our ability to, among other things:

- incur additional indebtedness;
- incur certain liens;
- pay dividends or make other distributions on equity interests;
- enter into agreements restricting their subsidiaries' ability to pay dividends;
- 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;
- alter the business conducted by them and their subsidiaries; and
- enter into sale and leaseback transactions.

In addition to these covenants, the agreement governing our SWK Loan Facility also contains two financial covenants, the first of which is measured quarterly, and requires us to achieve a specified minimum aggregate revenue (as defined therein) for the preceding 12-month period, and the second of which requires us to maintain a minimum liquidity (as defined therein) of the greater of $5.0 million and the sum of the operating burn (as defined therein) for the two prior consecutive fiscal quarters then ended. While we were in compliance with all covenants under the agreement as of December 31, 2024, there can be no guarantee that we will not breach these covenants in the future.

Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the collateral granted to them to collateralize such indebtedness. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

In addition, we may incur significant additional indebtedness in the future. Although the agreement governing our SWK Loan Facility contains restrictions on the incurrence of additional indebtedness by us, such restrictions are subject to a number of qualifications and exceptions, and the indebtedness incurred in compliance with these restrictions could be substantial. Also, these restrictions do not prohibit us from incurring obligations that do not constitute indebtedness as defined therein. To the extent that we incur additional indebtedness or such other obligations, the risks associated with our substantial indebtedness described above will increase.

Various events permit the lender under the SWK Loan Facility to terminate the agreement, following a cure period. Such events include, without limitation, 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. If the lender were to terminate either the SWK Loan Facility, the lender may declare all or any portion of these obligations to become immediately due and payable.

We face significant litigation related to our FiberCel and Viable Bone Matrix recalls, and have no more insurance coverage on the FiberCel recall.

In June of 2021, we announced our FiberCel Recall and in June 2023, we announced our VBM Recall and the market withdrawal of all of our VBM products produced after a specified date. Our VBM products, which encompass FiberCel, were included in the sale of our former Orthobiologics Business to Berkeley, but Berkeley did not assume any liabilities related to the FiberCel and VBM Recalls, our market withdrawal of all of our viable bone matrix products, or any claims or lawsuits related thereto.

We have been named in multiple lawsuits alleging that the plaintiffs contracted tuberculosis and are suffering substantial adverse symptoms following the implantation of FiberCel or VBM during spinal fusion or other operations, which are described in further detail in Part I, Item 3, "Legal Proceedings" and Note 17 to the consolidated financial statements included elsewhere in this Annual Report. As discussed below under "*We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance",* we have recorded a total estimated contingent liability of $20.4 million related to the resolution of all FiberCel and VBM lawsuits, comprised of $15.9 million for FiberCel and $4.5 million for VBM as of December 31, 2024. 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. In addition, this contingent liability excludes the future costs to defend against the lawsuits and claims.

As of December 31, 2024, insurance remains available to cover the cost of the VBM liability and related defense costs. However, conversely, we have no more insurance to cover the cost of the FiberCel liability and the related defense costs as of December 31, 2024. Because we have exhausted our insurance coverage for this matter, the entire contingent

liability for FiberCel Recall product liability losses is our financial responsibility. The satisfaction of this obligation and the future costs incurred are expected to have a material adverse effect on our cash flow, results of operations, financial position and prospects.

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

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing, investigating and marketing of medical devices and human and animal tissue products. For example, within our recently divested Orthobiologics Business, in June 2021, the FiberCel Recall occurred and in July 2023, the VBM Recall occurred. Since September 2021, we have received notice of 110 separate lawsuits or claims related to the FiberCel Recall alleging that the plaintiffs contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. As of December 31, 2024, 66 lawsuits or claims related to the FiberCel Recall and 15 lawsuits and claims related to the VBM Recall remain outstanding. These lawsuits and claims are described in further detail in See Part II, Item 1, "Legal Proceedings" and Note 17 to the consolidated financial statements included elsewhere in this Annual Report.

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

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

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

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

- decreased demand for our products.

Our product liability insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance. As of December 31, 2024, we have exhausted our insurance coverage for the FiberCel Recall product liability losses, meaning the remaining contingent liability estimated at $15.9 million at December 31, 2024 is entirely our financial responsibility. As of December 31, 2024, we have recorded insurance receivables of $4.8 million on our balance sheet as a loss recovery resulting from our insurance coverage for the VBM Recall.

As described above, our future FiberCel Recall litigation costs and obligations are now fully our financial responsibility and are expected to have a material adverse effect on our cash flow and financial position. Additionally, it is possible that future claims related to the VBM Recall or other product liability claims could exceed the limits of, or be excluded from, coverage under our policies, and claims against us could also increase the cost of maintaining our coverage. If these or other claims are excluded from our coverages, or if we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims, or if we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. One or more product liability claims could have a significant adverse effect on our business, financial condition and results of operations.

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.

Our future capital needs are uncertain and, as such, we may seek to raise additional capital through equity offerings, debt financings, collaborations or other arrangements to finance our ongoing operations, including our efforts to commercialize, market and sell EluPro, or as all or part of the consideration paid for acquisitions and strategic investments that we may make in the future. Any future funding requirements will depend on many factors, including, among other things:

- our ability to commercialize, market and sell our newly approved EluPro antibacterial envelope device;
- 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 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 damages payable (to the extent above the applicable insurance coverage), for example, in connection with lawsuits and claims involving the FiberCel Recall or VBM Recall;
- the cost and timing of additional regulatory approvals or certifications;
- costs associated with any product recall;
- the effect of competing technological and market developments;

- the expenses we incur in manufacturing and selling our products;
- the costs of developing and commercializing new products or technologies;
- 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; and
- unanticipated general, legal and administrative expenses.

In addition, our operating plan 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. Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds by selling additional shares of our common stock or other securities convertible (directly or indirectly) into or exercisable or exchangeable for shares of our common stock, the issuance of such securities will result in dilution to our stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by you. Furthermore, investors purchasing any securities we may issue in the future may have rights superior to your rights as a holder of our common stock.

In addition, any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and other arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us.

Furthermore, we cannot be certain that additional funding will be available to us on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition and results of operations.

Adverse changes in general domestic and global economic conditions and instability and disruption of credit markets could adversely affect our business, financial condition, results of operations and liquidity.

We are subject to risks arising from adverse changes in general domestic and global economic conditions, including any recession, economic slowdown or disruption of credit markets. During the year ended December 31, 2024, global markets continued to experience significant volatility, driven by concerns over persistent inflation, rising interest rates, slowing economic growth and geopolitical uncertainty. These events, and any financial crisis that may occur in the future, could make it more difficult and more expensive for hospitals and health systems to obtain credit, which may contribute to pressures on their operating margins. As a result, hospitals and healthcare systems may curtail and reduce capital and overall spending, which may have a significant adverse effect on our business.

In addition, we maintain our cash in accounts with financial institutions that exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, we could lose our deposits in excess of the federally insured or protected amounts and there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

In addition, the current volatility in the capital and credit markets could impede our access to capital. Should we have limited access to additional financing sources, we may need to defer capital expenditures or seek other sources of liquidity, which may not be available to us on acceptable terms or at all. All of these factors related to global economic

conditions, which are beyond our control, could adversely impact our business, financial condition, results of operations and liquidity.

Our long-term growth depends on our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings.

Our industry is highly competitive and subject to rapid change and technological advancements. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop products, services and processes with significant advantages over the products, services and processes that we offer or are seeking to develop. It is, therefore, important to our business that we continue to enhance our existing product offerings, expand our product indications and develop or otherwise introduce and successfully commercialize new products. Developing, acquiring and commercializing products is expensive and time-consuming and could divert management's attention away from our core business. Even if we are successful in developing additional products, the success of any new product offering or enhancements to any of our existing products will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- distinguish our products from those of our competitors;
- develop an effective and dedicated sales and marketing team;
- enter into successful agreements with commercial partners, independent sales agents and other third parties where it is beneficial for us to do so;
- adequately protect our intellectual property, avoid infringing, misappropriating or otherwise violating the intellectual property rights of third parties and obtain and maintain necessary intellectual property licenses from third parties;
- demonstrate, if required, the safety and efficacy of new products with data from pre-clinical and clinical studies;
- obtain the necessary regulatory clearances, certifications or approvals for new products, product enhancements and expanded indications;
- maintain full compliance with FDA medical devices regulations and other regulatory requirements applicable to new devices or products or modifications of existing devices or products;
- provide adequate training to potential users of our products;
- receive adequate coverage and reimbursement for our products; and
- otherwise compete effectively against products and enhancements developed by our competitors.

If we are not successful in expanding our indications and developing, acquiring and commercializing new products and product enhancements, our ability to increase our net sales may be impaired, which could have a material adverse effect on our business, financial condition and results of operations. In addition, our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology or other innovation.

Even if we are successful in obtaining the required regulatory clearance, there can be no assurances that we will be able to achieve market acceptance or that we will able to realize the intended benefits from commercializing this product candidate. In addition, we will be required to invest additional time and resources to address the outstanding items and provide the additional data requested to FDA, which could divert management's attention from core business and result in additional research and development expenses. For instance, on June 14, 2024, we received written notice from the FDA that it had reviewed our premarket notification report filed under Section 510(k) of the Federal Food, Drug and Cosmetic Act of 2022 related to the antibacterial envelope device known during development as CanGarooRM, and now known as EluPro, that the FDA had determined "substantial equivalence" with respect to such device, and that such device may be marketed and sold subject to the general controls provisions of that law. In order for Elutia to capitalize on such clearance however, the company will have to invest time and resources into commercializing and marketing EluPro in order to increase its sales and market penetration, and to leverage the company's drug-eluting bioenvelope technology into potential adjacent applications. These efforts will require significant investments. There can be no guarantee that Elutia will have or be able to obtain sufficient resources to make the necessary investments, or that if made, such investments will yield the results sought.

Even if we are able to successfully develop and commercialize new product offerings or enhancements, they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features and/or otherwise not produce sales in excess of the costs of development, any of which could also materially and adversely affect our business, financial condition and results of operations. Furthermore, to the extent we seek to enhance our products and broaden our product portfolio through acquisitions or other commercial transactions, we will be subject to additional risks. See "— *We regularly evaluate opportunities to make acquisitions of, investments in, and licenses or other commercial arrangements involving, other companies or technologies, and to enter into other strategic transactions. These transactions entail significant risks*."

We may not realize all of the potential consideration associated with the sale of our Orthobiologics Business.

On November 8, 2023, we completed the sale of the assets of our former Orthobiologics Business to Berkeley. In the sale, we received $14.6 million, and we may earn up to an additional $20 million, in the aggregate, in the form of earn-out payments. The earn-out payments are equal to 10% of the actual revenue earned by Berkeley in each of the five years after the closing of the sale from sales of specified Orthobiologics products under the purchase agreement (including improvements, modifications, derivatives and enhancements related to those products). Additionally, the purchase agreement provides for a customary indemnity holdback in the amount of $1.5 million to be retained by Berkeley for 24 months after close.

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

Because we depend upon a limited number of third-party suppliers and manufacturers and, in certain cases, exclusive suppliers for products essential to our business, we may incur significant product development costs and experience material delivery delays if we lose any significant supplier, which could materially and adversely affect our business, financial condition and results of operations.

We obtain some of our raw materials from a limited group of suppliers and, for reasons of quality assurance, cost-effectiveness, availability or constraints resulting from regulatory requirements, we rely on a single supplier, Cook, to source the SIS ECM biomaterial used to manufacture EluPro, CanGaroo and our Cardiovascular products. Additionally, with the sale of our Orthobiologics Business in November 2023 to Berkeley, we no longer operate our former Richmond, California human tissue processing and distribution facility; however, we continue to have contract manufacturing relationship with Berkeley under which we receive SimpliDerm. At present, Berkeley is our single source of supply for SimpliDerm, but we are evaluating additional options for supply redundancy.

For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs

and on a timely basis. Our efforts to maintain a continuity of supply and high quality and reliability may not be successful on a timely basis or at all. Manufacturing disruptions experienced by our suppliers may jeopardize our supply of finished products. Due to the stringent regulations and requirements of the FDA and other similar non-U.S. regulatory agencies regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources for certain raw materials. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those systems.

A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or supplies, could have a material and adverse effect on our business, financial condition, results of operations and cash flows. One or more of our suppliers may refuse to extend us credit with respect to our purchasing or leasing of equipment, supplies, products or components, or may only agree to extend us credit on significantly less favorable terms or subject to more onerous conditions. This could significantly disrupt our ability to purchase or lease required equipment, supplies, products and components in a cost-effective and timely manner, and could have a material adverse effect on our business, financial condition and results of operations. Any casualty, natural disaster or other disruption of any of our sole-source suppliers' operations or any unexpected loss of any existing exclusive supply contract could have a material adverse effect on our business, financial condition and results of operations. In addition, if a change in manufacturer results in a significant change to any product, a new 510(k) clearance from the FDA or similar international regulatory authorization, or certification may be necessary before we implement the change, which could cause substantial delays.

A substantial portion of our net sales is generated through our commercial partners and independent sales agents, which subjects us to various risks.

We currently rely on the efforts of our commercial partners and independent sales agents to generate a substantial portion of our net sales, and we expect to continue to rely on these third parties to generate a substantial portion of our net sales in the future while we work to grow our direct sales force. For example, we have commercial agreements with major medical device companies, including Boston Scientific, Tiger and LeMaitre Vascular. As a result, the impairment or termination of these relationships for any reason, or the failure of these parties to diligently sell our products and comply with applicable laws and regulations, has and could in the future materially and adversely affect our ability to generate revenue and profits. Because our commercial partners and independent sales agents control the relationships with our end customers, if our relationship with any commercial partner or independent sales agent ends, we will likely also lose our relationship with their customers. Furthermore, our success is partially dependent on the willingness and ability of the sales representatives and other employees of our commercial partners and independent sales agents to diligently sell our products. However, we cannot guarantee that they will be successful in marketing our products. In addition, because our commercial partners and independent sales agents do not sell our products exclusively, they may focus their sales efforts and resources on other products that produce better margins or greater commissions for them or are incorporated into a broader strategic relationship with a partner. Because we do not control the sales representatives and other employees of our commercial partners, we cannot guarantee that our sales processes, regulatory compliance and other priorities will be consistently communicated and executed. In addition, we do not have staff in many of the areas covered by our commercial partners and independent sales agents, which makes it particularly difficult for us to monitor their performance. While we may take steps to mitigate the risks associated with noncompliance by our commercial partners and independent sales agents, there remains a risk that they will not comply with regulatory requirements or our requirements and policies. Actions by the sales representatives and other employees of our commercial partners and independent sales agents that are beyond our control could adversely impact sales in that territory or result in harm to the reputation of the Company or our products or legal liability, any of which could have a material adverse effect on our business, financial condition and results of operations. In addition to the risk of losing customers, the operation of local laws and our agreements with our commercial partners and independent sales agents would make it difficult for us to replace a commercial partner or independent sales agent we believe is underperforming.

The loss of one or more significant commercial partners, a material reduction in their purchases of our product or their inability to perform their contractual obligations, including, for example, committed purchase requirements could adversely affect our business, financial condition and results of operations.

In order to increase our sales, we intend to develop relationships and arrangements with additional commercial partners and/or independent sales agents, which we may not be able to do on commercially reasonable terms or at all. If we are unable to establish new commercial partner and independent sales agent relationships and maintain our relationships with our existing commercial partners and independent sales agents, in each case, on commercially reasonable terms, we will be unable to increase sales of our products, which, in turn, could materially and adversely affect our business, financial condition and results of operations.

Our future growth depends on physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products.

We focus our sales, marketing and training efforts on physicians, surgeons and other healthcare professionals. The acceptance of our products depends in part on our ability to educate these individuals as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products compared to alternative products, procedures and therapies. We support our direct sales force, commercial partners and independent sales agents through in-person and online educational programs, among other things. We also produce and distribute marketing and educational materials, including materials outlining our products, for our sales teams using printed, video and multimedia formats. However, our efforts to educate physicians, surgeons and other healthcare professionals regarding our products may not be successful, particularly in markets where we rely exclusively on the efforts of our commercial partners and independent sales agents. If we do not adequately educate physicians, surgeons and other healthcare professionals about our products, as well as any adverse events involving these products, our products may not gain or maintain market acceptance, which may adversely affect our business, financial condition and results of operations.

Our success depends on the continued and future acceptance of our products by the medical community.

Even if we are able to increase awareness of our products among healthcare professionals, there can be no assurance that this will translate into greater acceptance of our products by the medical community. We believe physicians, surgeons and other healthcare professionals will only adopt our products if they determine, based on experience, clinical data and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to other available methods. Physicians also are more interested in using cost-effective products as they face increasing cost-containment pressure. In general, physicians may be slow to change their medical treatment practices and adopt our products for a variety of reasons, including, among others:

- their lack of experience using our products and the time that must be dedicated to learning how to use our products;
- lack of evidence supporting additional patient benefits from use of our products over conventional methods;
- pressure to contain costs;
- preference for other treatment modalities or our competitors' products;
- perceived liability risks generally associated with the use of new products and procedures; and
- limited availability of coverage and/or reimbursement from third-party payors.

The degree of market acceptance of our products will continue to depend on a number of factors, some of which are outside of our control, including, among other things:

- the actual and perceived safety and efficacy of our products;
- the potential and perceived advantages of our products over alternative treatments;
- clinical data and the clinical indications for which our products are approved or certified;

- product labeling or product insert requirements of the FDA or other regulatory authorities, including any limitations or warnings contained in approved labeling;
- the cost of using our products relative to the use of our competitors' products or alternative treatment modalities;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- our reputation and the reputation of our products;
- the prevalence and severity of any adverse events patients experience involving our products;
- the shelf life of our products and our ability to manage the logistics of the end-user supply chain; and
- sufficient and readily accessible third-party insurance coverage and reimbursement for procedures incorporating our products.

In addition, we believe recommendations for, and support of our products by, influential physicians are essential for market acceptance and adoption. If we do not receive this support (e.g., because we are unable to demonstrate favorable long-term clinical data or otherwise), physicians and hospitals may not use our products, which would significantly impair our ability to increase our sales and prevent us from achieving and sustaining profitability.

We may need to continue to expand our organization and managing growth may be more difficult than we expect.

Managing our growth may be more difficult than we expect. We anticipate that a period of significant expansion will be required to penetrate and service the markets for our existing and anticipated future products and to continue to develop new products. This expansion will place a significant strain on our management, operational and financial resources. To manage the expected growth of our operations and personnel, we must both modify our existing operational and financial systems, procedures and controls and implement new systems, procedures and controls. We must also expand our finance, administrative and operations staff. Management may be unable to hire, train, retain, motivate and manage necessary personnel or to identify, manage and exploit existing and potential strategic relationships and market opportunities. If we fail to meet these challenges effectively, there may be an adverse effect on our business, financial condition and results of operations.

We regularly evaluate opportunities to make acquisitions of, investments in, and licenses or other commercial arrangements involving, other companies or technologies, and to enter into other strategic transactions. These transactions entail significant risks.

Our success depends, in part, on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and advances in technologies. Accordingly, although we have no current commitments with respect to any acquisition or investment, we regularly review potential acquisitions of, investments in, and licenses or other commercial arrangements involving, complementary businesses, products or technologies instead of developing them ourselves. In addition, in regularly evaluating our financial and operating performance, we may decide to sell one or more of our product lines or another portion of our business as we did with our Orthobiologics Business. Opportunities to engage in these transactions may not be readily available to us at commercially reasonable prices, on other terms acceptable to us or at all. Even if such opportunities are available, these transactions involve significant risks. In connection with one or more of these transactions, we may:

- issue additional equity securities that would dilute the value of your investment in us;
- use cash that we may need in the future to operate our business;
- incur debt that could have terms unfavorable to us or that we might be unable to repay;
- structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;
- incur asset impairment or other acquisition-related charges, or unforeseen costs, expenditures and risks;
- be unable to realize the anticipated benefits, such as increased revenues, cost savings or synergies from additional sales of existing or newly acquired products;
- experience dis-synergies in shared functions following a divestment of any portion of our business;
- be unable to successfully integrate, operate, maintain and manage any newly acquired operations;
- divert management's attention from the existing business to integrate, operate, maintain and manage any newly acquired operations and personnel, or to manage the complexities involved in separating divested operations, services, products and personnel;
- be unable to secure the services of key employees related to an acquisition or, in the case of a divestiture, lose one or more of our key employees;
- face increased scrutiny and review of our company and operations from government and other regulatory authorities; and
- otherwise be unable to succeed in the marketplace with the acquisition.

The occurrence of any of the above could materially and adversely affect our business, financial condition and results of operations. Furthermore, business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Such liabilities could include lack of compliance with government regulations that could subject us to investigation, civil and criminal sanctions, litigation and/or other actions that make it impossible to realize the anticipated benefits of the transaction. For example, we may acquire a company that was not compliant with FDA quality requirements or was making payments or other forms of remuneration to physicians to induce them to use their products. Incurring unknown liabilities or the failure to complete or realize the anticipated benefits of an acquisition, sale, investment or other commercial arrangement, whether resulting from one or more of the factors described above or otherwise, could have a material and adverse effect on our business, financial condition and results of operations.

New lines of business and new products and services may subject us to additional risks.

From time to time, we may implement or acquire new lines of business or introduce new products and services within our existing business lines. There are risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed or are evolving. In developing and commercializing new lines of business and new products and services, we may invest significant time and resources. External factors, such as regulatory compliance obligations, competitive alternatives, lack of market acceptance and shifting market preferences, may also affect the successful implementation of a new line of business or a new product or service. Failure to successfully plan for and manage these risks in the development and implementation of new lines of business or new products or services could have a material adverse effect on our business, financial condition and results of operations.

We face significant and continuing competition from other companies, some of which have longer operating histories, more established products and/or greater resources than we do, which could adversely affect our business, financial condition and results of operations.

We operate in highly competitive markets that are characterized by intense competition, subject to rapid change and significantly affected by new product introductions, technological advancements and other market activities of industry participants. Our competitors have historically dedicated, and will continue to dedicate, significant resources to promote their products and to develop new products that compete with ours. Customers in our target markets consider many factors when selecting a product, including product efficacy, ease of use, price, availability of payor coverage and adequate third-party reimbursement for procedures using the product, customer support services for technical-, clinical- and reimbursement-related matters and customer preference for, and loyalty to, particular products or a particular manufacturer. We expect competition to remain intense as competitors introduce additional competing products and enhancements to their existing products, and continue expanding into geographic markets where we currently operate or plan to expand. Product introductions or enhancements by competitors, which may have advanced technology, better features or lower pricing, may make our products obsolete or less competitive. As a result, we will be required to devote continued efforts and financial resources to develop and commercialize new products and enhancements to our existing products, deliver cost-effective clinical outcomes, manage our costs and expand our geographic reach.

Many of our current and potential competitors have longer operating histories and substantially greater financial, technical, marketing, sales, distribution and other resources than we do, which may prevent us from achieving significant market penetration or improved operating results. Certain competitors' products, such as competitors of SimpliDerm, are subject to a simpler reimbursement process than are our products. Competitors may also be able to leverage their market share and other resources to set prices at a level below that which is profitable for us. These companies may also enjoy other competitive advantages, including, without limitation:

- greater company, product and brand recognition;
- better quality and greater volume of clinical data;
- more effective marketing to and education of physicians and other healthcare professionals;
- greater control of key intellectual property and more expansive portfolios of intellectual property rights;
- more experience in obtaining and maintaining regulatory clearances, certifications or approvals for products and product enhancements;
- more established relationships with hospitals and other healthcare providers, physicians, suppliers, customers and third-party payors;
- additional lines of products, and the ability to bundle products to offer greater incentives to gain a competitive advantage;
- more established sales, marketing and worldwide distribution networks;
- better product support and service;
- superior product safety, reliability and durability, particularly in light of the events involving the FiberCel and VBM Recalls; and
- more effective pricing and revenue strategies.

Our ability to achieve and maintain profitability will depend, in part, on our ability to develop or acquire proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement for

procedures using our products, and are safer and more effective than their alternatives, as well as our ability to otherwise compete effectively on the factors listed above. If we are unable to do so, our sales and/or margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations.

Pricing pressure as a result of cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could adversely affect our sales and profitability.

Medical technology companies, healthcare systems and group purchasing organizations ("GPOs") have intensified competitive pricing pressure as a result of industry trends and new technologies. The healthcare system is under significant financial pressure to reduce costs, and rising healthcare costs have resulted in numerous cost reform initiatives by legislators, regulators and third-party payors. This cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power and, as a result, purchasing decisions are increasingly shifting to hospitals, integrated delivery networks ("IDNs") and other hospital groups, and away from individual surgeons and physicians. Many existing and potential facility customers for our products within the United States are members of GPOs and IDNs, including accountable care organizations or public-based purchasing organizations, and our business is partly dependent on contracts with these organizations. Purchases of our products can be contracted under national tenders or with larger hospital GPOs. GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process and, at any given time, we are typically in various stages of responding to bids and negotiating and renewing GPO and IDN agreements. Bids are generally solicited from multiple manufacturers or service providers with the intention of obtaining lower pricing. Due to the highly competitive nature of the bidding process and the GPO and IDN contracting processes in the United States, we may not be able to obtain or maintain contract positions with major GPOs and IDNs across our product portfolio. Furthermore, GPO and IDN contracts are typically terminable without cause upon 60 to 90 days' notice. In addition, while having a contract with a major purchaser for a given product category can facilitate sales, there can be no guarantee that sales volumes for those products will be maintained. For example, GPOs and IDNs are increasingly awarding contracts to multiple suppliers for the same product category and, even when we are the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. If we are unable to maintain and renew our contracts with our current GPO and IDN customers and negotiate contracts with new customers on favorable terms, or if sales volumes under these agreements decline, our business, financial condition and results of operations could be materially and adversely affected.

In addition, most of our customers purchase our products directly and then bill third-party payors for procedures using those products. Because there is typically no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our products can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost or may negotiate for lower pricing. Further, any decline in the amount payors are willing to reimburse our customers for procedures using our products, including those as a result of healthcare reform initiatives, could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us. In addition to these competitive forces, we continue to see pricing pressure as hospitals introduce new pricing structures into their contracts and agreements, including fixed price formulas, capitated pricing and episodic or bundled payments intended to contain healthcare costs. If we are forced to lower the price we charge for our products, our margins will decrease, which could impair our ability to grow our business and have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices for our products.

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

We manufacture our porcine tissue products using technically complex processes requiring specialized facilities, highly specific raw materials, skill and diligence by our personnel and other production constraints. The complexity of

these processes, as well as strict company and government standards for the manufacture and storage of our products, subject us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non-compliance with regulatory requirements, including stability requirements or specifications. The occurrence of this or any other actual or suspected production or distribution problem can lead to lost inventory, customer returns and, in some cases, recalls, with consequential damage to our reputation and customer relationships and the risk of product liability.

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

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business, harm our reputation and impair our ability to provide our products on a timely basis or at all.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable, timely and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, delays, damage or destruction of any of our products, it would be costly to replace these products in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, equipment malfunctions or other service interruptions affecting the delivery services we use, would impair our ability to process orders for our products on a timely basis or at all, which could have a material adverse effect on our business, financial condition and results of operations.

If our facilities are damaged or become inoperable, we will be unable to continue to research, develop and supply our products and, as a result, there will be an adverse effect on our business until we are able to secure new facilities and rebuild our inventory.

We do not have redundant facilities. The SIS ECM biomaterial used in our medical device products are manufactured by Cook at their facility in West Lafayette, Indiana and converted to a finished product at our facility in Roswell, Georgia. Regulatory approvals or certifications of our products are limited to one or more specifically approved manufacturing facilities. As a result, if we fail to produce enough of a product at a facility, or if any of our production facilities were to be shut down or otherwise become unavailable for any reason, finding alternative manufacturing capabilities and obtaining the necessary regulatory approvals or certifications would require a considerable amount of time and expense and would cause a significant disruption in service to our customers.

Disruption to our facilities could arise for a variety of reasons, including technical, labor or other difficulties, equipment malfunction, contamination, the failure of our employees to follow specific protocols and procedures, the destruction of, or damage to, any facility (as a result of a natural or man-made disaster, including, but not limited to, a tornado, flood, fire, power outage or other event), quality control issues or other reasons. Any disruption in the operation of our facilities as a result of any of the above could impair our product development and commercialization efforts and result in lost sales, lost customers and harm to our reputation, any of which would negatively impact our growth prospects and profitability and have a material adverse effect on our business, financial condition and results of operations. In addition, certain of these events, such as natural or man-made disasters, would cause us to incur additional losses, including the time and expense required to repair and/or replace our equipment and to rebuild our inventory. Our insurance for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms or at all.

Increased prices for raw materials or supplies used in our products could adversely affect our business, financial condition and results of operations.

Our profitability is affected by the prices of the raw materials and supplies used in the manufacture of our products. These prices may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, delivery costs, competition, import duties, excises and other indirect taxes, currency exchange rates and government regulation. Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third-party payors, we may be unable to pass along cost increases for key supplies or raw materials through higher prices to our customers. If the cost of key supplies or raw materials increases, and we are unable to fully recover these increased costs through price increases or offset these increases through other cost reductions, we could experience lower margins and profitability. Significant increases in the prices of raw materials and supplies that cannot be recovered through productivity gains, price increases or other methods could adversely affect our business, financial condition and results of operations.

If we are not able to accurately forecast demand for our products and manage our inventory, our margins could decrease and we could lose sales, either of which could have a material adverse effect on our business, financial condition and results of operations.

While we must maintain sufficient inventory levels to operate our business successfully and meet customer demand for our products, we must be careful to avoid amassing excess inventory. To ensure adequate inventory supply, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for our products. Demand for our products can change, and has changed, rapidly and unexpectedly, including during the time between when raw materials are ordered from our suppliers and the finished product is offered for sale. Our ability to accurately forecast demand for our products could be negatively affected by a number of factors, many of which are beyond our control, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions, reimbursement or regulatory matters and weakening of economic conditions. Inventory levels that exceed the demand for our products may result in inventory write-downs or write-offs, which would adversely affect our gross margins. Conversely, if we underestimate demand for our products, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us or at all, and suppliers or our third-party manufacturer may not be able to allocate sufficient capacity in order to meet our increased requirements. As a result, we may not be able to meet customer demand for our products, resulting in lost sales and potential damage to our reputation and customer relationships, any of which would adversely affect our business, financial condition and results of operations.

In addition, while we seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, our products generally have a shelf life of two to three years. We are, therefore, subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our profitability and cash flows due to the resulting inventory impairment charges and costs required to replace such inventory.

If hospitals and other healthcare providers are unable to obtain coverage or adequate reimbursement for procedures performed with our products, it is unlikely our products will be widely used.

In the United States, the commercial success of our existing products and any products we may develop or acquire in the future will depend, in part, on the extent to which governmental payors at the federal and state levels, including Medicare and Medicaid, private health insurers and other third-party payors, provide coverage and establish adequate reimbursement levels for procedures utilizing our products. Hospitals and other healthcare providers that purchase our products for treatment of their patients generally rely on third-party payors to pay for all or part of the costs and fees associated with our products as part of a “bundled” rate for the associated procedures. The existence of coverage and adequate reimbursement for procedures using our products by government and private payors is critical to market acceptance of our existing and future products. Neither hospitals nor surgeons are likely to use our products if they do not receive adequate reimbursement for the procedures utilizing our products.

Many private payors currently base their reimbursement policies on the coverage decisions and payment amounts determined by the CMS which administers the Medicare program. Others may adopt different coverage or reimbursement policies for procedures performed with our products, while some governmental programs, such as Medicaid, have reimbursement policies that vary from state to state, some of which may not pay for the procedures performed with our products in an adequate amount, if at all. Because the Medicare and Medicaid programs are increasingly used as models for how private payors and other governmental payors develop their coverage and reimbursement policies, a Medicare national or local non-coverage decision, denying coverage for procedures using one or more of our products, could result in private and other third-party payors also denying coverage. Third-party payors also may deny reimbursement for procedures using our products if they determine that a product used in a procedure was not medically necessary, was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved use. Unfavorable coverage or reimbursement decisions by government programs or private payors underscore the uncertainty that our products face in the market and could have a material adverse effect on our business.

Many hospitals and clinics in the United States belong to GPOs, which typically incentivize their hospital members to make a relatively large proportion of purchases of similar products from a limited number of vendors that have contracted to offer discounted prices. Such contracts often include exceptions for purchasing certain innovative new technologies, however. Accordingly, the commercial success of our products may also depend to some extent on our ability to either negotiate favorable purchase contracts with key GPOs and/or negotiate direct pricing with hospitals and clinics.

The healthcare industry in the United States has experienced a trend toward cost containment as government and private payors seek to control healthcare costs by paying service providers lower rates. While it is expected that hospitals will be able to obtain coverage for procedures using our products, the level of payment available to them for such procedures may change over time. State and federal healthcare programs, such as Medicare and Medicaid, closely regulate provider payment levels and have sought to contain, and sometimes reduce, payment levels. Private payors frequently follow government payment policies and are likewise interested in controlling increases in the cost of medical care. In addition, some payors are adopting pay-for-performance programs that differentiate payments to healthcare providers based on the achievement of documented quality-of-care metrics, cost efficiencies or patient outcomes. These programs are intended to provide incentives to providers to deliver the same or better results while consuming fewer resources. As a result of these programs, and related payor efforts to reduce payment levels, hospitals and other providers are seeking ways to reduce their costs, including the amounts they pay to medical device manufacturers. We may not be able to sell our products profitably if third-party payors deny or discontinue coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. Adverse changes in payment rates by payors to hospitals could adversely impact our ability to market and sell our products and negatively affect our financial performance.

We bear the risk of warranty claims on our products.

We bear the risk of warranty claims on our products. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer, and any recovery from such supplier or vendor may not be adequate. Furthermore, we may not have any, or have an adequate, warranty provided by our supplier. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us. In addition, we have been, and in the future could be, subject to costs related to product recalls, and we could incur significant costs to correct any defects, warranty claims or other problems. Any such events could adversely affect our business, financial condition and results of operations.

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

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Quality and safety issues may occur with respect to any of our products, and our future operating results will depend on our ability to maintain an effective quality control system and effectively train and manage our workforce with

respect to our quality system. The development, manufacture and control of our products are subject to extensive and rigorous regulation by numerous government agencies, including the FDA. Compliance with these regulatory requirements, including but not limited to the FDA's Quality System Regulation ("QSR"), current Good Manufacturing Practices ("GMPs") and adverse events/recall reporting requirements in the United States and other applicable regulations worldwide, is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we fail to comply with our reporting obligations, the FDA or other regulatory authority could take action, including issuance of warning letters and/or untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in the clearance of future products.

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

If our products do not function as designed, or are designed improperly, we or the third-party manufacturer of such products may withdraw such products from the market, whether by choice or as a result of regulatory requirements. We had two recalls in products formerly distributed through our recently divested Orthobiologics Business – one in June 2021 and one in July 2023. These recalls had negative effects on our business, financial condition and results of operations and resulted in a number of lawsuits filed against us as discussed under the risk factor *"We face significant litigation related to our FiberCel and Viable Bone Matrix recalls, and have no more insurance coverage on the FiberCel recall"* included in this Annual Report. Any product recall we or a third-party manufacturer may conduct in the future, whether voluntary or required, could also have a negative impact on our business, financial condition and results of operations, and this effect may be material.

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

Our operating results may fluctuate significantly from quarter to quarter and year to year due to the seasonality of our business, as well as a variety of other factors, many of which are outside of our control.

Our quarterly and annual results of operations may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of our future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. One such factor includes seasonal variations in our sales. We have experienced and may in the future experience higher sales in the fourth quarter as hospitals in the United States increase their purchases of our products to coincide with the end of their budget cycles. Satisfaction of patient deductibles through the course of the year also results in increased sales later in the year. In general, our first quarter usually has lower sales than the preceding fourth quarter as patient deductibles are re-established with the new year, thereby increasing the patients' out-of-pocket costs.

Other factors that may cause fluctuations in our quarterly and annual results include, among other things:

- the timing of medical procedures using our products;
- the announcement or introduction of new products by our competitors;
- failure of government health benefit programs and private health plans to cover our products or to timely and adequately reimburse the users of our products;
- the rate of reimbursement for procedures using our products by government and private insurers;
- whether our products are granted pass-through reimbursement status or included in the "bundled" reimbursement structure;
- changes in purchasing patterns by our commercial partners or customers, or the loss of any significant customer or group of customers;
- our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations and infrastructure;
- changes in, or enactment of, new laws or regulations promulgated by federal, state or local governments;
- changes in our supply or manufacturing costs;
- cost containment initiatives or policies developed by government and commercial payors that create financial incentives not to use our products;
- our inability to demonstrate that our products are cost-effective or superior to competing products;
- our ability to develop new products;
- the degree of competition in our industry and any changes in the competitive landscape;
- discovery of product defects during the manufacturing process;
- initiation of a government investigation into potential non-compliance with laws or regulations, or the initiation of a voluntary or involuntary recall with respect to one or more of our products;
- sanctions imposed by federal or state governments due to non-compliance with laws or regulations;
- general global economic conditions and political instability, such as the conflict between Russia and Ukraine; and
- economic conditions specific to the healthcare industry.

We have based our current and future expense levels largely on our investment plans and estimates of future events, although certain of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in sales relative to our planned expenditures would have an immediate adverse effect on our business, results of operations and financial condition. Further, as a strategic response to changes in the competitive environment or to changes in laws and regulations,

we may from time to time make certain pricing, service or marketing decisions (e.g., reduce prices) that could have a material and adverse effect on our business, financial condition and results of operations. Due to the foregoing factors, our revenue and operating results are and will remain difficult to forecast.

Security breaches, loss of or damage to data, information technology system failures and other disruptions could compromise sensitive information related to our business or our customers' patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may become exposed to, or collect and store, sensitive data, including procedure-based information and legally protected health information, credit card, and other financial information, insurance information and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Regardless of any precautions we may take, our information technology ("IT") and infrastructure, and that of our technology partners and providers, may be vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

Attacks upon IT systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to unauthorized access to or acquisition of personal information, confidential information, intellectual property or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial-of-service attacks, social engineering and other means, to attain such unauthorized access or acquisition or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and often are not foreseeable or recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Any breakdowns or breaches of our systems, or resulting access, disclosure, or other loss of information, could significantly disrupt our business and result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation, any of which could have a material and adverse effect on our business, financial condition and results of operations.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and result in the unauthorized disclosure of sensitive or confidential patient or employee data, it could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world.

Despite our security measures, there can be no assurance that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems, or any resulting unauthorized access to, or disclosure and use of, non-public or other legally protected information. Our general liability and cybersecurity insurance coverage may not cover all claims, continue to be available to us on reasonable terms or be sufficient in amount to cover one or more large claims. Additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition.

Our success depends on our ability to retain and motivate key management personnel and other employees and consultants, to attract, retain and motivate additional qualified personnel and to effectively navigate changes in our senior management team.

Our success depends to a significant extent on our ability to attract, retain and motivate key management personnel and other employees and consultants for our business, including scientific, technical and sales and marketing personnel. There is currently a shortage of skilled executives and other personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms, given the competition among numerous regenerative medicine and other healthcare companies, for individuals with similar skill sets. Many of the companies that we compete against for qualified personnel have substantially greater financial and other resources and different risk profiles than we do. They may also provide more diverse opportunities, better chances for career advancement and/or more attractive compensation. Some of these characteristics may be more appealing to high quality candidates than what we can offer. Furthermore, in order to offer attractive compensation, we may need to increase the level of cash compensation that we pay to them, which will reduce funds available for research and development and support of our commercialization and sales growth objectives. In addition, any headcount reductions taken as part of cost saving initiatives and as our business strategy evolves may negatively impact our ability to attract qualified personnel in the future. There can be no assurance that we will have sufficient cash available to offer our employees and consultants attractive compensation or that we will realize any corresponding benefits from the payment of such compensation. We are also vulnerable to the risk that these individuals may take actions, either within or outside the scope of their duties, that intentionally or unintentionally tarnish our brand and reputation or otherwise adversely affect our business. We also cannot prevent our senior management team from terminating their employment with us. Losing the services of any member of our senior management team could materially harm our business until a suitable replacement is found, and such replacement may not have equal experience and capabilities. In addition, we do not maintain "key person" insurance policies on the lives of any of our management team or other employees. The inability to recruit or a loss of the services of any executive, key employee or consultant may impede the progress of our research, development, commercialization and sales growth objectives, which could have a material adverse effect on our business, financial condition, results of operations and our ability to grow our business.

We are subject to anti-bribery, anti-corruption and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, any of which would adversely affect our business, financial condition and results of operations.

We are subject to anti-corruption, anti-bribery, and other similar laws and regulations in various jurisdictions in which we operate, including the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.K. Bribery Act 2010 ("Bribery Act"), and other anti-corruption laws and regulations. These laws generally prohibit us and our officers, directors, employees and business partners acting on our behalf, including agents, from corruptly offering, promising, authorizing or providing anything of value to obtain or retain business or otherwise obtain favorable treatment and require companies to maintain accurate books and records and a system of internal controls or adequate procedures to prevent bribery.

We are also subject to economic sanctions laws, export control laws and regulations, as well as customs regulations, in the various jurisdictions in which we operate, including those administered and enforced by OFAC, the U.S. Department of State, BIS, His Majesty's Treasury of the United Kingdom, the United Nations Security Council, the European Union (and its member states) and other relevant sanctions authorities. Such laws and regulations prohibit or restrict certain operations, investment decisions, and sales activities, including dealings with certain countries or territories, and with certain governments and designated persons. Investigations of alleged sanctions and export controls violations can be expensive and disruptive.

As our international operations increase, we expect to implement policies and procedures designed to promote compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, the Bribery Act and other anti-corruption laws, as well as economic sanctions and export controls. We cannot assure you, however, that any such policies and procedures will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged, and will not engage, in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged, and will not engage, in conduct that could materially affect

their ability to perform their contractual obligations to us or result in our being held liable for such conduct. Violations of the FCPA, Bribery Act, other anti-corruption laws, economic sanctions, export control laws and/or anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.

Our officers, employees, independent contractors, principal investigators, consultants, commercial partners and independent sales agents may engage in misconduct or activities that are improper under other laws and regulations, which would create liability for us.

We are exposed to the risk that our officers, employees, independent contractors (including contract research organizations ("CROs")), principal investigators, consultants, commercial partners and independent sales agents may engage in fraudulent conduct or other illegal activity and/or may fail to disclose unauthorized activities to us. Misconduct by these parties could include, but is not limited to, intentional, reckless and/or negligent failures to comply with the laws and regulations of the FDA and its foreign counterparts, including, but not limited to, those relating to the manufacture, processing, packing, holding, investigating or distributing in commerce of medical devices, biological products and/or HCT/Ps, requiring the reporting of true, complete and accurate information to such regulatory bodies (including any safety problems associated with the use of our products), and relating to the conduct of clinical studies and the protection of human research subject.

In particular, companies involved in the manufacture of medical products are subject to laws and regulations intended to ensure that medical products that will be used in patients are safe and effective, and specifically that they are not adulterated or contaminated, that they are properly labeled, and have the identity, strength, quality and purity that they are represented to possess. Further, companies involved in the research and development of medical products are subject to extensive laws and regulations intended to protect research subjects and ensure the integrity of data generated from clinical studies and of the regulatory review process. Any misconduct in any of these areas, whether by our own employees or by contractors, vendors, business associates, consultants or other entities acting as our agents, could result in regulatory sanctions, criminal or civil liability and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such investigations or other actions or lawsuits are instituted against us, those actions could have a significant impact on our business, financial condition and results of operations, including, without limitation, the imposition of significant fines and other sanctions that may materially impair our ability to run a profitable business. Even if we are successful in defending against the imposition of any such fines or other sanctions, we could be required to incur substantial legal fees and other costs, and management's attention will be diverted from our core business operations, either of which would negatively affect our business, financial condition and results of operations.

Our ability to use certain tax attributes to offset future income tax liabilities may be subject to limitations.

We have net operating losses and other tax attributes, including net operating loss carryforwards ("NOLs") for federal income tax purposes of approximately $129.3 million and state NOLs of approximately $46.9 million as of December 31, 2024. If not utilized, $17.7 million of our NOLs will begin to expire for federal income tax purposes beginning in 2036, and our state NOLs will expire beginning in 2030. Our ability to utilize our federal NOLs will depend on our future income, and there is a risk that our NOLs could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our operating results.

In addition, our ability to utilize our NOLs may be subject to an annual limitation under the Internal Revenue Code of 1986, as amended (the "Code"). In general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs or tax credits to offset future taxable income. If we undergo an ownership change or have previously undergone an ownership change, our ability to utilize federal NOLs or tax credits could be limited by Sections 382 and 383 of the Code. Additionally, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our state NOLs or credits may also be impaired under state tax law. Accordingly, we may not be able to utilize a material portion of our federal and state NOLs or credits. Our ability to utilize our NOLs or credits is

conditioned upon our attaining profitability and generating U.S. federal and state taxable income. Valuation allowances have been provided for all deferred tax assets related to our federal and state NOLs.

In addition, other tax attributes, such as interest carryforwards, are also subject to various limits on their use under the Code. We have established valuation allowances for our interest carry forwards to reflect these limitations and their anticipated impact on our ability to utilize these tax attributes.

Changes in tax laws, unfavorable resolution of tax contingencies or exposure to additional income tax liabilities could have a material impact on our results of operations or financial condition.

We are subject to income taxes as well as non-income based taxes in the United States. We may from time to time be subject to tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of any tax audits to which we are subject in order to determine the appropriateness of our tax provision and have established contingency reserves for material, known tax exposures. However, the calculation of such tax exposures involves the application of complex tax laws and regulations in many jurisdictions. Therefore, there can be no assurance that we will accurately predict the outcomes of any tax audits to which we may be subject or that issues raised by tax authorities will be resolved at a financial cost that does not exceed our related reserves and the actual outcomes of any such audit could have a material impact on our results of operations or financial condition.

Changes in tax laws and regulations, or their interpretation and application, in the jurisdictions where we are subject to tax, could materially impact our effective tax rate. For example, changes in tax law implemented by the tax reform legislation known as H.R. 1, commonly referred to as the Tax Cuts and Jobs Act (the "TCJA") in the United States became effective in 2018 and 2019, and we expect the U.S. Treasury to continue to issue future notices and regulations under the TCJA. Certain provisions of the TCJA and the regulations issued thereunder could have a significant impact on our future results of operations as could interpretations made by us in the absence of regulatory guidance and judicial interpretations. In addition, in 2018, we established valuation allowances against all deferred tax assets (including interest carry forwards) to reflect certain limitations on these assets and their anticipated impact on our ability to utilize these tax assets following the adoption of the TCJA.

Additionally, the U.S. Congress, government agencies in jurisdictions outside the United States where we do business and the Organization for Economic Co-operation and Development (the "OECD") have recently focused on issues related to the taxation of multinational corporations. One example is in the area of "base erosion and profit shifting," where profits are claimed to be earned for tax purposes in low-tax jurisdictions, or payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. The OECD has released several components of its comprehensive plan to create an agreed set of international rules for fighting base erosion and profit shifting. As a result, the tax laws in the United States and other countries, in which we do business, could change on a prospective or retroactive basis and any such changes could materially adversely affect our business, financial condition and results of operations.

Unfavorable results from any of our pre-clinical or clinical studies, comparative effectiveness, economic or other studies, or from similar studies conducted by others, may negatively affect the use or adoption of our products by physicians, hospitals and payors, which could have a negative impact on the market acceptance of our products and their profitability.

We regularly conduct a variety of pre-clinical and clinical studies, comparative effectiveness studies and economic and other studies of our products in an effort to generate clinical and real-world outcomes and cost effectiveness data in order to obtain product approval and drive further penetration in the markets we serve. If a clinical study conducted by us or a third party fails to demonstrate statistically significant results supporting performance, use benefits or compelling health or economic outcomes from using our products, physicians may elect not to use our products. Furthermore, in the event of an adverse clinical study outcome, our products may not achieve "standard-of-care" status, where they exist, for the conditions in question, which could deter the adoption of our products. Also, if serious adverse events are reported during the conduct of a study, it could affect continuation of the study, product approval, certification or clearance and product adoption. In addition, U.S. and foreign regulatory authorities routinely conduct audits of clinical studies and such

audits may result in adverse regulatory actions. If we are unable to develop a body of statistically significant evidence from our clinical study program, whether due to adverse results or the inability to complete properly designed studies, domestic and international public and private payors could refuse to cover procedures using our products, limit the manner in which they cover our products or reduce the price they are willing to pay or reimburse for procedures using our products. Any of these events could have a negative impact on market acceptance of procedures using our products and their profitability, which could have a material adverse effect on our business, financial condition and results of operations.

As we conduct clinical studies designed to generate long-term data on some of our existing products, the data we generate may not be consistent with our existing data and may demonstrate less favorable safety or efficacy.

We are currently collecting and plan to continue collecting long-term clinical data regarding the quality, safety and effectiveness of some of our existing products. The clinical data collected and generated as part of these studies will further strengthen our clinical evaluation concerning safety and performance of these products. We believe that this additional data will help with the marketing of our products by providing surgeons and physicians with additional confidence in their long-term safety and efficacy. If the results of these clinical studies are negative, these results could reduce demand for our products and significantly reduce our ability to achieve expected net sales. We do not expect to undertake such studies for all of our products and will only do so in the future where we anticipate the benefits will outweigh the costs and risks. For these reasons, surgeons and physicians could be less likely to purchase our products than competing products for which longer-term clinical data are available. Also, we may not choose or be able to generate the comparative data that some of our competitors have or are generating and we may be subject to greater regulatory and product liability risks. If we are unable to or determine not to collect sufficient long-term clinical data supporting the quality, safety and effectiveness of our existing products, our business, financial condition and results of operations could be adversely affected.

Our estimates of market opportunity and forecasts of market and sales growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all.

Market opportunity estimates and growth forecasts are inherently uncertain. Our estimates of the annual total addressable markets for our products are based on a number of internal and third-party estimates and assumptions, including, without limitation, the number of implantable electronic device procedures as well as the number of procedures using biologic products annually in the United States. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for any of our products may prove to be incorrect. If the actual number of procedures, the price at which we are able to sell any of our products, or the annual total addressable market is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations.

Risks Related to Government Regulation

The regulatory approval, certification and clearance processes of the FDA and comparable foreign authorities and notified bodies are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval or other marketing authorizations or certifications for our products and product candidates, our business will be substantially harmed.

The medical device and biologics industries are regulated extensively by governmental authorities. The time required to obtain approval, clearance, certification of conformity or other marketing authorizations from the FDA and comparable foreign authorities is unpredictable but can often take many years following the commencement of clinical studies and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, policies, regulations, or the type and amount of clinical data necessary to gain clearance, certification or approval may change during a product candidate's development.

Before we can market or sell a new medical device or a new use of or a claim for or significant modification to an existing medical device in the United States, we must obtain either clearance from the FDA under Section 510(k) of

the Federal Food, Drug, and Cosmetic Act (the "FDCA") or approval of an application for premarket approval, or PMA, unless an exemption applies. In the United States, we have obtained 510(k) premarket clearance from the FDA to market products such as our EluPro, CanGaroo, VasCure, ProxiCor and Tyke products. In the 510(k) premarket clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support a finding of substantial equivalence. Under certain conditions, a medical device is required to be approved under a PMA before it may be legally marketed. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data, including, but not limited to, technical, nonclinical, clinical study, manufacturing and labeling data.

The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all. If the FDA requires us to go through a lengthier, more rigorous examination for our products than we expect, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. Further, even where a PMA is not required, we cannot assure you that we will be able to obtain 510(k) clearances with respect to such product candidates or modifications to previously cleared products.

The FDA or any foreign regulatory agency or notified body can delay, limit or deny approval, certification or clearance of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or the applicable foreign regulatory agency or notified body's disagreement with the design or implementation of our clinical studies;
- negative or ambiguous results from our clinical studies or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies;
- serious and unexpected drug or device-related side effects experienced by participants in our clinical studies or by individuals using devices similar to our products;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency or notified body that our product candidates are safe and effective for their intended uses, or in the case of the 510(k) clearance process, that our product candidate is substantially equivalent to a predicate device;
- the FDA's or the applicable foreign regulatory agency or notified body's disagreement with the interpretation of data from pre-clinical or clinical studies;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory agency or notified body's requirement for additional pre-clinical studies or clinical studies;
- the FDA's or the applicable foreign regulatory agency or notified body's disagreement regarding the formulation, labeling or the specifications of our products or future product candidates;
- the FDA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval or clearance policies or regulations of the FDA or the applicable foreign regulatory agencies or notified bodies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA or foreign regulatory approval or certification processes and are commercialized. The lengthy approval, marketing authorization or certification process, as well as the unpredictability of future clinical study results, may result in our failing to obtain regulatory clearance, approval, certification or other marketing authorization to market our product candidates, which would significantly harm our business, financial condition and results of operations.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

Certain marketed products are subject to Medical Device Reporting ("MDR") obligations, requiring us to report incidents to the FDA, EU competent authorities, or other foreign regulatory bodies if our products may have caused or contributed to a death, serious injury, or malfunction that could likely lead to such outcomes upon recurrence. The reporting timeline is triggered by our awareness of the adverse event. Failure to report within the prescribed timeframe or to recognize reportable adverse events could result in regulatory actions, such as warning letters, administrative actions, criminal prosecution, civil penalties, product seizure, or delays in clearance or approval for future products.

The FDA, the competent authorities of the EU member states, and foreign regulatory authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall for a medical device must be based on a finding that there is reasonable probability that the device could cause serious injury or death. With respect to human cells, tissues, and cellular and tissue-based products ("HCT/Ps"), the FDA may also require a recall where the conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission, or where the HCT/P is infected or contaminated so as to be a source of dangerous infections to humans. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

In the EU, compliance with the medical device vigilance system is imperative. Serious incidents and Field Safety Corrective Actions ("FSCAs") must be reported to the relevant authorities of EU member states, facilitated through Eudamed. FSCAs necessitate communication by the manufacturer or its legal representative to customers and end-users via Field Safety Notices ("FSNs"). In cases of similar incidents with the same device or type, manufacturers may submit periodic summary reports instead of individual incident reports.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or foreign regulatory authorities may require, or we may decide, that we will need to obtain new clearances, certifications or approvals for the device before we may market or distribute the corrected device. Seeking such clearances, certification or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA or foreign regulatory body warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Modifications to our medical device products may require new 510(k) clearances or other marketing authorizations or certifications, and if we make modifications to such products without obtaining requisite marketing authorization, we may be required to cease marketing or recall the modified products until clearances or other marketing authorizations or certifications are obtained.

Any significant modification to a cleared or approved medical device, affecting its safety, effectiveness, or intended use, necessitates a new 510(k) clearance or, in some cases, approval of a PMA. While the FDA expects manufacturers to make this determination, it retains the authority to review these decisions. Disagreement with the FDA on whether new clearances or approvals are necessary could lead to regulatory actions, including the cessation of marketing or product recalls until clearance or approval is obtained. This may result in substantial fines or penalties. Additionally,

the FDA may not approve our products for desired indications or could mandate clinical studies for modifications. Any delays or failures in obtaining required clearances or approvals may impede the timely introduction of new or enhanced products, adversely affecting our future growth and operating results.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our currently marketed products have been cleared by the FDA for specific indications. We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those authorized or certified by the FDA or by any foreign regulatory body or notified body may not effectively treat such conditions, which could harm our reputation in the marketplace.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, and higher than anticipated costs or lower than anticipated sales. Even after we have obtained the proper regulatory clearance to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations or certification of new products, new intended uses or modifications to existing products;
- withdrawals or suspensions of our current 510(k) clearances, or certifications resulting in prohibitions on sales of our products;

- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and

- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

Our ability to develop and gain approval for medical products is subject to potential challenges stemming from regulatory changes, particularly those initiated by the FDA and other authorities. The FDA may alter its clearance policies, introduce new regulations, or modify existing ones, possibly causing delays in the approval of our upcoming products or hindering our ability to make timely adjustments to currently cleared products. These changes in policy or regulations may impose additional requirements, potentially leading to delays in obtaining new clearances, increased compliance costs, or limitations on maintaining current product clearances. It's important to note that the FDA and other regulatory bodies may alter their policies, and new government regulations may emerge, further complicating the regulatory landscape.

The unpredictability of the likelihood, nature, and scope of future government regulations, both in the United States and internationally, adds an additional layer of uncertainty. Failure to promptly adapt to changing requirements or maintain regulatory compliance could result in the loss of marketing approval for our products.

Our HCT/P products are subject to extensive government regulation, and our failure to comply with these requirements could cause our business to suffer.

In the United States, we sell human tissue-derived allografts, termed HCT/Ps by the FDA. Certain HCT/Ps fall under Section 361 of the Public Health Service Act (“PHSA”) and are known as "Section 361 HCT/Ps." These products, meeting specific criteria like "minimally manipulated" and intended for "homologous use," do not require 510(k) clearance, PMA approval, or Biologics License Applications (“BLAs”) before marketing. Our HCT/Ps are believed to be regulated solely under Section 361, and we haven't sought 510(k) clearance, PMA approval, or BLA licensure. However, the FDA could disagree, potentially requiring us to cease marketing or recall products pending proper authorization. For example, FDA may decide that certain uses of SimpliDerm may not be considered HCT/Ps in specific breast reconstruction procedures, necessitating clinical studies and potential PMA approval. HCT/Ps are subject to donor eligibility, screening, Good Tissue Practices, labeling, and post-market reporting requirements. Failure to comply may result in FDA enforcement actions, including warning letters, fines, injunctions, recalls, seizures, and, in severe cases, criminal penalties.

The clinical study process is lengthy and expensive with uncertain outcomes. We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical study results, or the safety or efficacy profile for such products.

Clinical testing poses significant challenges, requiring careful design and implementation. It is time-consuming, expensive, and outcomes are uncertain. Results from pre-clinical and initial clinical studies may not accurately predict later studies. Interpretation of data is subjective, and past successes in early studies do not guarantee success in later stages. Clinical failure can occur at any point, leading to inconclusive or negative results. Factors like delays in study initiation, disagreements with regulatory authorities, difficulties in agreement with third-party contractors, unexpected costs, slow patient enrollment, protocol amendments, safety concerns, or manufacturing issues may disrupt or halt clinical studies. Factors influencing patient enrollment and study completion include the study protocol, patient proximity to clinical sites, eligibility criteria, compliance, competition from other studies, and perceptions of product advantages. Challenges such as extensive post-treatment procedures, concurrent competitor studies, patient dropouts, or unrelated adverse events can lead to delays, increased costs, or study failures. Regulatory changes may render existing data insufficient for approval. Unexpected side effects or characteristics in current or future products can also impact outcomes. The complex and unpredictable nature of clinical studies underscores the challenges and uncertainties inherent in the development of medical products.

Disruptions at the FDA and other government agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, certified or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The FDA's, foreign regulatory authorities', and notified bodies' ability to review and approve new products is influenced by various factors, including government budget, policy changes, and personnel availability. Average review times have fluctuated in recent years, and disruptions, such as government shutdowns and furloughs, can impede the clearance and approval process. Prolonged government shutdowns or pandemic-related disruptions could significantly affect the timely review of our regulatory submissions, posing a material adverse effect on our business.

We are bound by federal, state, and foreign fraud and abuse laws, violations of which could result in significant penalties. Challenges or investigations into our practices under these laws may lead to adverse publicity, incurring substantial response costs and potential harm to our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers and hospitals are subject to scrutiny under these laws. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal civil and criminal false claims laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil penalties, including treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- the federal Physician Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or CHIP, to report annually to CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include doctors, dentists, optometrists, podiatrists and chiropractors, certain non-physician providers such as physician assistants and nurse practitioners, and teaching hospitals, and applicable manufacturers and GPOs, to report annually ownership and investment interests held by such physicians and their immediate

family members. Manufacturers are required to submit annual reports to CMS and failure to do so may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests not reported in an annual submission and may result in liability under other federal laws or regulations. and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians or other potential purchasers of our products, as well as independent sales agents and distributors.

The heightened scrutiny of interactions between healthcare companies and providers by enforcement bodies enforcing healthcare regulatory laws has resulted in numerous investigations, prosecutions, and settlements within the industry. Responding to these inquiries can be resource-intensive and divert management attention. Any investigation or settlement may increase costs or adversely impact our business. Even an unsuccessful challenge could lead to adverse publicity and be expensive to address. Violations of healthcare laws may result in penalties, fines, exclusion from government programs, imprisonment, reputational harm, and operational curtailment or restructuring.

Members of our management, and their affiliations, have been and may be involved in healthcare industry investigations, prosecutions, convictions, or settlements. For instance, Kevin Rakin, our board chairman, faced allegations in the United States ex rel. Webb v. Advanced BioHealing, Inc., a whistleblower suit related to sales practices at ABH, where Mr. Rakin served as CEO. All claims were dismissed with prejudice in a settlement, where Mr. Rakin denied any wrongdoing. Such events could harm our reputation and adversely impact our business, financial condition, and results of operations.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition and results of operations.

The Affordable Care Act ("ACA"), enacted in March 2010, brought about substantial changes to healthcare financing, introducing reforms such as the creation of the Patient-Centered Outcomes Research Institute and payment system changes like bundled payments. Subsequent legislative changes post-ACA, including the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012, have impacted Medicare payments, influencing healthcare providers. The ongoing evolution of state, federal, and foreign healthcare reform measures suggests potential future changes that could limit reimbursement for healthcare products and services, adding pressure on pricing dynamics and impacting demand for our products.

Actual or perceived failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and/or adverse publicity and could negatively affect our business.

We and our partners are subject to federal, state, and foreign data protection laws, including the Health Insurance Portability and Accountability Act ("HIPAA") in the U.S., governing the collection, use, and protection of health-related and personal information. While we currently believe we are not directly regulated under HIPAA, criminal penalties may apply if we knowingly misuse health information from a HIPAA-covered entity. Additionally, the California Consumer Privacy Act ("CCPA"), effective since January 1, 2020, grants expanded rights to California residents regarding their personal information. The California Privacy Rights Act ("CPRA"), effective January 1, 2023, imposes more obligations on businesses, potentially increasing compliance costs and liabilities. Similar privacy laws in other states and at the federal level may pose challenges, with potential conflicting requirements.

Moreover, enforcement actions by the Federal Trade Commission ("FTC") and state Attorneys General are ongoing, targeting companies for unfair or deceptive online data practices. The FTC emphasizes the importance of reasonable and appropriate data security measures, and failure to comply may be deemed unfair under Section 5(a) of the Federal Trade Commission Act. Such regulatory scrutiny poses risks to our financial condition, emphasizing the need for robust data protection measures and compliance efforts.

Ensuring compliance with U.S. and foreign privacy and security laws may necessitate assuming more burdensome obligations in our contracts and engaging in costly compliance efforts. These regulations could impose restrictions on data collection, usage, and disclosure, potentially affecting our operations and those of our partners in specific jurisdictions. The evolving nature of these laws introduces varying interpretations, and non-compliance may lead to government investigations, civil or criminal penalties, fines, private litigation, and adverse publicity, negatively impacting our business and operating results. Additionally, contractual limitations imposed by patients and providers on information use and disclosure may hinder our operations. Claims of privacy violations, non-compliance with data protection laws, or breaches of contractual obligations, even if unfounded, can be resource-intensive to defend and result in adverse publicity, adversely affecting our business, financial condition, and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain, maintain and adequately protect our intellectual property rights, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Some of our intellectual property rights depend on licensing agreements with third parties, and our patent coverage includes protection provided by licensed patents. If in the future we no longer have rights to one or more of these licensed patents, our patent coverage may be compromised, which in turn could adversely affect our ability to protect our products and defend against competitors.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that we view as important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our existing products, any enhancements we may develop to our existing products or any new products we may develop or acquire and introduce in the future. We, or our licensors, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Other parties may have developed technologies that may be related or competitive to our system, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position.

The patent positions of regenerative medicine companies, including our patent position, may involve complex legal, scientific and factual questions, and, therefore, the scope, validity, ownership and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, narrowed, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we currently own or may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products. In recent years, patent rights have been the subject of significant litigation. Changes in either the patent laws or interpretation

of the patent laws in the United States and other countries may diminish the value of our owned or licensed patents or narrow the scope of our patent protection.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its inventorship, scope, validity or enforceability, and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our patents or develop and obtain patent protection for more effective technologies, designs or methods.

EluPro, CanGaroo and SimpliDerm are the only current products covered by issued patents. We rely on unpatented trade secrets and know-how for several of our current products to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect and enforce against third parties. Accordingly, we cannot be certain that these intellectual property rights will provide us with adequate protection or enable us to prevent third parties from developing or commercializing competitive products.

We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, current and former employees, distributors, commercial partners or independent sales agents. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if we were to prevail, may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Such proceedings could provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of the patents covering our products are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents we currently have, or may have, expire;
- we were the first to conceive and reduce to practice the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe, misappropriate or otherwise violate our owned or licensed patents and other intellectual property rights;

- any of our patents will ultimately be found to be valid and enforceable;
- ownership of our patents or patent applications will not be challenged by third parties;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- our competitors will not conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe, misappropriate or otherwise violate the patents and other intellectual property rights of others.
- Should any of these events occur, they could have a material and adverse effect on our business, financial condition and results of operations.

We may not enter into invention assignment and confidentiality agreements with all of our employees and contractors and such agreements could be ineffective or breached.

We rely, in part, upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees, consultants, independent sales agents, collaborators and third-party vendors. We also seek to enter into agreements with our employees and consultants that obligate them to assign any inventions created during their work for us to us and have non-compete agreements with some, but not all, of our consultants. However, we may not obtain these agreements in all circumstances and the assignment of intellectual property under such agreements may not be self-executing. If the employees, consultants or collaborators that are parties to these agreements breach or violate their respective terms, we may not have adequate remedies for any such breach or violation. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

The patent protection we obtain for our products may not be sufficient enough to provide us with any competitive advantage or our patents may be challenged.

Our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. For example, a third party may develop a competitive product that provides benefits similar to one or more of our products but falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our products is not sufficiently broad to impede such competition, our ability to successfully commercialize our products could be negatively affected, which would harm our business.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our collaborators or licensors, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our collaborators or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights

could be compromised. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid and enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our patents or applications that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office (the "USPTO") or to other patent offices around the world. Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter partes review, supplemental examinations or interference proceedings or challenges in district court, in the United States or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. In addition, if we seek to enforce our patents against third parties, third parties may initiate such challenges in response. An adverse determination in any such challenges may result in loss of the patent or in patent or patent application claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent or patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations could require us to spend significant time and money, prevent us from selling our products and adversely affect our stock price.

Our commercial success will depend in part on not infringing, misappropriating or otherwise violating the patents or other proprietary rights of third parties. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future,

assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product sales and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe, misappropriate or otherwise violate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation. We may in the future receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents.

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings, such as review, reexamination, inter parties review, interference or derivation proceedings before the USPTO and challenges in U.S. District Court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and/or invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe, misappropriate or otherwise violate the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, misappropriating or otherwise violating;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing, misappropriating or otherwise violating;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe, misappropriate or otherwise violate the intellectual property rights of third parties, we could be required to pay substantial damages (possibly treble damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement, misappropriation or violation. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe, misappropriate or otherwise violate the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our

products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

We may not have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the market price of shares of our Class A common stock. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, independent sales agents and other third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, it could have a material and adverse effect on our business, financial condition and results of operations.

We may be unable to enforce our intellectual property rights throughout the world.

Obtaining, maintaining and enforcing intellectual property rights is expensive and it is cost prohibitive to do so throughout the world. Accordingly, we may determine not to obtain, maintain or enforce intellectual property rights in certain jurisdictions. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation or other violation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and

foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in such intellectual property. Either outcome could harm our business and competitive position. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal data, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

Recent changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013, could affect us. The first to file provisions limit the rights of an inventor to patent an invention if the inventor was not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. This will require us to be cognizant going forward of the timing from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

In addition, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board (the "PTAB") provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. This applies to all of our U.S. patents, even those issued before March 16, 2013. Furthermore, because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S.

patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them. Any failure by us to adequately address the uncertainties and costs surrounding recent patent legislation could have a material and adverse effect on our business, financial condition and results of operations.

Outside of the United States we cannot be certain that any country's patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications.

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent or trademark protection. For example, we may elect not to seek patent protection in some jurisdictions or for some drug candidates in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources.

For example, the impact of the withdrawal of the U.K. from the EU will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain patents and trademarks in the U.K. In 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court, or UPC, for litigation of European patents. It is possible that implementation of the EU Patent Package will occur in the first half of 2023. If the EU Patent Package is ratified and in effect, all European patents, including those issued prior to ratification, would by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions. Under the EU Patent Package as currently proposed, once the UPC is established, patent holders are permitted to "opt out" of the UPC on a patent-by-patent basis during an initial seven year period after the EU Patent Package is ratified. Owners of traditional European patent applications who receive notice of grant after the EU Patent Package is ratified could either accept a Unitary Patent or validate the patent nationally and file an opt-out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. In addition, the USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position, could impair our ability to successfully commercialize our product candidates in any indication for which they are approved, and could have a material and adverse effect on our business, financial condition and results of operations.

In addition, any of the intellectual property rights that we own or license that are developed through the use of U.S. government funding will be subject to additional federal regulations. Pursuant to the Bayh-Dole Act of 1980 (the "Bayh-Dole Act"), the government will receive a license under inventions developed under a government-funded program and may require us to manufacture products embodying such inventions in the United States. Under certain circumstances, the government may also claim ownership in such inventions or compel us to license them to third parties. Any failure by

us to comply with federal regulations regarding intellectual property rights that were developed through the use of U.S. government funding could have a material and adverse effect on our business, financial condition and results of operations.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Amendments and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the United States, a patent that covers an FDA-approved drug, biologic or medical device may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved product, a method for using it or a method for manufacturing it may be extended. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

Further, under certain circumstances, patent terms covering our products or product candidates may be extended for time spent during the pendency of the patent application in the USPTO (referred to as Patent Term Adjustment ("PTA")). The laws and regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third-party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact our ability to exclude competitors. Because PTA added to the term of patents covering products has particular value, our business may be adversely affected if the PTA is successfully challenged by a third party and our ability to exclude competitors is reduced or eliminated. Any of the foregoing could have a material and adverse effect on our business, financial condition and results of operations.

We depend on certain technologies that are licensed to us. We do not control the intellectual property rights covering these technologies, and any loss of our rights to these technologies or the rights licensed to us could prevent us from selling our products and adversely impact our business.

We are a party to license agreements under which we are granted rights to intellectual property that is important to our business, and we may need to enter into additional license agreements in the future. We rely on these licenses in order to be able to use and sell various proprietary technologies that are material to our business, as well as technologies we intend to use in our future commercial activities. For example, we expect that we will be dependent on our licensing arrangements with Cook, relating to EluPro, CanGaroo and our cardiovascular products. Our rights to use these technologies and the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those license agreements. Our existing license agreements impose, and we expect that future license agreements will also impose on us, various diligence obligations, milestone payments, royalties and other obligations. If

we fail to comply with our obligations under these agreements, or if we are subject to a bankruptcy proceeding, the licensor may have the right to terminate the license, in which case we would not be able to market products covered by the license, which would adversely affect our business, financial condition and results of operations.

As we have done previously, we may need to obtain additional licenses from third parties in order to advance our research or allow commercialization of our products and technologies. The in-licensing and acquisition of third-party intellectual property is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Accordingly, we may not be able to obtain any of these licenses on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In the event that we are not able to acquire a license, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and technologies, which could materially harm our business. In addition, the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation and damages.

In some cases, we may not have the right to control the prosecution, maintenance or filing of the patents that are licensed to us, or the enforcement of these patents against infringement by third parties. Some of our patents and patent applications were not filed by us, but were either acquired by us or are licensed from third parties. Thus, these patents and patent applications were not drafted by us, and we did not control or have any input into the prosecution of these patents and patent applications prior to our acquisition of, or our entry into a license with respect to, such patents and patent applications. We cannot be certain that the drafting or prosecution of these patents and patent applications will result or has resulted in valid and enforceable patents. Further, since we do not always retain complete control over our ability to enforce our licensed patent rights against third-party infringement, we cannot be certain that our licensor will elect to enforce these patents to the extent that we would choose to do so, or in a way that will ensure that we retain the rights we currently have under the applicable license agreement. If our licensor fails to properly enforce the patents subject to our license agreement in the event of third-party infringement, our ability to retain our competitive advantage with respect to the applicable products may be materially and adversely affected.

Licensing of intellectual property is an important part of our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property that is subject to a license agreement, including, with respect to, among other things:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether our licensor had the right to grant the rights granted to us under the license agreement;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our involvement in the prosecution and enforcement of the licensed patents and our licensor's overall patent enforcement strategy;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and technologies, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and

- the amounts of royalties, milestones or other payments due under the license agreement.

In addition, we may become the owner of intellectual property that was obtained through assignments, which may be subject to re-assignment back to the original assignor upon our failure to prosecute or maintain such intellectual property, upon our breach of the agreement pursuant to which such intellectual property was assigned, or upon our bankruptcy.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or if intellectual property is re-assigned back to the original assignor, we may be unable to successfully develop and commercialize or continue selling products that utilize the affected intellectual property, any of which could impair our ability to execute our growth strategy and could have a material and adverse effect on our business, financial condition and results of operations.

We may not be able to protect and enforce our trademarks and trade names, or build name recognition in our markets of interest, thereby harming our competitive position.

We have not yet registered certain of our trademarks in all of our potential markets. If we apply to register these and other trademarks in the United States and other countries, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, the registered or unregistered trademarks or trade names that we own may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition. In addition, third parties may file for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our technologies, products or services. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Further, we may in the future enter into agreements with owners of such third party trade names or trademarks to avoid potential trademark litigation which may limit our ability to use our trade names or trademarks in certain fields of business.

In addition, opposition or cancellation proceedings may in the future be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. In addition, third parties may file first for our trademarks in certain countries. If they succeed in registering such trademarks, and if we are not successful in challenging such third party rights, we may not be able to use these trademarks to market our products in those countries. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Common Stock

We expect that the price of our Class A common stock will fluctuate substantially. You may not be able to sell the shares you purchase at or above the price you paid for such shares, and our common stock could be subject to delisting if its price falls too low.

The market price of our Class A common stock is likely to be highly volatile and may fluctuate substantially due to a variety of factors, many of which are outside of our control, including, among other things:

- our ability to successfully commercialize, market and sell our newly approved EluPro antibacterial envelope device;

- the volume and timing of sales of our products;
- the introduction of new products or product enhancements by us or others in our industry;
- disputes or other developments with respect to our or others' intellectual property rights;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- changes or proposed changes in laws or regulations or differing interpretations or enforcement thereof affecting our business;
- product liability claims, other litigation or regulatory investigations;
- annual or quarterly variations in our results of operations or those of others in our industry, or results of operations that otherwise vary from those expected by securities analysts and investors;
- publications, reports or other media exposure of our products or those of others in our industry, or of our industry generally;
- announcements by us or others in our industry, or by our or their respective suppliers, distributors or other business partners, regarding, among other things, significant contracts, price reductions, capital commitments or other business developments, the entry into or termination of strategic transactions or relationships, securities offerings or other financing initiatives, and public reaction thereto;
- additions or departures of key management personnel;
- changes in governmental regulations or in reimbursement;
- changes in earnings estimates or recommendations by securities analysts, or other changes in investor perceptions of the investment opportunity associated with our Class A common stock relative to other investment alternatives;
- the development and sustainability of an active trading market for our Class A common stock;
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and
- other factors discussed in this Part I, Item 1A. "Risk Factors" of our Annual Report.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our Class A common stock, regardless of our actual operating performance. If the market price of shares of our Class A common stock does not ever exceed the price you paid for your shares, you may not realize any return on your investment in us and may lose some or all of your investment.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources away from our business.

The listing of our common stock on the Nasdaq Capital Market ("Nasdaq") is subject to a number of conditions, including that the total market value of the Company's listed securities remain at or above a certain level. In the past, the Company has not maintained that required level and has been at risk of its common stock being delisted by Nasdaq. Although the Company was able to regain compliance with the rule and avoid having its common stock delisted, there is no guarantee that, in view of the volatility of the Company's stock and other factors, the Company might not run afoul of the market value listing condition or other similar listing conditions in the future. The delisting of the Company's common stock would have a material adverse effect on the liquidity of the common stock, and could have a material adverse effect on its price. Moreover, the threat of delisting could have similar consequences.

Our principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2024, our principal stockholder, HighCape Partners L.P. and its affiliates, held approximately 29.5% of our outstanding Class A common stock. As a result, HighCape Partners L.P. and its affiliates are able to significantly influence the management and affairs of our company and the outcome of most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the company, even if such change in control would benefit our other stockholders, thereby depriving our other stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets. Conversely, these stockholders may pursue acquisitions, divestitures and other transactions that, in their judgment, could enhance the value of their investment, even though such transactions might involve risks to you. Even in the absence of any actual conflict of interest, the degree of control possessed by these stockholders may affect the prevailing market price of our Class A common stock due to investors' perceptions that such conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders and may impair your ability to realize any return on your investment in us and may impair your ability to avoid losing some or all of your investment.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our Class A common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our outstanding Class A common stock in the public market could occur at any time. In addition, conversions of a substantial number of shares of our outstanding Class B common stock into Class A common stock and sales of such converted shares of our Class A common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of such shares intend to sell shares, could reduce the market price of our Class A common stock.

As of December 31, 2024, we had outstanding approximately 30.9 million shares of Class A common stock, of which 21.0 million shares of our Class A common stock were freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the "Securities Act"), by persons other than our "affiliates," as that term is defined under Rule 144 of the Securities Act and approximately 9.9 million shares were held by our affiliates and eligible for resale subject to volume, manner of sale and other limitations under Rule 144. Additionally, we had outstanding approximately 4.3 million shares of Class B common stock which may be converted on a one to one basis into shares of Class A common stock, of which all were freely tradable and held by persons other than our "affiliates." We also have registered shares of our Class A common stock issued and available for issuance under our equity compensation plans, which can be freely sold in the public market, subject to vesting requirements and volume limitations applicable to affiliates.

If these shares are sold, or if it is perceived that they will be sold, in the public market, or when we are required to register the sale of our stockholders' remaining shares of our Class A common stock, the trading price of our Class A common stock could decline. A decline in the trading price of our Class A common stock might impede our ability to raise capital through the issuance of additional shares of our Class A common stock or other equity securities and may impair your ability to sell shares of our Class A common stock at a price higher than the price you paid for them or at all.

The dual class structure of our common stock and the option of the holders of shares of our Class B common stock to convert into shares of our Class A common stock may limit your ability to influence corporate matters.

Our Class A common stock has one vote per share, while our Class B common stock is non-voting. Nonetheless, each share of our Class B common stock may be converted at any time into one share of Class A common stock at the option of its holder, subject to the limitations provided for in our certificate of incorporation that prohibit the conversion of our Class B common stock into shares of Class A common stock to the extent that, upon such conversion, such holder would beneficially own in excess of 4.9% of any class of our securities registered under the Exchange Act. Consequently, if holders of Class B common stock exercise their option to make this conversion, such exercise will have the effect of increasing the relative voting power of those prior holders of our Class B common stock (subject to the ownership limitation described in the previous sentence) and increasing the number of outstanding shares of our voting common stock, and correspondingly decreasing the relative voting power of the current holders of our Class A common stock, which may limit your ability to influence corporate matters. Because our Class B common stock is generally non-voting, stockholders who own more than 10% of our common stock overall but 10% or less of our Class A common stock will not be required to report changes in their ownership from transactions in our Class B common stock pursuant to Section 16(a) of the Exchange Act and would not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

You may be diluted by the future issuance of additional common stock in connection with any future public or private offerings of our securities, our incentive plans, acquisitions or otherwise.

As of December 31, 2024, we had 169,102,768 shares of Class A common stock authorized but unissued and 15,686,594 shares of Class B common stock authorized but unissued. We are authorized under our certificate of incorporation to issue these shares of common stock and other securities convertible into or exercisable or exchangeable for shares of our common stock for the consideration and on the terms and conditions established by our board of directors in its sole discretion, whether in connection with acquisitions or otherwise. As of December 31, 2024, we had a total of 3,220,991 shares of our Class A common stock issuable upon the exercise of outstanding options under our 2015 Stock Option/Stock Issuance Plan, as amended (the "2015 Plan") and our Amended and Restated 2020 Incentive Award Plan (the "2020 Plan") at a weighted average exercise price of $5.23 per share, 1,806,344 of which were vested as of such date, 1,417,123 shares of Class A common stock issuable upon the settlement of RSUs granted under our 2020 Plan to several of our executive officers, employees and consultants, 396,561 additional shares of our Class A common stock reserved for future issuance under our 2020 Plan, not including the additional shares of Class A common stock that will be reserved for future issuance under our 2020 Plan pursuant to provisions in the 2020 Plan that automatically increase the number of shares of our Class A common stock reserved for future issuance thereunder, and 471,126 shares of our Class A common stock available for future issuance under our 2020 Employee Stock Purchase Plan (the "2020 ESPP"), not including the additional shares of Class A common stock that will be reserved for future issuance under our 2020 ESPP pursuant to provisions in the 2020 ESPP that automatically increase the number of shares of our Class A common stock reserved for future issuance thereunder. Additionally, as of December 31, 2024, we had total warrants outstanding of 4,486,295 to purchase our Class A common stock comprised of up to 187,969 warrants issued to the lender under the SWK Loan Facility and 4,298,326 warrants issued to investors in our September 2023 Class A common stock private placement or June 2024 Class A common stock registered direct offering. In addition, subsequent to the end of 2024, on February 4, 2025, the Company sold, in a registered direct offering, an aggregate of 5,520,000 shares of Class A common stock and prefunded warrants to purchase up to an aggregate of 480,000 shares of Class A Common Stock. Any additional shares of common stock that we issue, including under our 2020 Plan, 2020 ESPP or other equity incentive plans that we may adopt in the future, or as a result of any exercise of outstanding warrants, would dilute the percentage ownership and voting power held by investors who purchase our common stock. In the future, we may also issue additional securities if we need to raise capital to finance our ongoing operations, including our efforts to commercialize, market and sell EluPro, or in connection with acquisitions or other strategic investments, which securities could constitute a material portion of our then-outstanding shares of our common stock.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act. Emerging growth companies and smaller reporting companies may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly-traded entities that are not emerging growth companies or smaller reporting companies.

With respect to emerging growth companies, these exemptions include:

- the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with a correspondingly reduced Management's Discussion and Analysis of Financial Condition and Results of Operations;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);

- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency" and "say-on-golden parachutes"; and

- not being required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

We have elected to take advantage of certain of these reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in the future. As a result, the information that we provide to our stockholders may be different than the information you might receive from other public reporting companies in which you hold equity interests. In addition, the JOBS Act permits emerging growth companies to delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies. We cannot predict whether investors will find our common stock less attractive because of our reliance on these exemptions. If some investors do find our common stock less attractive, there may be a less active trading market for our Class A common stock and our stock price may be reduced or more volatile.

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.

Even after we cease to be an emerging growth company, we will still be a smaller reporting company until such time as (i) we determine that the market value of the voting and non-voting shares held by non-affiliates is $250 million or more but less than $700 million as of the last business day of our second fiscal quarter and our annual revenues are $100 million or more during our most recently completed fiscal year, or (ii) the market value of the voting and non-voting shares held by non-affiliates is $700 million or more measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies, including reduced financial and executive compensation disclosure. In addition, even if we cease to be an emerging growth company, we will remain exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act provided we do

not qualify as an "accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if our annual revenue was $100 million or more during our most recently completed fiscal year and the market value of our common equity held by non-affiliates is $75 million or more as of the last business day of our most recently completed second fiscal quarter, and only after we have been subject to the reporting requirements of the Exchange Act for a period of at least 12 calendar months.

We will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices. Failure to comply may result in delisting of our common stock, government penalties or other materially adverse consequences.

As a public company, and particularly after we are no longer an emerging growth company, we incur and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives, which has and we expect will continue to divert their attention away from our core business operations and revenue-producing activities. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, which requires us to incur substantially higher costs to obtain the same or similar coverage or accept reduced policy limits and coverage, which in turn could also make it more difficult for us to attract and retain qualified individuals to serve on our board of directors and as our executive officers.

We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, if we fail to comply with these rules and regulations, we could be subject to a number of penalties, including the delisting of our Class A common stock, fines, sanctions or other regulatory action or civil litigation.

Governance requirements include matters such as the composition of our board of directors and its committees, and include matters such as the degree of independence of a director from the Company. Because of the Company's size and risk profile, among other reasons, it may be more difficult for the Company to recruit qualified directors than other companies. In the past, the Company has been out of compliance with certain board composition rules, which put the Company's common stock at risk of being delisted. Although the Company regained compliance with that rule and avoided delisting of its common stock, there can be no guarantee that the Company will be able to maintain such compliance, which could put the Company's common stock at risk of delisting again. The delisting of the Company's common stock would have a material adverse effect on the liquidity of the common stock, and could have a material adverse effect on its price. Moreover, the threat of delisting could have similar consequences.

If we fail to comply with these rules and regulations, we could be subject to a number of penalties, including the delisting of our Class A common stock, fines, sanctions or other regulatory action or civil litigation.

Provisions in our certificate of incorporation and bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our Class A common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current

management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created

by the Securities Act, the Exchange Act, the rules and regulations thereunder or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above.

We believe these provisions benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees or agents, which may discourage such lawsuits against us and our directors, officers and other employees and agents.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

General Risk Factors

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our business, financial condition and results of operations.

U.S. GAAP, and related accounting pronouncements, implementation guidelines and interpretations with regard to a wide range of matters that are relevant to our business are highly complex. These matters include, but are not limited to, revenue recognition, leases, income taxes, impairment of goodwill and long-lived assets, warrants and stock-based compensation. Changes in these rules, guidelines or interpretations could significantly change our reported or expected financial performance or financial condition.

In addition, the preparation of financial statements in conformity with GAAP requires management to make assumptions, estimates and judgments that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities and equity, and the amount of net sales and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We have designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Failure to comply with requirements to design, implement and maintain effective internal control over financial reporting could have a material adverse effect on our business and stock price.

As a public company, we are required to evaluate our internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404(a) of the Sarbanes-Oxley Act, or Section 404.

As a public company, we have significant requirements for enhanced financial reporting and internal controls. The process of designing, implementing and maintaining effective internal controls is a continuous effort that will require us to anticipate and react to changes in our business and the economic and regulatory environments. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. If we are unable to establish or maintain appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations on a timely basis, result in material misstatements in our consolidated financial statements and adversely affect our operating results. In addition, we are required, pursuant to Section 404, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation and testing. Testing and maintaining internal controls may divert our management's attention from other matters that are important to our business. In addition, once we are no longer an emerging growth company, provided we then qualify as an "accelerated filer" as defined in Rule 12b-2 under the Exchange Act, we will be required to include in the annual reports that we file with the SEC an attestation report on our internal control over financial reporting issued by our independent registered public accounting firm.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the remediation of any deficiencies identified by our independent registered public accounting firm in connection with the issuance of their attestation report. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Any material weaknesses could result in a material misstatement of our annual or quarterly consolidated financial statements or disclosures that may not be prevented or detected.

Furthermore, we may not be able to conclude, on an ongoing basis, that we have effective internal control over financial reporting in accordance with Section 404, or our independent registered public accounting firm may not be able to issue an unqualified attestation report once we become subject to the corresponding requirement under Section 404. If either we are unable to conclude that we have effective internal control over financial reporting or our independent registered public accounting firm is unable to provide us with an unqualified report, investors could lose confidence in our reported financial information, which could have a material adverse effect on the trading price of our Class A common stock.

If our operating and financial performance in any given period does not meet the guidance we provide to the public, the market price of our Class A common stock may decline.

We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised of forward-looking statements subject to certain risks and uncertainties similar to those described in this Annual Report and any additional risks and uncertainties described from time to time in our public filings or other public statements. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic uncertainty. If, in the future, we provide guidance, and our operating and/or financial results for a particular period do not meet such guidance or the expectations of investment analysts, or if we reduce, withdraw or otherwise change our guidance for future periods, or stop providing guidance, the market price of our Class A common stock will likely decline.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our Class A common stock, our stock price and trading volume would likely decline.

The trading market for our Class A common stock will be influenced by the research and reports that industry or securities analysts publish about us and our business. We do not control these analysts. We may be slow to attract research coverage and the analysts, who publish information about our Class A common stock, may have had relatively little experience with us or our industry, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. If no or few securities or industry analysts provide coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our financial performance, our stock price or otherwise, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline and result in the loss of all or a part of your investment in us.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management

We recognize the critical importance of maintaining the safety and security of our information technology systems and data, and we maintain a cybersecurity risk management program as a part of our overall risk management program that is focused on identifying, assessing and managing cybersecurity risk. Key elements of that program include:

- Alignment with the National Institute of Standards and Technology Cybersecurity Framework to prevent, detect and respond to cyberattacks;
- Engaging external cybersecurity experts in incident response development and management;
- An information security training program instructing company employees with access to our networks how to be aware of, and help defend against cybersecurity risks;
- Evaluating the cybersecurity risk of third party service providers; and
- Business continuity plans and critical recovery backup systems.

Our cybersecurity risk management program is supervised by our Director of Information Systems, who has over 20 years of relevant experience, and whose team is responsible for leading enterprise-wide information security strategy, policy, standards, architecture, and processes, as well as managing the Company's information security and risk management awareness program.

Cybersecurity Incident Response Process

We maintain and regularly update a cybersecurity incident response plan that outlines the steps we take to identify, investigate and take action in response to any potentially material cybersecurity incidents. Our incident response plan is designed to ensure that our Director of Information Systems and members of our senior management team are timely informed of and consulted with respect to any potentially material cybersecurity incidents.

Board Oversight of Cyber Risk

Our Board is engaged in the oversight of cybersecurity threat risk management. As reflected in the Audit Committee's charter, the Board has specifically delegated responsibility for oversight of cybersecurity matters to the Audit Committee, comprised solely of independent directors. The Audit Committee reviews and discusses our cybersecurity risks and threats and provides advice and guidance on the adequacy of the Company's initiatives on, among other things, cybersecurity risk management. Periodic updates are provided to the Audit Committee on, among other things, our cybersecurity risks and threats, the status of projects to strengthen the Company's information security systems, and the emerging threat landscape. We also engage third parties to periodically evaluate and audit aspects of our information security programs, including by conducting vulnerability assessments and penetration testing. These partnerships enable us to leverage specialized knowledge and insights, with the goal of ensuring our cybersecurity strategies and processes remain current. The results of those findings are reported to the Audit Committee and used to help identify potentially material risks and prioritize certain security initiatives.

We face a number of cybersecurity risks in connection with our business. Due to evolving cybersecurity threats, it has been and will continue to be difficult to prevent, detect, mitigate, and remediate cybersecurity incidents. We may also rely on information technology and third-party vendors to support our operations, including to collect and store sensitive data. Despite ongoing efforts to continued improvement of our ability to protect against cyber incidents, we may not be able to protect all information systems, and such incidents may lead to reputational harm, revenue and client loss, legal actions, statutory penalties, among other consequences.

Based on the information we have as of the date of this Annual Report, we do not believe that any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect the Company's business strategy, results of operations or financial position. See Item 1A, Risk Factors, of this Annual Report for further discussion of cybersecurity risks.

Item 2. Properties.

Our principal executive office at December 31, 2024 is located in Silver Spring, Maryland, where we lease approximately 5,052 square feet of office and laboratory space under a lease that expires in May 2025. We also occupy approximately 12,888 square feet of manufacturing and office space in Roswell, Georgia under a lease that expires in July 2029 (with an early termination right in October 2026), and 2,391 square feet for administrative space in San Diego, California that expires in February 2026. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed. Additionally, in March 2025, we signed a lease for 26,598 square feet in Gaithersburg, Maryland. This new facility will become our principal executive office and be utilized for office, manufacturing and laboratory space. We expect to occupy this new facility in the second quarter of 2025. This lease expires in January 2036 with early termination dates in 2029 and 2033.

Item 3. Legal Proceedings.

From time to time, we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. For information about legal proceedings in which we are involved, see Note 17 to the consolidated financial statements included elsewhere in this Annual Report.

Item 4. Mine Safety Disclosure.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Class A common stock is traded on The Nasdaq Capital Market under the symbol "ELUT."

Stockholders

As of March 3, 2025, there were approximately 29 holders of record of our Class A common stock and two affiliated holders of record of our Class B common stock. This number does not include "street name" or beneficial holders, whose shares are held of record by banks, brokers, financial institutions and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, our ability to pay cash dividends is currently restricted by the terms of the agreements governing our SWK Loan Facility.

Equity Compensation Plans

The information required by Item 5 regarding equity compensation plans is incorporated herein by reference to Part III, Item 12 in this Annual Report.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

None.

Item 6. [Reserved]

Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements reflecting our current expectations, estimates, plans and assumptions concerning events and financial trends that involve risks and may affect our future operating results and financial position. Actual results and the timing of events may differ materially from those contained in these forward-looking statements due to a number of factors, including those discussed in the sections entitled "Forward-Looking Statements," "Risk Factors Summary" and in Part I, Item 1A. "Risk Factors" of this Annual Report.

Overview

At Elutia, our mission is to humanize medicine so that patients can thrive without compromise. As a commercial-stage company, we seek to leverage our unique understanding of biologics combined with local drug delivery to improve the interaction between implanted medical devices and patients by reducing complications associated with these surgeries. These complications include infection, device migration, erosion, implant rejection, non-union of implants, fibrosis and scar formation.

We estimate that in 2024, more than 700,000 surgical procedures were performed annually in the United States involving the implantation of medical devices such as pacemakers, defibrillators, neurostimulators or tissue expanders for breast reconstruction. This number has been driven by advances in medical device technologies, reimbursement models focused on patient outcomes, and an aging population with a growing incidence of comorbidities, including diabetes, obesity and cardiovascular and peripheral vascular diseases. These comorbidities can exacerbate various immune responses and contribute to other complications upon device implant.

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

In Device Protection, we sell EluPro, a unique bioenvelope designed to mitigate CIED complications including infection, device migration and erosion. The bioenvelope features a biomatrix comprised of ECM, which supports healthy wound healing and may facilitate re-operative procedures by reducing scar formation and fibrosis. Additionally, EluPro is embedded with the powerful antibiotics rifampin and minocycline, which are gradually released into the surrounding tissue over several weeks post-implantation to provide antimicrobial protection. Currently, EluPro is the only drug-eluting biomatrix ("DEB") offering in the U.S. implantable electronic device protection market. Alongside EluPro, we market the CanGaroo bioenvelope, our first generation product, which uses the same biomatrix but does not contain antibiotics.

In Women's Health, we have developed both patented and proprietary technologies, culminating in the creation of SimpliDerm—a novel biological matrix that leverages the inherent science of natural healing processes. SimpliDerm's design uses human-based hydrated acellular dermal matrix with heightened structural integrity and superior handling capabilities, which may mitigate inflammation and enhance tissue incorporation, leading to a better healing experience as compared to other ADM products. We believe that these acellular dermal matrices represent an ideal choice for tissue repair and reconstruction, finding applications in fields such as breast reconstruction, sports medicine, hernia repair and trauma reconstruction.

With respect to pipeline products, we plan to expand our DEB offerings beyond EluPro and are pioneering DEBs to help solve problems unaddressed by available options. We also intend to leverage our DEB platform technology by developing and commercializing products for markets with similar unmet needs, including breast reconstruction and neurostimulation.

We sell EluPro and CanGaroo in the United States using our direct sales force and our commercial partner, Boston Scientific, which acts as a sales agent and gives us access to approximately 900 sales representatives and clinical specialists to further expand our footprint and accelerate our sales. Our primary customers are electrophysiologists, cardiac surgeons and neurosurgeons. Our direct sales force is focused on gaining additional market access and driving market penetration, not only by selling our products, but also, where appropriate, by managing our commercial partners and providing technical assistance for selling our products. Our sales team provides the critical knowledge of the advantages that EluPro and CanGaroo provide for patients over those of our competitors. We ship the product directly to hospitals.

We sell SimpliDerm through independent sales agents to plastic and reconstructive surgeons. Additionally, in March 2023, we entered into an agreement with Sientra, a medical aesthetics company uniquely focused on plastic surgery, to expand the distribution of SimpliDerm. In April 2024, such agreement was acquired by Tiger in connection with their asset acquisition of Sientra. Under the agreement terms, Elutia has granted Tiger certain non-exclusive rights in the United States to market, sell and distribute SimpliDerm. This agreement with Tiger gives us access to approximately 50 sales representatives to further expand our footprint and accelerate our sales.

We also sell legacy products into the Cardiovascular market. In Cardiovascular, we sell our specialized porcine small intestine submucosa, which is based on the same the biomatrix used to make EluPro and 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 distribution agreement with LeMaitre Vascular. This agreement also provided LeMaitre with an option to acquire the Cardiovascular product line, exercisable through March 2026.

We produce 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, the porcine tissue supplier of our raw materials for our CanGaroo and cardiovascular products. SimpliDerm has historically been processed by us at our Richmond, California facility; however, that facility was included with the divestiture of the Orthobiologics Business, and SimpliDerm is now provided to us on a go-forward basis through a long-term supply agreement with the purchaser of the Orthobiologics Business, Berkeley Biologics, LLC ("Berkeley"). We also intend to develop our own in-house capability for the production of SimpliDerm. To this end, in March 2025, we signed a lease for 26,598 square feet in Gaithersburg, Maryland for purposes of, among other things, the internal production of SimpliDerm. We expect to be able to internally produce SimpliDerm by the third quarter of 2025.

We have focused much of our attention recently on EluPro, which was cleared for marketing by the FDA in June 2024 and is indicated for use with implantable electronic devices including cardiac and neurostimulator devices. We believe the Company's success is highly dependent on the successful commercialization, marketing and sale of EluPro, as well as the extension of our DEB technology into potential adjacent applications. Furthermore, we believe the commercialization and marketing efforts with respect to EluPro will require significant investments in time and resources. However, there can be no assurance that we will have or be able to obtain sufficient resources to make the necessary investments in order to increase the sales and market penetration for EluPro, or that if made, such investments will yield the results sought.

Discontinued Operations – Sale of Orthobiologics Business

On November 8, 2023, we completed the sale of substantially all of the assets relating to our former Orthobiologics Business to Berkeley. The Orthobiologics Business was comprised of assets relating to researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing our Orthobiologics products, and the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products. The assets sold represent the entirety of our Orthobiologics segment. In the sale, we received $14.6 million, and we may earn up to an additional $20 million, in the aggregate, in the form of earn-out payments. The earn-out payments are equal to 10% of the actual revenue earned by Berkeley in each of the five years after the closing of the sale from sales of specified Orthobiologics products under the purchase agreement (including improvements, modifications, derivatives and enhancements related to those products). There have been no earn-out payments made to date. Additionally, the purchase agreement provides for a customary indemnity holdback in the amount of $1.5 million to be retained by Berkeley for 24 months after close. The indemnity holdback is available as a source of recovery for Berkeley for claims of indemnification under the purchase agreement, and some or all of the holdback may be retained by Berkeley if Berkeley is successful in asserting a claim or claims for indemnification against us. In the purchase agreement, the Company has retained the liabilities arising out of the viable bone matrix ("VBM") and FiberCel matters, as described in Note 17, both of which products were part of the Orthobiologics Business. We recognized a gain of $6.0 million on the sale of the Orthobiologics Business in 2023 and an additional gain of $0.2 million in 2024 from an adjustment payment related to the final working capital received by Berkeley at the sale date. Should we receive incremental proceeds in the future through an earn-out payment or payment of the holdback amount, an additional gain will be recorded upon the receipt of such amounts.

Product Recalls

In June 2021, we issued a voluntary recall pertaining to a single donor lot of our FiberCel Fiber Viable Bone Matrix, a bone repair product formerly manufactured under a contract with Medtronic PLC, which also distributed the product. The recall was issued after learning of postsurgical infections reported in several patients treated with the product,

including some patients that tested positive for tuberculosis. Additionally, in July 2023, we announced a voluntary recall of a single lot of one of our VBM products and the market withdrawal of all of our VBM products produced after a specified date. Notice of the voluntary recall was issued to centers after we learned of post-surgical tuberculosis infections in two patients treated with product from a single donor lot of our VBM product. Both of these products were part of our Orthobiologics Business, which we have fully divested as described above. These product recalls and the associated legal proceedings in which we are involved as well as their possible future financial implications are described in further detail in Part I, Item 3, "Legal Proceedings" and Note 17 to the consolidated financial statements, included elsewhere in this Annual Report.

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

Impact of Inflation

Inflationary factors, such as increases in our cost of goods sold or other operating expenses, may adversely affect our operating results. While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we do not believe inflation had a material effect on our financial condition or results of operations during the years ended December 31, 2024 and 2023. We cannot assure you, however, that we will be able to increase the selling prices of our products or reduce our operating expenses in an amount sufficient to offset the effects future inflationary pressures may have on our gross margin. Accordingly, we cannot assure you that our financial condition and results of operations will not be materially impacted by inflation in the future.

Components of Our Results of Operations

Net Sales

We recognize revenue on the sale of our products. Our Device Protection products are sold to hospitals and other healthcare facilities primarily through our direct sales force, commercial partners or independent sales agents. Our cardiovascular products are sold domestically through a distribution agreement with LeMaitre Vascular and were previously sold internationally through commercial partners. Our Women's Health products are sold directly to hospitals and other healthcare facilities through independent sales agents or through our distribution agreement with Tiger.

Expenses

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

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 Orthobiologics facility in Richmond, California. The Roswell facility has additional capacity, which if utilized, would further leverage our fixed overhead. Cost of goods sold also includes the amortization of intangibles generated from the CorMatrix Acquisition in 2017.

Sales and Marketing Expenses

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

General and Administrative Expenses

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

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of salaries and fringe benefits, laboratory supplies, clinical studies and outside service costs. Over the last several years, our product development efforts have primarily related to activities associated with the development of EluPro (referred to as CanGarooRM during development), our initial DEB product offering. See above Part I, Item 1, "Business" for discussion of the June 2024 FDA clearance of EluPro. Future development efforts are expected to focus on (i) expanding our EluPro offering with additional sizes and product features, (ii) developing new products within the DEB product portfolio and (iii) conducting clinical studies to validate the performance characteristics of our products and to capture patient data necessary to support our commercial efforts.

Litigation Costs, net

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

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

	Year Ended December 31,					
	2024		2023		Change 2023 / 2024	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Net sales	$ 24,375	100.0 %	$ 24,745	100.0 %	$ (370)	(1.5)%
Cost of goods sold	13,668	56.1 %	13,692	55.3 %	(24)	(0.2)%
Gross profit	10,707	43.9 %	11,053	44.7 %	(346)	(3.1)%
Sales and marketing	12,546	51.5 %	13,087	52.9 %	(541)	(4.1)%
General and administrative	18,659	76.5 %	14,104	57.0 %	4,555	32.3 %
Research and development	3,785	15.5 %	4,399	17.8 %	(614)	(14.0)%
Litigation costs, net	11,368	46.6 %	9,989	40.4 %	1,379	13.8 %
Total operating expenses	46,358	190.2 %	41,579	168.0 %	4,779	11.5 %
Loss from continuing operations	(35,651)	(146.3)%	(30,526)	(123.4)%	(5,125)	(16.8)%
Interest expense	4,779	19.6 %	5,796	23.4 %	(1,017)	(17.5)%
Loss on revaluation of warrant liability	14,878	61.0 %	4,140	16.7 %	10,738	259.4 %
Other (income) expense, net	(1,186)	(4.9)%	759	3.1 %	(1,945)	NM
Loss before provision of income taxes	(54,122)	(222.0)%	(41,221)	(166.6)%	(12,901)	(31.3)%
Income tax expense	7	0.0 %	28	0.1 %	(21)	(75.0)%
Net loss from continuing operations	(54,129)	(222.1)%	(41,249)	(166.7)%	(12,880)	(31.2)%
Income from discontinued operations	180	0.7 %	3,593	14.5 %	(3,413)	(95.0)%
Net loss	**$ (53,949)**	**(221.3)%**	**$ (37,656)**	**(152.2)%**	**$ (16,293)**	**(43.3)%**

NM = not meaningful

Net Sales

Net sales information for our products is summarized as follows:

	Years Ended December 31,					
	2024		2023		Change	
(in thousands, except percentages)	Amount	% of Net Sales	Amount	% of Net Sales	$	%
Products:						
Device Protection	$ 9,907	40.6 %	$ 9,401	38.0 %	$ 506	5.4 %
Women's Health	11,553	47.4 %	10,304	41.6 %	1,249	12.1 %
Cardiovascular	2,915	12.0 %	5,040	20.4 %	(2,125)	(42.2)%
Total Net Sales	**$ 24,375**	**100.0 %**	**$ 24,745**	**100.0 %**	**$ (370)**	**(1.5)%**

Total net sales decreased $0.4 million, or 1.5%, to $24.4 million in the year ended December 31, 2024 compared to $24.7 million in the year ended December 31, 2023. Revenues from Device Protection and Women's Health increased compared to the corresponding period of the prior year due to volume growth, but such increases were offset by a decrease in revenues from Cardiovascular due to lower sales volumes in the current year as well as the commencement in April 2023 of our distribution agreement with LeMaitre Vascular which provides for sales at a contracted price to the distributor versus sales prior to such agreement being made at end-user pricing. Revenues from EluPro, which are within the Device Protection segment, commenced in September 2024 (after its FDA clearance in June 2024) and contributed to the segment's current year sales increase. EluPro revenues as well as overall Device Protection revenues are expected to continue to grow as we further commercialize this product in 2025.

Cost of Goods Sold

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

	Year Ended December 31,					
	2024		2023			
(in thousands, except percentages)	Amount	Gross Margin %	Amount	Gross Margin %	Change 2023 / 2024 $	Change 2023 / 2024 %
Products:						
Device Protection	$ 3,594	63.7 %	$ 2,836	69.8 %	$ 758	(6.1)%
Women's Health	5,568	51.8 %	5,902	42.7 %	(334)	9.1 %
Cardiovascular	1,108	62.0 %	1,556	69.1 %	(448)	(7.1)%
Cost of goods sold, excluding intangible asset amortization	10,270	57.9 %	10,294	58.4 %	(24)	(0.5)%
Intangible asset amortization expense	3,398	(13.9)%	3,398	(13.7)%	—	(0.2)%
Total Cost of Goods Sold	**$ 13,668**	**43.9 %**	**$ 13,692**	**44.7 %**	**$ (24)**	**(0.7)%**

Total cost of goods sold was unchanged at $13.7 million for both the years ended December 31, 2024 and 2023. Gross margin was 43.9% in the year ended December 31, 2024 compared to 44.7% in the year ended December 31, 2023. Gross margin, excluding intangible asset amortization, was 57.9% in the year ended December 31, 2024 compared to 58.4% in the year ended December 31, 2023. The slight decline in gross margin was primarily due to the Cardiovascular business which decreased due to the commencement of the LeMaitre Vascular distribution agreement described above. Gross margin in the Device Protection segment is expected to slightly decline in 2025 versus 2024 due to a higher percentage of the revenues in such segment coming from EluPro and shifting away CanGaroo. Until we can achieve certain economies of scale and fully implement other cost reduction opportunities, our gross margins on EluPro will be lower than CanGaroo.

Operating Expenses

Sales and Marketing

Sales and marketing expenses decreased $0.6 million, or 4.1%, to $12.5 million in the year ended December 31, 2024 compared to $13.1 million in the year ended December 31, 2023. As a percentage of sales, sales and marketing expenses decreased to 51.5% in the year ended December 31, 2024 from 52.9% in the year ended December 31, 2023. The decrease in expense was largely attributable to a reduction in force which occurred in the first quarter of 2023 and primarily impacted certain members of sales and marketing management. Such decrease from the reduction in force was partially offset by an increase in expense from the non-cash equity compensation grants made in January 2024. We anticipate that our sales and marketing costs will increase in 2025 versus 2024 as we continue to commercialize EluPro.

General and Administrative

G&A expenses increased $4.6 million, or 32.3%, to $18.7 million in the year ended December 31, 2024 compared to $14.1 million in the year ended December 31, 2023. As a percentage of net sales, G&A expenses increased to 76.5% in the year ended December 31, 2024 from 57.0% in the year ended December 31, 2023. The increase in expense resulted largely from the non-cash equity compensation grants made in January 2024.

Research and Development

R&D expenses decreased to $3.8 million in the year ended December 31, 2024 compared to $4.4 million in the year ended December 31, 2023. Over the last several years, our R&D efforts have primarily related to activities associated with the development of EluPro (referred to as CanGarooRM during development). With the FDA's approval of EluPro in June 2024, the related costs were less in the year ended December 31, 2024 versus the prior year's comparable period.

Increases in non-cash equity compensation recognized in 2024 served to partially offset the EluPro development cost decrease noted above.

Litigation Costs, net

Litigation costs, net increased to $11.4 million in the year ended December 31, 2024 compared to $10.0 million in the year ended December 31, 2023. The continued evaluation and settlements of our FiberCel and VBM contingent litigation liabilities along with increases in legal defense costs resulted in higher expenses in the 2024 period. Such increase was partially offset by our recovery in September 2024 of $1.6 million in connection with the settlement of certain disputed indemnity and contribution amounts related to the FiberCel Litigation. See further discussion in Note 17 to the consolidated financial statements included elsewhere in this Annual Report.

Interest Expense

Interest expense was approximately $4.8 million in the year ended December 31, 2024 compared to $5.8 million in the year ended December 31, 2023. The decrease was primarily due to lower principal outstanding on the SWK debt in the current year period as a result of mandatory repayments in connection with our sale of the Orthobiologics Business in November 2023.

Discontinued Operations

Income from discontinued operations for the year ended December 31, 2024 was $0.2 million and the loss from discontinued operations for the year ended December 31, 2023 was $3.6 million. See Notes 1 and 4 to the consolidated financial statements included elsewhere in this Annual Report for further discussion.

Other (Income) Expense, net

Other (income) expense, net was income of approximately $1.2 million in the year ended December 31, 2024 and was primarily attributable to the $1.4 million gain on the revaluation of our Revenue Interest Obligation to Ligand. See Note 11 to the consolidated financial statements included elsewhere in this Annual Report for additional information.

Other (income) expense, net was an expense of approximately $0.8 million in the year ended December 31, 2023 and was attributable to the transaction fees incurred in connection with the 2023 Private Offering which were allocated to the Common Warrants (defined below) and Prefunded Warrants (defined below). See Note 14 to the consolidated financial statements included elsewhere in this Annual Report for additional information.

Non-GAAP Financial Measures

In this Part II. Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of the Annual Report, 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, 2024 and 2023 to the most directly comparable GAAP financial measure, which is our GAAP gross margin (in thousands).

	Year Ended December 31,	
	2024	2023
Net sales	$ 24,375	$ 24,745
Cost of goods sold	13,668	13,692
Gross profit	10,707	11,053
Intangible asset amortization expense	3,398	3,398
Gross profit, excluding intangible asset amortization	$ 14,105	$ 14,451
Gross margin	43.9 %	44.7 %
Gross margin, excluding intangible asset amortization	57.9 %	58.4 %

Seasonality

Historically, we have experienced seasonality in our first and fourth quarters, and we generally expect this trend to continue but may also see quarter-to-quarter fluctuations that are inconsistent with this trend. 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, 2024, we had cash and cash equivalents of approximately $13.2 million. Since inception, we have financed our operations primarily through amounts borrowed under our credit facilities, proceeds from our initial public offering ("IPO"), sales of our products and more recently, the sale of our Orthobiologics Business and proceeds from a follow-on offering and private placements of our common stock and warrants. Our historical cash outflows have primarily been associated with acquisitions and integration, manufacturing and administrative costs, general and marketing, research and development, clinical activity, purchase of property and equipment used in our production activities, litigation defense and settlement costs and investing in our commercial infrastructure through our direct sales force and our commercial partners in order to expand our presence and to promote awareness and adoption of our products. Such commercial infrastructure costs are likely to become more significant in the future as we further commercialize the newly approved EluPro product. As of December 31, 2024, our accumulated deficit was $229.6 million.

Subsequent to year-end, on February 4, 2025, we sold, in a registered direct offering ("2025 Registered Offering") an aggregate of (i) 5,520,000 shares of our Class A common stock and (ii) prefunded warrants ("2025 Prefunded Warrants") to purchase up to an aggregate of 480,000 shares of Class A Common Stock. The public offering price for each share of Class A Common Stock was $2.50, and the public offering price for each 2025 Prefunded Warrant was $2.499, for aggregate gross proceeds of approximately $15.0 million, before deducting offering expenses. The 2025 Prefunded Warrants have an exercise price of $0.001 per share of Class A Common Stock, are exercisable immediately and will expire when exercised in full.

On June 18, 2024, we sold, in a registered direct offering ("2024 Registered Offering") an aggregate of (i) 3,175,000 shares of our Class A common stock and (ii) prefunded warrants ("2024 Prefunded Warrants") to purchase up to an aggregate of 725,000 shares of Class A Common Stock. The public offering price for each share of Class A Common

Stock was $3.40, and the public offering price for each 2024 Prefunded Warrant was $3.399, for aggregate gross proceeds of approximately $13.3 million, before deducting offering expenses. The 2024 Prefunded Warrants have an exercise price of $0.001 per share of Class A Common Stock, are exercisable immediately and will expire when exercised in full.

On September 21, 2023, we sold, in a private offering ("Private Offering") an aggregate of (i) 6,852,811 units ("Common Units"), each comprised of (a) one share of our Class A common stock and (b) a warrant ("Common Warrant") to purchase one and one half shares of Class A Common Stock, and (ii) 503,058 units (the "Prefunded Units"), each comprised of (a) a prefunded warrant ("2023 Prefunded Warrant") to purchase one share of Class A Common Stock, and (b) a Common Warrant. The Common Units were sold at a purchase price of $1.4275 per unit, and the 2023 Prefunded Units were sold at a purchase price of $1.4265 per unit, for aggregate gross proceeds of approximately $10.5 million, before deducting offering expenses. Each Common Warrant was exercisable until July 31, 2024, the date which was 30 trading days after the clearance by the FDA of the Company's EluPro product, at an exercise price per share of $1.4275. All Common Warrants were exercised by such date yielding exercise proceeds of $15.7 million in 2024. Certain of these exercises ultimately resulted in their conversion to 2023 Prefunded Warrants. Each 2023 Prefunded Warrant is exercisable at any time at a nominal exercise price per share of $0.001 (with the remainder of the exercise price per share of Class A Common Stock having been prefunded to us).

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

In order to mitigate the current and potential future liquidity issues caused by the matters noted above, we may seek to raise capital through the issuance of common stock, such as the 2025 Registered Offering, 2024 Registered Offering and Private Offering described above, pursue asset sale or other transactions, such as the sale of the Orthobiologics Business described above. However, such transactions may not be successful, and we may not be able to raise additional equity, refinance our debt instruments, or sell assets on acceptable terms, or at all. As such, based on our current operating plans, we believe there is uncertainty as to whether our future cash flows along with our existing cash, issuances of additional equity and cash generated from expected future sales will be sufficient to meet our anticipated operating needs through twelve months from the financial statement issuance date. Due to these factors, there is substantial doubt about our ability to continue as a going concern within one year after the issuance of the financial statements.

Cash Flows for the Years Ended December 31, 2024 and 2023

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Net cash used in:		
Operating activities	$ (22,657)	$ (21,761)
Investing activities	(474)	14,208
Financing activities	17,094	9,840
Net increase (decrease) in cash	**$ (6,037)**	**$ 2,287**

Net Cash Used in Operating Activities

Net cash used in operating activities for the year ended December 31 2024 was $22.7 million compared to $21.8 million for the year ended December 31, 2023. The year-over-year increase was primarily due to cash disbursed in satisfaction of FiberCel legal settlements and related defense costs. In the second half of 2024, our insurance available to cover such costs was fully utilized.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2024 was $0.4 million compared to net cash provided by investing activities of $14.2 million for the year ended December 31, 2023. The current year period mainly reflects the purchase of property and equipment for our production facilities. The prior year period's cash generation resulted from the sale of substantially all of the assets relating to our former Orthobiologics Business to Berkeley which yielded proceeds of $14.6 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024 was $17.1 million compared to $9.8 million for the year ended December 31, 2023. Both years included proceeds from the issuance of common stock ($12.4 million in 2024 and $10.1 million in 2023); however, the year ended December 31, 2024 also included the proceeds from the exercise of Common Warrants yielding exercise proceeds of $15.7 million. Such cash infusions in 2024 were offset by payments on our Ligand revenue interest obligation which totaled $7.4 million during the year ended December 31, 2024.

Credit Facilities

General

On August 10, 2022 (the "Closing Date"), we entered into a senior secured term loan facility with SWK Funding LLC ("SWK"), as agent, and other lenders party thereto (as amended and modified subsequent to the Closing Date, the "SWK Loan Facility") for an aggregate principal amount of $25 million. An initial draw of $21 million was made on the Closing Date with the additional $4 million drawn on December 14, 2022. The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to $8 million, which has not been entered into to date. As of December 31, 2024, we had $23.5 million of indebtedness outstanding under our SWK Loan Facility and an exit fee liability to SWK of $0.9 million, with such balances being net of $0.5 million of unamortized discount and deferred financing costs.

Interest Rates

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate ("SOFR") loans and bear interest at a rate per annum equal to the sum of an applicable margin of (i) 7.75% and the "Term SOFR Rate" (based upon an interest period of 3 months), or (ii) if we have elected the PIK Interest option (as defined below), 3.75% and the "Term SOFR Rate." We may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% ("PIK Interest"), and such election may be made until November 15, 2025. The "Term SOFR Rate" is subject to a floor of 2.75%.

Mandatory Prepayments

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility) to the Company's total gross profit (as defined in the SWK Loan Facility) multiplied by the outstanding loans under the SWK Loan Facility, and (y) the difference between $1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. The closing of the sale of the Orthobiologics Business in November 2023 triggered the mandatory prepayment of $4.0 million. Of such amount, $2.0 million was paid shortly after closing of the divestiture of the Orthobiologics Business in 2023 and the remainder was paid on February 15, 2024 based on mutual agreement between the parties. No other such mandatory prepayments were required in the year ended December 31, 2024.

Optional Prepayment

The agreement, as amended, governing the SWK Loan Facility also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination plus $112,500.

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, 2025. Principal payments during the amortization period will be limited based on revenue-based caps. As of December 31, 2024, quarterly principal payments will be in an amount equal to 5% of the aggregate principal amount funded 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) for the preceding 12-month period or, alternatively, to maintain Consolidated Unencumbered Liquid Assets (as defined in the SWK Loan Facility) greater than either (i) the outstanding principal balance of the loan, or (ii) the aggregate operating cash burn (as defined in the SWK Loan Facility) for the preceding 12-month period. The second covenant requires us to maintain a minimum liquidity (as defined in the SWK Loan Facility) of the greater of (a) $5.0 million and (b) the sum of the operating cash burn for the two prior consecutive fiscal quarters then ended (the "Liquidity Covenant").

On March 27, 2024, we entered into an amendment to the SWK Loan Facility Agreement, which modified the Minimum Aggregate Revenue covenant under the SWK Facility to provide that as of the last business day of each fiscal

quarter of the Company beginning with the first fiscal quarter of 2024, our required Minimum Aggregate Revenue (as defined in the SWK Facility) for the trailing twelve-month period must be equal to or greater than $20.0 million.

On September 30, 2024, we entered into an amendment to the SWK Loan Facility Agreement, which (i) deferred the commencement of principal repayment under the SWK Facility from November 15, 2024 to November 15, 2025, (ii) extended the date until which the Company may elect a portion of the interest due under the SWK Facility to be paid in-kind from November 15, 2024 to November 15, 2025, and (iii) modified the exit fee upon termination of the SWK Facility from (a) 6.50% of the aggregate amount of Term Loan funded prior to such termination date plus $62,500 to (b) 6.50% of the aggregate amount of Term Loan funded prior to such termination date plus $112,500.

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, 2024, we were in compliance with the financial covenants and all other covenants.

Funding Requirements

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we further commercialize EluPro and 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, 2024, we had $23.9 million of indebtedness outstanding, consisting of $23.5 million outstanding under our SWK Loan Facility and $0.9 million of exit fee liabilities, net of $0.5 million of unamortized discount and deferred financing costs. Such indebtedness currently has a principal payment commencement date of November 15, 2025, with quarterly principal payments in an amount equal to 5% of the outstanding principal. In addition, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated ("Ligand") pursuant to a long-term obligation to Ligand (the "Revenue Interest Obligation"). The Revenue Interest Obligation, as amended in January 2024, requires us to pay Ligand 5.0% of future sales of our CanGaroo, ProxiCor, Tyke and VasCure products, and substantially similar products, such as EluPro, through May 31, 2027, subject to annual minimum payments of $4.4 million.

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

- the cost of fully commercializing our EluPro product;
- 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, associated litigation related to indemnity claims by other defendants to the FiberCel Litigation and any future litigation that we may be subject to (to the extent above the applicable insurance coverage);

- the cost and timing of additional regulatory approvals;

- costs associated with any product recall that may occur;

- the effect of competing technological and market developments;

- the expenses we incur in manufacturing and selling our products;

- the extent to which we acquire or invest in products, technologies and businesses in the future, although we may currently have no commitments or agreements relating to any of these types of transactions;

- the costs of operating as a public company;

- unanticipated general, legal and administrative expenses; and

- the effects on any of the above from any pandemic, epidemic or outbreak of infectious disease or any other public health crisis.

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 Part I, Item 1A. "Risk Factors — Risks Related to Our Business — *Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all*."

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

Off-Balance Sheet Arrangements

As of December 31, 2024, 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 inventories, receivables, long-lived assets, stock-based awards, revenue interest obligation, the warrant liability, the contingent liability for legal proceedings and deferred income taxes. Actual results may differ from those estimates. We have identified the following critical accounting policies:

Revenue Recognition

We enter into contracts to primarily sell and distribute products to healthcare providers or commercial partners. 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 to our customers. For all product sales, we have 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 our product revenue is generated from consigned inventory maintained at hospitals and from inventory physically held by distributors and direct sales representatives. For these types of products sales, we retain control until the product has been used or implanted, at which time revenue is recognized.

We 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.

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. 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 we determine 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 recorded 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, as amended in January 2024, require us to pay Ligand 5.0% of future sales of our CanGaroo, ProxiCor, Tyke and VasCure products, and substantially similar products, through May 31, 2027, subject to annual minimum payments of $4.4 million. Furthermore, a $5.0 million payment will be due if cumulative sales exceed $300 million or the assets related to CanGaroo and any substantially similar products undergo a change of control 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. The January 2024 amendment to the Revenue Interest Obligation changed the timing and extent of our future payments to Ligand and such change to the estimated future payments yielded a reduction to the total obligation of approximately $1.4 million during the year ended December 31, 2024. The resulting gain was recognized as other income in the accompanying consolidated statement of operations. There was no change to estimated future payments during the year ended December 31, 2023, 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 Legal Proceedings

We review every lawsuit and claim and are in contact with outside counsel on an ongoing basis in determining our Contingent Liability for Legal Proceedings. Where the available information is only sufficient to establish a range of probable liability, and no point within the range is more likely than any other, the lower end of the range has been used. When a material loss contingency is reasonably possible, but not probable, we do not record a liability, but instead disclose the nature of the matter and an estimate of the loss or range of loss, to the extent such estimate can be made.

An accrual is established for each lawsuit and claim, when appropriate, based on the nature of each such lawsuit or claim. The provision for litigation claims is 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.

Warrant Liability

We account for warrants in accordance with ASC 815, *Derivatives and Hedging – Contracts in Entity's Own Equity*, as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. The 2024 Prefunded Warrants from the Registered Offering and the Common Warrants and the 2023 Prefunded Warrants from the Private Offering (see Note 14 to the consolidated financial statements included elsewhere in this Annual Report) are classified as liabilities and are recorded at fair value. The warrants are subject to re-measurement at each settlement date and at each balance sheet date and any change in fair value is recognized in other (income) expense, net in the consolidated

statements of operations. The Company estimates the fair value of the Common Warrant liability using a Black-Scholes pricing model. We are required to make assumptions and estimates in determining an appropriate term, risk-free interest rate, volatility factor, dividend yield, and the fair value of common stock. Any significant adjustments to the unobservable inputs would have a direct impact on the fair value of the warrant liability. Different assumptions relative to the fair valuation of our Prefunded and Common Warrants would result in a change to such valuation and these differences could be material.

Stock-Based Compensation

Compensation costs associated with stock option awards, restricted stock units 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. We use the simplified method for estimating the expected term used to determine the fair value of options. 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. We have incorporated our historical stock trading volatility with those of our peer group for the calculation of volatility. Industry peers consist of several public companies in the medical device technology industry with comparable characteristics including enterprise value, risk profiles and position within the industry.

For our performance-based stock option and restricted stock unit 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 and restricted stock units 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 and restricted stock units 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 included elsewhere in this Annual Report for information 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 bear interest at variable rates, subject to an interest rate floor. Interest rate risk is highly sensitive due to many factors, including U.S. monetary and tax policies, U.S. and international economic factors and other factors beyond our control. A hypothetical 10% relative change in interest rates to our variable rate indebtedness outstanding during the years ended December 31, 2024 or 2023 would not have had a material effect on our financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Credit Risk

As of December 31, 2024, our cash and cash equivalents were maintained with two financial institutions in the United States. While our deposit accounts are insured up to the legal limit, the balances we maintain may, at times, exceed this insured limit. As of December 31, 2024 we maintained $12.2 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. One customer represented 14% of our accounts receivable as of December 31, 2024.

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, 2024 and 2023. We cannot assure you, however, that we will be able to increase the selling prices of our products or reduce our operating expenses in an amount sufficient to offset the effects future inflationary pressures may have on our gross margin. Accordingly, we cannot assure you that our financial condition and results of operations will not be materially impacted by inflation in the future.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

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

Evaluation of Disclosure Controls and Procedures

The Company's management has evaluated, with the participation of our principal executive officer and our principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on this evaluation, management concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2024.

Management's Annual Report on Internal Control Over Financial Reporting

Our management, with the participation of our principal executive officer and our principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control–Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

Our independent registered accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 of Sarbanes-Oxley Act of 2002 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months and year ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2024, none of our directors or officers (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any "non-Rule 10b5-1 trading arrangement" (as defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to the information that will be contained in our proxy statement related to our annual meeting of stockholders to be held in 2025 (the "2025 Annual Meeting of Stockholders"), which we intend to file with the SEC within 120 days of the year ended December 31, 2024. A copy of our Insider Trading Compliance Policy is filed as Exhibit 19 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management Related Stockholder Matters.

Equity Compensation Plan Information

The following table provides information on our equity compensation plans as of December 31, 2024.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Stockholders			
2015 Plan (1)	33,836	$ 5.94 (4)	—
2020 Plan (2)	4,604,278	$ 5.22 (4)	396,561
ESPP (3)	—	—	471,126
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	4,638,114	$ —	867,687

(1) In connection with our IPO, we adopted the Elutia Inc. 2020 Incentive Award Plan (the "2020 Plan") and, as of the consummation of our IPO, ceased making grants or awards under the Elutia Inc. 2015 Stock Option/Stock Issuance Plan (the "2015 Plan"). To the extent stock options outstanding under the 2015 Plan are forfeited, lapse unexercised or are settled in cash, the shares of Class A common stock subject to the stock options will be available for future issuance under the 2020 Plan.

(2) 1,685,962 shares of Class A common stock were initially available for issuance under the 2020 Plan. The number of shares of Class A common stock available for issuance under the 2020 Plan automatically increases on each January 1, until and including January 1, 2030, by an amount equal to the lesser of (A) 4% of the shares of Class A common stock outstanding (on an as-converted basis) on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of Class A common stock as determined by our board of directors (but no more than 1,636,000 shares of Class A common stock may be issued upon the exercise of incentive stock options). In addition, the shares reserved for issuance under the 2020 Plan will also include shares reserved but not issued under the 2015 Plan. In June 2023, the stockholders of the Company approved the amendment and restatement of the 2020 Plan which, among other things, increased the number of shares of Class A common stock reserved for issuance under the 2020 Plan by 2,000,000 shares.

(3) The number of shares of Class A common stock available for issuance under the ESPP automatically increases on each January 1, until and including January 1, 2030, by an amount equal to the lesser of (A) 1% of the shares of Class A and Class B common stock outstanding on the last day of the immediately preceding fiscal year and (B) such smaller number of shares of Class A common stock as determined by our board of directors.

(4) The calculation of the weighted average exercise price does not include outstanding equity awards that are received or exercised for no consideration.

The other information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2024.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2025 Annual Meeting of Stockholders, which we intend to file with the SEC within 120 days of the year ended December 31, 2024.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements

The Consolidated Financial Statements are included on pages F-2 through F-31 attached hereto and are filed as part of this Annual Report. See Index to Consolidated Financial Statements on page F-1.

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits

The following is a list of exhibits filed as part of this Annual Report.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
2.1	Asset Purchase Agreement, dated September 17, 2023, by and among Elutia Inc., Berkeley Biologics, LLC, and GNI Group, Ltd. (solely with respect to Section 11.18)	8-K	001-39577	10.1	9/19/2023	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
3.1a	Restated Certificate of Incorporation of Elutia Inc.	8-K	001-39577	3.1	10/13/2020	
3.1b	Certificate of Amendment to the Restated Certificate of Incorporation of Elutia Inc.	8-K	001-39577	3.1	09/07/2023	
3.2	Amended and Restated Bylaws of Elutia Inc.	8-K	001-39577	3.2	10/13/2020	
4.1	Second Amended and Restated Investor Rights Agreement, dated as of September 14, 2020, among the Registrant and the investors named therein	S-1	333-248788	4.1	09/14/2020	
4.2	Specimen stock certificate evidencing the shares of Class A common stock	S-1	333-248788	4.2	09/14/2020	
4.3	Specimen stock certificate evidencing the shares of Class B common stock	S-1/A	333-248788	4.3	09/30/2020	
4.4	Warrant to Purchase Stock, issued on August 10, 2022, by Elutia Inc.to SWK Funding LLC.	8-K	001-39577	4.1	8/15/2022	
4.5	Form of Common Warrant	8-K	001-39577	4.1	9/21/2023	
4.6	2023 Form of Prefunded Warrant	8-K	001-39577	4.2	9/21/2023	
4.7	Registration Rights Agreement, dated September 21, 2023, by and among Elutia Inc. and the Investors named therein	8-K	001-39577	10.2	9/21/2023	
4.8	2024 Form of Prefunded Warrant	8-K	001-39577	4.1	6/18/2024	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
4.9	Description of Securities	10-K	001-39577	4.4	03/15/2021	
10.1	Registration Rights Agreement, dated December 5, 2021, by and among Elutia Inc. and the Investors named therein.	8-K	001-39577	10.2	12/08/2021	
10.2	Royalty Agreement, dated as of May 31, 2017, by and between Elutia Med, LLC and Ligand Pharmaceuticals Incorporated	S-1	333-248788	10.15	09/14/2020	
10.3	License Agreement, dated as of May 31, 2017, by and between Cook Biotech Incorporated and Elutia Med, LLC	S-1	333-248788	10.16	09/14/2020	
10.4	December 2017 Amendment to License Agreement, dated as of December 21, 2017, by and between Cook Biotech Incorporated and Elutia Med, LLC	S-1	333-248788	10.17	09/14/2020	
10.5†	Elutia Inc. 2015 Stock Option/Stock Issuance Plan (as amended)	S-1	333-248788	10.1	09/14/2020	
10.6†	Elutia Inc. 2020 Incentive Award Plan and form of stock option agreements thereunder	10-K	001-39577	10.6	3/23/2023	
10.7†	Form of Restricted Stock Unit Award Agreement (approved August 2022)	10-Q	001-39577	10.4	11/14/2022	
10.8†	Form of Restricted Stock Unit Award Agreement (approved October 2020)	10-K	001-39577	10.8	3/23/2023	
10.9†	Elutia Inc. Non-Employee Director Compensation Program	S-1/A	333-248788	10.3	09/30/2020	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
10.10†	Elutia Inc. 2020 Employee Stock Purchase Plan	S-1/A	333-248788	10.4	09/30/2020	
10.11†	Amended and Restated Employment Agreement, by and between the Registrant and Ronald Lloyd, dated as of September 30, 2021	S-1/A	333-248788	10.6	09/30/2020	
10.12†	Separation and Release of Claims Agreement, dated June 21, 2022, by and between Ronald Lloyd and Elutia Inc.	8-K	001-39577	10.1	6/21/2022	
10.13†	Employment Agreement, dated June 21, 2022, by and between C. Randal Mills, Ph.D. and Elutia Inc.	8-K	001-39577	10.2	6/21/2022	
10.14†	Amended and Restated Employment Agreement, dated December 23, 2022, by and between Elutia Inc. and Thomas Englese	8-K	001-39577	10.2	12/30/2022	
10.15†	Letter Agreement, dated as of March 22, 2023, by and between Elutia Inc. and Thomas Englese	10-K	001-39577	10.15	3/23/2023	
10.16†	Amended and Restated Employment Agreement, dated December 23, 2022, by and between Elutia Inc. and Matthew Ferguson	8-K	001-39577	10.1	12/30/2022	
10.17†	Form of Indemnification Agreement for Directors and Officers	S-1/A	333-248788	10.12	09/30/2020	
10.18#	Credit Agreement, dated as of August 10, 2022, between Elutia Inc. and	8-K	001-39577	10.1	8/15/2022	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
	SWK Funding LLC, as Agent and the Lenders from time to time party thereto					
10.19	Amendment Letter, dated as of October 9, 2022 to Credit Agreement, dated as of August 10, 2022, between Elutia Inc. and SWK Funding LLC, as Agent and the Lenders from time to time party thereto	8-K	001-39577	10.1	10/13/2022	
10.20	Amendment Letter, dated as of November 10, 2022 to Credit Agreement, dated as of August 10, 2022, between Elutia Inc. and SWK Funding LLC, as Agent and the Lenders from time to time party thereto (as amended by the Amendment Letter dated as of October 9, 2022)	10-Q	001-39577	10.3	11/14/2022	
10.21	Amendment Letter, dated as of November 21, 2022, to the Credit Agreement, dated as of August 10, 2022, among Elutia Inc., SWK Funding LLC, as Agent, and the Lenders from time to time party thereto (as amended).	8-K	001-39577	10.1	11/28/2022	
10.22	Amendment Letter, dated as of November 30, 2022, to the Credit Agreement, dated as of August 10, 2022, among Elutia Inc., SWK Funding LLC, as Agent, and the Lenders from	8-K	001-39577	10.1	12/5/2022	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
	time to time party thereto (as amended).					
10.23	First Amendment, dated as of May 12, 2023, to the Credit Agreement, dated August 10, 2022, by and among Aziyo Biologics, Inc., SWK Funding LLC, as Agent and the Lenders from time to time party thereto	10-Q	001-39577	10.4	5/12/2023	
10.24†	Aziyo Biologics, Inc. Amended and Restated 2020 Incentive Award Plan	Proxy Statement	001-39577	Annex A	04/27/2023	
10.25	Distribution Agreement by and between Aziyo Biologics, Inc. and LeMaitre Vascular, Inc.	10-Q	001-39577	10.2	8/14/2023	
10.26	Securities Purchase Agreement, dated September 18, 2023, by and among Elutia Inc. and the Investors named therein.	8-K	001-39577	10.1	9/21/2023	
10.27	Amendment No. 1 to Royalty Agreement with Ligand Pharmaceuticals Incorporated	8-K	001-39577	10.1	1/12/2024	
10.28†	Form of Amendment to Stock Option Agreements, dated January 31, 2024, between the Company and C. Randal Mills, Ph.D.	8-K	001-39577	10.1	2/2/2024	
10.29†	Form of Amendment to Restricted Stock Unit Agreements, dated January 31, 2024, between the Company and C. Randal Mills, Ph.D.	8-K	001-39577	10.2	2/2/2024	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
10.30†	Form of Stock Option Agreement under the Elutia Inc. Amended and Restated 2020 Incentive Award Plan.	8-K	001-39577	10.3	2/2/2024	
10.31†	Form of Restricted Stock Unit Agreement under the Elutia Inc. Amended and Restated 2020 Incentive Award Plan.	8-K	001-39577	10.4	2/2/2024	
10.32	Second Amendment to Credit Agreement, dated March 27, 2024, by and among Elutia Inc., SWK Funding LLC, as Agent, and the Lenders from time to time party thereto.	8-K	001-39577	10.1	4/1/2024	
10.33	Placement Agency Agreement, dated June 16, 2024, by and between Elutia Inc. and Lake Street Capital Markets, LLC	8-K	001-39577	10.1	6/18/2024	
10.34	Form of Securities Purchase Agreement	8-K	001-39577	10.2	6/18/2024	
19	Insider Trading Compliance Policy					*
21.1	Subsidiaries of Elutia, Inc.	10-K	001-39577	21.1	03/8/2022	
23.1	Consent of PricewaterhouseCoopers LLP					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					**
97	Elutia Inc. Excess Incentive-based Compensation Recoupment Policy	10-K	001-39577	97	3/11/2024	
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					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.

** Furnished herewith.

† Denotes a management contract or compensation plan or arrangement.

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

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Elutia Inc.

Date: March 11, 2025

By: /s/ C. RANDAL MILLS, PH.D.
C. Randal Mills, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 11, 2025

/s/ MATTHEW FERGUSON
Matthew Ferguson
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/C. Randal Mills, Ph.D. C. Randal Mills, Ph.D.	President, Chief Executive Officer and Director *(principal executive officer)*	March 11, 2025
/s/Matthew Ferguson Matthew Ferguson	Chief Financial Officer *(principal financial officer and principal accounting officer)*	March 11, 2025
/s/Kevin Rakin Kevin Rakin	Chairperson of the Board of Directors	March 11, 2025
/s/W. Matthew Zuga W. Matthew Zuga	Director	March 11, 2025
/s/Maybelle Jordan Maybelle Jordan	Director	March 11, 2025
/s/David Colpman David Colpman	Director	March 11, 2025
/s/Brigid A. Makes Brigid A. Makes	Director	March 11, 2025

ELUTIA INC.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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. and its subsidiaries (the "Company") as of December 31, 2024 and 2023, 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, 2024 and 2023, 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.

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
Philadelphia, Pennsylvania
March 11, 2025
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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 13,239	$ 19,276
Accounts receivable, net	2,276	3,263
Inventory	3,911	3,853
Insurance receivables of litigation costs	4,760	2,696
Prepaid expenses and other current assets	1,986	2,165
Total current assets	26,172	31,253
Property and equipment, net	773	172
Intangible assets, net	8,273	11,671
Operating lease right-of-use assets and other	909	332
Total assets	**$ 36,127**	**$ 43,428**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,149	$ 3,191
Accrued expenses	7,104	9,485
Current portion of long-term debt	1,250	3,321
Current portion of revenue interest obligation	4,400	11,741
Contingent liability for legal proceedings	20,432	15,024
Current operating lease liabilities	460	275
Total current liabilities	37,795	43,037
Long-term debt	22,603	20,356
Long-term revenue interest obligation	5,490	5,360
Warrant liability	16,076	12,760
Long-term operating lease liabilities	423	—
Other long-term liabilities	—	515
Total liabilities	82,387	82,028
Commitments and contingencies (Note 17)		
Stockholders' equity (deficit):		
Class A Common stock, $0.001 par value, 200,000,000 shares authorized as of December 31, 2024 and December 31, 2023, and 30,897,232 and 18,884,196 shares issued and outstanding, as of December 31, 2024 and December 31, 2023, respectively	31	19
Class B Common stock, $0.001 par value, 20,000,000 shares authorized, as of December 31, 2024 and December 31, 2023 and 4,313,406 issued and outstanding as of December 31, 2024 and December 31, 2023	4	4
Additional paid-in capital	183,298	137,021
Accumulated deficit	(229,593)	(175,644)
Total stockholders' deficit	(46,260)	(38,600)
Total liabilities and stockholders' deficit	**$ 36,127**	**$ 43,428**

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,	
	2024	**2023**
Net sales	$ 24,375	$ 24,745
Cost of goods sold	13,668	13,692
Gross profit	10,707	11,053
Sales and marketing	12,546	13,087
General and administrative	18,659	14,104
Research and development	3,785	4,399
Litigation costs, net	11,368	9,989
Total operating expenses	46,358	41,579
Loss from continuing operations	(35,651)	(30,526)
Interest expense, net	4,779	5,796
Loss on revaluation of warrant liability	14,878	4,140
Other (income) expense, net	(1,186)	759
Loss before provision for income taxes	(54,122)	(41,221)
Income tax expense	7	28
Net loss from continuing operations	(54,129)	(41,249)
Income from discontinued operations	180	3,593
Net loss	**$ (53,949)**	**$ (37,656)**
Net loss per share from continuing operations attributable to common stockholders - basic and diluted	**$ (1.86)**	**$ (2.27)**
Income per share from discontinued operations attributable to common stockholders - basic and diluted	**$ 0.01**	**$ 0.20**
Net loss per share - basic and diluted	**$ (1.86)**	**$ (2.07)**
Weighted average common shares outstanding - basic and diluted	29,071,113	18,160,822

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				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2022	**11,823,445**	**$ 12**	**4,313,406**	**$ 4**	**$ 132,939**	**$ (137,988)**	**$ (5,033)**
Issuance of common stock in connection with private placement, net of issuance costs of $0.4 million	6,852,811	7	—	—	1,458	—	1,465
Issuance of common stock under Employee Stock Purchase Plan	104,905	—	—	—	219	—	219
Vesting of restricted stock units, net of shares withheld and taxes paid	103,035	—	—	—	(32)	—	(32)
Stock-based compensation	—	—	—	—	2,437	—	2,437
Net loss	—	—	—	—	—	(37,656)	(37,656)
Balance, December 31, 2023	**18,884,196**	**$ 19**	**4,313,406**	**$ 4**	**$ 137,021**	**$ (175,644)**	**$ (38,600)**
Issuance of common stock in connection with registered direct offering, net of issuance costs of $1.1 million	3,175,000	3	—	—	9,669	—	9,672
Exercise of stock options	1,960	—	—	—	7	—	7
Exercise of Common Warrants and Prefunded Warrants	7,963,373	8	—	—	29,744	—	29,752
Issuance of common stock under Employee Stock Purchase Plan	96,658	—	—	—	155	—	155
Vesting of restricted stock units, net of shares withheld and taxes paid	776,045	1	—	—	(1,189)	—	(1,188)
Stock-based compensation	—	—	—	—	7,891	—	7,891
Net loss	—	—	—	—	—	(53,949)	(53,949)
Balance, December 31, 2024	**30,897,232**	**$ 31**	**4,313,406**	**$ 4**	**$ 183,298**	**$ (229,593)**	**$ (46,260)**

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,	
	2024	**2023**
Net loss	$ (53,949)	$ (37,656)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,451	3,748
Gain on sale of Orthobiologics Business, excluding divestiture costs	(180)	(7,529)
Loss on revaluation of warrant liability	14,878	4,140
Gain on revaluation of revenue interest obligation	(1,443)	—
Amortization of deferred financing costs and debt discount	216	216
Interest expense recorded as additional revenue interest obligation and long-term debt	3,076	3,350
Stock-based compensation	7,891	2,437
Bad debt expense	460	590
Losses associated with viable bone matrix recall and market withdrawal	—	1,984
Changes in operating assets and liabilities, net:		
Accounts receivable	527	802
Inventory	(58)	(609)
Insurance receivables of litigation costs	(2,064)	11,118
Prepaid expenses and other	743	167
Accounts payable and accrued expenses	(1,148)	(2,113)
Contingent liability for legal proceedings	5,408	(2,336)
Other liabilities	(465)	(70)
Net cash used in operating activities	**(22,657)**	**(21,761)**
INVESTING ACTIVITIES:		
Proceeds from sale of Orthobiologics Business	180	14,554
Expenditures for property, plant and equipment	(654)	(346)
Net cash (used in) provided by investing activities	**(474)**	**14,208**
FINANCING ACTIVITIES:		
Proceeds from public offering or private placement with warrants, net of offering costs	12,390	10,085
Proceeds (repayments) of long-term debt	(2,000)	(1,955)
Proceeds from exercises of Common Warrants and Prefunded Warrants	15,725	—
Payments on revenue interest obligation	(7,400)	—
Proceeds from insurance premium financings	1,400	1,995
Repayments of insurance premium financings	(1,995)	(472)
Payments for taxes upon vesting of restricted stock units	(1,188)	(32)
Proceeds from stock option exercises and issuance of common stock under ESPP	162	219
Net cash provided by financing activities	**17,094**	**9,840**
Net (decrease) increase in cash	**(6,037)**	**2,287**
Cash and cash equivalents, beginning of year	**19,276**	**16,989**
Cash and cash equivalents, end of year	**$ 13,239**	**$ 19,276**
Supplemental Cash Flow and Non-Cash Financing Activities Disclosures:		
Cash paid for interest	$ 5,288	$ 2,321
Fair value of warrants issued	$ 2,464	$ 12,760
Operating lease right-of-use asset extensions executed, net of early terminations	$ 1,141	$ —
Conversion of Common Warrants and Prefunded Warrants to common stock	$ 19,584	$ —

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

Note 1. Organization and Description of Business

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

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Liquidity

The 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 subsidiary. Intercompany accounts and transactions have been eliminated in consolidation.

On November 8, 2023, the Company completed the sale of substantially all of the assets relating to its Orthobiologics segment (the "Orthobiologics Business") to Berkeley Biologics, LLC ("Berkeley"). The Orthobiologics Business was comprised of assets relating to researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing the Company's Orthobiologics products, and the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products. The assets sold represent the entirety of the Company's Orthobiologics segment. In the sale, the Company received $14.6 million, and the Company may earn up to an additional $20 million, in the aggregate, in the form of earn-out payments. The earn-out payments are equal to 10% of the actual revenue earned by Berkeley in each of the five years after the closing of the sale from sales of specified Orthobiologics products under the purchase agreement (including improvements, modifications, derivatives and enhancements related to those products). There have been no earn-out payments made to date. Additionally, the purchase agreement provides for a customary indemnity holdback in the amount of $1.5 million to be retained by Berkeley for 24 months after close. In the purchase agreement, the Company has retained the liabilities arising out of the VBM and FiberCel matters, as described in Note 17, both of which products were part of the Orthobiologics Business. The Company recognized a gain of $6.0 million on the sale of the Orthobiologics Business during the year ended December 31, 2023 and an additional gain of $0.2 million during the year ended December 31, 2024 from an adjustment payment related to the final working capital received by Berkeley at the sale date. The indemnity holdback is available as a source of recovery for Berkeley for claims of indemnification under the purchase agreement, and some or all of the holdback may be retained by Berkeley if Berkeley is successful in asserting a claim or claims for indemnification against the Company. The Company is aware of certain indemnity-related claims raised, including a claim from a former supplier alleging breach of contract. Based on the Company's ongoing assessment of these claims, along with the remaining indemnity holdback of $1.5 million, the Company does not consider a loss to be probable or estimable as of December 31, 2024. Should the Company receive incremental proceeds in the future through an earn-out payment or payment of the holdback amount, an additional gain will be recorded upon the receipt of such amounts. See Note 4 for further discussion of the sale of the Orthobiologics Business and the presentation of such business as discontinued operations for the year ended December 31, 2023. Unless indicated otherwise, the information in the notes to consolidated financial statements for the year ended December 31, 2023 relates to continuing operations.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. For the year ended

December 31, 2024, the Company incurred a net loss of $53.9 million, and as of December 31, 2024, the Company had an accumulated deficit of $229.6 million. In addition, during the year ended December 31, 2024, the Company used $22.7 million of cash in operating activities and expects to continue to incur cash outflows in 2025. Because of the numerous risks and uncertainties associated with the Company's commercialization and development efforts, the Company is unable to predict when it will become profitable, and it may never become profitable. The Company's inability to achieve and then maintain profitability would negatively affect its business, financial condition, results of operations and cash flows. Furthermore, even if the Company does achieve profitability, it may not be able to sustain or increase profitability on an ongoing basis, or, in general, be able to satisfy its obligations, including those related to the FiberCel Litigation and VBM Litigation described in Note 17, when they become due.

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

A reclassification has been made to prior year amounts to conform to current year financial statement presentation and had no impact on previously reported results. The reclassification relates to the separate presentation of the prior year loss on revaluation of warrant liability. Such loss was formerly shown as a component of other (income) expense, net 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 valuation of the warrant liability, the contingent liabilities for legal proceedings and deferred income taxes are made at the end of each financial reporting period by management. Management continually re-evaluates its estimates, judgments and assumptions, and management's evaluation could change. Actual results could differ from those estimates.

Net Loss per Share Attributable to Common Stockholders

Our common stock has a dual class structure, consisting of Class A common stock, $0.001 par value per share (the "Class A common stock") and Class B common stock, $0.001 par value per share (the "Class B common stock"). Other than voting rights, the Class B common stock has the same rights as the Class A common stock, and therefore both are treated as the same class of stock for purposes of the earnings per share calculation. The Company is also authorized to issue up to 10,000,000 shares of preferred stock with a par value of $.001. No shares have been issued or are outstanding as of December 31, 2024 and December 31, 2023.

Basic net income per share is computed by dividing net income available to each class of shares by the weighted-average number of shares of common stock and participating securities outstanding during the period. Participating securities include common and prefunded warrants. Net loss is not allocated to participating securities as they do not have

an obligation to fund losses. For purposes of the diluted net income per share attributable to common stockholders calculation, stock options, restricted stock units ("RSUs") and warrants are considered to be common stock equivalents. See Note 16 for further discussion of net loss per share attributable to common stockholders.

Fair Value of Financial Instruments

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

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

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

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

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

Cash and Cash Equivalents

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

Accounts Receivable and Allowances

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

The Company evaluates the collectability of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to the Company, a provision to the allowance for doubtful accounts is recorded to reduce the net recognized receivable to the amount that is reasonably expected to be collected. For all other customers, a provision to the allowance for credit losses is recorded based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowance for doubtful accounts are recorded to general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered. The Company's allowance for doubtful accounts was approximately $0.6 million and $0.7 million as of December 31, 2024 and 2023, respectively.

Inventories

Inventory, consisting of purchased materials, direct labor and manufacturing overhead, is stated at the lower of cost or net realizable value, with cost determined generally using the average cost method. At each balance sheet date, the Company also evaluates inventory for excess quantities, obsolescence or shelf-life expiration. This evaluation includes an 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 the estimated net realizable value.

Property and Equipment

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

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

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

Leases

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

Long-Lived Assets

Purchased intangible assets with finite lives are carried at acquired fair value, less accumulated amortization. Amortization is recorded 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, 2024 and 2023.

Warrant Liability

The Company accounts for its warrants in accordance with ASC 815, *Derivatives and Hedging – Contracts in Entity's Own Equity*, as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. The warrants issued in connection with the September 2023 private placement and June 2024 registered direct offering (see Note 14) are classified as liabilities and are recorded at fair value. The warrants are subject to re-measurement at each

settlement date and at each balance sheet date and any change in fair value is recognized in other (income) expense, net in the consolidated statements of operations. The Company estimates the fair value of the warrant liability using a Black-Scholes pricing model. We are required to make assumptions and estimates in determining an appropriate term, risk-free interest rate, volatility factor, dividend yield, and the fair value of common stock. Any significant adjustments to the unobservable inputs would have a direct impact on the fair value of the warrant liability.

Revenue Recognition

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

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

A portion of the Company's product revenue is generated from consigned inventory maintained at hospitals and from inventory physically held by distributors and direct sales representatives. For these types of product 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 not material in both the years ended December 31, 2024 and 2023.

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

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

Stock-Based Compensation Plans

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

Research and Development Costs

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

Concentration of Credit Risk

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

During the year ended December 31, 2024, there was one customer that represented 15% of the Company's net sales in such year, and during the year ended December 31, 2023, there was one customer that represented 10% of the Company's sales in such year. There was one customer that represented 14% of the Company's accounts receivable as of December 31, 2024, and there was one customer that represented 31% of the Company's accounts receivable as of December 31, 2023.

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, 2024 and 2023, the Company's net loss equaled its comprehensive loss and accordingly, no additional disclosure is presented.

Income Taxes

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

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

Note 3. Recently Issued Accounting Standards

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. This update improves reportable segment disclosure requirements, primarily through enhanced disclosures of significant segment expenses. The amendments in this update should be applied retrospectively to all prior periods presented in the consolidated financial statements and are effective for fiscal years beginning after December 31, 2023 and interim periods within fiscal years beginning after December 31, 2024. The adoption of this standard did not have a material impact on the Company's consolidated financial statements; however, the Company has expanded its disclosures in Note 18, Segment Information.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvement to Income Tax Disclosures. This update improves income tax disclosure requirements, primarily through enhanced transparency and decision usefulness of disclosures. The amendments in this update should be applied prospectively with the option to apply retrospectively and are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company does not expect the adoption of this guidance to have any material effects on its financial condition, results of

operations or cash flows. The Company is currently evaluating any new disclosures that may be required upon adoption of ASU 2023-09.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Topic 220-40). This update assesses the disaggregation of income statement expense which requires more detailed information about specified categories of expenses included in certain expense captions presented on the face of the income statement. The amendments are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating any new disclosures that may be required upon adoption of ASU 2024-03.

Note 4. Sale of Orthobiologics Business

As described in Note 2, on November 8, 2023, the Company completed the sale of its Orthobiologics Business. Accordingly, the Orthobiologics Business is reported as discontinued operations in accordance with ASC 205-20 - *Discontinued Operations* and the amounts for the years ended December 31, 2023 have been recast to conform to this discontinued operations presentation.

In accordance with ASC 205-20, only expenses specifically identifiable and related to a business to be disposed may be presented in discontinued operations. The following table shows the financial results of the discontinued operations from January 1, 2023 through the transaction closing date of November 8, 2023. Additionally, a gain of $0.2 million was recognized during the year ended December 31, 2024 related to the final working capital adjustment received from Berkeley.

Net sales	$	14,913
Cost of goods sold		12,682
Gross profit		2,231
Sales and marketing		1,784
General and administrative		1,534
Research and development		951
Total operating expenses		4,269
Interest Expense		348
Net income (loss)	$	(2,386)

Total operating and investing cash flows of discontinued operations from January 1, 2023 through the transaction closing date of November 8, 2023 are comprised of the following:

Significant operating non-cash reconciliation items:		
Depreciation	$	239
Stock-based compensation		86
Changes in operating assets and liabilities:		
Accounts receivable		882
Inventory		988
Prepaid expenses and other		(449)
Accounts payable and accrued expenses and other current liabilities		(1,562)
Obligations to tissue suppliers		(691)
Significant investing items:		
Expenditures for property, plant and equipment		(225)

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, and on June 8, 2023, the Company's stockholders approved the amendment and restatement of that plan (as amended and restated, the "2020 Plan"), which authorizes the grant of incentive and non-qualified stock options, restricted stock, restricted stock units and stock appreciation rights to employees, directors and consultants. Shares of Class A common stock totaling 1,636,000 were initially reserved for issuance pursuant to the 2020 Plan, and in June 2023, the number of shares of Class A common stock reserved for issuance under the 2020 Plan was increased by 2,000,000 shares. In addition, the shares reserved for issuance under the 2020 Plan also include shares reserved but not issued under the 2015 Plan as well as an annual increase as set forth in the 2020 Plan. As of December 31, 2024, the Company had 396,561 shares of Class A common stock available for issuance under the 2020 Plan, and on January 1, 2025, the shares available for issuance were increased by 1,408,426 pursuant to the automatic increase provisions of the plan.

Stock Options

The Company's policy is to grant stock options at an exercise price equal to 100% of the market value of a share of Class A common stock at closing on the date of the grant. The Company's stock options have contractual terms of ten years and generally 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, 2024 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2023	1,501,193	$ 8.37	7.8	$ -
Granted	1,790,654	$ 3.59		
Exercised	(1,960)	$ 3.61		
Forfeited	(68,896)	$ 9.39		
Outstanding, December 31, 2024	3,220,991	$ 5.23	7.3	$ 475
Vested and exercisable, December 31, 2024	1,806,344	$ 5.98	6.1	$ 301

As of December 31, 2024, there was approximately $3.2 million of total unrecognized compensation expense related to unvested stock options. These costs are expected to be recognized over a weighted-average period of 1.8 years. The weighted average grant date fair value of options granted during the years ended December 31, 2024 and 2023 were $2.38 and $1.63, respectively. The total intrinsic value of options exercised was not material for both the years ended December 31, 2024 and 2023.

The Company uses the Black-Scholes model to value its stock option grants that vest based on the passage of time or the achievement of certain performance criteria and expenses the related compensation cost using the straight-line method over the vesting period. The fair value of stock options is determined on the grant date using assumptions for the estimated fair value of the underlying common stock, expected term, expected volatility, dividend yield, and the risk-free interest rate. 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 based on the Company's historical stock data. 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, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Expected term (years)	5.9	6.0
Risk-free interest rate	3.3 %	3.9 %
Volatility factor	84.2 %	63.8 %
Dividend yield	—	—

In January 2024, the Company granted 390,625 options that vested on a defined date following the U.S. Food and Drug Administration's ("FDA") clearance of the Company's EluPro product (referred to as CanGarooRM during development) product. With the FDA's approval of EluPro in June 2024, such vesting occurred in August 2024. Consistent with the above, these performance vesting options were valued using the Black-Scholes model. During the year ended December 31, 2024, the Company also granted 162,500 stock options that vest in equal installments upon the achievement of certain share price thresholds for twenty consecutive days of trading at each respective threshold. For these stock options, the Company accounted for the awards as market condition awards and used an option pricing model, the Monte Carlo model, to determine the fair value of the respective equity instruments and an expense recognition term of approximately three years. As of December 31, 2024, there were a total of 345,011 stock options outstanding that are market condition stock option awards.

Restricted Stock Units

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

A summary of the RSU activity under the Company's 2020 Plan for the year ended December 31, 2024 is as follows:

	Number of Shares Underlying RSUs	Weighted-Average Grant Date Fair Value
Unvested, December 31, 2023	335,608	$ 3.64
Granted	2,377,500	$ 3.58
Vested	(1,129,748)	$ 3.68
Forfeited	(166,237)	$ 3.03
Unvested, December 31, 2024	1,417,123	$ 3.58

The total fair value of the RSUs granted during the years ended December 31, 2024 and 2023 was $8.5 million and $0.3 million, respectively. For the performance vesting RSUs, the fair value was based on the fair market value of the Company's Class A common stock on the date of grant. The market condition RSUs are valued as described below. The respective fair values are amortized to expense on a straight-line basis over the vesting period of generally three to four years.

As of December 31, 2024, $4.4 million of unrecognized compensation costs related to RSUs is expected to be recognized over a weighted average period of 2.0 years.

During the year ended December 31, 2024, the Company granted 554,375 RSUs that vested on a defined date following the FDA's clearance of the Company's EluPro product. With the FDA's approval of EluPro in June 2024, such vesting occurred in August 2024. These performance vesting RSUs were valued using the fair value of the Company's Class A common stock on the date of grant. The Company has also granted 162,500 RSUs that vest in equal installments upon the achievement of certain share price thresholds for twenty consecutive days of trading at each respective threshold. For these RSUs, the Company accounted for the awards as market condition awards and used a Monte Carlo model to

determine the fair value of these RSUs as well as the expense recognition term of approximately three years using the graded vesting method. As of December 31, 2024, there were 252,394 RSUs outstanding that were market condition RSU awards.

Employee Stock Purchase Plan

The Company makes shares of its Class A common stock available for purchase under 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 as set forth in the ESPP. As of December 31, 2024, the total shares of Class A common stock authorized for issuance under the ESPP was 774,341, of which 471,126 remained available for future issuance. During the year ended December 31, 2024, 96,658 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, 2024 and 2023 comprised of the following (in thousands):

	Year Ended December 31,	
	2024	2023
Sales and marketing	$ 1,475	$ 569
General and administrative	5,281	1,607
Research and development	964	122
Cost of goods sold	171	107
Total stock-based compensation expense	$ 7,891	$ 2,405

Note 6. Inventory

Inventory as of December 31, 2024 and 2023 was comprised of the following (in thousands):

	December 31,	
	2024	2023
Raw materials	$ 440	$ 242
Work in process	740	286
Finished goods	2,731	3,325
Total	$ 3,911	$ 3,853

Note 7. Property and Equipment

Property and equipment as of December 31, 2024 and 2023 were comprised of the following (in thousands):

	December 31,	
	2024	2023
Processing and research equipment	$ 1,023	$ 381
Leasehold improvements	103	92
Office equipment and furniture	87	86
Computer hardware and software	194	194
	1,407	753
Less: accumulated depreciation and amortization	(634)	(581)
Property and equipment, net	$ 773	$ 172

Depreciation and amortization expense on property and equipment totaled approximately $0.1 million in both of the years ended December 31, 2024 and 2023. Amounts included within cost of goods sold are not material.

Note 8. Leases

As of December 31, 2024, the Company leases one production facility, one administrative and research facility and one administrative facility under non-cancelable operating lease arrangements that expire through October 2026.

The following is a summary of the Company's ROU assets and operating lease liabilities as of December 31, 2024 and 2023 (in thousands):

	Classification on the Balance Sheet	December 31, 2024	December 31, 2023
Assets			
Operating leases assets	Operating lease right-of-use assets and other	$ 860	$ 271
Liabilities			
Operating leases current liabilities	Current operating lease liabilities and other	460	275
Operating leases non-current liabilities	Long-term operating lease liabilities	423	—
Total lease liabilities		$ 883	$ 275
Weighted average remaining lease term		1.7	0.6
Weighted average discount rate		13.1 %	7.2 %

For the years ended December 31, 2024 and 2023, the Company recognized operating lease costs of approximately $0.6 million and $0.5 million, respectively. Cash paid for amounts included in the measurement of operating lease liabilities are included in operating cash flows and were approximately $0.6 million for both the years ended December 31, 2024 and 2023.

The table below reconciles the Company's future cash obligations to the operating lease liabilities recorded on the balance sheet as of December 31, 2024 (in thousands):

Years ending December 31,	
2025	$ 546
2026	454
Total minimum lease payments	1,000
Less: amount of lease payments representing interest	(117)
Present value of future minimum lease payments	883
Less: current operating lease liabilities	(460)
Long-term operating lease liabilities	$ 423

In March 2025, the Company signed a new lease for 26,598 square feet. This new facility will be utilized for office, manufacturing and laboratory space. The lease expires in January 2036 with early termination dates in 2029 and 2033. Monthly lease payments (including allocation portions of property taxes, insurance and other landlord operating expenses) total approximately $75,000 with annual rent escalations of 3%. Rent is abated for the first 12 months of occupancy and is discounted at 50% for months 18 through 24.

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, 2024 and 2023 are as follows (in thousands):

	December 31, 2024			December 31, 2023		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Acquired products	$ 29,317	$ (22,186)	$ 7,131	$ 29,317	$ (19,260)	$ 10,057
Customer relationships	4,723	(3,581)	1,142	4,723	(3,109)	1,614
Total	$ 34,040	$ (25,767)	$ 8,273	$ 34,040	$ (22,369)	$ 11,671

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, 2024 and 2023, 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, 2024 through 2026 and approximately $1.5 million during the year ended December 31, 2027.

Note 10. Long-Term Debt

On August 10, 2022, the Company entered into a senior secured term loan facility with SWK Funding LLC, as agent, and other lenders party thereto for an aggregate principal amount of $25 million, and the Company amended the facility in May 2023, March 2024 and September 2024 (as amended, the "SWK Loan Facility"). An initial draw of $21 million was made in August 2022, and an additional $4 million was made on December 14, 2022. The SWK Loan Facility also allows for the establishment of a separate, new asset-based revolving loan facility of up to $8 million, which has not been entered into to date. The SWK Loan Facility matures on August 10, 2027 and accrues interest, payable quarterly in arrears. Principal amortization of the SWK Loan Facility, as amended in September 2024, starts in November 2025. Principal payments during the amortization period will be limited based on revenue-based caps, although as of December 31, 2024, no such caps are applicable and quarterly principal payments will be in an amount equal to 5% of the aggregate principal amount funded with the balance paid at maturity. The SWK Loan Facility also includes both revenue and liquidity covenants, restrictions as to payment of dividends, and is secured by all assets of the Company, subject to certain customary exceptions. As of December 31, 2024, Elutia was in compliance with its financial covenants under the agreement governing the SWK Loan Facility ("SWK Loan Facility Agreement").

All of the SWK Loan Facility borrowings take the form of Secured Overnight Financing Rate ("SOFR") loans and bear interest at a rate per annum equal to the sum of an applicable margin of (i) 7.75% and the "Term SOFR Rate" (based upon an interest period of 3 months), or (ii) if the Company has elected the PIK Interest option (as defined below), 3.75% and the "Term SOFR Rate." The Company may elect a portion of the interest due, to be paid in-kind at a rate per annum of 4.5% ("PIK Interest"), and such election may be made until November 15, 2025. The "Term SOFR Rate" is subject to a floor of 2.75%. The agreement governing the SWK Loan Facility also includes an exit fee equal to 6.5% of the aggregate principal amount funded prior to termination plus $112,500. The weighted average interest rate on the SWK Loan Facility was 13.4% and 13.2% for the years ended December 31, 2024 and 2023, respectively. The Company elected the PIK interest option for all four quarters of both 2024 and 2023.

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

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

The SWK Loan Facility Agreement requires certain mandatory prepayments, subject to certain exceptions, with: (1) 100% of any net casualty proceeds in excess of $250,000 and (2) for non-ordinary course asset sales, an amount equal to the difference between (x) the proportion of divested gross profit (as defined in the SWK Loan Facility Agreement) to the Company's total gross profit (as defined in the SWK Loan Facility Agreement) multiplied by the outstanding loans under the SWK Loan Facility and (y) the difference between $1,000,000 and the aggregate sale proceeds of any assets previously sold during the fiscal year. The closing of the divestiture of the Orthobiologics Business in November 2023 triggered the mandatory prepayment of $4.0 million. Of such amount, $2.0 million was paid shortly after closing of the divestiture in 2023 and the remainder was paid in February 2024 based on mutual agreement between the parties.

As noted above, the Company executed an amendment to the SWK Loan Facility in September 2024 which, among other items, served to defer the commencement of principal repayment from November 2024 to November 2025.

As of December 31, 2024, the contractual maturities of the long-term debt are as follows (in thousands):

Years ending December 31,	Term Loan
2025	$ 1,250
2026	5,000
2027	17,275
Total	23,525
Debt Discount	(318)
Deferred Financing Costs	(244)
Exit Fee Liability	890
Total, net	23,853
Current Portion	(1,250)
Long-term Debt	$ 22,603

In addition to the above, the Company finances the annual premiums of certain insurance policies through short-term financing arrangements and includes the liabilities associated with such arrangements within accrued liabilities in accompanying consolidated balance sheets. 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, 2024 and 2023.

Note 11. Revenue Interest Obligation

As part of the CorMatrix asset acquisition described in Note 9, the Company assumed a restructured, long-term obligation (the "Initial 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 Initial 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 EluPro. Furthermore, a $5.0 million payment would be due to Ligand if cumulative sales of these products exceed $100 million and a second $5.0 million will be due if cumulative sales exceed $300 million or the assets related to CanGaroo and any substantially similar products undergo a change of control during the ten-year term of the agreement which expires on May 31, 2027.

On January 10, 2024, the Company entered into an amendment to the Revenue Interest Obligation (the "Amended Revenue Interest Obligation"). Pursuant to the Amended Revenue Interest Obligation, the parties modified and restructured the Revenue Interest Obligation by revising the annual minimum payments for 2024 and each subsequent fiscal year during the term of the agreement from $2.75 million to $4.4 million. Such minimums are payable quarterly within 30 days after each quarter-end date. Additionally, the Company made payments totaling $3.0 million (50% paid in January 2024 and 50% paid in April 2024) in satisfaction of all royalty obligations for the first three fiscal quarters of 2023 and made a payment in February 2024 of $1.1 million in satisfaction of the royalty obligations for the fourth quarter

of 2023. Furthermore, as part of the Amended Revenue Interest Obligation, Ligand waived the Company's obligation to make the $5.0 million milestone payment that became due to Ligand in the second quarter of 2023.

The Company has estimated the value of the Initial Revenue Interest Obligation as of December 31, 2024 and 2023, 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. The Amended Revenue Interest Obligation changed the timing and extent of future payments by the Company to Ligand and such change to the estimated future payments yielded a reduction to the total obligation of approximately $1.4 million during the year ended December 31, 2024. The resulting gain was recognized as other income in the accompanying consolidated statement of operations. There was no change to estimated future payments during the year ended December 31, 2023, and thus, no re-measurement gain or loss was recognized.

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

Note 12. Fair Value Measurements

The following tables set 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, 2023 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market fund	$ 14,087	$ —	$ —	$ 14,087
Total	$ 14,087	$ —	$ —	$ 14,087
Liabilities:				
Revenue Interest Obligation*	$ —	$ —	$ 17,101	$ 17,101
Warrant liability	—	—	12,760	12,760
Total	$ —	$ —	$ 29,861	$ 29,861

	Fair Value Measurements at December 31, 2024 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market fund	$ 10,850	$ —	$ —	$ 10,850
Total	$ 10,850	$ —	$ —	$ 10,850
Liabilities:				
Revenue Interest Obligation*	$ —	$ —	$ 9,890	$ 9,890
Warrant liability	—	—	16,076	16,076
Total	$ —	$ —	$ 25,966	$ 25,966

*Net Present Value; see discussion of value below

The warrant liability in the table above consisted of the fair value of Common Warrants, 2023 Prefunded Warrants and 2024 Prefunded Warrants (as defined in Note 14 below) to purchase the Company's Class A Common Stock and, with respect to the Common Warrants, was based on significant inputs not observable on the market, which represents a Level 3 measurement within the fair value hierarchy. See Note 14 for discussion of the Company's valuation methods and related impacts on the consolidated statement of operations relative to the warrant liability.

See Note 11 for discussion of the fair valuation of the Company's Revenue Interest Obligation.

The following table provides a rollforward of the aggregate fair value of the Revenue Interest Obligation categorized with a Level 3 input for the years ended December 31, 2024 and 2023 (in thousands):

	Revenue Interest Obligation
Balance, January 1, 2023	$ 14,906
Interest accrued to Revenue Interest Obligation	2,195
Balance, December 31, 2023	$ 17,101
Payments on Revenue Interest Obligation	(7,400)
Interest accrued to Revenue Interest Obligation	1,632
Gain on revaluation of revenue interest obligation	(1,443)
Balance, December 31, 2024	$ 9,890

See Note 14 for the rollforward of the aggregate fair value of the warrant liability.

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,	
	2024	2023
Tax benefit at U.S. statutory rate	21.0 %	21.0 %
State income tax benefit, net of federal benefit	1.5 %	1.8 %
Nondeductible expenses	(6.6)%	(2.8)%
State law changes	0.2 %	0.6 %
Other	(0.6)%	(1.4)%
Change in valuation allowance	(15.5)%	(19.3)%
Effective tax rate	— %	(0.1)%

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, 2024 and 2023, significant components of the Company's net deferred income taxes are as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Tax goodwill	$ 2,549	$ 2,613
Net operating loss carryforwards	29,733	23,325
Inventory	94	137
Acquired intangibles	2,000	1,734
Revenue interest obligation	631	1,220
Interest expense	4,485	3,510
Research and development costs	2,375	2,412
Operating lease liability	193	52
Litigation costs	3,713	2,867
Other	2,262	1,653
Total assets	48,035	39,523
Deferred tax liabilities:		
Operating lease right-to-use assets	(188)	(51)
Prepaid expenses	(441)	(484)
Total liabilities	(629)	(535)
Total net deferred tax asset	47,406	38,988
Valuation allowance	(47,406)	(38,988)
Net deferred tax asset, net of valuation allowance	$ —	$ —

The Company did not recognize any deferred benefit for income taxes for the years ended December 31, 2024 and 2023, as the increases to the respective net deferred tax assets of $8.4 million and $7.1 million, respectively, were offset by corresponding increases to the Company's deferred tax asset valuation allowance due to the 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, 2024 and 2023, 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, 2024 and 2023 relates to current amounts due on certain state tax obligations.

As of December 31, 2024, the Company had net operating loss carryforwards for federal income tax purposes of approximately $129.3 million, comprised of $17.7 million that will expire beginning in 2036 and $111.6 million that have no expiration date. The Company also had state net operating loss carryforwards of approximately $46.9 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 the expiration of a portion of the net operating loss carryforwards before utilization.

As of December 31, 2024 and 2023, the Company had no unrecognized tax benefits.

Note 14. Common Stock and Warrants

Registered Direct Offerings of Common Stock and Warrants

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

Subsequent to December 31, 2024, on February 4, 2025, the Company sold, in a registered direct offering ("2025 Registered Offering") an aggregate of (i) 5,520,000 shares of our Class A common stock and (ii) prefunded warrants ("2025 Prefunded Warrants") to purchase up to an aggregate of 480,000 shares of Class A Common Stock. The public offering price for each share of Class A Common Stock was $2.50, and the public offering price for each 2025 Prefunded Warrant was $2.499, for aggregate gross proceeds of approximately $15.0 million, before deducting offering expenses. The 2025 Prefunded Warrants have an exercise price of $0.001 per share of Class A Common Stock, are exercisable immediately and will expire when exercised in full.

Private Placement of Common Stock and Warrants

On September 21, 2023, the Company sold, in a private offering ("Private Offering") an aggregate of (i) 6,852,811 units ("Common Units") each comprised of (a) one share of the Company's Class A common stock and (b) a warrant ("Common Warrant") to purchase one and one half shares of Class A Common Stock, and (ii) 503,058 units (the "Prefunded Units"), each comprised of (a) a prefunded warrant ("2023 Prefunded Warrant") to purchase one share of Class A Common Stock, and (b) a Common Warrant. The Common Units were sold at a purchase price of $1.4275 per unit, and the Prefunded Units were sold at a purchase price of $1.4265 per unit, for aggregate gross proceeds of approximately $10.5 million, before deducting offering expenses. Each Common Warrant was exercisable until July 31, 2024, the date which was 30 trading days after the clearance by the FDA of the Company's EluPro product, at an exercise price per share of $1.4275. As discussed below, all Common Warrants were exercised before they expired. Each 2023 Prefunded Warrant is exercisable at any time at a nominal exercise price per share of $0.001 (with the remainder of the exercise price per share of Class A Common Stock having been prefunded to the Company). The Company incurred transaction fees, including commissions and legal fees, of approximately $1.1 million in connection with the Private Offering, of which $0.4 million were allocated to the issuance of the common stock.

See below for discussion of the accounting for the warrants and the allocation of the remainder of the transaction fees from both the 2024 Registered Offering and Private Offering.

Warrant Liabilities

The Company has concluded that the 2024 Prefunded Warrants from the Registered Offering and the Common Warrants and the 2023 Prefunded Warrants from the Private Offering do not meet the equity contract scope exception under ASC 815-40 as in the event of a (i) fundamental transaction such as a merger and (ii) failure to timely deliver warrant

shares upon exercise, certain provisions of which may require the Company to adjust the settlement value in a manner that is not consistent with a fixed-for-fixed option pricing model.

As a result, with respect to the 2024 Prefunded Warrants, the Company allocated $2.5 million of the gross proceeds from the Registered Offering to such warrants based on their fair value. Similarly, with respect to the Common Warrants and 2023 Prefunded Warrants, the Company allocated $8.6 million of the gross proceeds from the Private Offering to such warrants based on their fair value. Additionally, the Company allocated a portion of the transaction fees from both the Registered Offering and the Private Offering to the respective warrants and recognized the expense within other (income) expense, net. Such expenses totaled $0.3 million during the year ended December 31, 2024, and $0.8 million during the year ended December 31, 2023.

As noted above, the last exercise date for the Common Warrants was July 31, 2024. All Common Warrants outstanding were exercised by such date yielding exercise proceeds of $15.7 million during the year ended December 31, 2024. Certain of these exercises ultimately resulted in their conversion to 2023 Prefunded Warrants. The liability associated with the 2024 Prefunded Warrants, Common Warrants and 2023 Prefunded Warrants is recorded as warrant liability in the accompanying consolidated balance sheet as of December 31, 2024 and December 31, 2023. A summary of the warrant activity for the years ended December 31, 2024 and 2023, respectively is as follows:

	Common Warrants	2023 Prefunded Warrants	2024 Prefunded Warrants
Outstanding, January 1, 2023	—	—	—
Issued	11,033,804	503,058	—
Outstanding, December 31, 2023	11,033,804	503,058	—
Issued	—	—	725,000
Conversions of Common Warrants to 2023 Prefunded Warrants	(3,896,130)	3,896,130	—
Exercised	(7,137,674)	(825,862)	—
Outstanding, December 31, 2024	—	3,573,326	725,000

The valuation of the warrants is adjusted to fair value (Level 3) at each subsequent balance sheet date until the warrants are settled. The following table provides a rollforward of the aggregate fair value of the warrant liability for the years ended December 31, 2024 and 2023, respectively (in thousands):

	Common Warrants	2023 Prefunded Warrants	2024 Prefunded Warrants	Total Offering Warrants
Warrant Liability, January 1, 2023	$ —	$ —	$ —	$ —
Fair value upon issuance	7,850	770	—	8,620
Loss on revaluation of warrant liability	3,820	320	—	4,140
Warrant Liability, December 31, 2023	11,670	1,090	—	12,760
Fair value upon issuance	—	—	2,464	2,464
Loss on revaluation of warrant liability	13,740	891	247	14,878
Conversions of Common Warrants to 2023 Prefunded Warrants	(8,898)	14,456	—	5,558
Exercised	(16,512)	(3,072)	—	(19,584)
Warrant Liability, December 31, 2024	$ —	$ 13,365	$ 2,711	$ 16,076

The fair value adjustments were driven mainly by changes in the Company's stock price and have been recorded as loss on revaluation of warrant liability in the accompanying consolidated statements of operations for the years ended December 31, 2024 and 2023.

The Company calculated the fair value of the Common Warrants using the Black-Scholes option pricing model with the following inputs as of June 30, 2024 (the last reporting date prior to all remaining Common Warrant exercises in July 2024) and December 31, 2023:

	June 30, 2024	December 31, 2023
Common stock price	$ 4.96	$ 2.16
Expected term (years)	0.1	0.7
Risk-free interest rate	5.5 %	5.1 %
Volatility factor	88.4 %	107.3 %
Dividend yield	— %	— %

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

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 $0.1 million and $0.3 million for the years ended December 31, 2024 and 2023, respectively.

Note 16. Net Loss Per Share

(in thousands, except share and per share data)	Year Ended December 31, 2024	Year Ended December 31, 2023
Numerator:		
Net loss from continuing operations	$ (54,129)	$ (41,249)
Net income from discontinued operations	$ 180	$ 3,593
Net loss	$ (53,949)	$ (37,656)
Denominator:		
Weighted average number of common shares - basic and diluted	29,071,113	18,160,822
Net loss per share from continuing operations attributable to common stockholders - basic and diluted	$ (1.86)	$ (2.27)
Net income per share from discontinued operations attributable to common stockholders - basic and diluted	$ 0.01	$ 0.20
Net loss per share - basic and diluted	$ (1.86)	$ (2.07)

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,	
	2024	2023
Options to purchase common stock	3,220,991	1,501,193
Restricted stock units	1,417,123	335,608
Class A common stock warrants	187,969	187,969
Common Warrants	—	11,033,804
2023 Prefunded Warrants	3,573,326	503,058
2024 Prefunded Warrants	725,000	—
Total	9,124,409	13,561,632

Note 17. Commitment and Contingencies

Cook Biotech License and Supply Agreements

Elutia has entered into a license agreement, as amended, with Cook Biotech ("Cook"), now owned by Evergen, for an exclusive, worldwide license to the porcine tissue for use in the Company's Cardiac Patch and CanGaroo products, subject to certain co-exclusive rights retained by Cook (the "Cook License Agreement"). The term of such license is through the date of the last to expire of the licensed Cook patents, which is anticipated to be July 2031. Along with this license agreement, Elutia entered into a supply agreement whereby Cook would be the exclusive supplier to Elutia of licensed porcine tissue. Under certain limited circumstances, Elutia has the right to manufacture the licensed product and pay Cook a royalty of 3% of sales of the Elutia-manufactured tissue. The supply agreement expires on the same date as the related license agreement. No royalties were paid or due to be paid to Cook during the years ended December 31, 2024 or 2023. The Cook License Agreement also provides for a worldwide exclusive license to the porcine tissue for use with neuromodulation devices in addition to cardiovascular devices and includes license fee payments of $0.1 million per year in each of the years 2021 through 2026. Such license payments would accelerate if a change in control, as defined in the Cook License Agreement, occurs within Elutia. The Company, in its sole discretion, can terminate the Cook License Agreement at any time.

Legal Proceedings

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

FiberCel Litigation

In June 2021, the Company announced a voluntary recall of a single lot of FiberCel fiber viable bone matrix. Since September 2021, 110 product liability lawsuits or claims have been filed or asserted against the Company involving FiberCel. As of December 31, 2024, there were 66 active lawsuits or claims against the Company, including 23 lawsuits or claims where settlements have been reached but not yet been paid as of December 31, 2024. The lawsuits, which have been filed against Elutia, certain Medtronic entities, and others, allege that the plaintiffs were exposed to and/or contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of FiberCel during orthopedic fusion operations. Such lawsuits were filed in the Superior Court of Marion County, Indiana (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

Montgomery County, Ohio and the U.S. District Court of the Southern District of Ohio (the "Ohio Complaints"); the U.S. District Court for the Western District and Eastern District of North Carolina (collectively, the "North Carolina Federal Complaints"); the Circuit Court of Okaloosa County, Florida, and the U.S. District Court for the Northern District and the Southern District of Florida (collectively, the "Florida Complaints"); the U.S. District Courts for 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 Circuit Court of Fayette County, Kentucky 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");the Circuit Court of Cook County, Illinois and the U.S. District Court for the Northern District of Illinois (collectively, the "Illinois Complaints"); the U.S. District Court for the Eastern District of Pennsylvania ("Pennsylvania Federal Complaint); the U.S. District Court for the Eastern District of Virginia ("Virginia Federal Complaint"); the U.S. District Court for the Central District of California ("California Federal Complaint"); the U.S. District Court of Arizona ("Arizona Federal Complaint"); and the U.S. District Court for the Northern District of Georgia ("Georgia Federal Complaint").

Plaintiffs in the Indiana State Complaints allege a cause of action under Indiana's Product Liability Act, citing manufacturing defects, defective design and failure to properly warn and instruct, and several of the complaints allege loss of consortium. Plaintiffs in these actions assert that the defendants are strictly liable or have breached the duty of care owed to plaintiffs by failing to exercise reasonable care in designing, manufacturing, marketing and labeling FiberCel and seek various types of damages, including economic damages, non-economic damages and loss of consortium. Plaintiffs in one of the Indiana State Complaints allege causes of action for product liability, negligence, breach of express and implied warranties, and punitive damages. Each of the plaintiffs in the Delaware State Complaints alleges negligence, breach of implied warranty, breach of express warranty, medical monitoring, and punitive damages, and two also allege loss of consortium. Plaintiffs in the Delaware State Complaints seek 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 Complaints contain 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 Complaints allege causes of action for negligence, defective design, breach of implied warranty, breach of express warranty, and loss of consortium, and seek 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, and breach of express warranty and seeks recovery for medical monitoring. The Illinois Complaints contain claims of strict liability, defective design and manufacturing, breach of express warranty, breach of implied warranty and negligence and seek compensatory damages. The Pennsylvania Federal Complaint asserts claims for strict liability, negligence, breach of implied warranty, and breach of express warranty, as well as claims under the Wrongful Death Act and the Survival Act, and seeks compensatory and punitive damages. The Virginia Federal Complaint asserts causes of action for negligent failure to warn, negligence, breach of implied warranty, and breach of express warranty and seeks recovery for medical monitoring, compensatory damages and punitive damages. The California Federal Complaint advances claims of strict liability (defective design and manufacture), negligence and breach of implied warranty and seeks compensatory damages and recovery for medical monitoring. The Arizona Federal Complaint asserts strict product liability claims for defective design, manufacture and failure to warn, negligence, breach of implied warranty and breach of express warranty and seeks recovery for medical monitoring, loss of consortium, compensatory damages, and punitive damages. The Georgia Federal Complaint asserts causes of action for negligence, including negligent design, negligent failure to warn, negligent manufacturing, and negligent misrepresentation; strict liability claims based on manufacturing defect, design defect, and

failure to warn; breach of implied warranty of merchantability; breach of implied warranty of fitness for a particular purpose; breach of express warranty; and loss of consortium and it seeks compensatory damages and punitive damages.

The Company refers to the aforementioned litigation and claim notices collectively as the "FiberCel Litigation."

Viable Bone Matrix Litigation

In July 2023, the Company announced a voluntary recall of a single lot of a certain viable bone matrix ("VBM") product and the market withdrawal of all of its VBM products produced after a specified date. Notice of the voluntary recall was issued to centers after the Company learned of post-surgical Mycobacterium tuberculosis ("MTB") infections in two patients treated with a VBM product from a single donor lot. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism. Based on our discussions with the CDC, the Company believes that a total of 36 patients were treated with product from the single donor lot. Since August 2023, 24 product liability lawsuits or claims have been filed or asserted against the Company involving VBM. As of December 31, 2024, there were 15 active lawsuits or claims against the Company, including three lawsuits or claims where settlements had been reached but not yet paid. Furthermore, there is one claim where the statute of limitation to file a lawsuit has expired. The lawsuits, which have been filed against Elutia and others, allege that the plaintiffs were exposed to and/or contracted tuberculosis and/or suffered substantial symptoms and complications following the implantation of VBM during orthopedic fusion operations. To date, these lawsuits have been filed in California Superior Court (collectively, the "California State Complaints"), the United States District Court for the Southern District of California (the "California Federal Complaint"), the United States District Court for the Eastern District of Louisiana (collectively, the "Louisiana Federal Complaints"), and the United States District Court for the Western District of Texas (the "Texas Federal Complaint").

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

The Company refers to the aforementioned litigation and claim notices collectively as the "VBM Litigation."

Medtronic Litigation

In June 2024, the Company filed an action against Medtronic Sofamor Danek USA, Inc. ("Medtronic") in the Superior Court of the State of Delaware. The Company's complaint alleges breach of the 2019 Tissue Product Supply Agreement (the "Supply Agreement") between the Company and Medtronic. In particular, the complaint alleges that Medtronic did not honor its contractual obligations to obtain insurance coverage and to defend and indemnify the Company for over 100 lawsuits against the Company alleging claims arising from the use of FiberCel products distributed by Medtronic. The complaint does not specify the amount of damages owed by Medtronic for these breaches. On July 31, 2024, Medtronic responded to the complaint by denying Elutia's claims and asserting a single counterclaim alleging that Elutia breached certain representations and warranties under the Supply Agreement and owes ongoing indemnity obligations to Medtronic. The counterclaim does not specify the amount of any alleged damages. On October 15, 2024,

Medtronic filed a motion to dismiss Elutia's claims. The court held a hearing on January 9, 2025, and has not yet issued a ruling on the motion to dismiss. Given the early stages of this matter and the Company's intention to vigorously defend this counterclaim, we do not consider a loss to be probable or estimable at this time.

Contingent Liability for Legal Proceedings

FiberCel Litigation

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 44 of the cases was settled for a total cash outlay of approximately $14.4 million. For the remaining 66 cases, the Company estimated a probable loss related to each case and has recorded a liability at a total estimated amount of $15.9 million at December 31, 2024, which is recorded as Contingent Liability for Legal Proceedings in the accompanying consolidated balance sheets. Such liability includes $8.2 million for which the settlements have been reached but have not yet been paid.

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

VBM Litigation

Since June 2023, the Company has also engaged in a process to negotiate and attempt to resolve many of the cases in the VBM Litigation. In total, Elutia's liability in nine of the cases has been settled for a total cash outlay of approximately $1.0 million. For the remaining 26 cases, which includes unasserted claims that the Company believes are probable of assertion, the Company estimated a probable loss at an estimated amount of $4.5 million at December 31, 2024, which is recorded as Contingent Liability for Legal Proceedings in the accompanying consolidated balance sheets. Such liability includes $0.5 million for which the settlements have been reached but have not yet been paid. The expense related to this estimate was recorded within Litigation costs, net in the accompanying consolidated statement of operations, with the entirety of such expense offset by insurance recoveries received or receivable as further described below.

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

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

Insurance Receivables of Litigation Costs

The Company has purchased insurance coverage that, subject to common contract exclusions, provided coverage for the FiberCel Litigation and VBM Litigation product liability losses as well as legal defense costs. 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 as of December 31, 2024 and 2023 totaled $4.8 million and $2.7 million, respectively and are recorded as Insurance Receivables of Litigation Costs in the accompanying consolidated balance sheets. All such receivables as of December 31, 2024 related to the VBM Litigation, and nearly all of such receivables at December 31, 2023 related to the FiberCel Litigation.

The Company had been pursuing additional recovery amounts in respect of indemnity and contribution claims with certain insurance providers. During the year ended December 31, 2024, the Company resolved these matters through a settlement totaling $1.6 million, with such recovery being recorded within Litigation costs, net in the accompanying consolidated statement of operations for the year ended December 31, 2024.

As of both December 31, 2024 and 2023, the Company was not a party to, or aware of, any legal matters or claims with material financial exposure, except for the FiberCel Litigation, VBM Litigation and Medtronic matter.

Note 18. Segment Information

With the divestiture of the Orthobiologics Business, the Company now operates in three segments. The Company determined its operating and reportable segments to be consistent with its major product groupings – Device Protection, Women's Health and Cardiovascular. The accounting policies of the segments are the same as those described in the summary of significant accounting policies.

The Chief Operating Decision Maker ("CODM") is the Chief Executive Officer. The CODM evaluates the performance of our segments based upon, among other things, segment net sales and segment gross profit, excluding intangible asset amortization ("segment gross profit"). Segment gross profit is what the CODM uses in evaluating our results of operations and the financial measure that provides insight into our overall performance and financial position. The CODM considers budget-to-actual variances and variances against prior years using segment gross profit when making decisions about allocating resources to the segments. Asset information is not provided as the Company's CODM does not regularly review or utilize detailed asset data to assess segment performance.

For the year ended December 31, 2024, the Company's segment gross profit was comprised of the following (in thousands):

	Device Protection	Women's Health	Cardiovascular	Total
Net sales	$ 9,907	$ 11,553	$ 2,915	$ 24,375
Cost of goods sold, excluding intangible asset amortization	3,594	5,568	1,108	
Segment gross profit	$ 6,313	$ 5,985	$ 1,807	$ 14,105

The net sales for the year ended December 31, 2024 include the revenues derived from one customer which represents 14% of total net sales. Such customer is included within the Cardiovascular segment.

For the year ended December 31, 2023, the Company's segment gross profit was comprised of the following (in thousands):

	Device Protection	Women's Health	Cardiovascular	Total
Net sales	$ 9,401	$ 10,304	$ 5,040	$ 24,745
Cost of goods sold, excluding intangible asset amortization	2,836	5,902	1,556	
Segment gross profit	$ 6,565	$ 4,402	$ 3,484	$ 14,451

The net sales for the year ended December 31, 2023 include the revenues derived from one customer which represents 10% of total net sales. Such customer is included within the Cardiovascular segment.

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, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Segment gross profit	$ 14,105	$ 14,451
Adjustments:		
Intangible asset amortization expense	3,398	3,398
Sales and marketing	12,546	13,087
General and administrative	18,659	14,104
Research and development	3,785	4,399
Litigation costs, net	11,368	9,989
Loss from operations	(35,651)	(30,526)
Interest expense	4,779	5,796
Loss on revaluation of warrant liability	14,878	4,140
Other (income) expense, net	(1,186)	759
Loss before provision for income taxes	$ (54,122)	$ (41,221)

During the years ended December 31, 2024 and 2023, the Company did not have any material international product sales, and the Company did not own any long-lived assets outside the United States.