

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

FORM 8-K  
CURRENT REPORT

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

Date of Report (Date of earliest event reported): November 15, 2023 (~~November 8, 2023~~)

**ELUTIA INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation)

**001-39577**  
(Commission  
File Number)

**47-4790334**  
(IRS Employer  
Identification No.)

**12510 Prosperity Drive, Suite 370, Silver Spring, MD 20904**

(Address of principal executive offices) (Zip Code)

**(240) 247-1170**

(Registrant's telephone number, including area code)

**N/A**

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

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

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

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

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

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

Emerging growth company

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

**Item 1.01. Entry Into a Material Definitive Agreement.**

The information required by this Item 1.01 with respect to the Amendment Letter and the Manufacturing Agreement (each as defined below) is set forth in Item 2.01 below, and is incorporated herein by reference.

**Item 2.01 Completion of Acquisition or Disposition of Assets.**

As previously announced, on September 17, 2023, Elutia Inc. (the “Company” or “Elutia”) executed an Asset Purchase Agreement (as amended, the “Purchase Agreement”) with Berkeley Biologics, LLC (“Berkeley”), a Delaware limited liability company and wholly-owned subsidiary of GNI Group, Ltd. (Tokyo Stock Exchange: 2160.T) (“GNI”). On November 8, 2023 (the “Closing Date”), pursuant to the Purchase Agreement, Berkeley completed its purchase (the “Asset Purchase”) of substantially all of the assets of the Company related to (i) the Company’s business of researching, developing, administering, insuring, operating, commercializing, manufacturing, selling and marketing the Company’s Orthobiologics products identified in the Purchase Agreement (the “Products”), and (ii) the business of contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products (but excluding the business of contract manufacturing of acellular dermis products for use in the field of breast reconstruction) (the “Closing”).

Shortly after the Closing Date, Elutia received an initial cash payment of approximately \$14.6 million, after customary adjustments. In addition, for each of the five years following the Closing, the Company is eligible under the Purchase Agreement to receive an earn-out payment (each, an “Earn-Out Payment”) equal to 10% of the actual revenue earned by Berkeley in the applicable year that is derived from sales of those Products defined as “Earn-Out Products” under the Purchase Agreement, and from any improvements, modifications, derivatives and enhancements related to the Earn-Out Products, with the aggregate amount of Earn-Out Payments capped at \$20 million.

***Amendment Letter with SWK Funding LLC***

In connection with the Closing, the Company entered into an amendment letter (the “Amendment Letter”) with SWK Funding LLC amending that certain Credit Agreement, dated as of August 10, 2022, among Elutia, as Borrower, SWK Funding LLC, as Agent, and the lenders from time to time party thereto (as amended and supplemented from time to time, the “SWK Facility”). The Amendment Letter provides for the Company’s use of a portion of the Orthobiologics sale proceeds to pay down certain amounts owed under mandatory prepayment provisions of the SWK Facility. Pursuant to the Amendment Letter and an associated partial release of lien entered into by Elutia, Berkeley and the Agent, approximately \$2.0 million of the proceeds from the Asset Purchase were paid to the Agent shortly after the Closing Date. The Company will also be required to pay an additional \$2.0 million, representing the remainder of the mandatory prepayment amounts owed under the SWK Facility, by the earlier of (i) February 15, 2024 or (ii) two business days following written request by the Agent (the “Deferred Prepayment”). Until the time the Deferred Prepayment is made, the Company will be required to maintain an amount of Consolidated Unencumbered Liquid Assets (as such term is defined in the SWK Facility) increased by the amount of the Deferred Prepayment.

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## **Contract Manufacturing Agreement**

In connection with the Closing, the Company and Berkeley also entered into a Contract Manufacturing Agreement (the “Manufacturing Agreement”) pursuant to which Berkeley will manufacture, supply and distribute the SimpliDerm Hydrated Acellular Dermal Allograft product for the Company for a period of two years following the Closing.

The foregoing description of the Purchase Agreement and the Asset Purchase does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Purchase Agreement, which was filed as Exhibit 10.1 to the Current Report on Form 8-K filed by the Company on September 19, 2023 and is incorporated herein by reference. The Purchase Agreement is not intended to provide any other factual information about the Company, Berkeley, or their respective owners, subsidiaries and affiliates. The representations, warranties and covenants contained in the Purchase Agreement (i) were made solely for purposes of the Purchase Agreement and as of the date of the Purchase Agreement, (ii) were solely for the benefit of the parties to the Purchase Agreement, (iii) may be subject to qualifications and limitations agreed upon by the parties to the Purchase Agreement, including being qualified by confidential disclosures made for the purposes of allocating contractual risk among the parties to the Purchase Agreement instead of establishing these matters as facts and (iv) may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to security holders of the Company. Investors and security holders of the Company should not rely on the representations, warranties and covenants or any description thereof as characterizations of the actual state of facts or condition of the Company. Moreover, information concerning the subject matter of the representations, warranties and covenants may change after the date of the Purchase Agreement, which subsequent information may or may not be fully reflected in public disclosures by the Company.

The foregoing descriptions of the Amendment Letter and the Manufacturing Agreement do not purport to be complete and are subject to, and qualified in their entirety by, the full text of the Amendment Letter and Manufacturing Agreement, which are filed as Exhibits to this Current Report on Form 8-K and are incorporated herein by reference.

## **Forward-Looking Statements**

This report contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements can be identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential,” “promise” or similar references to future periods. All statements contained in this report that do not relate to matters of historical fact should be considered forward-looking statements, including any statements and information concerning our expectations for receiving the earnout payments under our agreement with Berkeley Biologics, LLC. Forward-looking statements are based on management’s current assumptions and expectations of future events and trends, which affect or may affect our business, strategy, operations or financial performance, and actual results may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, and other important factors that may cause actual results, performance or achievements to differ materially from those contemplated or implied in this press release, including, but not limited to: risks associated with shifting focus to our drug-eluting biomatrix solutions in the cardiovascular and breast reconstruction areas and away from our Orthobiologics business; risks regarding the ability to successfully execute or realize the anticipated benefits under our distribution arrangements with LeMaitre Vascular and Sientra; risks relating to the potential removal of our securities from listing on the Nasdaq Capital Market; our inability to generate sufficient revenue to achieve or sustain profitability; adverse changes in economic conditions and instability and disruption of credit markets; our ability to continue as a going concern; our ability to successfully achieve expected benefits from the divestiture of our Orthobiologics business; our products and our ability to enhance, expand, develop and commercialize our product offerings; the impact on our business of the recall of a single lot of our FiberCel product and the discontinuation of its sales by our distribution partner; consequences of our recall of a single lot of one of our viable bone matrix products and market withdrawal of all of our viable bone matrix products; our dependence on our commercial partners; the impact of the bankruptcy of Surgalign Holdings, Inc., a significant customer of the Company, on our future revenues; physician awareness of the distinctive characteristics, and acceptance by the medical community, of our products; the ability to obtain regulatory approval or other marketing authorizations, including with respect to our FDA 510(k) submission with respect to our CanGarooRM product; our intellectual property rights; and risks that the requirements for any or all of the Earn Out Payments might not be achieved and that any or all of the additional consideration tied to the Earn Out Payments might not be received by the Company; and other important factors which can be found in the “Risk Factors” section of Elutia’s public filings with the Securities and Exchange Commission (“SEC”), including Elutia’s Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in Elutia’s other filings with the SEC, including Elutia’s Quarterly Reports on Form 10-Q, accessible on the SEC’s website at [www.sec.gov](http://www.sec.gov) and the Investor Relations page of Elutia’s website at <https://investors.elutia.com>. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. Any forward-looking statement made by Elutia in this press release is based only on information currently available and speaks only as of the date on which it is made. Except as required by applicable law, Elutia expressly disclaims any obligations to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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**Item 9.01 Financial Statements and Exhibits.**

(b) Pro Forma Financial Information

The unaudited pro forma consolidated financial information of the Company as of and for the nine months ended September 30, 2023 and for each of the years ended December 31, 2022 and December 31, 2021 is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<a href="#"><u>2.1*†</u></a>	<a href="#"><u>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) (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 19, 2023)</u></a>
<a href="#"><u>10.1</u></a>	<a href="#"><u>Amendment Letter, dated November 8, 2023, by and between Elutia Inc. and SWK Funding LLC</u></a>
<a href="#"><u>10.2*</u></a>	<a href="#"><u>Contract Manufacturing Agreement, dated November 8, 2023, by and between Elutia Inc. and Berkeley Biologics, LLC</u></a>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Unaudited Pro Forma Consolidated Financial Statements of the Company</u></a>
104	Cover Page Interactive Data File (formatted as Inline XBRL document)

\*Certain confidential information contained in this Exhibit, marked in brackets, has been omitted, because it is both not material and of the type of information that the registrant treats as private or confidential.

† Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the SEC.

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**SIGNATURES**

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

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

Date: November 15, 2023

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

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November 8, 2023

Elutia Inc.  
12510 Prosperity Drive, Suite 370  
Silver Spring, MD 20904  
Attn: Jeffrey D. Hamet

RE: **Amendment Letter**

Ladies and Gentlemen:

Reference is made to (i) that certain Credit Agreement, dated as of August 10, 2022, by and among Elutia Inc., a Delaware corporation (f/k/a Aziyo Biologics, Inc.) (the "Borrower"), each of the undersigned financial institutions (individually each a "Lender" and collectively the "Lenders") and SWK Funding LLC, a Delaware limited liability company, in its capacity as administrative agent for the other Lenders (in such capacity, "Agent") (as amended, restated, supplemented or otherwise modified from time to time, the "Credit Agreement"), and (ii) that certain letter agreement among Borrower, Agent and Berkeley Biologics LLC, dated as of November 8, 2023 (the "Lien Release Letter Agreement").

All capitalized terms used in this amendment letter (this "Amendment Letter") and not otherwise defined herein, shall have the respective meanings given such terms in the Credit Agreement.

At the request of Borrower, Agent hereby agrees to release its lien on the "Released Collateral" (as defined in the Lien Release Letter Agreement) in accordance with the Lien Release Letter Agreement upon receipt of payment of \$2,004,920.00 (the "Partial Payoff Amount") notwithstanding anything set forth in Section 2.8(c) of the Credit Agreement to the contrary. As consideration for such accommodation by Agent, Borrower hereby agrees that \$50,000 of the Partial Payoff Amount shall be retained by Agent as an extension fee, which shall be deemed fully-earned and non-refundable as of the date hereof, with the remaining \$1,954,920 being applied to the principal balance of the Term Loan. In addition, Borrower shall pay the remaining \$2,000,000 otherwise due and owing to Agent pursuant to Section 2.8(c) of the Credit Agreement in connection with the sale of the "Released Collateral" (the "Deferred Payoff Amount") on the earlier of (i) February 15, 2024 or (ii) two (2) Business Days following written request for payment thereof by Agent.

In addition to the forgoing, Borrower and Agent hereby agree that, until payment of the Deferred Payoff Amount has been received by Agent, the amount of Consolidated Unencumbered Liquid Assets otherwise required to be maintained by Borrower pursuant to Section 7.13.1 of the Credit Agreement shall be increased by the amount of the Deferred Payoff Amount.

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Except for the amendments expressly set forth above, all of the terms, provisions and conditions of the Credit Agreement and the other Loan Documents shall remain and continue in full force and effect. This Amendment Letter shall not apply to any other past, present or future deviations from the Credit Agreement or any other Loan Document. Except as expressly provided herein, Agent or any Lender's failure to exercise any right, privilege or remedy as a result of the matters set forth above shall not directly or indirectly in any way whatsoever either: (a) impair, prejudice or otherwise adversely affect Agent or any Lender's right at any time to exercise any right, privilege, or remedy in connection with the Credit Agreement, the other Loan Documents, any other agreement, or any other contract or instrument in connection therewith, or (b) amend or alter any provision of the Credit Agreement, the other Loan Documents, any other agreement, or any other contract or instrument in connection therewith, or (c) constitute any course of dealing or other basis for altering any obligations of Borrower or any right, privilege, or remedy of Agent or any Lender under the Credit Agreement, the other Loan Documents, any other agreement, or any other contract or instrument in connection therewith. Agent and each Lender hereby reserve all rights granted under the Credit Agreement, the other Loan Documents, this Amendment Letter and any other contract or instrument between Borrower, Agent or any Lender in connection therewith. Except as expressly stated herein, Agent and each Lender reserve all of their respective rights, privileges and remedies under the Credit Agreement, the other Loan Documents, each other agreement and any other contracts or instruments executed by Borrower for the benefit of Agent or such Lender in connection therewith.

Borrower hereby represents and warrants that (i) each of the representations and warranties contained in the Credit Agreement, is true, correct and complete in all material respects as of the date hereof; provided, however, that those representations and warranties expressly referring to a specific date shall be true, correct and complete in all material respects as of such date and (ii) no Default or Event of Default exists.

This Amendment Letter shall not become effective until Agent has received an executed and delivered signature page to this Amendment Letter by the Borrower.

Borrower represents that it has discussed this Amendment Letter with its counsel.

THE TERMS AND PROVISIONS OF SECTION 10.17 (GOVERNING LAW) AND 10.18 (FORUM SELECTION; CONSENT TO JURISDICTION) OF THE CREDIT AGREEMENT ARE HEREBY INCORPORATED HEREIN BY REFERENCE, AND SHALL APPLY TO THIS AMENDMENT LETTER *MUTATIS MUTANDIS* AS IF FULLY SET FORTH HEREIN.

This Amendment Letter may be executed in multiple counterparts, each of which shall constitute an original hereof, and all of which taken together shall constitute one and the same agreement. One or more counterparts of this Amendment Letter may be delivered by facsimile or electronic (including "PDF") transmission, with the intention that delivery by such means shall have the same effect as delivery of an original counterpart thereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

**IN WITNESS HEREOF**, as of the date above-written, the undersigned hereby agree to the terms and conditions set forth in this Amendment Letter.

Very truly yours,

**AGENT AND LENDER:**

**SWK FUNDING LLC**  
As Agent and a Lender

By: SWK Holdings Corporation  
its sole manager

By: /s/ John Tamas  
Name: John Tamas  
Title: Authorized Signatory

*[Additional signature pages follow]*

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**ACCEPTED AND AGREED TO:**

**BORROWER:**

**ELUTIA INC., (f/k/a Aziyo Biologics, Inc.)**

By: /s/ Jeffrey D. Hamet

Name: Jeffrey D. Hamet

Title: Senior Vice President, Finance

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CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH “[\*\*\*]”. SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (i) NOT MATERIAL AND (ii) THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS THAT INFORMATION AS PRIVATE OR CONFIDENTIAL.

## TRANSITION TISSUE PROCESSING, SUPPLY AND DISTRIBUTION AGREEMENT

THIS TRANSITION TISSUE PROCESSING, SUPPLY AND DISTRIBUTION AGREEMENT (this “Agreement”) is made and entered into effective as of November 8, 2023 (the “Effective Date”), by and between Berkeley Biologics LLC, a Delaware limited liability company with offices at 2800 7th Street, Berkeley, CA 94710 (“Purchaser”), and Elutia Inc., a Delaware corporation with offices at 12510 Prosperity Drive, Suite 370, Silver Spring, MD 20904 (“Elutia”).

### RECITALS:

**WHEREAS**, Purchaser and Elutia have entered into that certain Asset Purchase Agreement, by and between Elutia and Purchaser as of September 17, 2023 (the “APA”);

**WHEREAS**, Purchaser has purchased from Elutia a facility (the “Facility”) that procures, develops, processes and distributes human cellular and tissue based products and is accredited by the American Association of Tissue Banks (“AATB”);

**WHEREAS**, Elutia stores, markets and distributes human tissue products and medical devices and is registered with the FDA to do the same; and

**WHEREAS**, Purchaser shall use the purchased Facility to continue to procure, develop, and process, and Elutia shall continue to market and distribute, an allograft product having certain specifications for transplantation during the Term (as defined below).

**NOW, THEREFORE**, in consideration of the mutual covenants and agreements contained herein, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

### ARTICLE 1 DEFINED TERMS

1.1 “AATB” shall have the meaning set forth in the recitals.

1.2 “Action” shall have the meaning set forth in **Section 5.3**.

1.3 “Affiliates” shall have the meaning set forth in **Section 6.2**.

1.4 “Agreement” shall have the meaning set forth in the preamble.

1.5 “APA” shall have the meaning set forth in the recitals.

1.6 “Confidential Information” shall have the meaning set forth in **Section 6.2**.

1.7 “Detectable Nonconformance” shall the meaning set forth in **Section 3.3**.

1.8 “Donor” means a human, cadaveric tissue donor that is the source of tissue for transplantation, in accordance with agreed upon and established medical criteria and procedures and the Donor Eligibility Criteria.

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1.9 “Donor Eligibility Criteria” means that criteria set forth in the current version of Elutia standard operating procedure “Donor Screening Guidance Document DE-001” referenced in **Exhibit 1**, its amendments or successors.

1.10 “Effective Date” shall have the meaning set forth in the preamble.

1.11 “Elutia” shall have the meaning set forth in the preamble.

1.12 “Elutia Indemnitees” shall have the meaning set forth in **Section 5.1**.

1.13 “Equipment” shall have the meaning set forth in **Section 2.5**.

1.14 “FDA” means the United States Food and Drug Administration.

1.15 “Field of Use” means any use outside the field of orthopedics.

1.16 “Force Majeure” shall have the meaning set forth in **Section 8.5**.

1.17 “Good Tissue Practices”, equivalently Current Good Tissue Practice (CGTP), means requirements under Title 21 Code of Federal Regulations, Part 1271 (21 CFR Part 1271), Subparts D and E.

1.18 “Initial Term” shall have the meaning set forth in **Section 7.1**.

1.19 “Law” or “Laws” means all federal, state and local laws, rules, regulations, standards and guidelines that apply to the procurement, processing, supply, distribution and marketing of human cells, tissues or tissue-based products, or the performance of either Party’s obligations under this Agreement, including without limitation (i) the United States National Organ Transplant Act, (ii) the Public Health Service Act, (iii) the Federal Food, Drug and Cosmetic Act, (iv) Title 21 of the Code of Federal Regulations Part 1271 (Human Cells, Tissues and Cellular and Tissue Based Products) and (v) any other rules, regulations or standards promulgated by the AATB, FDA or any other applicable governmental agency, as each may be amended from time to time.

1.20 “Order” shall have the meaning set forth in **Section 3.2**.

1.21 “Party” means Purchaser or Elutia; “Parties” means Purchaser and Elutia.

1.22 “Payment Default” shall have the meaning set forth in **Section 7.2(i)**.

1.23 “Press Release” shall have the meaning set forth in **Section 8.12**.

1.24 “Product” means the SimpliDerm<sup>®</sup> Hydrated Acellular Dermal Allograft product having the Specifications in **Appendix-1**.

1.25 “Product Fees” shall have the meaning set forth in **Section 3.5**.

1.26 “Processed Tissue” means human musculoskeletal tissue, including bone and connective tissue, after debridement, sectioning, processing, and microbiological and serological clearance, provided in the form of Product by Purchaser pursuant to this Agreement, as further described in **Exhibit 1** and the Specifications.

1.27 “Product Withdrawal” shall have the meaning set forth in **Section 4.6**.

1.28 “Purchaser” shall have the meaning set forth in the preamble.

- 1.29 “Purchaser Indemnitees” shall have the meaning set forth in **Section 5.2**.
- 1.30 “Specifications” shall have the meaning set forth in **Section 2.2**.
- 1.31 “Term” shall have the meaning set forth in **Section 7.1**.
- 1.32 “Tissue” means human musculoskeletal tissues acquired by Purchaser pursuant to this Agreement, which meet the Donor Eligibility Criteria.
- 1.33 “Tissue Withdrawal” shall have the meaning set forth in **Section 4.7**.
- 1.34 “Territory” shall mean the world.

## ARTICLE 2 SUPPLY OF PRODUCT; EQUIPMENT

2.1 **Supply of Processed Tissue.** Subject to the terms and conditions set forth in this Agreement, Elutia shall order, and Purchaser shall procure, test, and make final eligibility determinations of, process, preserve, sterilize, release and supply to Elutia (in the form of Product), Processed Tissue as defined and as specified in SPEC-0179, *Hydrated Acellular Dermal Matrix (HADM) Allograft Product Specification* pursuant to Orders made and accepted in accordance with **Section 3** below. Except as explicitly set forth in **Section 2.3**, this Agreement shall not prevent Purchaser or its Affiliates from processing Tissue for its own distribution or otherwise limit or restrict in any way Purchaser’s or its Affiliates’ conduct of its present or future business.

2.2 **Supply of Product.** Elutia has developed proprietary specifications for the Product, which are set forth in **Appendix-1** (the “Specifications”). If Elutia seeks a change to the Specifications or there is a change in applicable Laws that would necessitate a change in the Specifications, Elutia will promptly provide Purchaser with Elutia’s proposed revisions to the Specifications and Purchaser and Elutia will each use their commercially reasonable efforts to agree on such revised Specifications; provided that any proposed change in the Specifications, including the timing thereof, will be effective only with the written consent of Purchaser. Elutia shall be responsible for all costs associated with any revision to the Specifications, including without limitation modifications to the Equipment, acquisition of new equipment or increase in the Product Fees; however, Purchaser must provide notice to Elutia of any such costs that would be incurred due to revisions in the Specifications and obtain Elutia’s prior written consent to such cost; provided that this sentence shall not limit Purchaser’s rights under **Section 3.5(i)**. Purchaser shall process, package and supply Product in accordance with requirements shown in the applicable **Statement of Work**, pursuant to Orders made and accepted in accordance with **Section 3.2** below. Purchaser shall use FEFO (first expired, first out) inventory procedures with respect to Product so that stock to expire first is exhausted first. Purchaser shall promptly notify Elutia if Purchaser determines that, despite its commercially reasonable efforts, it is unable to timely fabricate, process and package Product in conformance with the Specifications.

2.3 **Exclusive Rights.** All of Elutia’s rights under this Agreement with respect to the Product, including the right to market, distribute and sell the Product are exclusive in the Field of Use, given that the Specifications are proprietary to Elutia.

2.4 **Product Testing.** For every lot of material processed, Purchaser will provide a final certificate of conformance for lot release according to SOP-0169, *Quality Assurance Record Review* and FORM-0316, *Elutia Biologics Product Certificate of Conformance*.

## 2.5 Equipment.

- (i) On the Effective Date of this Agreement, Elutia will provide to Purchaser, at no additional cost, all machinery and other equipment that is owned by Elutia and used primarily for the manufacturing or production of the Product immediately prior to the date of the APA (collectively but not including any Transferred Assets (as defined in the APA), the “Equipment”). Elutia represents and warrants to Purchaser that the Equipment, when conveyed to Purchaser, (a) shall be sufficient for Purchaser to perform its obligations under this Agreement and (b) shall be good operating condition and repair in all material respects and shall not be in need of maintenance or repairs except for ordinary, routine maintenance and repairs that are not material in nature or cost. ELUTIA DOES NOT PROVIDE, AND EXPRESSLY DISCLAIMS, ANY AND ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, RELATING TO THE EQUIPMENT.
- (ii) In the event that this Agreement is terminated by (a) the mutual agreement of the Parties prior to the expiration of the Initial Term or (b) Elutia pursuant to **Section 7.2(i)** during the Initial Term, then Elutia shall have the right, at its election, to purchase the Equipment from Purchaser for the price of \$[\*\*\*] by providing written notice to Purchaser of Elutia’s intent to exercise such right within fifteen (15) days of such termination; provided that the transfer and conveyance of the Equipment to Elutia (including without limitation all disassembly, shipping, assembly and testing) shall be solely at Elutia’s expense and shall occur in a manner that does not interfere in any material respect with Purchaser’s business operations at such time. IN THE CASE OF A SALE OF EQUIPMENT TO ELUTIA PURSUANT TO THE FOREGOING SENTENCE, SUCH SALE SHALL BE “AS IS” AND PURCHASER SHALL NOT PROVIDE, AND EXPRESSLY DISCLAIMS, ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, RELATING TO THE EQUIPMENT.
- (iii) Purchaser is free to use the Equipment in Purchaser’s business operations unrelated to the Product in Purchaser’s sole discretion and at no additional cost.

## ARTICLE 3. ORDER COMMITMENT AND ORDERS

### 3.1 Transfer of Title and Shipment.

- (i) At the time that Purchaser completes the production, packaging, labeling and release of Product pursuant to an Order (such time, with respect to such Order, the “Time of Completion”), Elutia shall become the owner of, and shall hold title to, such Product, and from the Time of Completion Elutia shall bear the risk of loss and risk of expiration of such Product. Purchaser will store such Product in Purchaser’s facilities until shipping such Product in accordance with **Section 3.1(ii)** provided that Purchaser may dispose of expired Product in its discretion.
- (ii) Purchaser will (a) ship all Product to Elutia or its customers in accordance with the Specification and applicable Laws based on each Order provided and accepted in accordance with **Section 3.2** and (b) only ship orders to the address stipulated in the Order or to a different destination timely designated by Elutia in writing; provided that Purchaser shall not be obligated under this Agreement to ship any Product outside the continental United States, the District of Columbia, Alaska, or Hawaii. As set forth in **Section 3.5(i)** Product Fees include the costs of Purchaser labor, Product storage, preparation of shipments, shipping containers and other shipping supplies, and shipment costs.

### 3.2 Orders and Order Forecast.

- (i) Elutia shall provide Purchaser with a binding purchase order specifying the Product, quantity, size, delivery location and requested delivery date (an “Order”) at least [\*\*\*] days prior to the requested delivery date. Purchaser will have [\*\*\*] business days following receipt to review each Order and may reject the order by providing written notice to Elutia if (A) Purchaser anticipates in its reasonable judgment that it will be unable to fulfill the Order or (B) there is at such time a Payment Default. In the case of rejection in accordance with clause (A) of the foregoing sentence, each Party will use its commercially reasonable efforts to mutually agree on revised Order terms.
- (ii) At least [\*\*\*] days prior to the start of each calendar quarter, Elutia will provide Purchaser with a non-binding forecast of Elutia’s anticipated Orders for such quarter, including the expected timing and quantity of each Order, together with other applicable details reasonably requested by Purchaser.

3.3 **Rejection and Cure.** Upon Elutia or its customers’ use of Product, Elutia or its customers shall perform an initial physical inspection of such Product and review any related documentation. If a batch of Product (including without limitation any documentation related thereto) fails, in whole or in part, to conform to the applicable Specifications, then Elutia or its customers shall have the right to reject the batch which contains such nonconforming portion of the shipment of Product (but, for clarity, not other batches included in such shipment). Elutia or its customers shall give written notice to Purchaser of its rejection hereunder as soon as possible, but in any event no more than [\*\*\*] days after Elutia’s or its customer’s use of the Product (the “Inspection Deadline”), specifying the grounds for such rejection, and if no such notice is received by Purchaser by the Inspection Deadline, Elutia or its customer (as applicable) shall be deemed to have accepted such Product and shall have no right to reject the Product under this **Section 3.3**; provided that (i) the Inspection Deadline shall in no event be more than [\*\*\*] days after Elutia or the applicable customer has received such shipment and (ii) neither (a) the expiration of Product (if such Product had not expired at the time it arrived at the shipping destination specified in the applicable Order) nor (b) any nonconformance attributable to any action or omission of Elutia or the applicable customer shall be grounds for rejection. Purchaser shall have the opportunity to cure the nonconformance if possible (e.g., if related to documentation) to Elutia’s reasonable satisfaction within [\*\*\*] days of notification. If the nonconformance cannot be cured, Purchaser shall direct the disposition of the nonconforming batch at its expense. Purchaser shall use commercially reasonable efforts to replace each nonconforming batch of Product with conforming Product. If Elutia or its customer returns nonconforming Product after paying for such nonconforming Product, Purchaser may, in its reasonable discretion (A) offset the fees paid for the returned Product, including the cost of the return, against any yet unpaid invoice received from Purchaser or (B) require Purchaser to reimburse Elutia for any payments made for and expenses incurred in connection with the returned Product. Notwithstanding anything to the contrary in this Agreement, the provisions of this **Section 3.3** provide Elutia’s sole remedy for any defect in Product, or failure of Product to meet the Specifications, to the extent that such defect or failure was reasonably discoverable by the Inspection Deadline (any such failure, a “Detectable Nonconformance”).

### 3.4 Labeling of Product.

- (i) Labeling of Product. Purchaser shall package and label Product in accordance with all applicable Laws and shall also label Product in accordance with the Specifications in the quantities of units requested pursuant to the applicable Order. Product supplied from Purchaser to Elutia shall be labeled as approved in writing by Elutia with the brand name “SimpliDerm® Hydrated Acellular Dermal Allograft” with packaging artwork and design provided by Elutia. Each unit of Product shall have a unique identification number.

(ii) Obligations of the Parties as to Distribution and Marketing of Products.

- a. Each party shall maintain any applicable licenses, permits, registrations or other state or federal government approval (collectively, "Licenses") required to perform its obligations under this Agreement and, to the extent Elutia engages in promotion or distribution of Product, Elutia shall maintain any applicable Licenses necessary for such activities.
- b. Each party shall comply with all applicable Laws and shall refrain from making or promising to make payment or transfer of anything of value that would have the purpose or effect of public or commercial bribery, or acceptance of or acquiescence in extortion, kickbacks, or other unlawful or improper means of obtaining business. At all times while performing under this Agreement, the parties shall comply with the requirements of the U.S. Foreign Corrupt Practices Act and all other applicable anti-bribery and anti-corruption laws, rules and regulations. The parties will not export or re-export or knowingly allow the export or re-export of any Products or information that it learns pursuant to this Agreement in violation of any Law.
- c. Each Party hereby gives the other Party the right, upon sixty (60) days' advance notice and not more frequently than one time during the Term, to conduct audits, either directly or through a designee, of the other Party's storage facilities for the Products, shipping and distribution channels, and Product patient records, as applicable, relating only to the Product distributed pursuant to this Agreement, in order to ensure the other Party's compliance with the terms of this Agreement.
- d. Except as otherwise specifically provided herein, Elutia shall bear all costs and expenses associated with its distribution of the Products including, but not limited to, amounts due to employees or agents of Elutia, advertising, promotion, distribution, bad debt expense, inventory losses, commissions, and taxes. In no event shall Purchaser be liable for any expenses incurred by Elutia unless Purchaser has agreed in advance in writing to pay such expense.
- e. Products will be promoted and used in conjunction with FDA 361 HCT/P homologous use guidance and in accordance with Products Indications For Use (IFU).

3.5 **Product Fees and Taxes.**

- (i) Elutia shall pay to Purchaser the product fees for Product ordered by Elutia hereunder pursuant to an Order ("Product Fees"). The Product Fees shall initially be \$[\*\*\*] per square centimeter of Product; provided that the Product Fees shall be adjusted once in accordance with this **Section 3.5(i)**. Reasonably promptly following the date that is [\*\*\*] days after the inventory of Product existing as of the Effective Date is depleted such that Elutia places Orders for Product manufactured by Purchaser pursuant to this Agreement (such [\*\*\*]-day period, the "Initial Production Period"), Purchaser shall inform Elutia of Purchaser's good-faith determination of the average cost to Purchaser, per square centimeter of Product, of obtaining, producing, storing and handling the Product (including, for the avoidance of doubt, the share of the operating costs of the Facility allocable to the Product) and associated raw materials and of packaging, labelling, providing and shipping (including preparation of shipments, shipping containers and other shipping supplies and shipment costs) the Product, including the cost of replacing defective Product produced in the ordinary course of the production process (collectively, the "Relevant Costs"), during the Initial Production Period and such average cost shall be the Product Fee per square centimeter of Product, effective as of the date Purchaser provides written notice of the same to Elutia; provided that the Product Fee shall not be adjusted pursuant to this sentence to exceed \$[\*\*\*] per square centimeter or be less than \$[\*\*\*] per square centimeter. Once the Product Fees are determined as set forth in this **Section 3.5(i)**, the Product Fees shall not be further adjusted during the Term except by the mutual written agreement of Purchaser and Elutia. For clarity only and without creating any obligations on the part of either Party, the Parties' expectation is that the Initial Production Period will begin approximately [\*\*\*] following the Effective Date.

- (ii) The Product Fees are limited to the Relevant Costs; there is no charge associated with the Tissue itself (other than service fees relating to the acquisition of the Tissue), which is donated, and do not include any foreign, federal, state or local taxes that may be applicable to the sale of the Products. In the event that such taxes are applicable and Purchaser has the legal obligation to collect such taxes, Purchaser shall be entitled to add to the applicable invoice the amount of such taxes and Elutia shall pay such amount unless Elutia provides Purchaser with a valid tax exemption certificate authorized by the appropriate taxing authority. Other than the foregoing, Elutia shall be solely responsible for paying all such taxes.

3.6 **Billing and Payment.** Purchaser shall invoice Elutia at the Time of Completion of each Order. Elutia shall pay such invoices (excluding any amounts for Product rejected in accordance with **Section 3.3** hereof or contested reasonably and in good faith in accordance with this **Section 3.6**) within [\*\*\*] days of receipt of such invoice by Elutia. Following its receipt of an invoice, Elutia will have [\*\*\*] business days to notify Purchaser of any reasonable, good faith objections to any amounts set forth in the invoice, including an explanation in reasonable detail of any such objections; provided that if Elutia does not provide any such notice to Purchaser by such date, Elutia shall be deemed to have accepted the invoice and waived any objections thereto. Elutia shall pay all amounts that are not subject to objection in accordance with the foregoing sentence by wire transfer of freely available funds to a bank account designated in writing by Purchaser, and the Parties shall each use their reasonable efforts to resolve any such objections as expeditiously as possible. No amounts shall be withheld from any payments hereunder except as, and only to the extent, required by Law.

3.7 **Purchaser's Representations and Warranties.**

- (i) Purchaser represents and warrants to Elutia, upon each shipment of Product on and as of such date, that: such Product shall (a) conform in all material respects with the applicable Specification therefor; and (b) have been, in all material respects, procured, processed, manufactured, labeled, stored, handled, packaged and shipped in accordance with the applicable Specification and all applicable Laws, including Good Tissue Practices, AATB Standards, and the National Organ Transplant Act. All documentation supplied by Purchaser to Elutia in connection with Product shall, to the knowledge of Purchaser, be accurate and complete in all material respects. With respect to Donors, Purchaser represents and warrants that (1) the Donors shall conform to the Donor Eligibility Criteria in all respects and (2) Product shall be, in all material respects, procured, packaged and shipped in accordance with the Donor Eligibility Criteria and applicable Laws.
- (ii) The representation and warranty provided in this **Section 3.7** does not apply to any Product that:
  - a. has been subjected to abuse, misuse, neglect, negligence, accident, improper testing, improper installation, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by Purchaser;
  - b. has been reconstructed, repaired, or altered by persons other than Purchaser; or
  - c. has been used with any third-party products, hardware, or product that has not been previously approved in writing by Purchaser.



- (iii) Notwithstanding any other provision of this Agreement (except for **Section 3.3**), **Section 5.1** contains Elutia's exclusive remedy for any breach of **Section 3.7(i)**.
- (iv) EXCEPT FOR THE EXPRESS LIMITED WARRANTY SET FORTH IN **SECTION 3.7(i)** ABOVE, PURCHASER GRANTS NO WARRANTIES FOR THE PRODUCTS, TISSUE OR PROCESSED TISSUE, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND PURCHASER SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF QUALITY, WARRANTY OF MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF NON-INFRINGEMENT. SEVERAL FACTORS RELATING TO PATIENTS, DIAGNOSIS, TREATMENT, SURGICAL PROCEDURES, AND OTHER MATTERS BEYOND PURCHASER'S CONTROL MAY DIRECTLY AFFECT THE PRODUCTS, TISSUE, THE PROCESSED TISSUE AND THE RESULTS OBTAINED THEREFROM; PURCHASER HEREBY DISCLAIMS ANY RESPONSIBILITY FOR ALL OF THE FOREGOING. WITHOUT LIMITING THE FOREGOING, IT IS AGREED AND ACKNOWLEDGED THAT PURCHASER EXPRESSLY DISCLAIMS AND SHALL NOT BE OBLIGATED PURSUANT TO THIS AGREEMENT, TO PROVIDE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, IN CONNECTION WITH THE TISSUE, THE PROCESSED TISSUE OR THE PRODUCT TO ANY THIRD PARTY.

3.8 **Elutia's Representations and Warranties.** Elutia represents and warrants to Purchaser that, as of the date it places each Order:

- (i) this Agreement (assuming due authorization, execution, and delivery by Purchaser) constitutes the legal, valid, and binding obligation of Elutia, enforceable against Elutia in accordance with its terms, except as may be limited by any applicable bankruptcy, insolvency, reorganization, moratorium, or similar Laws and equitable principles related to or affecting creditors' rights generally or the effect of general principles of equity;
- (ii) Elutia is in compliance, in all material respects, with all applicable Laws relating to this Agreement, and the Product;
- (iii) the Specifications comply with applicable Laws;
- (iv) Elutia is not insolvent and is in good standing with its creditors; and
- (v) (A) Elutia owns or duly licenses all intellectual property that is purported to be licensed to Purchaser under this Agreement, (B) Elutia has the rights in such intellectual property necessary to provide all licenses that are purported to be provided to Purchaser hereunder and (C) Purchaser's use of such intellectual property in the performance of its obligations in accordance with the terms of this Agreement shall not violate the intellectual property rights of any third party.
- (vi) Following Elutia's receipt of Product from Purchaser under this Agreement, Elutia will remain, in all material respects, in compliance with all applicable Laws in respect of such Product.

3.9 **Debarment.** Each Party represents, warrants and covenants to the other Party that it has never been, is not currently, and, during the Term, will not become, a Debarred Entity, Excluded Entity or Convicted Entity. Each Party further warrants and represents that no Debarred Individual, Debarred Entity, Excluded Individual, Excluded Entity, Convicted Individual or Convicted Entity (each as defined below) has performed or rendered, or will perform or render, any services or assistance on its behalf relating to activities taken pursuant to this Agreement.

- (i) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a(a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application, or an employer, employee or partner of a Debarred Individual.

- (ii) A “Debarred Entity” is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a(a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or an employee, partner, shareholder, member, subsidiary or affiliate of a Debarred Entity.
- (iii) An “Excluded Individual” or “Excluded Entity” is (a) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (b) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).
- (iv) A “Convicted Individual” or “Convicted Entity” is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.
- (v) If any of the foregoing warranties or representations becomes untrue (by way of example only, if a Party or any individual or entity performing services on its behalf hereunder becomes excluded, debarred or suspended after the Effective Date of this Agreement), such Party shall immediately notify the other Party and this shall constitute grounds for immediate termination by the other Party as a material breach pursuant to **Section 7.2(i)**.

#### ARTICLE 4 QUALITY ASSURANCE AND ADDITIONAL OBLIGATIONS

4.1 **Quality Assurance.** The Parties will agree upon, implement and maintain a quality assurance program relating to the processing, storage and distribution of Product, and each Party will bear its own expenses in connection therewith. Purchaser shall be responsible for maintaining traceability for all Product provided by Purchaser and distributed for Elutia and Elutia shall be responsible for maintaining traceability for Product (if any) provided by Purchaser and distributed by Elutia. Tracking records and allograft usage cards shall be maintained by Elutia in accordance with applicable AATB and FDA standards and regulations. Elutia shall promptly notify Purchaser in writing of any product complaint or adverse event alleging patient injury or risk that is associated with Product provided to Elutia by Purchaser. Such written notification shall include necessary tracking data, on a per Donor basis, for all implicated Product procured by Purchaser and shipped to Elutia or its designee.

4.2 **Regulatory Inspections.** As required by Law, each Party shall permit the FDA or other applicable accrediting or regulatory agency, or its or their representatives or agents, to inspect facilities, including, without limitation, production, labeling, shipping, packaging and quality control facilities, and records relating to the production, storage, sterilization, or delivery of the Tissue or Product or this Agreement for the purposes of verifying compliance with applicable regulatory requirements and each Party’s obligations under this Agreement.

4.3 **Records and Training.** Each Party shall maintain accurate and complete records of its procurement and processing of Donors, Tissue and Processed Tissue and processing of Product hereunder for the longer of ten (10) years after shipment of Product, or the period of time required by applicable Laws. Upon reasonable prior written request, each Party shall provide the other Party with such information, including documentation, reasonably requested regarding quality control and quality assurance of Product supplied hereunder, and records documenting the training of personnel. Such information is considered Confidential Information in accordance with the provisions of **Section 6.2**.

4.4 **Legal Compliance.** With respect to each Party's performance under this Agreement, Elutia and Purchaser shall each comply with all applicable Laws, including, without limitation, all applicable regulations and guidelines established by the AATB and FDA, specifically 21 C.F.R. §§ 1270 and 1271 and AATB Standards and Policies at all times. Both Parties must maintain compliance with AATB's Policy for the Use of Trademarks, Service Marks and Certification Marks. Each Party is obligated to notify the other Party in writing, within five (5) calendar days, of receipt of any written notification from the AATB, FDA or other applicable regulatory body of (i) a loss, suspension or limitation of accreditation, (ii) loss of establishment registration or (iii) loss of good standing, including violation of any applicable Law. Failure to provide such notification shall be a material breach of this Agreement and may result in termination of this Agreement pursuant to **Section 7.2**.

4.5 **Complaints.** Elutia and Purchaser shall each provide the other with written notification of any complaint or adverse claim directly or indirectly related to the Tissue, Processed Tissue or Product supplied hereunder within [\*\*\*] business days of such Party's receipt of such complaint or claim. Each Party agrees to provide reasonable assistance and cooperation to the other Party in the investigation and resolution of any such complaint or claim.

4.6 **Product Withdrawal.** In the event either Party (in such capacity, the "Product Withdrawing Party") believes it is necessary to conduct a recall, correction, market withdrawal, stock recovery, or other similar action with respect to Product received hereunder (a "Product Withdrawal"), the Product Withdrawing Party shall notify the other Party immediately of the circumstances involving such Product Withdrawal, and the Parties shall collectively discuss whether a Product Withdrawal should be initiated. The Product Withdrawing Party shall make the final decision as to such Product Withdrawal and the other Party shall reasonably cooperate with the Product Withdrawing Party in any Product Withdrawal. The Product Withdrawing Party shall be responsible for notification to the FDA and any other governmental authority, as well as all submissions and communications regarding the Product Withdrawal. The Product Withdrawing Party shall bear all costs (including, without limitation, the other Party's costs) in connection with any such Product Withdrawal; provided, however, that, upon the written request of the Product Withdrawing Party, the other Party shall reimburse Product Withdrawing Party for any reasonable costs paid with respect to the withdrawn Product (but, for clarity, not other Product), including all reasonable out-of-pocket expenses, incurred by the Product Withdrawing Party in connection with any such Product Withdrawal attributable to any breach of this Agreement by the other Party, provided that the Product Withdrawing Party used its reasonable discretion in determining that a Product Withdrawal was necessary and that the Product Withdrawing Party shall use its commercially reasonable efforts to minimize any such costs and expenses; and provided further that this shall not limit the Product Withdrawing Party's rights pursuant to **Article 5** (but, for clarity, no Party shall be entitled to recover for the same Losses more than once under this Agreement).

4.7 **Tissue Withdrawal.** In the event that Purchaser believes it is necessary to conduct a recall, field correction, market withdrawal, stock recovery, or other similar action with respect to any Tissue or Processed Tissue supplied hereunder (a "Tissue Withdrawal"), Purchaser shall notify Elutia immediately of the circumstances involving such Tissue Withdrawal, and Elutia and Purchaser shall collectively discuss whether a Tissue Withdrawal should be initiated. Purchaser shall make the final decision as to such Tissue Withdrawal and Elutia shall reasonably cooperate with Purchaser in any Tissue Withdrawal. Purchaser shall be responsible for notification to the FDA and any other governmental authority, as well as all submissions and communications regarding the Tissue Withdrawal. Purchaser shall bear all costs in connection with any such Tissue Withdrawal; provided, however, that, upon the written request of Purchaser, Elutia shall reimburse Purchaser for any reasonable costs paid with respect to the withdrawn Tissue (but, for clarity, not other Tissue), including all reasonable out-of-pocket expenses, incurred by Purchaser in connection with any such Tissue Withdrawal attributable to any breach of this Agreement by Elutia, provided that Purchaser used its reasonable discretion in determining that a Tissue Withdrawal was necessary and that Purchaser shall use its commercially reasonable efforts to minimize any such costs and expenses; and provided further that this shall not limit Purchaser's rights pursuant to **Article 5** (but, for clarity, no Party shall be entitled to recover for the same Losses more than once under this Agreement).

## ARTICLE 5

### INDEMNITY AND INSURANCE

5.1 **Purchaser Indemnity.** Subject to the limitations on liability set forth in **Section 5.4**, Purchaser shall defend, indemnify and hold harmless Elutia, its directors, officers, employees, agents, equity holders, affiliates, and their respective successors and assigns (the “**Elutia Indemnitees**”) from and against any and all direct losses, liabilities, third party claims, actions, proceedings, damages and expenses (including, without limitation, reasonable outside attorneys’ fees and expenses) (collectively, “**Losses**”) relating to or arising from (i) any material breach by Purchaser of this Agreement or (ii) the gross negligence, recklessness or willful misconduct of Purchaser; provided, however, this **Section 5.1** shall not impose any obligation on Purchaser to indemnify Elutia Indemnitees (x) for any Detectable Nonconformance, (y) for any actual defect in any Product (except to the extent that Tissue or Processed Tissue supplied by Purchaser fails to comply with the applicable Specification if (a) such non-compliance is the source of the actual defect and (b) such defect is discovered by Elutia prior to the expiry date of such Tissue or Processed Tissue), or (z) to the extent that any Losses arise as a result of any breach of this Agreement by Elutia or to the extent of any gross negligence, recklessness or willful misconduct) of Elutia.

5.2 **Elutia Indemnity.** Subject to the limitations on liability set forth in **Section 5.4**, Elutia shall defend, indemnify and hold harmless Purchaser, its directors, officers, employees, agents, shareholders, affiliates, and their respective successors and assigns (the “**Purchaser Indemnitees**”) from and against any and all Losses relating to or arising from (i) any material breach by Elutia of this Agreement or (ii) the gross negligence, recklessness or willful misconduct of Elutia; provided, however, this **Section 5.2** shall not impose any obligation on Elutia to indemnify Purchaser Indemnitees to the extent that any Losses arise as a result of any breach of this Agreement by Purchaser or to the extent of any gross negligence, recklessness or willful misconduct) of Purchaser.

5.3 **Notice of Claim.** Promptly after receipt by an indemnitee of the commencement of any such claim, demand, action, suit or proceeding asserted by a third party (each, an “**Action**”) which is the subject of a Party’s indemnification obligations hereunder, such indemnitee shall notify the other Party of the commencement of the Action, provided that any failure to provide such notice shall not relieve the indemnifying Party of its indemnification obligations hereunder unless and to the extent the indemnifying Party proves that it has been materially prejudiced by such failure. The indemnifying Party shall have the sole right to select and retain attorneys to assert or negotiate, and sole right to control, the defense and any settlement of the Action, except that under no circumstances shall the indemnifying Party enter into any settlement that involves an admission of liability, negligence or other culpability by the indemnitee, or requires the indemnitee to contribute to the settlement, without the indemnitee’s prior written consent. Without limiting a Party’s foregoing right to select and retain attorneys and to sole control of the defense and settlement of such Action, the indemnitee may, at its own expense, participate in the defense of, or otherwise consult with counsel of its own choice in connection with, an Action that is the subject of the other Party’s indemnification and defense obligations.

5.4 **Limitation on Liability.** EXCEPT FOR A BREACH OF **ARTICLE 6**, NO PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, EXEMPLARY, LOST PROFITS OR OTHER NON-DIRECT DAMAGES OF ANY KIND ARISING OUT OF OR RELATING TO THIS AGREEMENT (INCLUDING CLAIMS FOR LOSS OF GOODWILL), WHETHER FORESEEABLE OR UNFORESEEABLE, AND WHETHER BASED IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, EVEN IF A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT FOR A BREACH OF **SECTION 3.8**, **ARTICLE 6** OR **SECTION 8.1**, THE CUMULATIVE LIABILITY OF A PARTY FOR ALL CLAIMS RELATING TO THIS AGREEMENT SHALL NOT EXCEED THE AMOUNT PAID AND PAYABLE TO PURCHASER UNDER THIS AGREEMENT DURING THE PAST [\*\*\*].

5.5 **Insurance.** Each Party agrees to procure and maintain in full force and effect during the Term, at its sole cost and expense, general liability and product liability insurance in amounts of not less than \$[\*\*\*\*] per incident and \$[\*\*\*\*] annual aggregate, which insurance shall (i) be written on a “occurrence” basis policy form, or, in the alternative, shall continue for a period of two (2) years following the termination or expiration of this Agreement and (ii) be with a reputable insurance carrier. Each Party shall, on the reasonable request of the other Party, provide to the other Party a copy of a certificate of coverage or other written evidence reasonably satisfactory to the other Party of such insurance coverage.

## **ARTICLE 6 INTELLECTUAL PROPERTY AND CONFIDENTIALITY**

6.1 **Intellectual Property.** Purchaser agrees that Elutia owns all right, title and interest in the Products, Specifications and in all of Elutia patents, trademarks, trade names, inventions, copyrights, know-how, and trade secrets. Elutia agrees that Purchaser owns all right, title, and interest in any Purchaser products and in all of Purchaser’s patents, trademarks, trade names, inventions, copyrights, know-how and trade secrets, including those relating to its manufacturing, processing and procurement services. The use by either Party of the other Party’s intellectual property rights is authorized only for the express purpose herein set forth, and upon termination or expiration of this Agreement, for any reason, such authorization shall immediately cease without further notice, except to the extent necessary for Purchaser to complete its obligations to fulfill outstanding Orders in accordance with **Section 7.3**. This Agreement does not grant to either Party any license by implication or estoppel to the other Party’s intellectual properties except as expressly set forth herein.

6.2 **Confidentiality.** Neither Party, nor any of their affiliates, or any directors, shareholders, officers, employees or agents of the foregoing (collectively, the “Affiliates”) shall use the other Party’s Confidential Information (as hereinafter defined) for any purpose other than for the performance of obligations under this Agreement, or divulge to anyone any of the other Party’s Confidential Information, except: (i) as required in the course of performing the obligations hereunder, (ii) to attorneys, accountants and other advisors acting in a fiduciary capacity, (iii) with the express written consent of the other Party or (iv) as required by Law. If a Party makes a disclosure of Confidential Information which is permitted by the terms of this Agreement, such Party shall be responsible for ensuring that the person to whom it is disclosed maintains the confidentiality and non-use obligations related to such Confidential Information and that such recipient is bound by a written confidentiality and non-use agreement, the terms of which are no less rigorous than those found in this Agreement. The term “Confidential Information” shall mean any proprietary information of a Party which is of a private, secret or confidential nature concerning such Party or such Party’s business or financial affairs, and includes inventions, products, Specifications, processes, methods, techniques, formulas, compositions, compounds, projects, developments, projections, plans, research data, clinical data, technical data, financial data, personnel data, regulatory agency audit reports, computer programs, and customer and supplier lists. Confidential Information shall not include any information which (a) becomes public knowledge without a breach by the receiving Party of this Agreement; (b) is obtained by the receiving Party (or the receiving Party’s Affiliates) from a person or business entity that was not obligated to keep such Confidential Information confidential, (c) is demonstrated to have been known by the receiving Party at the time of receipt thereof as evidenced by receiving Party’s written records dated prior to receipt; or (d) is disclosed by the receiving Party pursuant to a requirement (but only to the extent required) of a governmental agency, rule or regulation of the NASDAQ or New York Stock Exchange. The receiving Party may produce or disclose Confidential Information if and to the extent required pursuant to applicable Laws or court order, provided, to the extent permitted by applicable Law, the receiving Party has given the disclosing Party prompt prior written notice thereof so that the disclosing Party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this **Section 6.2**. If such protective order or other remedy is not obtained, or the disclosing Party waives compliance with the provisions of this **Section 6.2**, the receiving Party shall furnish only that portion of the Confidential Information that the receiving Party is legally required to disclose and shall exercise all commercially reasonable efforts to obtain reliable assurance that confidential treatment shall be accorded the Confidential Information.

6.3 **Confidentiality of Donor Information.** All Donor information obtained under this Agreement will be maintained in a confidential manner. Purchaser agrees to be bound by all conditions set forth on donation consent forms and to inform Elutia of any limitations or requirements provided for in such forms. The Parties acknowledge that Purchaser is not a “covered entity” and that Elutia is not acting as a “business associate” of Purchaser, as those terms are defined in the Privacy Regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Rule), 45 C.F.R. § 160.103, as may be amended from time to time. Elutia will be obtaining individually identifiable health information from Purchaser that has been obtained from hospitals and other health care providers to facilitate tissue donations and transplants. The Parties acknowledge and agree that the HIPAA Privacy Rule does not apply to sharing individually identifiable health information for the purposes described in this Agreement. The Parties agree that any such information disclosed or shared between the Parties shall be kept confidential in accordance with industry standards and applicable state Laws, if any, and will not be disclosed except as necessary to carry out their duties under this Agreement or as permitted or required by Law, regulation or the policies or standards of AATB. Both Parties to this Agreement shall take reasonable measures to cause their respective Affiliates to act in accordance with this **Article 6** and all applicable Laws regarding the confidentiality of individually identifiable health information.

## ARTICLE 7 TERM AND TERMINATION

7.1 **Term.** Unless otherwise terminated as set forth in **Section 7.2**, this Agreement will commence and be effective as of the Effective Date and will continue in effect for a period of twenty-four (24) months (the “Initial Term”). This Agreement will automatically renew at the end of the Initial Term and each subsequent renewal term for additional [\*\*\*] renewal terms (the “Renewal Term”, together with the Initial Term, the “Term”) unless either Party provides written notice of non-renewal to the other Party at least [\*\*\*] days prior to the end of the then-current Term.

### 7.2 **Early Termination.**

- (i) Either Party has the right to terminate this Agreement by written notice to the other Party effective immediately upon the receipt of such notice, upon any material default in the performance of or material breach of any agreement, covenant, representation, warranty, obligation or undertaking of the other Party made hereunder, if such default or breach shall not be remedied to the reasonable satisfaction of the Party giving notice of termination within thirty (30) days of delivery of such notice (except there shall be no such 30-day cure period for a breach of **Section 3.9(v)**); provided that this shall not apply in the case of Elutia’s breach of any payment obligation hereunder (including, without limitation a breach of **Section 3.6**) (a “Payment Default”). In the event of a Payment Default, Purchaser may terminate this Agreement with immediate effect if such Payment Default has not been remedied in full within ten (10) business days after Purchaser provides written notice of such Payment Default to Elutia.
- (ii) Either Party has the right to terminate this Agreement with immediate effect by providing written notice to the other Party if such other Party (i) becomes insolvent or is generally unable to pay, or fails to pay, its debts as they become due, (ii) files or has filed against it, a petition for voluntary or involuntary bankruptcy or otherwise becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency Law, (iii) makes or seeks to make a general assignment for the benefit of its creditors, or (iv) applies for or has appointed a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

7.3 **Effect of Termination or Expiration.** After either Party provides written notice of its intent to terminate or not to renew this Agreement to the other Party, the Parties shall continue to perform their respective obligations hereunder until the effective date of such termination or expiration. Upon termination or expiration of this Agreement, Purchaser shall supply Product to Elutia, pursuant to this Agreement, in accordance with pending Orders submitted and accepted prior to the effective date of termination or expiration in accordance with **Section 3.2** and Elutia shall pay the applicable fees in accordance with the terms and conditions of this Agreement. Each Party agrees to return or destroy (at the election of the disclosing party) upon the expiration or termination of this Agreement all Confidential Information acquired from the other Party, except as to such information it may be required to retain under applicable Laws, which information shall be retained in secure storage and not used or disclosed except to the extent necessary to comply with such Laws.

## **ARTICLE 8 MISCELLANEOUS**

8.1 **Mutual Representations and Warranties.** Each of the Parties represents and warrants that (i) it is fully authorized to enter into this Agreement; (ii) its entering into and performance under this Agreement does not violate or breach its organization documents or any agreement or contract to which it is a Party; (iii) there is no claim, demand, action, suit, proceeding or investigation pending or currently threatened against it or any of its affiliates that, if adversely determined, would restrict it from entering into this Agreement and carrying out its obligations under this Agreement.

8.2 **Independent Contractor.** Both Parties are independent contractors and nothing in this Agreement creates the relationship of partnership, joint venture, sales agency or principal and agent, and neither Party is the agent of the other, and neither Party may hold itself out as such to any other person and neither Party has the power or authority in any way to bind the other Party contractually. Each Party shall be free to manage and control its business as it sees fit without the management, control or assistance of the other Party, except as may otherwise be expressly prescribed herein.

8.3 **Entire Agreement; Amendment.** This Agreement and the Exhibits and Appendices attached hereto contain the entire understanding of the Parties with respect to the matters contained herein. This Agreement may be amended, modified or altered only by an instrument in writing duly executed by both Parties.

8.4 **Waiver.** Waiver of a breach of any provision of this Agreement shall not be deemed a waiver of any other breach of the same or a different provision of this Agreement.

8.5 **Force Majeure.** In the event that one Party fails to perform any obligation under this Agreement as a result of a strike, lockout or other labor difficulty, fire, explosion, flood, earthquake, embargo, act of war, terrorism, Act of God, regulation or restriction of government or law, failure of suppliers, public utilities or common carrier or any other occurrence or circumstances beyond the reasonable control of such Party ("Force Majeure"), that Party shall not be liable in damages or otherwise for failure to perform its obligations hereunder and, in addition, such failure shall constitute grounds for the other Party to terminate this Agreement only if such Force Majeure event prevents the other Party from performing its obligations under this Agreement for more than ninety (90) consecutive days. Both Parties hereby agree that each will use reasonable business efforts to remedy a Force Majeure event.

8.6 **Severability.** If any one or more of the provisions of this Agreement shall for any reason be held to be illegal or unenforceable, such invalidity or unenforceability shall not affect any other provision of this Agreement or the validity or enforceability of such provision. The unenforceable provision shall be treated as severable and the remaining provisions shall nevertheless continue in full force and effect, giving maximum effect to the intent of the Parties in entering this Agreement.

8.7 **Assignment.** Neither Party shall have the right to assign this Agreement (including by operation of law) or any rights, benefits or obligations under this Agreement without the prior written consent of the other Party, which such consent shall not be unreasonably withheld, delayed or conditioned, except that each Party may assign this Agreement and the rights, benefits and obligations of such Party to any purchaser of all or substantially all of its assets or to any successor entity resulting from any merger or consolidation of such Party with or into such entity. Purchaser must obtain Elutia's written consent (which may not be unreasonably withheld, conditioned or delayed) prior to engaging any third-party contractors to assist with or perform any portion of its obligations hereunder. Purchaser may not engage any third-party manufacturers to assist with or perform any portion of its obligations hereunder without obtaining Elutia's written consent (which may not be unreasonably withheld, conditioned or delayed). In the event that either Party assigns or transfers this Agreement as permitted herein, it is expressly agreed that the entity to which this Agreement has been assigned shall be bound by the same terms as those set forth in this Agreement. Any attempted assignment or delegation in violation hereof shall be void. Subject to the provisions hereof restricting assignment, this Agreement will bind and inure to the benefit of the parties and their respective successors and permitted assigns.

8.8 **Notices.** Any notice required, permitted or contemplated by this Agreement must be in writing, sent by facsimile with positive confirmation, electronic mail, or nationally recognized overnight carrier, addressed to the other Party as set forth below, or to such other address as may from time to time be substituted therefore by notice, or delivered in person to such other Party. For purposes of notices, the addresses of the Parties will be:

If to Elutia: Elutia, Inc.  
Attn: Jeffrey D. Hamet  
12510 Prosperity Drive  
Suite 370  
Silver Spring, MD 20904  
Email: jhamet@Elutia.com

If to Purchaser: Berkeley Biologics LLC  
2800 7th Street  
Berkeley, CA 94710  
Attention: Ying Luo  
Email: yluo@gnipharma.com

8.9 **Exhibits and Appendices.** Each Exhibit and Appendix to this Agreement shall be considered a part hereof as if set forth herein in full.

8.10 **Survival.** Notwithstanding the expiration or termination of this Agreement for any reason, rights and obligations set forth in **Section 3.6, Section 3.8, Section 4.3, Article V and Article VI, Section 7.3** and this **Article VIII** will remain in full force and effect.

8.11 **Counterparts.** This Agreement may be executed in multiple counterparts, each of which will constitute an original, but all of which together will constitute one and the same Agreement. A Party may execute this Agreement by facsimile, by .pdf or by other electronic means, which signature shall have the same operation and effect as would an original signature.



8.12 **Press Release.** No public or press announcement or news release relating to this Agreement, its terms or the Party's business relationship (collectively, a "Press Release") shall be made without the other Party's prior written approval, except as required by Law. Each Party agrees to submit each Press Release it proposes to make to the other Party for purposes of such other Party's review, comment and approval. Each Party further agrees to respond as promptly as reasonably possible.

8.13 **Choice of Law, Arbitration and Jurisdiction.** This Agreement shall be governed by the laws of the State of Delaware, without regard to conflicts of laws principles. Any dispute between the Parties arising out of or relating to this Agreement or its breach that cannot be resolved within sixty (60) days of written notice of the existence of a dispute will be resolved through binding arbitration. Upon either Party's written demand for arbitration, the Parties shall, in good faith, and within twenty (20) days of such demand, agree upon a single arbitrator to conduct the arbitration. The arbitrator's fees shall be split evenly by the Parties unless responsibility to pay such fees is shifted as part of any arbitration award. The arbitration hearing shall be conducted within sixty (60) days of the appointment of the arbitrator, unless the Parties agree otherwise. The arbitrator shall issue his/her award within thirty (30) days of the closing of the hearing. The arbitrator shall have the discretion to order, as part of any award, that the non-prevailing Party pay the legal fees and expenses of the prevailing Party, in part or in whole. Judgment upon any arbitration award may be entered in any court of competent jurisdiction including in any Delaware state court. Nothing herein shall preclude a Party from seeking an injunction or order requiring performance from any court of competent jurisdiction, if such is necessary to prevent irreparable harm.

8.14 **No Third-Party Beneficiaries.** This Agreement benefits solely the parties to this Agreement and their respective permitted successors and permitted assigns and nothing in this Agreement, express or implied, confers on any other person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

*[Remainder of page intentionally left blank]*

*Proprietary and Confidential*

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the last date of signature below.

**BERKELEY BIOLOGICS LLC**

By: /s/ Ying Luo

Name: Ying Luo

Title: President

Date: November 6, 2023

**ELUTIA INC.**

By: /s/ Jeffrey D. Hamet

Name: Jeffrey D. Hamet

Title: Senior Vice President, Finance

Date: November 3, 2023

[Signature Page to Contract Manufacturing Agreement]

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**EXHIBIT 1 DONOR ELIGIBILITY CRITERIA**

Elutia Donor Screening Guidance Document SOP-0006

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**APPENDIX-1**

**Specifications**

**1. Product Description**

“Product” is a Hydrated Acellular Dermal Allograft as specified in SPEC-0179, *Hydrated Acellular Dermal Matrix (HADM) Allograft Product Specification*, as detailed below.

<b>SKU</b>	<b>Size (cm)</b>	<b>Thickness (mm)</b>	<b>Description</b>
SD.090.1620P	16x20	0.90-1.99	Hydrated Acellular Dermal Matrix - Perforated
SD.090.1020ELP	10x20	0.90-1.99	Hydrated Acellular Dermal Matrix – Perforated, Medium Ellipse
SD.090.2020P	20x20	0.90-1.99	Hydrated Acellular Dermal Matrix - Perforated
SD.090.1616P	16x16	0.90-1.99	Hydrated Acellular Dermal Matrix - Perforated
SD.090.1321ELP	13x21.5	0.90-1.99	Hydrated Acellular Dermal Matrix – Perforated, Large Ellipse
SD.090.0816	8x16	0.90-1.99	Hydrated Acellular Dermal Matrix
SD.090.0616	6x16	0.90-1.99	Hydrated Acellular Dermal Matrix
SD.090.0820	8x20	0.90-1.99	Hydrated Acellular Dermal Matrix
SD.090.1620	16x20	0.90-1.99	Hydrated Acellular Dermal Matrix
SD.090.0407S	4x7	0.90-1.99	Hydrated Acellular Dermal Matrix (Samples)

**2. Manufacturing Services**

Contract manufacturing services include donor procurement, testing, and final eligibility determination, processing, preservation, sterilization, final product release, storage and distribution as defined in SPEC-0179, *Hydrated Acellular Dermal Matrix (HADM) Allograft Product Specification*, set forth below.

**3. Storage and Preservation**

“Product” will be packaged, terminally sterilized and stored at 1° to 25°C.

**4. Shelf Life**

“Product” expiry is a minimum of [\*\*\*] months from the date of terminal sterilization.

**5. Detailed Specifications**

SPEC-0179, *Hydrated Acellular Dermal Matrix (HADM) Allograft Product Specification* means:

**UNAUDITED PRO FORMA CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

On November 8, 2023, Elutia Inc. (the “Company”) completed the previously announced sale of its Orthobiologics segment (the “Orthobiologics Business”) to Berkeley Biologics, LLC (“Berkeley”). The sale was structured as an asset purchase, which occurred by divestiture of all the Orthobiologics Business assets and liabilities. After the divestiture, the Company will no longer consolidate the Orthobiologics Business into its financial results (the entire transaction is being referred to as the “Sale”).

The unaudited pro forma consolidated financial information is based on historical financial statements of the Company as adjusted for the unaudited pro forma effects of the Sale. The unaudited pro forma consolidated financial information should be read in conjunction with:

- the historical consolidated financial statements and accompanying notes of the Company included in its Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 23, 2023;
- the unaudited historical condensed consolidated financial statements and accompanying notes of the Company included in its Quarterly Report on Form 10-Q for the nine months ended September 30, 2023 filed with the SEC on November 14, 2023;

The following unaudited Pro Forma Condensed Consolidated Statement of Operations for the nine months ended September 30, 2023 and for the years ended December 31, 2022 and 2021 reflect the Company’s results as if the Sale had occurred as of January 1, 2021 in that they reflect the reclassification of the Orthobiologics Business as discontinued operations for all periods presented. The adjustments in the “Transaction Accounting Adjustments” column in the unaudited Pro Forma Condensed Consolidated Statement of Operations for the year ended December 31, 2022 give effect to the Sale and related transactions as if they had occurred on January 1, 2022. The following unaudited Pro Forma Condensed Balance Sheet as of September 30, 2023 presents the financial position of the Company as if the Sale had occurred on September 30, 2023.

The unaudited pro forma adjustments and related assumptions are described in the accompanying notes to the unaudited pro forma consolidated financial information. The unaudited pro forma consolidated financial information has been prepared based upon currently available information and assumptions that are deemed appropriate by the Company’s management. The unaudited pro forma consolidated financial information is for informational and illustrative purposes only and is not intended to be indicative of what actual results would have been had the Sale occurred on the dates assumed, nor does such data purport to represent the consolidated financial results of the Company for future periods. The pro forma adjustments are based on currently available information, estimates and assumptions that the Company believes are reasonable in order to reflect, on a pro forma basis, the impact of this disposition on our historical financial information. The actual financial position and results of operations may differ significantly from the unaudited pro forma amounts reflected herein due to a variety of factors.

**ELUTIA INC.**  
**PRO FORMA CONDENSED CONSOLIDATED BALANCE SHEET**  
**As of September 30, 2023**  
**(In Thousands, Except for Share and Per Share Data)**

(UNAUDITED)

Assets	Historical	Transaction Accounting Adjustments	Pro Forma
<b>Assets</b>			
Current assets:			
Cash	\$ 14,517	\$ 11,826(b)	\$ 26,343
Accounts receivable	2,883	—	2,883
Inventory	6,503	—	6,503
Receivables of FiberCel litigation costs	7,452	—	7,452
Prepaid expenses and other current assets	452	—	452
Current assets of discontinued operations	7,320	(7,320)(a)	-
<b>Total current assets</b>	<b>39,127</b>	<b>4,506</b>	<b>43,633</b>
Property and equipment, net	175	—	175
Intangible assets, net	12,520	—	12,520
Operating lease right-of-use assets and other	155	—	155
Noncurrent assets of discontinued operations	2,603	(2,603)(a)	—
<b>Total assets</b>	<b>\$ 54,580</b>	<b>\$ 1,903</b>	<b>\$ 56,483</b>
<b>Liabilities and Stockholders' Deficit</b>			
Current liabilities:			
Accounts payable	\$ 2,962	\$ —	\$ 2,962
Accrued expenses	10,723	900(c)	11,623
Payables to tissue suppliers	707	—	707
Current portion of revenue interest obligation	11,053	—	11,053
Contingent liability for FiberCel litigation	15,702	—	15,702
Current operating lease liabilities	399	—	399
Current liabilities of discontinued operations	3,190	(3,190)(a)	—
Current portion of long-term debt	—	1,977(d)	1,977
<b>Total current liabilities</b>	<b>44,736</b>	<b>(313)</b>	<b>44,423</b>
Long-term debt	25,278	(3,955)(d)	21,323
Long-term revenue interest obligation	5,471	—	5,471
Warrant liability	7,550	—	7,550
Other long-term liabilities	433	—	433
Noncurrent liabilities from discontinued operations	585	(585)(a)	—
<b>Total liabilities</b>	<b>84,053</b>	<b>(4,853)</b>	<b>79,200</b>
Stockholders' equity (deficit):			
Class A Common stock	19	—	19
Class B Common stock	4	—	4
Additional paid-in capital	136,834	—	136,834
Accumulated deficit	(166,330)	6,756(e)	(159,574)
<b>Total stockholders' deficit</b>	<b>(29,473)</b>	<b>6,756</b>	<b>(22,717)</b>
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 54,580</b>	<b>\$ 1,903</b>	<b>\$ 56,483</b>

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

**ELUTIA INC.**  
**PRO FORMA CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**  
**For the Nine Months Ended September 30, 2023**  
**(In Thousands, Except Share and Per Share Data)**

(UNAUDITED)

	Historical	Transaction Accounting Adjustments	Pro Forma
Net sales	\$ 18,870	\$ —	\$ 18,870
Cost of goods sold	9,943	—	9,943
Gross profit	8,927	—	8,927
Sales and marketing	10,514	—	10,514
General and administrative	10,137	—	10,137
Research and development	3,016	—	3,016
FiberCel litigation costs, net	7,278	—	7,278
Total operating expenses	30,945	—	30,945
Loss from operations	(22,018)	—	(22,018)
Interest expense	4,285	—	4,285
Other income, net	(312)	—	(312)
Loss before provision for income taxes	(25,991)	—	(25,991)
Income tax expense	36	—	36
<b>Net loss from continuing operations</b>	<b>\$ (26,027)</b>	<b>\$ —</b>	<b>\$ (26,027)</b>
Net loss from continuing operations per share - basic and diluted	<b>\$ (1.58)</b>	<b>\$ —</b>	<b>\$ (1.58)</b>
Weighted average common shares outstanding - basic and diluted	16,464,262	—	16,464,262

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

**ELUTIA INC.**  
**PRO FORMA CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**  
**For the Twelve Months Ended December 31, 2022**  
**(In Thousands, Except Share and Per Share Data)**

(UNAUDITED)

	Historical	Orthobiologics Discontinued Operations (Note a)	Adjusted for Discontinued Operations	Transaction Accounting Adjustments	Pro Forma
Net sales	\$ 49,187	\$ (25,338)	\$ 23,849	\$ —	\$ 23,849
Cost of goods sold	29,965	(17,755)	12,210	—	12,210
Gross profit	19,222	(7,583)	11,639	—	11,639
Sales and marketing	20,195	(2,345)	17,850	—	17,850
General and administrative	16,627	(576)	16,051	900(c)	16,951
Research and development	8,940	(1,213)	7,727	—	7,727
FiberCel litigation costs, net	5,200	—	5,200	—	5,200
Total operating expenses	50,962	(4,134)	46,828	900	47,728
Loss from operations	(31,740)	(3,449)	(35,189)	(900)	(36,089)
Interest expense	5,282	(164)	5,118	—	5,118
Other income, net	(4,159)	—	(4,159)	—	(4,159)
Loss before provision for income taxes	(32,863)	(3,285)	(36,148)	(900)	(37,048)
Income tax expense	34	—	34	—	34
<b>Net from continuing operations loss</b>	<b>\$ (32,897)</b>	<b>\$ (3,285)</b>	<b>\$ (36,182)</b>	<b>\$ (900)</b>	<b>\$ (37,082)</b>
Net loss from continuing operations per share - basic and diluted	<b>\$ (2.38)</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (2.68)</b>
Weighted average common shares outstanding - basic and diluted	13,832,887	—	—	—	13,832,887

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



**ELUTIA INC.**  
**PRO FORMA CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**  
**For the Twelve Months Ended December 31, 2021**  
**(In Thousands, Except Share and Per Share Data)**

(UNAUDITED)

	Historical	Orthobiologics Discontinued Operations (Note a)	Adjusted for Discontinued Operations	Transaction Accounting Adjustments	Pro Forma
Net sales	\$ 47,390	\$ (26,934)	\$ 20,456	\$ —	\$ 20,456
Cost of goods sold	28,368	(17,192)	11,176	—	11,176
Gross profit	19,022	(9,742)	9,280	—	9,280
Sales and marketing	18,825	(2,170)	16,655	—	16,655
General and administrative	13,687	(563)	13,124	—	13,124
Research and development	9,266	(1,512)	7,754	—	7,754
FiberCel litigation costs, net	276	—	276	—	276
Total operating expenses	42,054	(4,245)	37,809	—	37,809
Loss from operations	(23,032)	(5,497)	(28,529)	—	(28,529)
Interest expense	5,324	—	5,324	—	5,324
Other income, net	(3,579)	—	(3,579)	—	(3,579)
Loss before provision for income taxes	(24,777)	(5,497)	(30,274)	—	(30,274)
Income tax expense	55	—	55	—	55
<b>Net loss from continuing operations</b>	<b>\$ (24,832)</b>	<b>\$ (5,497)</b>	<b>\$ (30,329)</b>	<b>\$ —</b>	<b>\$ (30,329)</b>
Net loss from continuing operations per share - basic and diluted	<b>\$ (2.38)</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (2.90)</b>
Weighted average common shares outstanding - basic and diluted	10,444,767	—	—	—	10,444,767

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

ELUTIA INC.

NOTES TO THE UNAUDITED PRO FORMA CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**Orthobiologics Business Discontinued Operations:**

- (a) Reflects the discontinued operations, including associated assets and liabilities and results attributable to the Orthobiologics Business, which were previously included in the Company’s historical financial statements. The Sale is accounted for retrospectively in accordance with ASC 205-20, “Discontinued Operations” for all periods presented.

**Transaction Accounting Adjustments:**

- (b) *Adjustments to cash.*

**(In Thousands)**

Cash received from sale of Orthobiologics Business at closing	\$ 14,554
Cash paid in repayment of SWK loan at closing	(1,977)
Cash paid for transaction fees at closing	(750)
<b>Total Pro Forma Adjustment to Cash</b>	<b>\$ 11,826</b>

- (c) *Costs to complete the sale transaction.* Reflects additional estimates of costs to complete the Sale that have not yet been reflected in the historical statements. This adjustment excludes \$0.7 million in fees paid at closing. The remainder of the fees are expected to be paid in 2024.
- (d) *Repayment of Debt.* The Company is contractually obligated to use a portion of the Sale proceeds to repay \$3.9 million of the SWK term loan facility. \$2.0 million of the required repayment was paid at closing with the remainder expected to be paid in February 2024 based on a mutual agreement between the parties. The repayment amount is based on the outstanding principal loan balance and the Orthobiologics Business’ portion of the Company’s gross profit for the most recent twelve-month period. The pro forma adjustment is based on the September 30, 2023 principal loan balance, before unamortized discount and deferred financing costs, of \$26.1 million.
- (e) *Effect on shareholders’ equity.* Reflects the effect on total shareholders’ equity of the adjustments described in notes (b) through (d) above.