# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

### **FORM 10-K**

(Mark One)

■ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-40228

### **CARMELL CORPORATION**

(Exact Name of Registrant as Specified in its Charter)

Delaware

86-1645738

( State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

2403 Sidney Street, Suite 300 Pittsburgh, Pennsylvania (Address of principal executive offices)

15203 (Zip Code)

Registrant's telephone number, including area code: (919) 313-9633

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

U	1				
Title (	of each class	Trading Symbol(s)	Name of each exchange on which registered		
Common Stock, par value \$0.0001 per share Redeemable Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of \$11.50		CTCXW	The Nasdaq Stock Market LLC  The Nasdaq Stock Market LLC		
Indicate by check mark if the Reg	gistrant is not required to file reports pursu	ant to Section 13 or 15(d) of the	Act. YES □ NO 🗵		
•			or 15(d) of the Securities Exchange Act of 1934 during the preceding ubject to such filing requirements for the past 90 days. YES ⊠ NO I		
•	the Registrant has submitted electronically ing 12 months (or for such shorter period		ired to be submitted pursuant to Rule 405 of Regulation S-T ( $\S 232.40$ o submit such files). YES $\boxtimes$ NO $\square$		
			ated filer, smaller reporting company, or an emerging growth companying growth company" in Rule 12b-2 of the Exchange Act.		
Large accelerated filer			Accelerated filer		
Non-accelerated filer	$\boxtimes$		Smaller reporting company		
Emerging growth company	$\boxtimes$				
	indicate by check mark if the registrant irsuant to Section 13(a) of the Exchange A		ded transition period for complying with any new or revised financia		
,		C	sment of the effectiveness of its internal control over financial reporting that prepared or issued its audit report. $\Box$		
If securities are registered pursual of an error to previously issued fit		check mark whether the financia	l statements of the registrant included in the filing reflect the correction		
•	any of those error corrections are restatement vant recovery period pursuant to §240.10I		ysis of incentive-based compensation received by any of the registrant		
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as reported on the Nasdaq Capital Market on June 30, 2023, was approximately \$159.1 million. This determination of affiliate status is not a determination for other purposes. The number of shares of Registrant's Common Stock outstanding as of March 27, 2024 was 19,245,248.

#### DOCUMENTS INCORPORATED BY REFERENCE

The aggregate market value of the registrant's Class A Common Stock held by non-affiliates of the registrant, based on the closing price of the registrant's Class A Common Stock

Information required in response to Part III of this Annual Report on Form 10-K is hereby incorporated by reference to portions of the registrant's Proxy Statement for the Annual Meeting of Stockholders to be held in 2024. The Proxy Statement will be filed by the registrant with the U.S. Securities and Exchange Commission no later than 120 days after the end of the registrant's fiscal year ended December 31, 2023

### **Table of Contents**

		Page
PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	10
Item 1B.	Unresolved Staff Comments	31
Item 1C.	Cybersecurity	31
Item 2.	Properties	32
Item 3.	Legal Proceedings	32
Item 4.	Mine Safety Disclosures	32
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	33
Item 6.	[Reserved]	33
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	34
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	39
Item 8.	Financial Statements and Supplementary Data	40
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	72
Item 9A.	Controls and Procedures	72
Item 9B.	Other Information	72
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	72
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	73
Item 11.	Executive Compensation	73
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	73
Item 13.	Certain Relationships and Related Transactions, and Director Independence	73
Item 14.	Principal Accounting Fees and Services	73
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	74
Item 16.	Form 10-K Summary	76



#### PART I

#### Item 1. Business.

Unless the context requires otherwise, references in this Annual Report on Form 10-K (this "Annual Report") to "Carmell," the "Company," "we," "us," or "our," prior to the closing of the Business Combination (as defined below), are intended to refer to Carmell Therapeutics Corporation, a Delaware corporation, ("Legacy Carmell") and, after the closing of the Business Combination, are intended to refer to Carmell Corporation, a Delaware corporation, and its consolidated subsidiaries.

### Forward-Looking Statements

This Annual Report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forwardlooking statements are based on current expectations and projections about future events. These forward-looking statements are subject to known and unknown risks, uncertainties, and assumptions about us that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. In some cases, forward-looking statements can be identified by terminology such as "may," "might," "should," "could," "will," "would," "expect," "intends," "plan," "possible," "potential," "predict," "project," "anticipate," "believe," "estimate," "continue," or the negative of such terms or other similar expressions, but the absence of these words does not mean that a statement is not forward-looking. Such statements include, but are not limited to, statements and expectations regarding our expected future growth and our ability to manage such growth, the ability to maintain the listing of our common stock and warrants on the Nasdaq Capital Market ("Nasdaq"), our estimates regarding anticipated operating losses, future revenue, capital requirements and our needs for, and ability to raise, financing in the future, our success in retaining or recruiting officers, key employees or directors, factors relating to our business, operations and financial performance, including the success of our development efforts with respect to our products, our ability to develop, obtain regulatory approval for and commercialize our products, market acceptance of our products, our ability to compete effectively and developments within our industry, market conditions in our industry, the ability to recognize the anticipated benefits of the Business Combination (as defined herein), as well as all other statements other than statements of historical fact included in this Annual Report.

The forward-looking statements contained in this Annual Report are based on current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties and other assumptions that may cause actual results or performance to be materially different than those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those listed under Part I, Item 1A. "Risk Factors," Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report and those risks described in our other filings with the U.S. Securities and Exchange Commission (the "SEC"). Given these risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. The forward-looking statements contained in this Annual Report are made as of the date of this Annual Report. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Any public statements or disclosures by us following this Annual Report that modify or impact any of the forward-looking statements contained in it will be deemed to modify or supersede such statements in this Annual Report.

### **Business Overview**

Carmell is a bio-aesthetics company that utilizes the Carmell Secretome<sup>TM</sup> to support skin and hair health. The Carmell Secretome<sup>TM</sup> consists of a potent cocktail of growth factors and proteins extracted from allogeneic human platelets sourced from U.S. Food and Drug Administration-approved tissue banks. Over the past seven years, Carmell has extensively tested the technology underpinning the Carmell Secretome<sup>TM</sup>. In addition, we have developed a novel microemulsion formulation that enables delivery of lipophilic and hydrophilic ingredients without relying on the Foul Fourteen<sup>TM</sup>, which are 14 potentially harmful excipients that are commonly used by other companies to impart texture, stability, and other desirable physicochemical attributes to cosmetic products. Additionally, Carmell's microemulsion formulations do not utilize mineral or vegetable oils across its entire product line and are designed to be non-comedogenic. We are also developing a line of men's products and a line of topical haircare products. All of our cosmetic skincare and haircare products are tailored to meet the demanding technical requirements of professional care providers and discerning retail consumers. Our product pipeline also includes innovative regenerative bone and tissue healing products that are under development.

1

### **Recent Developments**

#### **Business Combination**

On July 14, 2023 (the "Closing Date"), we consummated a business combination (the "Business Combination") pursuant to the terms of the Business Combination Agreement, date as of January 4, 2023 (the "Business Combination Agreement"), by and among Alpha Healthcare Acquisition Corp. III, a Delaware corporation and the predecessor to Carmell ("Alpha"), Carmell Therapeutics Corporation, a Delaware corporation, ("Legacy Carmell"), and Candy Merger Sub, Inc., a Delaware corporation ("Merger Sub"), pursuant to which Merger Sub merged with and into Legacy Carmell, with Legacy Carmell as the surviving company of the Business Combination. Pursuant to the Business Combination Agreement, on the Closing Date, Alpha changed its name to "Carmell Therapeutics Corporation" and Legacy Carmell changed its name to "Carmell Regen Med Corporation." On August 1, 2023, Carmell filed an amendment to its Third Amended and Restated Certificate of Incorporation with the Delaware Secretary of State to change its name to "Carmell Corporation."

Pursuant to the Business Combination Agreement, at the effective time of the Business Combination (the "Effective Time"), (i) each outstanding share of common stock of Legacy Carmell (the "Legacy Carmell common stock") was converted into the right to receive a number of shares of common stock, par value \$0.0001 per share, of the Company (the "Common Stock") equal to the applicable Exchange Ratio (as defined in the Business Combination Agreement); (ii) each outstanding share of preferred stock of Legacy Carmell was converted into the right to receive the aggregate number of shares of Common Stock that would be issued upon conversion of the underlying Legacy Carmell common stock, multiplied by the applicable Exchange Ratio; (iii) each outstanding option and warrant to purchase Legacy Carmell common stock was converted into an option or warrant, as applicable, to purchase a number of shares of Common Stock equal to the number of shares of Legacy Carmell common stock subject to such option or warrant multiplied by the applicable Exchange Ratio; and (iv) each outstanding share of Alpha Class A common stock, par value \$0.0001 per share ("Class A Common Stock"), and each share of Alpha Class B common stock, par value \$0.0001 per share ("Class B Common Stock"), was converted into one share of Common Stock. As of the Closing Date, the Exchange Ratio with respect to Legacy Carmell common stock was 0.06154, and the Exchange Ratio with respect to each outstanding derivative equity security of Legacy Carmell was between 0.06684 and 0.10070.

On July 11, 2023, the record date for the special meeting of Alpha's stockholders to approve the Business Combination (the "Special Meeting"), there were (i) 15,444,103 shares of Class A Common Stock issued and outstanding and (ii) 3,861,026 shares of Class B Common Stock issued and outstanding and held by AHAC Sponsor III LLC, Alpha's sponsor (the "Sponsor"). In addition, on the closing date of Alpha's initial public offering (the "IPO"), Alpha had issued 455,000 warrants to purchase Class A Common Stock to the Sponsor in a private placement. Prior to the Special Meeting, holders of 12,586,223 shares of Class A Common Stock included in the units issued in the IPO (excluding 1,705,959 shares of the Alpha's Class A Common Stock purchased by Meteora (as defined below) directly from the redeeming stockholders under the Forward Purchase Agreement (as defined below)) exercised their right to redeem such shares for cash at a price of approximately \$10.28 per share (net of the withholding for federal and franchise tax liabilities), for an aggregate redemption price of \$29,374,372. The redemptions were paid out of Alpha's trust account, which, after taking into account the redemptions but before any transaction expense, had a balance of \$29,376,282 at the Closing Date.

#### Forward Purchase Agreement

On July 9, 2023, Alpha and each of Meteora Special Opportunity Fund I, LP ("MSOF"), Meteora Capital Partners, LP ("MCP") and Meteora Select Trading Opportunities Master, LP ("MSTO") (with MCP, MSOF, and MSTO collectively as the "Sellers" or "Meteora") entered into a forward purchase agreement (the "Forward Purchase Agreement") providing for an over-the-counter equity forward transaction relating to, prior to the Effective Time, the Class A Common Stock and, after the Effective Time, the Common Stock. The primary purpose of entering into the Forward Purchase Agreement was to help ensure the Business Combination would be consummated.

Pursuant to the terms of the Forward Purchase Agreement, at the closing of the Business Combination, the Sellers purchased directly from the redeeming stockholders of Alpha 1,705,959 shares of Class A Common Stock (the "Recycled Shares") at a price of \$10.28 per share (the "Initial Price"), which is the price equal to the redemption price at which holders of Class A Common Stock were permitted to redeem their shares in connection with the Business Combination pursuant to Section 9.2(a) of Alpha's Second Amended and Restated Certificate of Incorporation, as amended (the "Second Amended Charter"). In accordance with the terms of the Forward Purchase Agreement, at the Closing Date, the Company paid to the Sellers an aggregate cash amount of \$17,535,632, which was equal to the product of (a) the Recycled Shares and (b) the Initial Price.

The settlement date will be the earliest to occur of (a) the first anniversary of the Closing Date, and (b) after the occurrence of (i) a Delisting Event (as defined in the Forward Purchase Agreement) or (i) a Registration Failure (as defined in the Forward Purchase

Agreement), upon the date specified by Meteora in a written notice delivered to the Company at Meteora's discretion (which settlement date shall not be earlier than the date of such notice). Any Recycled Shares not sold in accordance with the early termination provisions described below will incur a \$0.50 per share termination fee payable by the Company to Meteora at settlement.

From time to time and on any date following the Business Combination (any such date, an "OET Date") and subject to the terms and conditions below, Meteora may, in its absolute discretion, and so long as the daily volume-weighted average price ("VWAP Price") of the Recycled Shares is equal to or exceeds the Reset Price (as defined in the Forward Purchase Agreement), terminate the transaction in whole or in part by providing written notice (an "OET Notice") in accordance with the terms of the Forward Purchase Agreement. The effect of an OET Notice given shall be to reduce the number of shares by the number of Terminated Shares (as defined in the Forward Purchase Agreement) specified in such OET Notice with effect as of the related OET Date. As of each OET Date, the Company shall be entitled to an amount from Meteora, and Meteora shall pay to the Company an amount equal to the product of (a) the number of Terminated Shares multiplied by (b) the Initial Price in respect of such OET Date.

The Reset Price is initially \$11.50 and subject to a \$11.50 floor (the "Reset Price Floor"). The Reset Price will be adjusted on the first scheduled trading day of every week commencing with the first week following the seventh day after the closing of the Business Combination to be the lowest of (a) the then-current Reset Price and (b) the VWAP Price of the shares of the Common Stock of the prior week; provided that the Reset Price shall be no lower than the Reset Price Floor. On July 9, 2023, in connection with the Forward Purchase Agreement, the Sellers entered into a Non-Redemption Agreement with the Company, pursuant to which the Sellers agreed not to exercise redemption rights under the Second Amended Charter with respect to an aggregate of 100,000 shares of Common Stock.

### Axolotl Biologix Acquisition

On August 9, 2023 (the "Merger Closing Date"), we completed the acquisition of Axolotl Biologix, Inc. ("AxoBio"), pursuant to an Agreement and Plan of Merger, dated July 26, 2023 (the "Merger Agreement"), by and among the Company, AxoBio, Aztec Merger Sub, Inc., a wholly-owned subsidiary of the Company ("Merger Sub I"), and Axolotl Biologix LLC, a wholly owned subsidiary of the Company ("Merger Sub II"). Upon the closing of the transactions contemplated by the Merger Agreement (the "Merger Closing"), (a) Merger Sub I merged with and into AxoBio, after which the separate corporate existence of Merger Sub I ceased, and AxoBio continued as a the surviving corporation, and (b) AxoBio merged with and into Merger Sub II, after which AxoBio ceased to exist, and Merger Sub II survived as a wholly-owned subsidiary of the Company (collectively, the "AxoBio Acquisition"). AxoBio's commercial product is a human amnion allograft that is primarily used as a structural barrier for diabetic foot ulcers. At the effective time of the AxoBio Acquisition (the "Merger Effective Time"), each share of AxoBio's common stock, par value \$0.001 per share ("AxoBio Common Stock"), (other than Dissenting Shares (as defined in the Merger Agreement) and shares held as treasury stock) issued and outstanding as of immediately prior to the Merger Effective Time was canceled and converted into the right to receive a pro-rata share of:

- \$8,000,000 in cash (the "Closing Cash Consideration"), payable upon delivery of AxoBio's audited financial statements;
- 3,845,337 shares of Common Stock and 4,243 shares of the Company's newly designated Series A Convertible Voting Series A Preferred Stock, \$0.0001 par value per share (the "Series A Preferred Stock"), issued upon the Merger Closing Date (the "Closing Share Consideration"); and
- Up to \$9,000,000 in cash and up to \$66,000,000 in shares of Common Stock that, in each case, were subject to a performance-based earnout (the "Earnout").

The Closing Share Consideration of \$57,000,000 was calculated using a 30-day average daily VWAP of \$7.05 per share. Pursuant to the terms of the Series A Preferred Stock, each share of Series A Preferred Stock will automatically convert into 1,000 shares of Common Stock upon stockholder approval of the issuance of the shares of Common Stock issuable upon such conversion and will cease to have any rights other than with respect to such conversion.

### Axolotl Biologix Disposition

On March 20, 2024, we entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with the former stockholders of AxoBio (the "Buyers") to sell all of the outstanding limited liability company interests of AxoBio to the Buyers in exchange for the return of the Closing Share Consideration, the cancellation of the notes payable by the Company to the Buyers in an aggregate principal amount of \$8,000,000 issued as the Closing Cash Consideration and termination of the Company's obligations with respect to the Earnout (the "AxoBio Disposition"). AxoBio did not produce any revenue from its products from November 2023 onwards, and revenue from such products is not anticipated in the future due to anticipated changes in Centers for Medicare & Medicaid Services ("CMS") reimbursement policies. The assets and liabilities of AxoBio are classified as available for sale on the accompanying

consolidated balance sheets, and the results of its operations are reported as discontinued operations in the accompanying consolidated statements of operations. The AxoBio Disposition closed on March 26, 2024.

#### **Our Product Portfolio**

Carmell Cosmetic Skincare Product and Product Pipeline

We are leveraging our proprietary formulation of growth factors, proteins and peptides to create the world's first cosmetic skincare line using the Carmell Secretome<sup>TM</sup>. This proprietary formulation is derived from allogeneic human platelets, which support the body's own innate regenerative healing system. Our team of scientists and engineers have worked on past projects focused on the biologics and medical device space and have extensive experience and technical expertise in creating biologically active materials that are safe and effective.

Our skincare products use allogeneic platelet-rich plasma ("PRP") sourced from FDA-registered and American Association of Blood Banks-accredited U.S. blood banks. Before being processed into the Carmell Secretome<sup>TM</sup>, each unit of PRP is individually tested to ensure that it is free from blood-borne pathogens. As an additional safety precaution, the pooled plasma is heat-treated and irradiated to inactivate any viruses. Carmell Secretome<sup>TM</sup> manufacturing is a highly controlled process with multiple in-process checks and release testing. Two additional sterilization steps, including gamma irradiation, are incorporated into every batch. Our formulation contains over 1000 growth factors, proteins, and peptides, but no live cells.

Our technology is based on the premise that a healthy human body can heal itself from simple wounds and fight against microbes. Platelets play a key role in both fighting infections and in healing. Platelets contain growth factors and other proteins that play a crucial role in the body's healing response. Growth factors and proteins in PRP have been known to stimulate collagen production, tissue repair and cell regeneration. This can lead to improved skin texture, reduced appearance of fine lines and wrinkles, and an overall rejuvenation of the skin.

When the body responds to a natural injury, platelets break apart to release proteins and growth factors to aid healing. During the creation of Carmell Secretome<sup>TM</sup>, this same natural process is utilized. Platelets are activated with calcium chloride, causing the release of their protein secretome, which is carefully processed to ensure safety and shelf stability. No intact cells or platelets remain. We have conducted protein assays to test for protein potency and stability testing under various temperature conditions to ensure that our product remains bioactive on the shelf in real-world conditions.

In addition, we have also developed a novel microemulsion formulation to help support the permeability of our ingredients into the stratum corneum, which is the outermost layer of the skin. Additionally, our microemulsion formulations do not utilize mineral or vegetable oils across our entire product line and are designed to be non-comedogenic.

We also believe that what is not in our products is a key differentiator. Our skincare products do not contain the "Foul 14", which are chemicals and excipients that may harm human health and the environment. These fourteen chemicals and excipients include sulfates, silicones, silicates, phthalates, petrolatum, parabens, parfums, formaldehydes, food allergens, ethanolamines, ethyl alcohols, PFAs (perand polyfluoroalkyls), coal tar dyes, and benzene.

Our cosmetic products are developed and manufactured in the United States.

### Skincare Product Portfolio

Our first cosmetic skincare product, Carmell G.L.E.E, was commercially launched in March 2024, with nine more skincare products in our pipeline. Our product portfolio includes the following:

#### General

- Carmell G.L.E.E. Gold limited edition exclusive daily cream to reduce the appearance of wrinkles and blemishes.
- Youth restoring formula daily cream to reduce the appearance of wrinkles and blemishes.
- Ultra-brightening formula extra strength anti-blemish and skin brightening actions.
- Ultra-hydrating formula extra strength skin hydrating and plumping action.

### **Undereye**

- Undereye AM formula reduce the appearance of dark circles, crepey skin, and photoprotection during the daytime.
- Undereye PM formula calm and strengthen undereye skin at bedtime.

#### Mother & Child

- Mother care formula formulated for sensitive and mechanically stressed skin during pregnancy.
- Ultra-gentle formula formulated for daily use for the most sensitive skin types.

### **Doctor Dispensed**

- Treatment-enhancing formula for use by professional care providers to soothe and repair the skin barrier following aesthetic treatments.
- Rapid Recovery formula for use by professional care providers to support recovery.

### **Marketing and Competition**

According to a May 2023 study conducted by McKinsey & Company, *State of Fashion: Beauty*, the skincare and haircare markets were approximately \$280 billion in 2022 and are expected to grow at a 6.4% compound annual growth rate ("CAGR"). In addition, the aesthetics market is growing 36% faster than pharmaceuticals, according to Statista.

We plan to employ an omnichannel distribution strategy and sell our products through retailers in the United States and online through direct e-commerce channels.

- *E-commerce*. E-commerce is expected to be an important component of our engagement and innovation model. Our digital engagement model is expected to drive conversion on our e-commerce website, where we plan to sell our full product offerings. We also plan to make our products available at other e-commerce sites to make them more widely accessible to our consumers.
- *National retailers.* We plan to sell our products in the United States primarily through mass and specialty retail channels.
- *International*. We are also exploring the potential of selling in various international markets but do not have any current plans to sell our products internationally.

The beauty industry is relatively concentrated, with a significant portion of retail sales in the United States generated by brands owned by a few large multinational companies, such as L'Oréal, Estee Lauder, Coty, Revlon, Shiseido, Johnson & Johnson, and Procter & Gamble. These large multinational companies typically own multiple brands. In addition to the traditional brands against which we compete, small independent companies continue to enter the market with new brands and customized product offerings.

### Bone and Tissue Healing Products

Our Bone Healing Accelerant ("BHA") and tissue healing accelerant ("THA") product candidates are based on patents licensed from Carnegie Mellon University ("CMU") that claim the ability to plasticize allogeneic platelet-enriched plasma and crosslink proteins with genipin, a derivative of the gardenia plant, to provide a controlled degradation profile in vivo. BHA, a biologic, has been designated by the FDA as a combination product containing the Company's core technology of plasma-based material plus  $\beta$  Tri-Calcium Phosphate (" $\beta$ -TCP"), an already approved medical device.

Legacy Carmell's early years were focused on discovering and formulating the plasma-based materials technology, filing for now-issued patents, conducting preclinical experiments aimed at exploring promising areas for accelerated and enhanced healing and conducting a Phase 2 clinical trial. Beginning in 2016, Legacy Carmell focused on moving BHA and THA from research to development. BHA is designed to be used in multiple bone applications, such as trauma fixation surgeries, including severe tibia fractures, spinal fusion, foot/ankle fusion and dental bone graft substitutes. THA is designed to be used in chronic wound care and aesthetic applications and is similar in formulation to BHA minus one material,  $\beta$ -TCP. The form of these two product candidates would feel different to the physicians/surgeons, with BHA being a "putty" form (due to the  $\beta$ -TCP) and THA being a "paste" form.

Carmell has conducted multiple preclinical studies that support our belief that BHA has the potential to heal wounds and accelerate bone healing of high quality, as measured by density, vascularity, and the presence of woven bone. The Company has submitted its BHA product candidate to the FDA as an Investigational New Drug ("IND") in severe open tibia fractures, and the FDA agreed that the

Company could pursue its proposed Phase 2 clinical trial under the IND. The FDA also granted a fast-track designation for the BHA program as the product candidate has the potential to meet a significant unmet need. However, following the closing of the AxoBio Acquisition, we have reprioritized further development and ceased clinical studies of our product candidates so that we can focus on the near-term commercialization of our cosmetic skincare and haircare product lines.

The production of our product candidates and any future research and development activities related to our product candidates are subject to extensive regulation by numerous governmental authorities in the United States, including the FDA. Prior to marketing in the United States, any product candidate we develop must undergo rigorous preclinical (animal) and clinical (human) testing and an extensive regulatory approval process implemented by the FDA under the Federal Food, Drug and Cosmetics Act (the "FDCA"). If we pursue research and development activities related to these product candidates in the future, there can be no assurance that we will not encounter problems in preclinical testing or clinical trials that will cause us or the FDA to delay or suspend the clinical trials for such product candidates or delay or prohibit us from initiating future clinical trials. The marketing of our product candidates, if approved, would also be subject to extensive regulation by numerous governmental authorities in the United States.

In addition to FDA approval, the success of BHA and THA will depend in part on our ability to obtain patents and product license rights, maintain trade secrets, and operate without infringing on the proprietary rights of others, both in the United States and other countries. There can be no assurance that patents issued to or licensed by us will not be challenged, invalidated, or circumvented or that the rights granted thereunder will provide us with proprietary protection or competitive advantages.

### CMU Exclusive License Agreement

In 2008, Carmell and CMU entered into an exclusive license agreement. Under the terms of the agreement, as subsequently amended, CMU granted the Company the exclusive rights to develop and commercialize plasma-based bioactive material, also known as "Biocompatible Plasma-Based Plastics," for all fields of use and all worldwide geographies (the "Amended License Agreement"). The Company is required to use its best efforts to introduce the licensed technology into the commercial market as soon as possible and meet certain milestones as stipulated within the Amended License Agreement. CMU retains the right to use any derivative technology developed by the Company as a result of its use of this technology and retains the intellectual property rights to the licensed technology under the Amended License Agreement, including patents, copyrights, and trademarks. The terms of the Amended License Agreement apply only to our BHA and THA products.

The Amended License Agreement is effective until January 30, 2028, or until the expiration of the last-to-expire patent relating to this technology, whichever comes later, unless otherwise terminated pursuant to another provision within the Amended License Agreement. The last-to-expire patent relating to the technology is expected to expire on September 2, 2030. Failure to perform in accordance with the agreed-upon milestones is grounds for CMU to terminate the Amended License Agreement prior to the expiration date, in addition to our default in the payment of any amount required to be paid under the Amended License Agreement. Prior to a qualified initial public offering or a qualified sale, CMU has the right to subscribe for additional equity securities so as to maintain its then percentage of ownership in the Company. The Business Combination did not qualify as a qualified initial public offering or qualified sale under the Amended License Agreement.

We have agreed to pay certain royalties to CMU under the Amended License Agreement at the rate of two and seven-hundredths percent (2.07%) of net sales of (as defined in the Amended License Agreement) until the Amended License Agreement expires or is terminated in accordance with its terms. We have also agreed to pay CMU twenty-five percent (25%) of sublicense fees received, due and payable upon receipt of sublicense fees by the Company. No royalties have been accrued or paid under the Amended License Agreement, as no products utilizing the licensed technology have been commercialized.

The Company is not obligated to make milestone payments but is required to meet certain minimum performance requirements to maintain the license under the Amended License Agreement as exclusive. Such Minimum Performance Requirements include: (i) CE Mark submission under the European Medical Devices Regulation by December 31, 2023, (ii) FDA BLA submission involving the first licensed product by December 31, 2026, (iii) Biologics License Application ("BLA") approval for the first licensed product by December 31, 2027, and (iv) introduction of a licensed product to be achieved within 12 months of receipt of FDA clearance to market.

### **Trademarks and Other Intellectual Property**

We believe that our intellectual property has substantial value and will contribute significantly to the success of our business. Our primary trademarks include, among others, "Carmell Cosmetics," "Carmell Secretome," "Foul 14," and Carmell's branding logos, including its clover-shaped logo, all of which are registered or have registrations pending with the U.S. Patent and Trademark Office for our goods and services of primary interest. Our trademarks are expected to be valuable assets that reinforce the distinctiveness of our brands and our consumers' perception of our products. In addition to trademark protection, we own several domain names, including the domain name of our e-commerce website. We also rely on and use commercially reasonable measures to protect our unpatented

proprietary technology, which includes our expertise and product formulations, continuing innovation and other know-how to develop and maintain our competitive position. In addition, the intellectual property related to our BHA and THA products include twenty-one patents that include exclusive, worldwide licenses from CMU.

#### **Government Regulation**

### Regulation of Cosmetics

We are subject to various federal, state and international laws and regulations, including regulation in the United States by the FDA, the Consumer Product Safety Commission (the "CPSC") and the Federal Trade Commission (the "FTC"), among others. These laws and regulations principally relate to the ingredients, proper labeling, advertising, packaging, marketing, manufacture, safety, shipment and disposal of our products.

In the United States, the FDCA defines cosmetics as articles or components of articles intended for application to the human body to cleanse, beautify, promote attractiveness, or alter the appearance, with the exception of soap. The labeling of cosmetic products is subject to the requirements of the FDCA, the Fair Packaging and Labeling Act, the Poison Prevention Packaging Act and other FDA regulations. Cosmetics are not subject to pre-market approval by the FDA; however, certain ingredients, such as color additives, must be pre-approved for the specific intended use of the product and are subject to certain restrictions on their use. If a company has not adequately substantiated the safety of its products or ingredients by, for example, performing appropriate toxicological tests or relying on already available toxicological test data, then a specific warning label is required. The FDA may, by regulation, require other warning statements on certain cosmetic products for specified hazards associated with such products. FDA regulations also prohibit or otherwise restrict the use of certain types of ingredients in cosmetic products.

In addition, the FDA requires that cosmetic labeling and claims be truthful and not misleading. Moreover, cosmetics may not be marketed or labeled for their use in treating, preventing, mitigating, or curing disease or other conditions or in affecting the structure or function of the body, as such claims would render the products to be a drug and subject to regulation as a drug. The FDA has issued warning letters to cosmetic companies alleging improper drug claims regarding their cosmetic products. In addition to FDA requirements, the FTC, as well as state consumer protection laws and regulations, can subject a cosmetics company to a range of requirements and theories of liability, including similar standards regarding false and misleading product claims, under which FTC or state enforcement or class-action lawsuits may be brought.

In the United States, the FDA has not promulgated regulations establishing mandatory Good Manufacturing Practices ("GMP") for cosmetics. However, the FDA's draft guidance on cosmetic GMP, most recently updated in June 2013, provides recommendations related to process documentation, recordkeeping, building and facility design, equipment maintenance and personnel, and compliance with these recommendations can reduce the risk that the FDA finds such products have been rendered adulterated or misbranded in violation of applicable law. The FDA also recommends that manufacturers maintain product complaints and recall files and voluntarily report adverse events to the FDA.

The FDA monitors compliance of cosmetic products through market surveillance and inspection of cosmetic manufacturers and distributors to ensure that the products are not manufactured under unsanitary conditions or labeled in a false or misleading manner. Inspections also may arise from consumer or competitor complaints filed with the FDA. In the event the FDA identifies unsanitary conditions, false or misleading labeling, or any other violation of FDA regulation, the FDA may request, or a manufacturer may independently decide to conduct a recall or market withdrawal of products. In addition, under the Modernization of Cosmetic Regulation Act of 2022 ("MoCRA"), manufacturers of cosmetic products will become subject to more onerous FDA obligations once implemented via regulation, including adverse event reporting and record retention requirements, safety substantiation requirements, facility registration requirements, product listing requirements, mandatory GMP requirements and labeling requirements for certain products. Under MoCRA, the FDA was also granted new enforcement authorities over cosmetics, such as the ability to initiate mandatory recalls and to obtain access to certain product records.

Moreover, the FTC regulates and can bring enforcement action against cosmetic companies for deceptive advertising and lack of adequate scientific substantiation for claims. The FTC requires that companies have a reasonable basis to support marketing claims. What constitutes a reasonable basis can vary depending on the strength or type of claim made or the market in which the claim is made, but objective evidence substantiating the claim is generally required.

### Regulation of BHA and THA

In the United States, biological products, including our BHA and THA products, are licensed by the FDA for marketing under the Public Health Service Act (the "PHS Act") and regulated under the FDCA. Both the FDCA and the PHS Act and their corresponding regulations

govern, among other things, the testing, manufacturing, safety, purity, potency, efficacy, labeling, packaging, storage, record keeping, distribution, marketing, sales, import, export, reporting, advertising and other promotional practices involving drug and biological products. FDA clearance of an IND must be obtained before initiating clinical testing of biologic products. FDA licensure also must be obtained before marketing biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

There are also various laws and regulations regarding laboratory practices and the use and disposal of hazardous or potentially hazardous substances, among others, in connection with the research. In each of these areas, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort, and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended, each BLA may be accompanied by a significant user fee. Under federal law, the submission of most applications is subject to an application user fee. The sponsor of an approved application is also subject to an annual program fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. As a condition for approval, the FDA may also require additional nonclinical testing as a Phase 4 commitment.

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP.

In the event our BHA and THA products are commercialized, we also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or inpatient populations that are not consistent with the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval or license revocation, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect.

#### Other Government Regulation

We are also subject to a number of federal, state and international laws and regulations that impact companies conducting business on the Internet, including regulations related to consumer protection, the promotion and sale of merchandise, privacy, use and protection of consumer and employee personal information and data (including the collection of data from minors), behavioral tracking, and advertising and marketing activities (including sweepstakes, contests and giveaways).

### **Supply Chain**

We manufacture our products at our primary location in Pittsburgh, Pennsylvania. We recognize the importance of our employees at our manufacturing facilities and have programs in place to ensure operating safety. In addition, we implement programs to ensure that our manufacturing and distribution facilities comply with applicable environmental rules and regulations.

We purchase the raw materials for all our products from various third parties. We also purchase packaging components that are manufactured to our design specifications. We collaborate with our suppliers to meet our stringent design and creative criteria. We believe that we currently have adequate sources of supply for all our products. We review our supplier base periodically with the specific objectives of improving quality, increasing innovation and speed-to-market, ensuring supply sufficiency and reducing costs.

We have experienced no disruptions in our supply chain, and we actively work to anticipate and respond to actual and potential disruptions. We continually benchmark the performance of our supply chain, augment our supply base, enhance our forecasting and planning capabilities, and adjust our inventory strategy based on the business's changing needs. We also continue to explore options to further optimize our supply chain operations as our cosmetic skincare products are commercialized.

### **Environmental Compliance**

We are subject to numerous federal, state, municipal and local environmental, health and safety laws and regulations relating to, among other matters, safe working conditions, product stewardship and environmental protection, including those relating to emissions to the air, discharges to land and surface waters, generation, handling, storage, transportation, treatment and disposal of hazardous substances and waste materials, and the evaluation of chemicals. We maintain policies and procedures to monitor and control environmental, health and safety risks and to monitor compliance with applicable environmental, health and safety requirements. Compliance with such laws and regulations pertaining to the discharge of materials into the environment or otherwise relating to the protection of the environment has not had a material effect on our capital expenditures, earnings or competitive position.

### **Segments**

Operating and reportable segments (referred to as "segments") reflect the way the Company is managed and for which separate financial information is available and evaluated regularly by the Company's chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. Our chief executive officer, who is our CODM, views the Company's operations and manages its business in one operating segment, which is principally the business of development and commercialization of bio-aesthetic and our bone and tissue healing products.

### **Employees and Human Capital**

As of March 15, 2024, we have nine full-time employees and one part-time employee. We have relied on and plan on continuing to rely on independent organizations, advisors and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. Such services may not always be available to us on a timely basis or at costs that we can afford. Our future performance will depend in part on our ability to successfully integrate newly hired officers and engage and retain consultants, as well as our ability to develop an effective working relationship with our management and consultants.

#### **Corporate Information**

Legacy Carmell was incorporated under the laws of the State of Delaware on November 5, 2008. ALPA was incorporated under the laws of the State of Delaware on January 21, 2021 in order to effect a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination with one or more businesses or entities.

Our principal corporate office is located at 2403 Sidney Street, Suite 300, Pittsburgh, PA 15293, and our telephone number is (412) 894-8248. Our website is www.carmellcorp.com. The information contained in or accessible from our website is not incorporated by reference in this Annual Report or in any other filings we make with the SEC. We have included our website address in this Annual Report solely as an inactive textual reference.

#### Item 1A. Risk Factors.

A description of the risks and uncertainties associated with our business and industry is set forth below. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report, including our audited consolidated financial statements and notes thereto and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this Annual Report before deciding whether to purchase shares of our Common Stock. If any of the following risks are realized, our business, financial condition, operating results and prospects could be materially and adversely affected. In that event, the price of our Common Stock could decline, perhaps significantly. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operation. The following risks and uncertainties include risks related to our business following the completion of the Business Combination.

### **Summary of Risk Factors**

The following is a summary of principal risks to which our business, operations and financial performance are subject. Each of these risks is more fully described in the individual risk factors immediately following this summary.

- We have limited experience as a commercial company, and we may not be successful in commercializing our marketed
  products, our current product candidates or any future product candidates, if and when approved, and we may be unable to
  generate meaningful product revenue.
- Our commercial success depends upon attaining and maintaining significant market acceptance of our current products, product candidates and future product candidates, if approved, among physicians, patients, healthcare payors and treatment centers
- Certain of the products we process are derived from human tissue and, therefore, have the potential for disease transmission.
- If we cannot successfully address quality issues that may arise with our products, our brand reputation could suffer, and our business, financial condition, and results of operations could be adversely impacted.
- Product liability lawsuits against us could cause us to incur substantial liabilities and limit the commercialization of any products that we may develop.
- Our product candidates are at an early stage of development and may not be successfully developed or commercialized.
- The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our research and development products, including those in clinical trials and those that may advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.
- If the FDA or any other regulatory authorities outside of the United States change the classification of a product candidate, we may be subject to additional regulations or requirements.
- Additional time may be required to obtain regulatory approval for our research and development products because of their status as combination products.
- We have conducted and may in the future conduct clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.
- We rely on patents and patent applications and various regulatory exclusivities to protect some of our product candidates, and our ability to compete may be limited or eliminated if we are not able to protect our products.
- We cannot be certain we will be able to obtain patent protection to protect our product candidates and technology.
- If we fail to comply with our obligations in the agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.
- Our intellectual property may not be sufficient to protect our products from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.
- Our future success is dependent, in part, on the performance and continued service of our officers and directors.
- We may require additional capital to support our growth plans, and such capital may not be available on terms acceptable to us, if at all. This could hamper our growth and adversely affect our business.
- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.
- We may become involved in litigation that may materially adversely affect us.

- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- The current economic downturn may harm our business and results of operations.
- We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.
- We expect the price of our Common Stock may be volatile and may fluctuate substantially.

### Risks Related to Our Business and Operations

We have limited experience as a commercial company and the marketing and sale of our cosmetic products and, if approved, our product candidates, may be unsuccessful.

Due to our limited history and experience as a commercial company, we face significant risks and uncertainties relating to the commercialization of our cosmetic products and, if approved, our product candidates. In order to successfully commercialize our products or any of our product candidates that may be approved, we must build on our marketing, sales, distribution, managerial and other capabilities or make arrangements with third parties to perform these services. We may face challenges that will inhibit our efforts, including::

- the inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability to supply the market with our products, including manufacturing or distribution challenges; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to accomplish our commercialization objectives and manage these challenges, we will not be able to generate operating revenue from our cosmetic products and, if approved, our product candidates.

### The cosmetics industry is highly competitive, and if we are unable to compete effectively, our results will suffer.

We face vigorous competition from companies throughout the world, including large multinational consumer products companies that have many cosmetics brands under ownership and standalone beauty and skincare brands, including those that may target the latest trends or specific distribution channels. Competition in the cosmetics industry is based on the introduction of new products, pricing of products, quality of products and packaging, brand awareness, perceived value and quality, innovation, in-store presence and visibility, promotional activities, advertising, editorials, e-commerce and mobile-commerce initiatives and other activities. We must compete with a high volume of new product introductions as well as existing products by diverse companies across several different distribution channels. Many of the multinational consumer companies that we compete with have greater financial, technical or marketing resources, longer operating histories, greater brand recognition or larger customer bases than we do and may be able to respond more effectively to changing business and economic conditions than we can. We also expect to encounter increased competition as we enter new markets and as we attempt to penetrate existing markets with new products. Our competitors may attempt to gain market share by offering products at prices at or below the prices at which our products are typically offered, including through the use of large percentage discounts. Competitive pricing may require us to reduce our prices, which would decrease our profitability or result in lost sales. Our competitors may be better able to withstand these price reductions and lost sales. In addition, our competitors may develop products that are safer, more effective, and more widely used and may be more successful than us in manufacturing and marketing their products.

It is difficult to predict the timing and scale of our competitors' activities or whether new competitors will emerge in the cosmetics industry. Technological breakthroughs, including new and enhanced technologies that increase competition in the online retail market, new product offerings by competitors and the strength and success of our competitors' marketing programs may further impede our growth and the implementation of our business strategy. Our ability to compete depends on the continued strength of our brand and products, the success of marketing, innovation and execution strategies, the continued diversity of product offerings, the successful management of new product introductions and innovations, strong operational execution, including in order fulfillment, and success in entering new markets and expanding our business in existing geographies. If we are unable to continue to compete effectively, it could have a material adverse effect on our business, financial condition and results of operations.

### Our new product introductions may not be as successful as we anticipate.

The cosmetics industry is driven in part by skincare and haircare trends, which may shift quickly. Our continued success depends on our ability to anticipate, gauge and react in a timely and cost-effective manner to changes in consumer preferences for skincare and haircare products, consumer attitudes toward our industry and brand and where and how consumers shop for and use these products. With the launch of our first skincare product and the anticipated launch of our remaining nine skincare products during the summer of 2024, we must continually establish and enhance the recognition of our brand, maintain a favorable mix of products that are acceptable to the market, develop our approach as to how and where we market and sell our products and work to develop, produce and market

new products. We have an established process for the development, evaluation and validation of our new product concepts. Nonetheless, each new product launch involves risks, as well as the possibility of unexpected results. For example, the acceptance of new product launches and sales to our consumers may not be as high as we anticipate, due to lack of acceptance of the products themselves or their price, or limited effectiveness of our marketing strategies. In addition, our ability to launch new products may be limited by our ability to timely manufacture, distribute and ship new products. In the future, we may also experience a decrease in sales of our existing products as a result of newly launched products. Any of these occurrences could delay or impede our ability to achieve our sales objectives, which could have a material adverse effect on our business, financial condition and results of operations.

### Acceptance of our formulations or products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate revenue.

Our future financial performance will depend, at least in part, upon the introduction and consumer acceptance of our products. Even if approved for marketing by the necessary regulatory authorities, our formulations or products may not achieve market acceptance. The degree of market acceptance will depend upon a number of factors, including:

- receipt of any necessary regulatory approval of marketing claims for the uses that we are developing;
- establishment and demonstration of the advantages, safety and efficacy of our formulations, products and technologies;
- our ability to attract corporate partners to assist in commercializing our proposed products; and
- our ability to market our products and, if approved, our product candidates and any future product candidates.

Further, any loss of confidence on the part of consumers in our products or product candidates or in the ingredients used in or with such products or product candidates could materially harm the image of our brand and cause consumers to choose other products. Allegations regarding any of the above, even if untrue, may require us to expend significant time and resources investigating and responding to such allegations and could, from time to time result in a recall or market withdrawal of a product from any or all of the markets in which the affected product was distributed. See "Our products may cause or contribute to undesirable side effects that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations" below.

Consumers or those within the medical community in general may be unwilling to accept, utilize or recommend any of our products, proposed formulations or, if approved, product candidates. If we are unable to obtain maintain the confidence of consumers or those who may otherwise utilize or recommend our products or product candidates or, if required, obtain regulatory approval for, or commercialize and market, our proposed formulations or product candidates when planned, we may not achieve market acceptance or generate any revenue.

### Our BHA and THA product candidates, if approved, may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. We believe our success depends in part on obtaining and maintaining coverage and adequate reimbursement for our product candidates, if approved, and the extent to which patients will be willing to pay out-of-pocket for such products.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new products are typically made by CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and neither experimental nor investigational.

There can be no assurance that any of our product candidates, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary and/or cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, even if they are approved for sale.

We are unable to predict what changes will be made to the reimbursement methodologies used by third-party payers in the future. As a result of the continuing evaluation and assessment of these expected payments, our estimates for expected payments could change. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, the level of such reimbursement. Reimbursement may impact the demand for, or the price of, any product candidates for which we obtain marketing approval. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in our products and future product development. If reimbursement is not available only at limited levels, our ability to successfully commercialize any product candidates for which we obtain marketing approval may be adversely affected.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

#### Certain of the products we process are derived from human tissue and therefore have the potential for disease transmission.

The utilization of human tissue creates the potential for transmission of communicable disease, including, without limitation, human immunodeficiency virus, viral hepatitis, syphilis and other viral, fungal or bacterial pathogens. We are required to comply with federal and state regulations intended to prevent communicable disease transmission.

We maintain strict quality controls designed in accordance with GMP to ensure the safe procurement and processing of our tissue, including terminal sterilization of our products. These controls are intended to prevent the transmission of communicable disease. However, risks exist with any human tissue implantation. In addition, negative publicity concerning disease transmission from other companies' improperly processed donated tissue could have a negative impact on the demand for our products and adversely affect our business, financial condition and results of operations.

### If we cannot successfully address quality issues that may arise with our products, our brand reputation could suffer, and our business, financial condition, and results of operations could be adversely impacted.

In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third-party components included in our products, as any quality issues or defects may negatively impact consumer use of our products. Although we have established internal procedures to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. If the quality of our products does not meet the expectations of our consumers or the cosmetics market generally, then our brand reputation could suffer and our business could be adversely impacted. We must also ensure any promotional claims made for our products conform with government regulations.

# Our products may cause or contribute to undesirable side effects that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations.

The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us. The FDA regulates our cosmetic products. In the United States, FDA regulations govern, among other things, the activities that we perform, including product development, product testing, product labeling, product storage, manufacturing, advertising, promotion, product sales, reporting of certain product adverse events and failures, and distribution. The FDA has the authority to require the recall or recommend the market withdrawal, as applicable, of commercialized products in the event of that a product has a reasonable probability of causing a serious adverse health risk due to adulteration or misbranding. Companies may also choose to voluntarily recall a product if any material deficiency or regulatory violation is discovered. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals, clearances or certifications for the product before we may market or distribute the corrected product. Seeking such approvals, clearances or certifications may delay our ability to replace the recalled products in a timely manner. Moreover, if we do not adequately address problems associated with our products, we may face additional regulatory enforcement action, including warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or clearances; seizures or recalls of products; total or partial suspension of production

or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for products; clinical holds; refusal to permit the import or export of products; and criminal prosecution. Companies are required to maintain certain records of recalls and corrective actions, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, it could require that we report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with consumers, potentially lead to product liability claims against us and negatively affect sales.

### Our success depends largely upon consumer satisfaction with the aesthetic results of our products.

In order to generate repeat business from consumers, our consumers must be satisfied with the aesthetic results of our cosmetic products. Our products are cosmetic in nature and the success of the results are highly subjective. Accordingly, cosmetics consumers' perception of their aesthetic results may greatly vary even if our products and systems associated therewith are shown to be objectively successful. If cosmetics consumers are not satisfied with the aesthetic benefits of our products or feel that they are too expensive for the aesthetic results obtained, our reputation and future sales could suffer.

## Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products.

Our business exposes us to the risk of product liability claims that are inherent to the development, clinical validation studies and testing to demonstrate aesthetic improvement and marketing of aesthetic, skincare and haircare products. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of those products. Although we maintain general liability insurance in an amount that we believe is reasonably adequate to insulate us from potential claims, this insurance may not fully cover potential liabilities. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business.

In addition, our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing and marketing of human tissue products. We may be subject to such claims if our products cause, or appear to have caused, an injury. Claims may be made by patients, healthcare providers or others selling our products. Product liability claims can be expensive to defend (regardless of merit), divert our management's attention, result in substantial damage awards against us, harm our reputation, and generate adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market.

### To be commercially successful, we must educate physicians, where appropriate, how and when our products are proper alternatives to existing treatments and that our products should be used in their procedures.

We believe physicians will only use our products if they determine, based on their independent medical judgment and experience, clinical data, and published peer-reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to other treatments. Physicians may be hesitant to change their existing medical treatment practices for the following reasons, among others:

- their lack of experience with advanced therapeutics, such as our products;
- lack of evidence supporting additional patient benefits of advanced therapeutics, such as our products, over conventional methods in certain therapeutic applications;
- perceived liability risks generally associated with the use of new products and procedures; and
- limited availability of reimbursement from third-party payers.

#### If we do not manage inventory in an effective and efficient manner, it could adversely affect our results of operations.

Many factors affect the efficient use and planning of inventory of certain components and other materials used in our manufacturing processes to manufacture our marketed products, such as effectiveness of predicting demand, effectiveness of preparing manufacturing to meet demand, efficiently meeting product demand requirements and expiration of materials in inventory. We may be unable to manage our inventory efficiently, keep inventory within expected budget goals, keep inventory on hand or manage it efficiently, control expired inventory or keep sufficient inventory of materials to meet product demand due to our dependence on third-party suppliers. Finally, we cannot provide assurances that we can keep inventory costs within our target levels. Failure to do so may harm our long-term growth prospects.

### The price and sale of our BHA and THA products may be limited by health insurance coverage and government regulation.

Maintaining and growing sales of our BHA and THA products will depend in large part on the availability of adequate coverage and the extent to which third-party payers, including health insurance companies, health maintenance organizations, and government health administration authorities such as the military, Medicare and Medicaid, private insurance plans and managed care programs will pay for the cost of the products and related treatment.

Many private payers in the U.S. use coverage decisions and payment amounts determined by CMS, as guidelines in setting their coverage and reimbursement policies. Future action by CMS or other government agencies, including the imposition of coverage and reimbursement limitations, may diminish payments to physicians, outpatient centers and/or hospitals for covered services. Additionally, payers may require us to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products and current and future product candidates to such payers' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products and future products might not ultimately be considered cost-effective. As a result, we cannot be certain that the procedures performed with our products will be reimbursed at a cost-effective level or reimbursed at all. Furthermore, the healthcare industry in the U.S. has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Increasingly, third-party payers have attempted to control costs by challenging the prices charged for medical products. Therefore, we cannot be certain that our products will be reimbursed at a cost-effective level. Nor can we be certain that third-party payers using a methodology that sets amounts based on the type of procedure performed, such as those utilized in many privately managed care systems and by Medicare, will view the cost of our products as justified so as to incorporate such costs into the overall cost of the procedure.

### We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly in order to develop and commercialize our cosmetic products going forward, and to make significant investments to support our business growth. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we launch our new skincare products throughout 2024. We also expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. To obtain such funding, we may need to engage in equity, equity-linked or debt financings, including for possible use in acquisitions. If we raise additional funds through future issuances of equity, equity-linked or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our Common Stock. Given current uncertainty in the capital markets and other factors, such funding may not be available on terms favorable to us or at all.

Any additional debt financing that we secure in the future could involve offering additional security interests and undertaking restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. Additionally, if we seek to access additional capital or increase our borrowing, there can be no assurance that debt or equity financing may be available to us on favorable terms, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly impaired, and our business, results of operations and financial condition may be harmed.

In addition, disputes may also arise between us and our investors or lenders. Such disputes may result in expensive arbitration, litigation or other dispute resolution, which may not be resolved in our favor and may adversely impact our financial condition. For example, on the closing of the Business Combination, the Company repaid \$2,649,874 to the Holders, which represented the original principal amount of the Convertible Notes (as defined in Note 8 to the accompanying consolidated financial statements) plus accrued interest at a rate of 25%, which the Company believes is the maximum rate permissible under New York State usury laws. In addition, the Company issued Puritan 25,000 shares of freely tradeable Common Stock, Following the closing of the Business Combination, both Holders have provided notice to the Company demanding additional payment of principal and interest on the Convertible Notes, in approximate amount of \$600,000 per each Holder at the closing of the Business Combination with additional interest thereon. In the case of Puritan, following the Business Combination, Puritan alleged that the Business Combination constituted a "Fundamental Transaction" under the terms of the Convertible Note Warrants, resulting in a purported right for Puritan to require the Company to repurchase such Convertible Note Warrants at a purchase price equal to the Black-Scholes Value of the unexercised portion of such Convertible Note Warrants as of the closing of the Business Combination. Puritan calculated the cash amount of such repurchase to be \$1,914,123. The Company believes that this calculation is inaccurate. In the case of the other Holder, that Holder demanded to be provided its share of the Convertible Note Warrants. Puritan has also asserted damages in connection with the timing of the issuance to it of 25,000 shares of freely tradeable Common Stock. The Company believes that it provided freely tradeable shares to Puritan at the same time as other public shareholders. Puritan's total claims inclusive of the amounts paid at Closing Date exceed \$4,050,000 in connection with a loan for which the Company received \$1,000,000. Management of the Company believes that its obligations under the Convertible Notes and Convertible Note

Warrants have been satisfied and that no additional payments are due to the Holders, and the Company has conveyed its position to the Holders. There can be no assurance that these or similar matters will not result in expensive arbitration, litigation or other dispute resolution, including but not limited to in the litigation filed by Puritan, which may not be resolved in our favor and may adversely impact our financial condition.

### Our financial condition, results of operations and cash flow may be adversely affected by changing economic conditions, including interest rates and inflation.

In recent years, the U.S. market has experienced cyclical or episodic downturns, and worldwide economic conditions remain uncertain and volatile, as a result of current geopolitical conditions including the Israel-Hamas War, the ongoing Russia-Ukraine War and conflict between China and Taiwan, instability in the U.S. and global banking systems, increased inflation, the downgrading of the U.S.'s credit rating and the possibility of a recession. A decline in economic conditions, such as recession, economic downturn, and/or inflationary conditions in the U.S. could an adversely and negatively impact our financial condition, results of operations and cash flow.

### Risks Related to the Legal and Regulatory Matters

#### Our product candidates may not be successfully developed or commercialized.

Following the closing of the AxoBio Acquisition, we have reprioritized further development and ceased clinical studies of our product candidates so that we can focus on the near-term commercialization of our cosmetic skincare and haircare product lines. Prior to such delay, our product candidates were in the early stage of development and will require substantial further capital expenditures, development, testing and regulatory approval prior to any future commercialization. The development and regulatory approval process takes many years, and it is not likely that our product candidates, technologies or processes, even if we decide to pursue regulatory approval, s would be commercially available over the next several years. Of the large number of product candidates in development, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if, in the future, we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized, if approved. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our product candidates, could materially impair our business and future growth.

# Any product candidates advanced into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize such product candidates, if approved.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates and commercialization, if approved, are subject to extensive regulation by the FDA in the U.S. and by comparable health authorities in foreign markets. In the U.S., we may not market our product candidates until we receive approval of our BLA from the FDA. The process of obtaining regulatory approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the product candidate involved. In addition to the significant clinical testing requirements, our ability to obtain marketing approval for these product candidates depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations may change and the FDA has substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

- The FDA or comparable foreign regulatory authorities may disagree with the design or implementation of clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the U.S.;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering our preclinical studies or clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. Any delay in obtaining, or inability to obtain, applicable regulatory approvals could prevent us from commercializing our product candidates. Specifically, Carmell plans to submit for a CE Mark approval in the European Union, which may or may not be successful. The new Medical Devices Regulation (Regulation (EU) 2017/745) in the European Union ("EU MDR") became applicable in the European Union on May 26, 2021 and may make approval times longer and standards more difficult to pass, given the new Regulation imposes more stringent requirements in respect of device safety and clinical evaluation. Any delay in obtaining, or inability to obtain, applicable regulatory approvals could prevent us from commercializing our product candidates, if approved. In addition, our Notified Body is experiencing significant EU MDR-related delays, which has significantly limited our ability to interact and work with our Notified Body. It is not known when these delays will be resolved, and this could significantly delay any potential EU CE Mark approvals.

### Delays in the commencement of clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective clinical research organizations, and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different clinical research organizations and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining an IRB or ethics committee approval to conduct a clinical trial at a prospective site; and
- identifying, recruiting and enrolling patients to participate in a clinical trial; retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or other issues.

Any delays in the commencement of clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

### Suspensions or delays in the completion of clinical testing could result in increased costs to us and delay or prevent our ability to complete development of that product candidate or generate product revenue from commercialization if approved.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- stopping rules contained in the protocol;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial;
- changes in regulatory requirements; and/or
- advances in medicine and science.

In addition, FDA may not agree that information submitted to our IND is sufficient to support our planned clinical development and may impose a clinical hold. The FDA may require us to conduct additional preclinical studies or make other changes, which could delay development of our product candidates. For example, for our BHA program, the FDA has indicated that we must resolve certain chemistry, manufacturing, and controls comments from the FDA prior to submitting protocols to initiate clinical studies intended to provide the primary evidence of effectiveness to support a marketing authorization. Our inability to resolve these comments from the FDA, or to provide the information needed to support initiation of pivotal trials, could impact our ability to advance our lead candidate

through the regulatory approval process. Additionally, changes in the current regulatory requirements and guidance also may occur, and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and the likelihood of a successful completion of a clinical trial. If we experience delays in the completion of, or if we must suspend or terminate, any clinical trial of any product candidate, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

### We have conducted and may in the future conduct clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

Our only clinical study completed to date was conducted outside the U.S., in South Africa, and while we plan to conduct our next clinical trial primarily in the U.S., we may also conduct future clinical trials outside the U.S. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice ("GCP") regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

### Even if our current product candidates received regulatory approval, they may still face future development and regulatory difficulties.

If we decide to pursue obtaining regulatory approval for our current product candidates and are able to obtain such regulatory approval, that approval would be subject to ongoing requirements by the FDA governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our Contract Manufacturing Organizations, Contract Research Organizations, or clinical trial investigators for any post-approval clinical trials that we may conduct. The safety profile of any product candidate, if approved, will continue to be closely monitored by the FDA after approval. If the FDA becomes aware of new safety information after approval of our product candidates, it may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy, impose significant restrictions on such product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drugs, biologics, devices and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current GMP, GCP, and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue Form FDA 483s, warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners and payors;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;

- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our product candidates, if approved, and generate revenue from such product candidates.

Advertising and promotion of any product candidate that obtains approval in the U.S. is heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of Health and Human Services, state attorneys general, members of Congress and the public. A company can make only those claims relating to safety and efficacy, purity and potency that are consistent with the FDA approved label.

Violations, including actual or alleged promotion of our product candidates, if approved, for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, as well as prosecution under various healthcare laws, including the federal False Claims Act. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business.

### We may fail to retain or recruit necessary personnel, and we may be unable to secure the services of consultants.

As of March 15, 2024, we have nine full-time employees and one part-time employee.

Certain of our directors, officers, scientific advisors, and consultants serve as officers, directors, scientific advisors, or consultants of other healthcare and life science companies or institutes that might be developing competitive products. None of our directors are obligated under any agreement or understanding with us to make any additional products or technologies available to us. Similarly, we can give no assurances, and we do not expect and investors should not expect, that any biomedical or pharmaceutical product or technology identified by any of our directors or affiliates in the future would be made available to us other than corporate opportunities. We can give no assurances that any such other companies will not have interests that are in conflict with its interests.

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the aesthetics and biomedical field, and we may not be able to attract and retain the qualified personnel we need to develop our business. We rely on independent organizations, advisors and consultants to perform certain services for us, including handling substantially all aspects of regulatory compliance, conduct of our clinical validation and testing, and, if we intend to pursue approval of our product candidates, regulatory approval and clinical studies, and we expect to rely on organizations and individuals for the marketing, and sales of our products and, if approved, our product candidates. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis, which may limit or delay our ability to develop or commercialize our products.

### We rely on third parties to supply certain raw materials and packaging components and, if our third-party suppliers do not timely supply these products, it may delay or impair our ability to develop, manufacture and market our products.

We purchase the raw materials and packaging components that are designed to our specifications for all our cosmetic products from various third parties. We collaborate with these suppliers to meet our stringent design and creative criteria. While we believe that we currently have adequate sources of supply for all our products, we and our suppliers may, in the future, not be able to (i) perform under any definitive manufacturing, supply or service agreements or (ii) remain in business for a sufficient time to successfully produce and market our cosmetic products. If we do not maintain important supplier and service relationships, we may fail to find a replacement supplier which could delay or impair our ability to commercialize, produce and distribute our cosmetic products and substantially increase our costs or deplete profit margins, if any. If we do find replacement suppliers, we may not be able to enter into agreements with suppliers on favorable terms and conditions.

## We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We may employ individuals who were previously employed at universities or pharmaceutical or cosmetics companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition

to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

### Business interruptions could adversely affect future operations and financial conditions, and may increase our costs and expenses.

Our operations, and those of our directors, employees, advisors, contractors, consultants, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, other extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics, such as the COVID-19 pandemic, and other natural and man-made disaster or business interruptions, many of which are beyond our and such third parties' control. Our phones, electronic devices and computer systems and those of our directors, employees, advisors, contractors, consultants, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man-made disasters. These locations may be subject to additional security and other risk factors due to the limited control of our employees. If such an event as described above were to occur in the future, it may cause interruptions in our operations, delay research and development programs, clinical validation, regulatory compliance activities, manufacturing and quality assurance activities, sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities.

Likewise, we rely and will continue to rely on third parties to conduct clinical trials, and similar events as those described in the prior paragraph relating to their business systems, equipment and facilities could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development, commercialization, marketing and sales of our products and, if we decide to seek regulatory approval for our product candidates, of our product candidates, could be delayed or altogether terminated.

### Our employees or others acting on our behalf may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We may be exposed to the risk that our employees, independent contractors, consultants, distributors and vendors and other individuals or entities with whom we have arrangements to act on our behalf may engage in unethical, fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws and regulations of the FDA, including those laws requiring the reporting of true, complete and accurate information to the FDA; (ii) manufacturing standards; or (iii) laws that require the true, complete and accurate reporting of financial information or data. Misconduct by employees or others acting on our behalf could also involve the improper use of information obtained in the course of clinical validation studies or other testing of our cosmetic products, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions or investigations are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions or investigations could result in government investigations, legal proceedings, the imposition of significant fines or other sanctions, including the imposition of monetary penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

### Risks Related to our Intellectual Property

### We may not be able to protect our proprietary technology, which could harm our ability to operate profitably.

The patent positions of medical device, biologics and cosmetics companies are uncertain and involve complex legal and factual questions. These industries place considerable importance on obtaining patent and trade secret protection for new technologies, cosmetic products and processes. We may incur significant expenses in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expenses and divert the attention of our management.

Others may file patent applications or obtain patents on similar technologies that compete with our products. We cannot predict how broad the claims in any such patents or applications will be and whether they will be allowed. Once claims have been issued, we cannot predict how they will be construed or enforced. We may infringe upon intellectual property rights of others without being aware of it. If another party claims we are infringing their technology, we could have to defend an expensive and time consuming lawsuit, pay a large sum if we are found to be infringing, or be prohibited from selling or licensing our products unless we obtain a license or redesign our products, which may not be possible.

We also rely on trade secrets and proprietary know-how to develop and maintain our competitive position. Some of our current or former employees, consultants, scientific advisors, contractors, current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefits. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know-how or gain access to our proprietary information through some other means.

### We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, as well as costs associated with lawsuits.

If any other person filed patent applications, or is issued patents, claiming technology also claimed by us, we may be required to participate in interference or derivation proceedings in the U.S. Patent and Trademark Office to determine priority and/or ownership of the invention. Our licensors or we may also need to participate in interference proceedings involving issued patents and pending applications of another entity.

The intellectual property environment in our industry is particularly complex, constantly evolving and highly fragmented. Other companies and institutions have issued patents and have filed or will file patent applications that may issue into patents that cover or attempt to cover products, processes or technologies similar to us. We have not conducted freedom-to-use patent searches on all aspects of our cosmetic products, product candidates or potential product candidates, and may be unaware of relevant patents and patent applications of third parties. In addition, the freedom-to-use patent searches that have been conducted may not have identified all relevant issued patents or pending patent applications. We cannot provide assurance that our cosmetic products or proposed products will not ultimately be held to infringe one or more valid claims owned by third parties which may exist or come to exist in the future or that in such case we will be able to obtain a license from such parties on acceptable terms.

We cannot guarantee that our technologies will not conflict with the rights of others. We may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost of any litigation or other proceeding relating to these areas, even if deemed frivolous or resolved in our favor, could be substantial and could distract management from its business. Uncertainties resulting from initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

### If we infringe the rights of others, we could be prevented from selling products or forced to pay damages.

Our research, development and commercialization activities may infringe or otherwise violate or be alleged to infringe or otherwise violate patents owned or controlled by other parties. Competitors in the field of aesthetics and cosmetics have developed large portfolios of patents and patent applications in fields relating to our business. Additionally, there may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages and/or we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Further, if a patent infringement suit were brought against us, during the pendency of the litigation, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. If our products, methods, processes, and other technologies are found to infringe the rights of other parties, we could be required to pay damages, or may be required to cease using the technology or to license rights from the prevailing party. Any prevailing party may be unwilling to offer us a license on commercially acceptable terms.

### We cannot be certain we will be able to obtain patent protection to protect our products, product candidates and technology.

We cannot be certain that all patents applied for will be issued. If a third party has also filed a patent application relating to an invention claimed by us or one or more of our licensors, we may be required to participate in an interference or derivation proceeding declared or instituted by the U.S. Patent and Trademark Office, which could result in substantial uncertainties and cost for us, even if the eventual outcome is favorable to us. The degree of future patent protection for our cosmetic products, product candidates and technology is uncertain. For example:

- we or our licensors might not have been the first to make the inventions covered by our issued patents, or pending or future patent applications;
- we or our licensors might not have been the first to file patent applications for the inventions;
- others may independently develop duplicative, similar or alternative technologies;
- it is possible that our patent applications will not result in an issued patent or patents, or that the scope of protection granted by any patents arising from our patent applications will be significantly narrower than expected;

- any patents under which we hold ultimate rights may not provide us with a basis for commercially- viable products, may
  not provide us with any competitive advantages or may be challenged by third parties as not infringed, invalid, or
  unenforceable under United States or foreign laws;
- any patent issued to us in the future or under which we hold rights may not be valid or enforceable; or
- we may develop additional technologies that are not patentable and which may not be adequately protected through trade secrets; for example, if a competitor independently develops duplicative, similar, or alternative technologies.

If we fail to comply with our obligations in the Amended License Agreement with CMU and any future license agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose rights that are important to our business.

We have entered to the Amended License Agreement with CMU under which CMU granted to us the exclusive rights to develop and commercialize plasma-based bioactive material, also known as "Biocompatible Plasma-Based Plastics," for all fields of use and all worldwide geographies, which applies only to our BHA and THA products. In the future, we may be required to enter into additional intellectual property license agreements that are important to our business. The Amended License Agreement imposes, and future license agreements may impose, various diligence, milestone payment, royalty and other obligations on us. For example, under the Amended License Agreement, we have agreed to pay certain royalties and sublicense fees to CMU. If we fail to comply with any obligations under the Amended License Agreement or under our any future license agreements, we may be subject to termination of such license agreement in whole or in part, increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreements will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology, products, methods and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third party expresses interest in an area under a license that we are not pursuing, under the certain terms of our license agreement, we may be required to sublicense rights in that area to the third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over the intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may need to obtain licenses from third parties to advance our research to allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

Under the Amended License Agreement, we are required to use our best efforts to effect introduction of the licensed technology into the commercial market as soon as possible and meet certain milestones as stipulated within the Amended License Agreement. CMU retains the right to use any derivative technology developed by us as a result of the use of this technology and retains the intellectual property rights to the licensed technology under the Amended License Agreement including patents, copyrights, and trademarks. We may establish all proprietary rights for us in the intellectual property developed by us which includes, or is based in whole or in part on, the licensed technology under the Amended License Agreement, which may also include Carmell-created modifications, enhancements or other technology, whether in the nature of trade secrets, copyrights, patents or other rights. CMU has the right to use such intellectual property developed by us solely for research, education, academic and/or administrative purposes. In addition, we own all right, title and interest (including patents, copyrights and trademarks) in and to the results of collaboration that are developed solely by CMU. Our rights to use these patents and employ the inventions claimed in these licensed patents, as well as the exploitation of licensed technology and know-how, are subject to the continuation of, and our compliance with, the terms of the Amended License Agreement. If the Amended License Agreement is terminated, we may not be able to develop, manufacture, market or sell the product candidates covered by such agreement and those that may be tested or approved in combination with such product candidate. Such an occurrence could materially adversely affect the value of the product candidates being developed under any such agreement.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our cosmetic products or product candidates.

Our success will depend in part on our ability to operate without infringing, misappropriating or otherwise violating the trademarks, patents, copyrights, trade secrets and other proprietary rights of others. We cannot guarantee that our cosmetic products or product candidates, or manufacture or use of our cosmetic products or product candidates, will not infringe, misappropriate or otherwise violate such third-party rights. From time to time, we may receive allegations of trademark or patent infringement and third parties have filed claims against us with allegations of intellectual property infringement. In addition, third parties may involve us in intellectual property disputes as part of a business model or strategy to gain competitive advantage.

Depending against such allegations and litigation could be costly, affect our results of operations, divert the attention of managerial and scientific personnel, and have an adverse impact on our ability to bring products to market. Some of these third parties may be better capitalized and have more resources than us. In that event we are to infringe or violate a third party's intellectual property rights, we may need to halt commercialization of the relevant cosmetic product(s) or product candidate(s), obtain a license, which may not be available to us on commercially reasonable terms, and redesign or rebrand our marketing strategy or cosmetic product candidates, which may not be possible or may be costly. In addition, there is a risk that a court will order us to pay the other party damages for having violated or infringed upon the other party's intellectual property rights.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any such litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If we fail to protect or enforce our intellectual property or confidential proprietary information relating to cosmetic products or product candidates, we may not be able to compete effectively, which may negatively affect our business as well as limit our partnership or acquisition appeal.

Our success depends in part on our ability to protect our intellectual property rights. We rely on a combination of trademarks, trade secrets, confidential proprietary information, domains, licensed patent rights and other intellectual property rights to protect our intellectual property. We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property will be sufficient to prevent third parties from designing around the patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our products; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research
  and development, clinical validation and testing, and commercialization activities, due to a potential deterioration of our
  financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own; and, the result of these challenges may narrow the claim scope of or invalidate intellectual property rights that are integral to our cosmetic products or product candidates in the future. There can be no assurance that we will be able to successfully defend our intellectual property rights in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation among other factors.

Changes to patent law, for example the Leahy-Smith America Invests Act, AIA or Leahy-Smith Act, of 2011 and the Patent Reform Act of 2009 and other future article of legislation in the U.S., may substantially change the regulations and procedures surrounding patent applications, issuance of patents, prosecution of patents, challenges to patent validity, and patent enforcement. We can give no assurances that our patents and those of our licensor(s) can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the U.S. Patent and Trademark Office and courts, and protection of our intellectual property rights could be reduced or eliminated for non-compliance with these requirements.

### If we are not able to protect and control our unpatented trade secrets, know-how and other proprietary technology, we may suffer competitive harm.

We also rely on proprietary trade secrets and unpatented know-how to protect our research and development activities, particularly when we do not believe that patent protection is appropriate or available. However, trade secrets are difficult to protect. We will attempt to protect our trade secrets and unpatented know-how by requiring our employees, consultants, collaborators, and advisors to execute a confidentiality and non-use agreement. We cannot guarantee that these agreements will provide meaningful protection, that these agreements will not be breached, that we will have an adequate remedy for any such breach, or that our trade secrets will not otherwise become known or independently developed by a third party. Our trade secrets, and those of our present or future collaborators with which we have agreements authorizing our use or access to such trade secrets, may become known or may be independently discovered by others, which could adversely affect the competitive position of our product candidates.

## If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our target markets and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or consumers in our target markets. If we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

### **Risks Related to our Financial Condition**

### Our future success is dependent, in part, on the performance and continued service of our officers and directors.

We are presently dependent largely upon the experience, abilities and continued services of our senior management, including our Chief Executive Officer, Rajiv Shukla. The loss of services of Mr. Shukla could have a material adverse effect on our business, financial condition or results of operation. Other key executives are important to our ongoing capability to develop, commercialize and, if necessary, obtain regulatory approval for our cosmetic products and product candidates. The competition of executive talent may make it difficult to replace any of these key positions in a timely manner. We do not maintain "key employee" insurance policies on any of our executive officers that would compensate us for the loss of their services. The time and cost required to replace a key employee may have a material adverse effect on our results of operations and financial condition.

### Management has concluded that there is substantial doubt about our ability to continue as a going concern.

As of December 31, 2023 we had cash on hand of \$2,912,461 and working capital of \$951,495, excluding the assets and liabilities associated with AxoBio, which are classified as assets and liabilities available for sale in the accompanying balance sheets.

The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern, which assumes the realization of assets and the satisfaction of liabilities in the normal course of business. As of December 31, 2023, we have had no income from continuing operations, and, excluding AxoBio, we did not have a commercial product or service. The Company has historically relied on raising capital to fund the Company's operations. Based on our cash balance as of December 31, 2023 and projected cash needs for the next twelve months, management estimates that it will need to raise additional capital to cover operating and capital requirements. Management will need to raise the additional funds through issuing additional shares of Common Stock or other equity securities or obtaining debt financing. There can be no assurance that any required future financing can be successfully completed on a timely basis, or on terms acceptable to the Company. Based on these circumstances, management has determined there is substantial doubt about the Company's ability to continue as a going concern.

The accompanying consolidated financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern.

#### We may become involved in litigation that may materially adversely affect us.

From time to time, we may become involved in various legal proceedings relating to matters incidental to the ordinary course of our business, including intellectual property, commercial, product liability, employment, class action, whistleblower, shareholder derivative suits and other litigation and claims, and governmental and other regulatory investigations and proceedings. The Holders of the Convertible Notes have alleged that the Company owes additional principal and interest thereon and is required to repurchase the Convertible Note Warrants. Puritan has filed suit seeking to recover such amounts allegedly owed. Management of the Company

believes that its obligations under the Convertible Notes have been satisfied and that no additional payments are due to the Holders, and the Company has conveyed its position to the Holders. Nevertheless, we cannot assure you that we will prevail. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability or require us to change our business practices. Because of the potential risks, expenses and uncertainties of litigation, we may, from time to time, settle disputes, even where we believe that we have meritorious claims or defenses. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business.

#### We have a history of net losses, and we may not be able to achieve or maintain profitability in the future.

We have incurred net losses each year since our inception, and we may not be able to achieve or maintain profitability in the future. For the year ended December 31, 2023 and 2022, we had a loss from continuing operations of \$16,205,252 and \$9,051,334, respectively, and negative cash flows from operations of \$8,348,208 and \$3,428,707, respectively. To date, we have financed our operations primarily through the sale of equity securities and convertible debt. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials, and we anticipate that our expenses will continue to increase over the next several years as we develop and launch our cosmetic products, expand into new markets and increase our sales and marketing efforts. These efforts may be more costly than we expect and may not result in increased revenue or growth in our business. Accordingly, we expect to continue to incur substantial operating losses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year.

Any failure to increase our revenue sufficiently to keep pace with our investments and other expenses could prevent us from achieving or maintaining profitability or positive cash flow on a consistent basis. If we are unable to successfully address these risks and challenges as we encounter them, our business, financial condition, results of operations and prospects could be adversely affected. If we are unable to generate adequate revenue and manage our expenses, we may continue to incur significant losses in the future and may not be able to achieve or maintain profitability. In addition, even if we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would depress the value of our company and could impair our ability to maintain our research and development efforts, expand our business, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

### The current economic downturn may harm our business and results of operations.

Our overall performance depends, in part, on worldwide economic conditions. the U.S. and global markets have experienced cyclical or episodic downturns, and worldwide economic conditions remain uncertain and volatile, as a result of current geopolitical conditions including the Israel-Hamas War, the ongoing Russia-Ukraine War and conflict between China and Taiwan, instability in the U.S. and global banking systems, increased inflation, the downgrading of the U.S.'s credit rating and the possibility of a recession. Impacts of such economic weakness include:

- falling overall demand for goods and services, leading to reduced profitability;
- reduced credit availability;
- higher borrowing costs;
- reduced liquidity;
- volatility in credit, equity and foreign exchange markets; and
- bankruptcies.

These developments could lead to supply chain disruption, inflation, higher interest rates, and uncertainty about business continuity, which may adversely affected our business and our results of operations.

Recent increases in interest rates may increase our borrowing costs, and may also affect our ability to obtain working capital through borrowings such as bank credit lines and public or private sales of debt securities, which may result in lower liquidity, reduced working capital and other adverse impacts on our business.

Continued increases in interest rates will increase the cost of new indebtedness/servicing our outstanding indebtedness/refinancing our outstanding indebtedness, and could materially and adversely affect our results of operations, financial condition, liquidity and cash flows.

Hostilities in Ukraine and Israel could have a material adverse effect, including the availability and cost of services that we rely upon for our business operations, which could have a material adverse impact on our business operations.

Russia's invasion of Ukraine, which has persisted for months, and the global response, including the imposition of sanctions by the United States and other countries, could create or exacerbate risks facing our business. In addition, recent hostilities in Israel could also

create or exacerbate risks facing our business. Given the continuing conflicts, our supply chain could be disrupted due to the demise of commercial activity in impacted regions and due to the severity of sanctions on the businesses that we and our suppliers rely on. Further, state-sponsored cyberattacks could expand as part of the conflict, which could adversely affect our and our suppliers' ability to maintain or enhance key cyber security and data protection measures.

## Significant disruptions of information technology systems, computer system failures or breaches of information security could adversely affect our business.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we may contract, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we intend to invest in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Our internal computer systems, and those of our business vendors on which we may rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. Any interruption or breach in our systems could adversely affect our business operations or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our cosmetic products and future product candidates could be delayed and our business could be otherwise adversely affected.

### We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As of March 15, 2024, we have nine full-time employees and one part-time employee. We will need to grow the size of our organization in order to support our continued development and commercialization of our cosmetic products and potential commercialization of our product candidates in the future. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources will increase. Our management, personnel and systems currently in place will not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- Managing our clinical validation and any future clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and expanding our facilities.

If our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our cosmetic products and product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate for our company. To that end, we must be able to manage our development efforts and preclinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

### We expect to continue to incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we incur and expect to continue to incur additional significant legal, accounting and other expenses in relation to our status as a public reporting company. We expect that these expenses will further increase after we are no longer an emerging growth company. We may need to hire additional accounting, finance and other personnel in connection with our continuing efforts to comply with the requirements of being a public company, and our management and other personnel will need to continue to devote a substantial amount of time towards maintaining compliance with these requirements. In addition, the Sarbanes-Oxley Act of 2002 and rules

subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

### If we market products in a manner that violates healthcare laws, we may be subject to civil or criminal penalties.

Although our products are not currently covered by any third-party payor, including any commercial payor or government healthcare program, we may nonetheless be subject to federal and state healthcare laws, including fraud and abuse, anti-kickback, false claims and transparency laws with respect to payments or other transfers of value made to physicians and other healthcare professionals. These laws may impact, among other things, financial arrangements with physicians, sales, marketing and education programs and the manner in which any of those activities are implemented. If our operations are found to be in violation of any of those laws or any other applicable governmental regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, imprisonment, exclusion from government healthcare programs or the curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and our financial condition. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices including compensation of physicians with stock or stock options, could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

### As compliance with healthcare regulations becomes more costly and difficult for us or our consumers, we may be unable to grow our business.

Participants in the healthcare industry are subject to extensive and frequently changing regulations under numerous laws administered by governmental entities at the federal, state, local and foreign levels, some of which are, and others of which may be, applicable to our business. The healthcare market itself is highly regulated and subject to changing political, economic and regulatory influences. Failure to keep up and comply with such requirements may subject us to significant costs, sanctions, or penalties. For example, regulations implemented pursuant to the Health Insurance Portability and Accountability Act, or HIPAA, including regulations governing the privacy and security of individually identifiable health information held by healthcare providers and their business associates may require us to make significant and unplanned enhancements of software applications or services, result in delays or cancellations of orders, cause us to be subject to significant penalties or fines for violations, or result in the revocation of endorsement of our products and services by healthcare participants, among others.

In addition, significant changes to the regulatory requirements for cosmetic products are scheduled in the next several years. On December 29, 2022, Congress enacted MoCRA that adds significant new regulatory requirements to cosmetic products. Some of the requirements became applicable on December 29, 2023, although many of the requirements, such as those relating to labeling, will become applicable in 2024 and 2025. For example, cosmetic manufacturing and processing facilities will need to be registered with FDA, and products will need to be listed with FDA. Adulterated or misbranded cosmetic products will be subject to recalls that are mandated by FDA, similar to medical devices. In addition, a responsible person will be required to report any serious adverse events that result from the use of a cosmetic product manufactured, packaged, or distributed by the associated entity, and the records relating to each adverse event report will be required to be kept for six years. Notably, MoCRA requires FDA to promulgate proposed rules for Good Manufacturing Practices for cosmetic products by December 29, 2024, and final rules by December 29, 2025. Subsequently,

compliance with such GMP requirements will become mandatory for manufacturers of cosmetic products. Additionally, cosmetic labels will need to identify the responsible person for the purpose of serious adverse event reporting, and cosmetic labels will also need to identify fragrance allergens. We, as the manufacturer, and our products, will become subject to these requirements, and will need to expend capital to ensure that our manufacturing practices and labeling processes are compliant. Additionally, we may need to hire additional personnel to implement the adverse event reporting procedures and to ensure compliance with these new requirements. There may be certain challenges to compliance with these requirements and failure to comply may result in enforcement actions from FDA and other regulatory agencies that could disrupt our business operations.

#### Risks Related to our Common Stock

### We expect the price of our Common Stock may be volatile and may fluctuate substantially.

The stock market in general and the market for cosmetics companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our Common Stock may be influenced by many factors, including:

- commercialization and sales of our products;
- the results of our efforts to discover, develop, acquire or in-license products or product candidates, if any;
- failure or discontinuation of any of our research programs;
- actual or anticipated results from, and any delays in, any future clinical validation, testing or clinical trials, as well as results of regulatory reviews relating to the approval of any product candidates we may choose to develop;
- the level of expenses related to any products or product candidates that we may choose to develop or clinical development programs we may choose to pursue;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures and capital commitments;
- additions or departures of key scientific or management personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- new products, product candidates or new uses for existing products introduced or announced by our competitors, and the timing of these introductions or announcements;
- results of clinical validation, testing or clinical trials of products or product candidates of our competitors;
- general economic and market conditions and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- regulatory or legal developments in the United States and other countries;
- changes in the structure of healthcare payment systems;
- conditions or trends in the cosmetics industries:
- actual or anticipated changes in earnings estimates, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of Common Stock by us or our stockholders in the future, as well as the overall trading volume of our Common Stock;
   and
- the other factors described in this "Risk Factors" section.

In the past, following periods of volatility in companies' stock prices, securities class-action litigation has often been instituted against such companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business and financial condition.

### Future resales of Common Stock may cause the market price of our securities to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our Common Stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our Common Stock.

As restrictions on resale end and registration statements for the sale of the shares held by parties who have contractual registration rights are available for use, the sale or possibility of sale of these shares could have the effect of increasing the volatility in the market price of our Common Stock, or decreasing the market price itself. As a result of any such decreases in price of our Common Stock, purchasers who acquire shares of our Common Stock may lose some or all of their investment.

Any significant downward pressure on the price of our Common Stock as the selling stockholders sell the shares of our Common Stock, or the prospect of such shares could encourage short sales by the selling stockholders or others. Any such short sales could place further downward pressure on the price of our Common Stock.

We are required to register the issuance of the shares underlying the warrants issued in the IPO. We may incur substantial costs in connection with such registration statement and the issuance of such shares may result in dilution to holders of our Common Stock and the issuance of any such shares upon a cashless exercise of the warrants would not result in the receipt by us of any cash proceeds thereof.

Pursuant to the warrant agreement entered into upon closing of the IPO, we agreed to file a registration statement with the SEC to register the issuance of the shares of Common Stock upon exercise of the warrants issued in the IPO. We prepared and filed such registration statement on August 7, 2023. The registration statement was not declared effective by the 60<sup>th</sup> business day following the closing of the Business Combination. As a result, until such registration statement is declared effective by the SEC, such warrants may be exercised by the holders thereof on a cashless basis.

We have incurred substantial costs in connection with the filing of the registration statement. We will be required to amend the registration statement to include certain financial statements of AxoBio and to update certain financial and other information since the date of the original filing of the registration statement. We may incur substantial costs in connection with such amendment and completion of the SEC review process. In addition, for as long as the warrants remain exercisable on a cashless basis until the effectiveness of the registration statement, we would not be able to receive any cash proceeds from the exercise thereof, preventing such potential proceeds from improving our liquidity position. Any shares issuable upon exercise of the warrants, for cash or on a cashless basis, would also increase the number of shares outstanding and available for sale, which could result in downward pressure on the price of our Common Stock.

### We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our Common Stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). For so long as we remain an emerging growth company, we will be permitted to and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our Common Stock less attractive if we rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and the price of our Common Stock price may be more volatile.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future; capital appreciation, if any, will be your sole source of gain as a holder of our Common Stock.

We have never declared or paid cash dividends on shares of our capital stock. We currently plan to retain all of our future earnings, if any, and any cash received as a result of future financings to finance the growth and development of our business. Accordingly, capital appreciation, if any, of our Common Stock will be the sole source of gain for holders of our Common Stock for the foreseeable future.

### If we were to be delisted from Nasdaq, it could reduce the visibility, liquidity and price of our Common Stock.

There are various quantitative listing requirements for a company to remain listed on Nasdaq, including maintaining a minimum bid price of \$1.00 per share and Nasdaq equity standards. There is no guarantee that we will be able to continue complying with the minimum bid price rule, the minimum equity standard or other Nasdaq requirements.

Provisions in our amended and restated certificate of incorporation and Delaware law may inhibit a takeover of us, which could limit the price investors might be willing to pay in the future for our Common Stock and could entrench management.

Our amended and restated certificate of incorporation contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. These provisions include a staggered board of directors and the ability of the board of directors to designate the terms of and issue new series of preferred shares, which may make the removal of management more difficult and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities.

We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together these provisions may make the removal of management more difficult and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities.

#### Item 1B. Unresolved Staff Comments.

None

### Item 1C. Cybersecurity.

Managing cybersecurity risk is a crucial part of our overall strategy for safely operating our business. We incorporate cybersecurity practices into our Enterprise Risk Management ("ERM") approach, which is subject to oversight by our Board of Directors (the "BOD").

Consistent with our overall ERM program and practices, our cybersecurity program includes:

- *Vigilance:* We maintain a cybersecurity program that endeavors to identify risks, protect assets, detect threats, respond to incidents, and recover from damaging events in a prompt and effective manner with the goal of minimizing business disruptions through effective governance of people, processes, and technologies.
- External Collaboration: We collaborate with third-party service providers to identify, assess and mitigate cybersecurity risks.
- Systems Safeguards: We deploy technical safeguards that are designed to protect our information systems, products, operations and sensitive information from cybersecurity threats, including compromises of our information systems and our data's confidentiality, integrity, and availability. These include firewalls, disaster recovery capabilities, malware and ransomware prevention, access controls, and encryption.
- *Education:* We provide monthly training for all personnel regarding cybersecurity threats, with such training appropriate to the roles, responsibilities and access of the relevant Company personnel. Our policies require all workers to report any real or suspected cybersecurity events.
- *Incident Response Planning:* We have established and maintain incident response plans that direct our response to cybersecurity events and incidents. Such plans include the protocol by which a material incident would be communicated to executive management, our BOD, external regulators and shareholders.
- Governance: Our BOD's oversight of cybersecurity risk management is led by the Company's Audit Committee, which oversees our ERM program. Cybersecurity threats, risks and mitigation are reviewed by the Audit Committee on at least an annual basis and such reviews include internal and independent assessment of risks, controls and overall program effectiveness.

Our risk assessment efforts have indicated that we are a potential target for theft of intellectual property, financial resources, personal information, and trade secrets from a wide range of actors including nation states, organized criminal groups, malicious insiders and activists. The impacts of attacks, abuse and misuse of the Company's systems and information include, without limitation, loss of assets, operational disruption and damage to the Company's reputation.

A key element of managing cybersecurity risk is the ongoing assessment and testing of our processes and practices through assessments and other exercises focused on evaluating the sufficiency and effectiveness of our cybersecurity risk management efforts. If a material weakness in our cybersecurity risk management program is identified, it will be reported to the Audit Committee and the BOD, as appropriate, and we will make adjustments to our cybersecurity processes and practices as necessary to eliminate or compensate for that weakness.

Our CFO is principally responsible for overseeing our cybersecurity risk management program, in partnership with other Company management. We believe our business leaders, including our CFO, have the appropriate expertise, background and depth of experience to manage risks arising from cybersecurity threats. Our CFO collaborates with other Company business leaders to implement a program designed to manage our exposure to cybersecurity risks and to promptly respond to cybersecurity incidents.

The Audit Committee oversees cybersecurity risk management, including the policies, processes and practices that management implements to operationalize our cybersecurity risk management program. The Audit Committee will promptly receive information regarding any material cybersecurity incident that may occur, including any ongoing updates. The Audit

Committee periodically discusses our approach to cybersecurity risk management with our CFO, who oversees the Company's information systems.

As of the date of this Form 10-K, we are not aware of any cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company, including our business strategy, results of operations, or financial condition at this time.

### Item 2. Properties.

Our corporate headquarters, research and development manufacturing, and facilities are located in Pittsburgh, Pennsylvania where we lease approximately 11,385 square feet of space. This lease expires in 2028. We believe that our existing facilities are adequate to support our existing operations.

### Item 3. Legal Proceedings.

The information under the headings "January 2022 Convertible Notes" in Note 8 – Debt and Note 10 – Contingencies in the notes to the accompanying audited consolidated financial statements is incorporated herein by reference.

### Item 4. Mine Safety Disclosures.

None.

## **PART II**

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

Market information for Common Stock

Our Common Stock began trading on the Nasdaq Capital Market under the symbol "CTCX" on July 17, 2023. Prior such date, Alpha's Class A Common Stock traded on the Nasdaq Capital Market under the symbol "ALPA".

On March 27, 2024, the closing price for our Common Stock as reported by the Nasdaq Capital Market was \$2.58.

## Holders of record

As of March 27, 2024, the approximate number of holders of record of our Common Stock was 215. This number does not include beneficial owners whose shares are held by nominees in street name.

#### Dividends

Since the IPO, we have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and covenants and other factors that our board of directors may deem relevant.

## Item 6. [Reserved]

# Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying audited consolidated financial statements and the related notes contained in Part II, Item 8 of this Annual Report. Certain information in this discussion and analysis or as set forth elsewhere in this Annual Report contains forward-looking statements that involve numerous risks and uncertainties, including, but not limited to, those described under the section entitled "Forward-Looking Statements" in Part I, Item 1. "Business" in this Annual Report and under Part I, Item 1A. "Risk Factors" in this Annual Report. We assume no obligation to update any of these forward-looking statements. Actual results may differ materially from those contained in any forward-looking statements.

#### **Overview**

Carmell is a bio-aesthetics company that utilizes the Carmell Secretome<sup>TM</sup> to support skin and hair health. The Carmell Secretome<sup>TM</sup> consists of a potent cocktail of growth factors and proteins extracted from allogeneic human platelets sourced from U.S. Food and Drug Administration-approved tissue banks. Over the past 7 years, Carmell has extensively tested the technology underpinning the Carmell Secretome<sup>TM</sup>. In addition, we have developed a novel microemulsion formulation that enables delivery of lipophilic and hydrophilic ingredients without relying on the Foul Fourteen<sup>TM</sup>, which are 14 potentially harmful excipients that are commonly used by other companies to impart texture, stability, and other desirable physicochemical attributes to cosmetic products. Additionally, Carmell's microemulsion formulations do not utilize mineral or vegetable oils across its entire product line and are designed to be non-comedogenic. We are also developing a line of men's products and a line of topical haircare products. All of our cosmetic skincare and haircare products are tailored to meet the demanding technical requirements of professional care providers and discerning retail consumers. Our product pipeline also includes innovative regenerative bone and tissue healing products that are under development.

We are developing and plan to begin the commercial launch of our line of cosmetic skincare products in the first half of 2024. We plan to employ an omni-channel distribution strategy and sell our products online through direct e-commerce channels and through retailers and distributors in the United States.

## **Recent Developments**

#### **Business Combination**

On the Closing Date, we consummated the Business Combination pursuant to the Business Combination Agreement, following which Legacy Carmell became a wholly owned subsidiary of the Company. Pursuant to the Business Combination Agreement, on the Closing Date, Alpha changed its name to "Carmell Therapeutics Corporation" and Legacy Carmell changed its name to "Carmell Regen Med Corporation." See "*Recent Developments*" in Part I, Item 1. "*Business*" in this Annual Report for additional information regarding the Business Combination.

## Name Change

On August 1, 2023, the Company filed an amendment to its Third Amended and Restated Certificate of Incorporation with the Delaware Secretary of State to change its name to "Carmell Corporation."

## Axolotl Biologix Acquisition

On August 9, 2023, we completed the AxoBio Acquisition pursuant to the Merger Agreement. At the Merger Effective Time, each share of AxoBio Common Stock (other than Dissenting Shares (as defined in the Merger Agreement) and shares held as treasury stock) issued and outstanding as of immediately prior to the Merger Effective Time was canceled and converted into the right to receive a pro rata share of:

- \$8.0 million in cash, or the "Closing Cash Consideration, payable upon delivery of AxoBio's audited financial statements;
- 3,845,337 shares of Common Stock and 4,243 shares of Series A Preferred Stock, or the Closing Share Consideration, issued upon the Merger Closing Date; and
- up to \$9 million in cash and up to \$66 million in shares of Common Stock that, in each case, were subject to the Earnout.

See "Recent Developments" in Part I, Item 1. "Business" in this Annual Report for additional information regarding the AxoBio Acquisition.

## Axolotl Biologix Disposition

On March 20, 2024, we entered into the Purchase Agreement with the Buyers, the former stockholders of AxoBio, for the AxoBio Disposition. The AxoBio Disposition, as contemplated by the Purchase Agreement, closed on March 26, 2024. In connection with the AxoBio Disposition, upon the terms and subject to the conditions set forth in the Purchase Agreement, we will sell all of the outstanding limited liability company interests of AxoBio to the Buyers in exchange for the return of the Closing Share Consideration, the cancellation of the notes payable by the Company to the Buyers in an aggregate principal amount of \$8 million issued as the Closing Cash Consideration and termination of the Company's obligations with respect to the Earnout. AxoBio did not produce any revenue from its products from November 2023 onward, and revenue from such products is not anticipated in the future. See "Recent Developments" in Part I, Item 1. "Business" in this Annual Report for additional information regarding the AxoBio Disposition.

In accordance with Financial Accounting Standards Board Accounting Standards Codification ("ASC") 205, *Presentation of Financial Statements, Discontinued Operations, Other Presentation Matters*, the assets and liabilities of AxoBio are classified as available for sale on the accompanying consolidated balance sheets, and the results of its operations are reported as discontinued operations in the accompanying consolidated statements of operations.

#### **Macroeconomic Conditions**

Economic uncertainty in various global markets caused by political instability and conflicts, such as the ongoing conflicts in Ukraine and Israel, and economic challenges, including those related to the COVID-19 pandemic, have led to market disruptions, such as significant volatility in commodity prices, credit and capital market instability, and supply chain interruptions, which have caused record inflation globally. Our business, financial condition, and results of operations could be materially and adversely affected by further negative impacts on the global economy and capital markets resulting from these global economic conditions, particularly if such conditions are prolonged or worsen. Although, to date, our results of operations have not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which our operations may be impacted in the short and long term. The extent and duration of these market disruptions, whether as a result of the military conflict between Russia and Ukraine, the effects of the Russian sanctions, the conflict between Israel and Hamas, geopolitical tensions, inflation, or otherwise, are impossible to predict. Any such disruptions may also magnify the impact of other risks described or incorporated by reference in this Annual Report. See Part I, Item 1A, "Risk Factors" in this Annual Report for further discussion of the potential impact of these general macroeconomic factors and other risks on our business.

## Impact of Macroeconomic Events

Economic uncertainty in various global markets caused by political instability and conflicts, such as the ongoing conflicts in Ukraine and Israel, and economic challenges have led to market disruptions, including significant volatility in commodity prices, credit and capital market instability, and supply chain interruptions, which have caused record inflation globally. Our business, financial condition, and results of operations could be materially and adversely affected by further negative impacts on the global economy and capital markets resulting from these global economic conditions, particularly if such conditions are prolonged or worsen. Although, to date, our results of operations have not been materially impacted by these global economic and geopolitical conditions, it is impossible to predict the extent to which our operations may be impacted in the short and long term. The extent and duration of these market disruptions, whether as a result of the military conflict between Russia and Ukraine, the effects of the Russian sanctions, the conflict between Israel and Hamas, geopolitical tensions, inflation, or otherwise, are impossible to predict. Any such disruptions may also magnify the impact of other risks described or incorporated by reference in this Annual Report.

## Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations is based on our audited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these audited consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the audited consolidated financial statements, as well as the reported revenue expenses and net loss incurred during the reporting periods. Our estimates are based on our historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

## Going Concern and Management Plan

The audited consolidated financial statements included elsewhere herein for the year ended December 31, 2023, were prepared under the assumption that we would continue our operations as a going concern, which contemplates the realization of assets and the satisfaction of liabilities during the normal course of business. However, as of December 31, 2023, we had cash and cash equivalents of \$2,912,461, an accumulated deficit of \$58,503,401 and liabilities of \$39,199,793. We have incurred substantial recurring losses from

continuing operations, have used, rather than provided, cash from our continuing operations and are dependent on additional financing to fund future operations. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued. The audited consolidated financial statements included elsewhere herein do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

In the third quarter of 2023, we significantly reduced our future operating expenses by terminating certain executives serving as part-time consultants and full-time employees in non-core areas or overlapping business functions. This workforce reduction is expected to result in \$2,000,000 to \$3,000,000 in annual savings. In addition, we have refocused our research and development efforts on aesthetic products that have near-term commercial potential and have reprioritized further development and ceased clinical studies of product candidates that will take more than a year to commercialize. We are also exploring out-licensing certain research and development programs to generate non-dilutive liquidity. Furthermore, we expect the sale of AxoBio will further reduce our operating expenses, which is anticipated to assist us in extending our cash runway.

## Comparison of Results of Operations for the Years Ended December 31, 2023 and 2022

The following table sets forth our results of operations for the years ended December 31, 2023 and 2022:

	F			
	202	.3	2022	Change
Operating expenses:				
Research and development	\$ 2,49	97,218 \$	2,196,063	\$ 301,155
General and administrative	2,62	22,945	3,217,280	(594,335)
Depreciation and amortization of intangibles	9	97,113	94,298	2,815
Restructuring charges	72	26,280		726,280
Total operating expenses	5,94	43,556	5,507,641	435,915
Loss from operations	(5,94	43,556)	(5,507,641)	(435,915)
Other (expenses) income, net	(10,26	61,696)	(3,543,693)	(6,718,003)
Net loss from continuing operations before taxes	\$ (16,20	)5,252) \$	(9,051,334)	\$ (7,153,918)

## Operating Expenses

Total operating expenses were \$5,943,556 and \$5,507,641 for the years ended December 31, 2023 and 2022, respectively. This increase reflects a higher level of expenses in 2023 resulting from the execution of our strategic plan to commercialize our technologies.

Research and development expenses were \$2,497,218 and \$2,196,063 for the years ended December 31, 2023, and 2022, respectively. This increase was principally due to an increase in salaries and benefits of our research and development personnel.

General and administrative expenses were \$2,622,495 and \$3,217,280 for the years ended December 31, 2023 and 2022, respectively. This decrease was primarily driven by the \$1,278,062 write-off of costs associated with the Company's aborted initial public offering in October 2022, prior to pursuing the Business Combination. The decrease in general and administrative expenses was partially offset by an increase in salaries and benefits for personnel.

Depreciation and amortization expense was \$97,113 for the year ended December 31, 2023, in line with \$94,298 for the comparable period of 2022.

Restructuring charges of \$726,280 for the year ended December 31, 2023, were related to our strategic realignment and consist of severance from the termination of employees in non-core areas or overlapping business functions (see "Restructuring" below).

## Other Income (Expenses), Net

Other expenses, net were \$10,261,696 for the year ended December 31, 2023, as compared to \$3,543,693 in 2022. The increase between periods was primarily due to an unfavorable change in the fair value of the Forward Purchase Agreement of \$10,268,130 since the Closing Date, partially offset by a decrease of \$2,859,950 in interest expense and the amortization of debt discount, reflecting a lower level of average debt outstanding in 2023. In addition, the 2022 fiscal year includes a loss on debt extinguishment of \$1,064,692.

Income from Discontinued Operations, Net

Excluding the impact of a \$13,482,292 reduction in the Earnout liability, the Company had a loss from discontinued operations of \$12,722,127, net of tax, in 2023, which reflects the results of the AxoBio business from the closing of the AxoBio Acquisition through December 31, 2023. Quarterly sales from AxoBio's products for the fourth quarter of 2023 were only \$800,000, and there has been no revenue from the sale of AxoBio's products since October 2023. This decrease was driven by uncertainty relating to Medicare reimbursement for numerous wound healing products, including AxoBio's products. See Note 1 and Note 15 to the accompanying consolidated financial statements.

## Liquidity, Capital Resources, and Going Concern

As of December 31, 2023, we had cash of \$2,912,461 and an accumulated deficit of \$58,503,401. Since inception through December 31, 2023, we have financed operations principally through public and private issuances of equity securities and debt financing. Further, we received \$13,415,542 in proceeds from the Business Combination, net of \$17,535,632 remitted to Meteora under the Forward Purchase Agreement and tax obligations assumed. We incurred approximately \$1,600,000 of transaction costs related to the Business Combination, consisting of banking, legal, and other professional fees, which were recorded as a reduction of proceeds to additional paid-in capital. See Note 1 to the accompanying consolidated financial statements.

In addition to the anticipated cost savings from the restructuring detailed below and the completed sale of AxoBio, we plan to launch a line of cosmetic skincare products in the first half of 2024 based on the technologies we developed through our research and development activities. Management anticipates that revenue from the commercialization of its cosmetic skincare products and the anticipated cost savings from the restructuring will assist us in extending our cash runway. In addition, we are exploring out-licensing of certain research and development programs to generate non-dilutive liquidity.

However, the cash available to us may not be sufficient to allow us to operate for the next 12 months due to our current and potential liabilities. We may need to raise additional capital through equity or debt issuances. If we are unable to raise additional capital, we may be required to take additional measures to conserve liquidity, which could include, but not necessarily be limited to, curtailing operations and reducing overhead expenses. We cannot provide any assurance that new financing will be available on commercially acceptable terms, if at all, or will be completed on a timely basis. These conditions raise substantial doubt about our ability to continue as a going concern.

The accompanying audited consolidated financial statements have been prepared in conformity with GAAP, which contemplates the continuation of the Company as a going concern, the realization of assets, and the satisfaction of liabilities in the ordinary course of business. The audited consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty, or that may be necessary should we be unable to continue as a going concern.

## Restructuring

During the third quarter of 2023, we significantly reduced our future operating expenses by terminating certain executives serving as part-time consultants and full-time employees in non-core areas or overlapping business functions. This workforce reduction is expected to result in \$2,000,000 to \$3,000,000 in annual savings. In addition, we have refocused our research and development efforts on aesthetic products that have near-term commercial potential and have reprioritized further development and ceased clinical studies of product candidates that will take more than a year to commercialize. We also expect to further reduce our expenses as a result of the AxoBio Divestiture. Management anticipates that these cost-saving efforts will assist us in extending our cash runway.

## Debt

As of December 31, 2023, we had outstanding indebtedness with principal totaling \$1,308,147 as of December 31, 2023 (Note 8 to the accompanying consolidated financial statements). In addition, the Holders of the Convertible Notes have demanded additional payment of principal and interest on the Convertible Notes and certain payments with respect to the Convertible Note Warrants, as more fully described under the section *Contingencies* below.

#### Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2023, and 2022:

	Year Ended I		
	2023	2022	Change
Net cash used in operating activities	\$ (8,348,208)	\$ (3,428,707)	\$ (4,919,501)
Net cash used in investing activities	(30,470)	(7,164)	(23,306)
Net cash provided by financing activities	11,162,990	3,551,658	7,611,332

## **Operating Activities**

Net cash used in operating activities for the year ended December 31, 2023 increased by \$4,919,501 as compared to 2022. This increase was primarily driven by a higher net loss, an increase in prepaid expenses, and decreases in accounts payable and accrued expenses and other liabilities.

## **Investing Activities**

Net cash used in investing activities was \$30,470 for the year ended December 31, 2023, as compared to \$7,164 for the year ended December 31, 2022 due to slightly higher purchases of equipment.

## Financing Activities

Net cash provided by financing activities was \$11,162,990 for the year ended December 31, 2023, as compared to \$3,551,658 for the year ended December 31, 2022. This increase was primarily due to the proceeds of \$30,951,174 from the Business Combination and \$1,859,980 in proceeds from the issuance of debt in 2023, partially offset by the cash transferred in connection with the Forward Purchase Agreement of \$17,535,632 and \$2,649,874 of payments on the Company's Convertible Notes.

## **Contingencies**

On November 8, 2023, Puritan filed a complaint captioned Puritan Partners LLC v. Carmell Regen Med Corporation et al., No. 655566/2023 (New York Supreme Court, New York County) naming the Company as defendant. In the complaint, Puritan asserts that the Company breached its obligations under the Convertible Notes and the Convertible Note Warrants. Puritan also asserts the Company did not comply with its obligations to provide Puritan with 25,000 freely tradeable shares on a timely basis. Puritan asserts claims for declaratory judgment, breach of contract, conversion, foreclosure of its security interest, replevin, unjust enrichment, and indemnification, and seeks remedies including damages totaling \$2,725,000 through November 1, 2023, additional fees and interest thereafter, costs and attorney's fees, an order of foreclosure on its security interest, and other declaratory relief. The Company has moved to dismiss the complaint and intends to defend itself vigorously against this litigation.

#### **Contractual Obligations and Commitments**

In addition to financing obligations under our debt agreements, our contractual and commercial commitments include expenditures for operating leases and royalty payments. For further information on our license agreement (see Note 10 to the accompanying consolidated financial statements included herein).

## Emerging Growth Company and Smaller Reporting Company Status

The JOBS Act permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. Although we qualify as an emerging growth company, we have elected not to "opt-out" of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt-out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than \$700 million, and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year, and the market value of our stock held by non-affiliates is less than \$700 million. If we are a smaller reporting company at the time that we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our

Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not required.

## Item 8. Financial Statements and Supplementary Data

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

## **CARMELL CORPORATION**

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID 3686)	41
Consolidated Balance Sheets as of December 31, 2023 and 2022	42
Consolidated Statements of Operations for the Years ended December 31, 2023 and 2022	43
Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the Years ended December 31, 2023 and 2022	44
Consolidated Statements of Cash Flows for the Years ended December 31, 2023 and 2022	45
Notes to Consolidated Financial Statements	47



## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Carmell Corporation

## **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Carmell Corporation (the Company) as of December 31, 2023 and 2022, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years ended December 31, 2023 and 2022, in conformity with accounting principles generally accepted in the United States of America.

## Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 4 to the financial statements, the Company has a net loss from operations, negative cash flows from operations, and an accumulated deficit that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 4. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **Basis for Opinion**

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

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

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

We have served as the Company's auditor since 2022.

Adeptes bather, LLC

Adeptus Partners, LLC

PCAOB ID: 3686 Ocean, New Jersey April 1, 2024

## CONSOLIDATED BALANCE SHEETS

	December 31,			,
		2023		2022
ASSETS				
Current assets:				
Cash	\$	2,912,461	\$	128,149
Prepaid expenses		761,271		55,069
Forward purchase agreement		5,700,451		_
Assets available for sale		53,321,372		_
Income taxes receivable		204,559		_
Deferred offering costs				394,147
Other current assets				28,175
Total current assets		62,900,114		605,540
Property and equipment, net of accumulated depreciation of \$622,714 and \$530,116, respectively		192,846		254,974
Operating lease right of use asset		831,656		859,331
Intangible assets, net of accumulated amortization of \$46,560 and \$42,044, respectively		24,187		28,702
Total assets	\$	63,948,803	\$	1,748,547
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)				
Current liabilities:				
Accounts payable	\$	4,417,234	\$	2,138,732
Accrued interest		1,175,845		477,720
Accrued expenses and other liabilities		1,595,434		944,573
Loans payable		1,288,598		
Operating lease liability		150,136		129,502
Liabilities available for sale		29,874,831		
Convertible notes payable				2,777,778
Derivative liabilities		_		826,980
Total current liabilities	_	38,502,078		7,295,285
Long-term liabilities:				, ,
Operating lease liability, net of current portion		697,715		827,728
Total liabilities		39,199,793		8,123,013
				0,==0,0=0
Commitments and contingencies (see Note 10)				
Mezzanine equity:				
Series C-1 Preferred Stock, \$0.001 par value; -0- and 3,436,863 shares authorized; -0- and 426,732				
shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively		_		772,028
Series C-2 Preferred Stock, \$0.001 par value; -0- and 6,011,960 shares authorized; -0- and 5,857,512				772,020
shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively				15,904,275
Series B Preferred stock, \$0.001 par value; -0- and 2,893,515 shares authorized; -0- and 2,824,881 shares		_		13,704,273
issued and outstanding as of December 31, 2023 and December 31, 2022, respectively				7,025,434
Series A Preferred stock, \$0.001 par value; -0- and 2,010,728 shares authorized, issued and outstanding		_		7,023,434
as of December 31, 2023 and December 31, 2022, respectively		_		7,714,336
as of December 51, 2025 and December 51, 2022, respectively				7,711,550
Stockholders' equity (deficit):				
Series A convertible voting preferred stock, \$0.001 par value; 4,243 and -0- shares authorized, issued and				
outstanding at December 31, 2023, and December 31, 2022, respectively		1		
Common stock, \$0.0001 and \$.001 par value, 250,000,000 and 240,000,000 shares authorized, and				
23,090,585 and 896,580 shares issued and outstanding at December 31, 2023 and December 31, 2022,				
respectively		2,309		897
Additional paid-in capital		83,250,101		4,590,855
Accumulated deficit		(58,503,401)		(42,382,291)
Total stockholders' equity (deficit)		24,749,010		(37,790,539)
Total liabilities, mezzanine equity and stockholders' equity (deficit)	\$	63,948,803	\$	1,748,547

## CONSOLIDATED STATEMENTS OF OPERATIONS

## For the Years Ended December 31, 2023 and 2022

		2023		2022
Operating expenses:				
Research and development	\$	2,497,218	\$	2,196,063
General and administrative		2,622,945		3,217,280
Depreciation and amortization of intangible assets		97,113		94,298
Restructuring charges		726,280		
Total operating expenses		5,943,556		5,507,641
Loss from operations		(5,943,556)		(5,507,641)
Other income (expense):				
Other income		68,772		10,922
Interest expense, related party		<u> </u>		(52,471)
Interest expense		(853,805)		(1,652,498)
Amortization of debt discount		(35,513)		(2,044,241)
Loss on forward purchase agreement		(10,268,130)		
Change in fair value of derivative liabilities		826,980		1,259,287
Loss on debt extinguishment				(1,064,692)
Total other income (expense)		(10,261,696)		(3,543,693)
Loss from continuing operations before provision for income taxes		(16,205,252)		(9,051,334)
Provision for income taxes				_
Loss from continuing operations		(16,205,252)		(9,051,334)
Income from discontinued operations attributable to common shareholders		760,165		_
Net loss		(15,445,087)		(9,051,334)
Dividends on Series A, Series C-1, and C-2 preferred stock		(676,023)		(556,501)
Net loss attributable to common stockholders	<u>\$</u>	(16,121,110)	\$	(9,607,835)
Net loss attributable to common stockholders	<u> </u>	(10,121,110)	<u>Ф</u>	(7,007,033)
Net (loss) income per common share - basic and diluted:				
Net loss from continuing operations	\$	(1.53)	\$	(5.47)
Discontinued operations, net of tax		0.07		
Net loss per common share	<u>\$</u>	(1.46)	<u>\$</u>	(5.47)
Weighted average of common shares outstanding - basic and diluted		11,021,167		1,756,817

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

## For Years Ended December 31, 2023 and 2022

		es A Preferred Additional Stock Common Stock Treasury Stock Paid-in				Additional Paid-in			
	Shares	Amount	Shares	Stock Amount	Shares	Stock Amount	Paid-in Capital	Accumulated Deficit	Total
Balance at January 1, 2022		s —	2,274,373	\$ 2,275		\$ —	\$ 3,195,135	\$ (32,774,456)	\$ (29,577,046)
Accrued Series A preferred stock dividend	_	_			_	_		(307,927)	(307,927)
Accrued Series C-1 preferred stock									
dividend	_	_	_	_	_	_	_	(9,470)	(9,470)
Accrued Series C-2 preferred stock									
dividend	_	_	_	_	_	_	_	(239,104)	(239,104)
Issuance of common stock for service	_	_	12,534	12	_	_	26,465	_	26,477
Exercise of common stock purchase									
warrants	_	_	20,940	21	_	_	37,405	_	37,426
Warrants issued in connection with notes	_	_	_	_	_	_	409,483	_	409,483
Warrants issued in connection with Series									
C-1 Preferred Stock	_	_	_	_	_	_	312,088	_	312,088
Repurchase of common stock	_	_	_	_	(1,411,825)	(2,294)	_	_	(2,294)
Cancellation of common stock	_		(1,411,825)	(1,412)	1,411,825	2,294	(882)	_	
Exercise of common stock option	_	_	558	1	_	_	1,270	_	1,271
Stock-based compensation expense	_	_	_	-	_	_	609,891	_	609,891
Net loss								(9,051,334)	(9,051,334)
Balance at December 31, 2022	_		896,580	897	_	_	4,590,855	(42,382,291)	(37,790,539)
				• =====					
Accrued Series A preferred stock dividend	_	_	_	_	_	_	_	(164,510)	(164,510)
Accrued Series C-1 preferred stock									
dividend	_	_	_	_	_	_	_	(40,551)	(40,551)
Accrued Series C-2 preferred stock								. , ,	
dividend	_	_	_	_	_	_	_	(470,962)	(470,962)
Exercise of common stock options	_	_	21,158	21	_	_	41,052	`	41,073
Warrants issued in connection with notes	_	_	· —	_	_	_	55,062	_	55,062
Change in par value of Common Stock	_	_		(827)	_	_	827	_	_
Business Combination with Alpha, net of									
transaction costs	_	_	18,302,510	1,830	_	_	55,992,222	_	55,994,052
Common stock issued to convertible									
noteholder at Merger	_	_	25,000	3	_	_	249,997	_	250,000
Common and Series A preferred stock									
issued at AxoBio Acquisition	4,243	1	3,845,337	385	_	_	21,652,404	_	21,652,790
Stock-based compensation expense	_	_	_	_	_	_	667,682	_	667,682
Net loss								(15,445,087)	(15,445,087)
Balance at December 31, 2023	4,243	\$ 1	23,090,585	\$ 2,309		\$ —	\$ 83,250,101	\$ (58,503,401)	\$ 24,749,010

## CONSOLIDATED STATEMENTS OF CASH FLOWS

## For Years Ended December 31, 2023 and 2022

	2023	2022
Cash flows from operating activities:		
Net loss from continuing operations attributable to common stockholders	\$ (16,205,252)	\$ (9,051,334)
Discontinued operations, net of tax	760,165	_
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	667,682	636,368
Depreciation and amortization of intangible assets	97,113	94,298
Amortization of right of use assets	27,675	148,258
Amortization of debt discount	35,513	2,044,241
Change in fair value of forward purchase agreement	10,268,130	<u> </u>
Change in fair value of derivative liabilities	(826,980)	(1,259,287)
Non-cash interest expense	250,000	
Loss on extinguishment of debt		1,064,692
Interest recognized upon default	_	555,556
Changes in operating assets and liabilities:		
Prepaid expenses	(659,927)	(55,069)
Assets available for sale	18,938,353	_
Income taxes receivable	(204,559)	
Other current assets	28,175	(28,175)
Accounts payable	(449,873)	1,059,946
Accrued expenses and other liabilities	570,221	429,790
Lease liability	(257,720)	(124,840)
Accrued interest - related and third-party	(109,379)	1,056,849
Liabilities available for sales	(20,732,104)	_
Income tax payable	(545,441)	_
Net cash used in operating activities	(8,348,208)	(3,428,707)
Cash flows from investing activities:		
Purchases of property and equipment	(30,470)	(7,164)
Net cash used in investing activities	(30,470)	(7,164)
Cash flows from financing activities:		
Gross proceeds from Business Combination	30,951,174	
Transaction costs paid in connection with the Business Combination	(951,898)	
Cash transferred in connection with Forward Purchase Agreement		<u>—</u>
Proceeds from common stock option exercises	(17,535,632) 41,073	1,271
Proceeds from issuance of loans and related warrants	1,859,980	1,4/1
Payment of loans	(551,833)	<del></del>
•	\ ' '	<u>—</u>
Proceeds from convertible notes	(2,649,874)	2 745 074
Proceeds from convertible notes Issuance of Series C-1 preferred stock	<del>-</del>	2,745,974
Repurchase of common stock		1,064,317
	<del>-</del>	(2,294)
Payment of debt financing fee	_	(382,222)
Payment of offering costs Proceeds from warrant exercise	<del>-</del>	(20,332)
	11 1 (2 000	144,944
Net cash provided by financing activities	11,162,990	3,551,658
Net increase in cash	2,784,312	115,787
Cash - beginning of the period	128,149	12,362
Cash - end of the period	\$ 2,912,461	\$ 128,149

## CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

## For Years Ended December 31, 2023 and 2022

		2023	2022
Supplemental cash flow information:			
Interest paid	\$	283,526	\$ 92,593
Income tax paid		750,000	_
Non-cash financing activity:			
Net assets acquired in AxoBio Acquisition	4	43,135,082	
Earnout liability and deferred consideration payable in connection with AxoBio			
Acquisition	2	21,482,292	_
Issuance of Series A preferred stock and common stock in connection with AxoBio			
Acquisition		21,652,790	
Accrued Series A preferred stock dividends		164,510	307,926
Accrued Series C-1 preferred stock dividends		40,551	9,470
Accrued Series C-2 preferred stock dividends		470,962	239,104
Debt discount recorded in connection with loans payable		55,062	
Conversion of common stock and preferred stock in connection with the Business			
Combination	3	32,092,096	_
Conversion of convertible notes and accrued notes to Series C-2 preferred stock			15,665,171
Warrants issued in connection with convertible notes		_	409,483
Warrants issued in connection with Series C-1 preferred stock			312,088
Initial recognition of derivative liabilities		_	1,321,860

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### NOTE 1 — NATURE OF THE ORGANIZATION AND BUSINESS

Unless the context requires otherwise, references to "Carmell," or the "Company") prior to the closing of the Business Combination (as defined below), are intended to refer to Carmell Therapeutics Corporation, a Delaware corporation, ("Legacy Carmell"), and, after the closing of the Business Combination, are intended to refer to Carmell Corporation, a Delaware corporation, and its consolidated subsidiaries.

Carmell Corporation is a bio-aesthetics company developing cosmetic skincare and haircare products that utilize the human platelet secretome to topically deliver proteins and growth factors to support skin and hair health. The Company's product pipeline also includes innovative bone and wound healing products that are under development. Carmell's operations are based in Pittsburgh, Pennsylvania. The Company operates as a single segment, and all of its operations are located in the United States. Carmell's common stock, par value \$0.0001 per share (the "Common Stock") and Redeemable Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of \$11.50 (the "Public Warrants") trade on the Nasdaq Capital Market under the ticker symbols "CTCX" and "CTCXW", respectively.

## **Business Combination**

On July 14, 2023 (the "Closing Date"), the Company consummated a business combination (the "Business Combination") pursuant to the terms of the Business Combination Agreement, dated as of January 4, 2023 (the "Business Combination Agreement"), by and among Alpha Healthcare Acquisition Corp. III, a Delaware corporation and the predecessor of Carmell ("Alpha"), Candy Merger Sub, Inc., a Delaware corporation ("Merger Sub") and Legacy Carmell, pursuant to which Merger Sub merged with and into Legacy Carmell, with Legacy Carmell as the surviving company of the Business Combination. After giving effect to the Business Combination, Legacy Carmell became a wholly-owned subsidiary of the Company. Pursuant to the Business Combination Agreement, on the Closing Date, Alpha changed its name to "Carmell Therapeutics Corporation" and Legacy Carmell changed its name to "Carmell Regen Med Corporation." On August 1, 2023, the Company filed an amendment to its Third Amended and Restated Certificate of Incorporation with the Delaware Secretary of State to change its name to "Carmell Corporation."

Pursuant to the Business Combination Agreement, at the effective time of the Business Combination (the "Effective Time"), (i) each outstanding share of common stock of Legacy Carmell (the "Legacy Carmell common stock") was converted into the right to receive a number of shares of Common Stock equal to the applicable Exchange Ratio (as defined below); (ii) each outstanding share of preferred stock of Legacy Carmell was converted into the right to receive the aggregate number of shares of Common Stock that would be issued upon conversion of the underlying Legacy Carmell common stock, multiplied by the applicable Exchange Ratio; (iii) each outstanding option and warrant to purchase Legacy Carmell common stock was converted into an option or warrant, as applicable, to purchase a number of shares of Common Stock equal to the number of shares of Legacy Carmell common stock subject to such option or warrant multiplied by the applicable Exchange Ratio; and (iv) each outstanding share of Alpha Class A common stock, par value \$0.0001 per share ("Class A Common Stock") and each share of Alpha Class B common stock, par value \$0.0001 per share ("Class B Common Stock") was converted into one share of Common Stock. As of the Closing Date, the Exchange Ratio with respect to Legacy Carmell common stock was 0.06154 and the Exchange Ratio with respect to each other outstanding derivative equity security of Legacy Carmell was between 0.06684 and 0.10070.

On July 11, 2023, the record date for the special meeting of Alpha's stockholders to approve the Business Combination (the "Special Meeting"), there were (i) 15,444,103 shares of Class A Common Stock issued and outstanding and (ii) 3,861,026 shares of Class B Common Stock issued and outstanding and held by AHAC Sponsor III LLC, Alpha's sponsor (the "Sponsor"). In addition, on the closing date of Alpha's initial public offering (the "IPO"), Alpha had issued 455,000 warrants to purchase Class A Common Stock to the Sponsor in a private placement. Prior to the Special Meeting, holders of 12,586,223 shares of Alpha Class A Common Stock included in the units issued in Alpha's IPO (excluding 1,705,959 shares of the Class A Common Stock purchased by Meteora (as defined below) directly from the redeeming stockholders under the Forward Purchase Agreement (as defined below)) exercised their right to redeem such shares for cash at a price of approximately \$10.28 per share (net of the withholding for federal and franchise tax liabilities), for an aggregate redemption price of approximately \$29,374,372. The per share redemption price was paid out of Alpha's trust account, which, after taking into account the redemptions, but before any transaction expense, had a balance of \$29,376,282 at the Closing Date .

The Business Combination was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the Unites States ("GAAP"), and under this method of accounting, Alpha was treated as the acquired company for financial reporting purposes and Legacy Carmell was treated as the accounting acquirer. Operations prior to the Business Combination are those of Legacy

Carmell. Unless otherwise noted, the Company has retroactively adjusted all common and preferred share and related share price information to give effect to the Exchange Ratio established in the Business Combination Agreement.

## Forward Purchase Agreement

On July 9, 2023, Alpha and each of Meteora Special Opportunity Fund I, LP ("MSOF"), Meteora Capital Partners, LP ("MCP") and Meteora Select Trading Opportunities Master, LP ("MSTO") (with MCP, MSOF, and MSTO collectively as the "Sellers" or "Meteora") entered into a forward purchase agreement (the "Forward Purchase Agreement") providing for an over-the-counter equity forward transaction relating to, prior to the Effective Time, the Class A Common Stock and, after the Effective Time, the Common Stock. Pursuant to the terms of the Forward Purchase Agreement, at the closing of the Business Combination, the Sellers purchased directly from the stockholders of Alpha 1,705,959 shares of Class A Common Stock (the "Recycled Shares") at a price of \$10.28 per share (the "Initial Price"), which is the price equal to the redemption price at which holders of Class A Common Stock were permitted to redeem their shares in connection with the Business Combination pursuant to Section 9.2(a) of Alpha's Second Amended and Restated Certificate of Incorporation, as amended (the "Second Amended Charter").

In accordance with the terms of the Forward Purchase Agreement, at the Closing Date, the Company paid to the Sellers an aggregate cash amount of \$17,535,632, which was equal to the product of (a) the Recycled Shares and (b) the Initial Price. The settlement date will be the earliest to occur of (a) the first anniversary of the Closing Date and (b) after the occurrence of (i) a Delisting Event (as defined in the Forward Purchase Agreement) or (ii) a Registration Failure (as defined in the Forward Purchase Agreement), upon the date specified by Meteora in a written notice delivered to the Company at Meteora's discretion (which settlement date shall not be earlier than the date of such notice). Any Recycled Shares not sold in accordance with the early termination provisions described below will incur a \$0.50 per share termination fee payable by the Company to Meteora at settlement.

From time to time and on any date following the Business Combination (any such date, an "OET Date") and subject to the terms and conditions below, Meteora may, in its absolute discretion, and so long as the daily volume-weighted average price ("VWAP Price") of the Recycled Shares is equal to or exceeds the Reset Price (as defined in the Forward Purchase Agreement), terminate the transaction in whole or in part by providing written notice (an "OET Notice") in accordance with the terms of the Forward Purchase Agreement. The effect of an OET Notice given shall be to reduce the number of shares by the number of Terminated Shares (as defined in the Forward Purchase Agreement) specified in such OET Notice with effect as of the related OET Date. As of each OET Date, the Company shall be entitled to an amount from Meteora, and Meteora shall pay to the Company an amount equal to the product of (a) the number of Terminated Shares multiplied by (b) the Initial Price in respect of such OET Date.

The Reset Price is initially \$11.50 and subject to a \$11.50 floor (the "Reset Price Floor"). The Reset Price will be adjusted on the first scheduled trading day of every week commencing with the first week following the seventh day after the closing of the Business Combination to be the lowest of (a) the then-current Reset Price, and (b) the prior week VWAP Price of the shares of Common Stock; provided that the Reset Price shall be no lower than the Reset Price Floor. On July 9, 2023, in connection with the Forward Purchase Agreement, the Sellers entered into a Non-Redemption Agreement with the Company pursuant to which the Sellers agreed not to exercise redemption rights under the Second Amended Charter with respect to an aggregate of 100,000 shares of Common Stock.

## Axolotl Biologix Acquisition

On August 9, 2023 ("Merger Closing Date"), the Company completed the acquisition of Axolotl Biologix, Inc. ("AxoBio") pursuant to an Agreement and Plan of Merger, dated July 26, 2023 (as amended, the "Merger Agreement"), by and among the Company, AxoBio, Aztec Merger Sub, Inc., a wholly owned subsidiary of the Company ("Merger Sub I"), and Axolotl Biologix LLC, a wholly owned subsidiary of the Company ("Merger Sub II"). Upon the closing of the transactions contemplated by the Merger Agreement (the "Merger Closing"), (a) Merger Sub I merged with and into AxoBio, after which the separate corporate existence of Merger Sub I ceased and AxoBio continued as a the surviving corporation, and (b) AxoBio merged with and into Merger Sub II, after which AxoBio ceased to exist and Merger Sub II survived as a wholly owned subsidiary of the Company (collectively, the "AxoBio Acquisition"). At the effective time of the AxoBio Acquisition (the "Merger Effective Time"), each share of AxoBio's common stock, par value \$0.001 per share ("AxoBio Common Stock"), (other than Dissenting Shares (as defined in the Merger Agreement) and shares held as treasury stock) issued and outstanding as of immediately prior to the Merger Effective Time was canceled and converted into the right to receive a pro rata share of:

- \$8,000,000 in cash (the "Closing Cash Consideration"), payable upon delivery of AxoBio's audited financial statements;
- 3,845,337 shares of Common Stock and 4,243 shares of a newly designated series of Series A Convertible Voting Preferred Stock (the "Series A Preferred Stock") issued upon the Merger Closing Date (the "Closing Share Consideration"); and
- up to \$9,000,000 in cash and up to \$66,000,000 in shares of 'Common Stock that, in each case, were subject to the achievement of certain revenue targets and research and development milestones (the "Earnout").

#### Axolotl Biologix Disposition

On March 20, 2024, the Company entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with the former stockholders of AxoBio, including Burns Ventures, LLC, a Texas limited liability company ("BVLLC"), H. Rodney Burns, an individual resident of Texas ("Burns"), AXO XP, LLC, an Arizona limited liability company ("AXPLLC"), and Protein Genomics, LLC, a Delaware corporation ("PGEN" and together with BVLLC, Burns, and AXPLLC, collectively, the "Buyers" and each, a "Buyer"), providing for, upon the terms and subject to the conditions set forth therein, the sale by the Company of all outstanding limited liability company interests of AxoBio (the "AxoBio Disposition") to the Buyers for an aggregate consideration of as described below. The AxoBio Disposition closed on March 26, 2024. See Note 1 and Note 16 to the accompanying consolidated financial statements.

The consideration for the AxoBio Disposition consisted of (i) the Closing Share Consideration, initially issued as consideration to the Buyers under the Merger Agreement, (ii) cancellation of the notes payable by the Company to the Buyers in an aggregate principal amount of \$8,000,000 as the Closing Cash Consideration and (iii) termination of the Company's obligations with respect to the Earnout.

#### Risks and Uncertainties

Disruption of global financial markets and a recession or market correction, including the ongoing military conflicts between Russia and Ukraine and the related sanctions imposed against Russia as well as the conflict between Israel and Hamas, the ongoing effects of the COVID-19 pandemic, and other global macroeconomic factors such as inflation and rising interest rates, could reduce the Company's ability to access capital, which could in the future negatively affect the Company's liquidity and could materially affect the Company's business and the value of its common stock.

#### NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## Basis of Presentation

The consolidated financial statements have been prepared in accordance with GAAP and the applicable rules and regulations of the U.S. Securities and Exchange Commission (the "SEC"). The Company's consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries, and all intercompany accounts and transactions have been eliminated in consolidation.

## Emerging Growth Company Status

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the Jumpstart our Business Startups Act of 2012 (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

## Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates in these financial statements include those related to the forward purchase asset, earnout liabilities, derivative liabilities, long-term assets and goodwill impairment, the provision or benefit for income taxes and the corresponding valuation allowance on deferred tax assets, and contingent liabilities. If the underlying estimates and assumptions upon which the financial statements are based change in the future, actual amounts may differ from those included in the accompanying financial statements.

#### **Business Combinations**

The Company allocates the fair value of the purchase consideration of its acquisitions to the tangible assets, liabilities, and intangible assets acquired based on their estimated fair values. The excess of the fair value of purchase consideration over the fair values of these identifiable assets and liabilities is recorded as goodwill. Acquisition-related expenses are expensed as incurred and included in general and administrative expenses.

The allocation of the purchase price requires management to make significant estimates in determining the fair values of assets acquired and liabilities assumed, especially with respect to intangible assets. These estimates are based on information obtained from management of the acquired companies and historical experience. These estimates can include, but are not limited to, the cash flows that an asset is expected to generate in the future, and the cost savings expected to be derived from acquiring an asset. These estimates are inherently uncertain and unpredictable, and if different estimates were used, the purchase price for the acquisition could be allocated to the acquired assets and liabilities differently from the allocation that the Company has made.

## Discontinued Operations

On March 20, 2024, the Company entered into the Purchase Agreement to sell AxoBio to its former owners (see Note 1 to the accompanying consolidated financial statements). In accordance with Financial Accounting Standards Board Accounting Standards Codification ("ASC") 205, *Presentation of Financial Statements, Discontinued Operations, Other Presentation Matters*, the assets and liabilities of AxoBio are classified as available for sale on the accompanying consolidated balance sheets, and the results of its operations are reported as discontinued operations in the accompanying consolidated statements of operations.

## Segment Reporting

ASC Topic No. 280, Segment Reporting ("ASC 280"), establishes standards for the way that public business enterprises report information about operating segments in their annual consolidated financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. ASC 280 also establishes standards for related disclosures about products and services, geographic areas and major customers. The Company's business segments are based on the organization structure used by the chief operating decision maker for making operating and investment decisions and for assessing performance. Our chief executive officer, who is our chief operating decision maker, views the Company's operations and manages its business in one operating segment, which is principally the business of development and commercialization of aesthetic and regenerative care products.

## Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents are held by financial institutions and are federally insured up to certain limits. At times, the Company's cash and cash equivalents balance exceeds the federally insured limits, which potentially subject the Company to concentrations of credit risk. For the years ended December 31, 2023 and 2022, the Company has experienced no losses related to its cash and cash equivalents that exceed federally insured deposit limits. As of December 31, 2023, the Company had cash in excess of federally insured limits from continuing operations of \$2,518,378 and from discontinued operations of \$554,277. As of December 31, 2023 and 2022, the Company had cash equivalents of \$30,000 and \$0, respectively. The cash equivalents as of December 31, 2023, are a component of discontinued operations.

## Accounts Receivables, net

Accounts receivable are recorded at the original invoice amount. Receivables are considered past due based on the contractual payment terms. The Company reserves a percentage of its trade receivable balance based on collection history and current economic trends that it expects will impact the level of credit losses over the life of the Company's receivables. These reserves are re-evaluated on a regular basis and adjusted, as needed. Once a receivable is deemed to be uncollectible, such balance is charged against the reserve. The Company had no reserve related to the potential likelihood of not collecting its receivables as of December 31, 2023. As of December 31, 2023, all of the Company's trade receivables were related to AxoBio and classified as a component of assets available for sale in the accompanying consolidated balance sheets.

#### *Inventories*

The Company's inventory consists of finished goods and are stated at the lower of cost or net realizable value. Cost is calculated by applying the first-in-first-out method. The Company regularly reviews inventory quantities on hand and writes down to its net realizable value any inventory that it believes to be impaired. Management considers forecast demand in relation to the inventory on hand, competitiveness of product offerings, market conditions and product life cycles when determining excess and obsolescence and net realizable value adjustments.

At the Merger Closing Date, AxoBio's inventory was adjusted to fair value less selling costs, as specified by ASC 805, Business

Combinations. In conjunction with the Company's year-end evaluation for impairment, it was determined that AxoBio's inventory was impaired based (i) no sales of products since October 2023 and (ii) no future sales of these products are expected. Accordingly, the AxoBio inventory was written down to historical cost, which approximates its realizable value. This loss of \$4,754,357 is included as a component of discontinued operations in the accompanying consolidated statements of operations. The Company had no reserve for obsolescence as of December 31, 2023. All of the Company's inventory was related to AxoBio at December 31, 2023 and is classified as a component of assets available for sale in the accompanying consolidated balance sheets.

#### Offering Costs Associated with a Public Offering

The Company complies with the requirements of ASC 340-10-S99-1 and SEC Staff Accounting Bulletin Topic 5A - "Expenses of Offering." ASC 340-10-S99-1 states that specific incremental costs directly attributable to a proposed or actual offering of equity securities incurred prior to the effective date of the offering may be deferred and charged against the gross proceeds of the offering when the offering occurs. The costs of an aborted offering may not be deferred and charged against the proceeds of a subsequent offering. In October 2022, the Company aborted an initial public offering and began pursuing an acquisition by Alpha. In October 2022, the Company wrote off capitalized costs of \$1,278,062 relating to the aborted initial public offering. As of December 31, 2022, the Company had capitalized deferred offering costs relating to the Business Combination of \$394,147. Contemporaneously with the closing of the Business Combination, the Company recorded \$1,581,070 of transaction costs as a reduction of proceeds in additional paid-in capital.

## Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Maintenance and repair charges are expensed as incurred. Fixed assets are depreciated using the straight-line method using the following estimated useful lives:

- Equipment 5-7 years
- Leasehold improvements The lesser of 10 years or the remaining life of the lease
- Furniture and fixtures 7 years

## Goodwill and Intangible Assets

Goodwill is not amortized but tested for impairment on an annual basis in the fourth quarter, and more frequently if events or changes in circumstances indicate that the asset may be impaired. The Company's impairment tests are based on a single reporting unit structure. The carrying value and ultimate realization of these assets is dependent upon estimates of future earnings and benefits that the Company expects to generate from their use. If the expectations of future results and cash flows are significantly diminished, intangible assets and goodwill may be impaired and the resulting charge to operations may be material. First, the Company assesses qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. If, after assessing qualitative factors, the Company determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. If deemed necessary, a two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. An impairment charge is recognized for the amount by which the carrying amount exceeds the reporting unit's fair value. However, the impairment loss recognized should not exceed the total amount of goodwill allocated to that single reporting unit.

As of December 31, 2023, the goodwill associated with the AxoBio Acquisition, as shown below, is classified as a component of assets available for sale in the accompanying consolidated balance sheets.

Balance as of January 1, 2023	\$ _
AxoBio Acquisition	19,188,278
Balance as of December 31, 2023	\$ 19,188,278

Finite-lived intangible assets are carried at cost and amortized based on an economic benefit period, which is seven to twenty years. The Company evaluates finite lived intangible assets for impairment by assessing the recoverability of these assets whenever adverse events or changes in circumstances or business climate indicate that expected undiscounted future cash flows related to such intangible assets may not be sufficient to support the net book value of such assets. An impairment charge is recognized in the period of identification to the extent the carrying amount of an asset exceeds the fair value of such asset. Costs billed to the Company as reimbursement for third parties' patent submissions are considered as license fees and expensed as incurred. Intangible assets related to AxoBio are classified as a component of assets available for sale in the accompanying consolidated balance sheets.

Finite-lived intangible assets are amortized using the straight-line method using the following useful lives:

- Customer contracts 20 years
- Trade name 7 years
- Intellectual property 7 years
- Patents 16 years

Significant judgments required in assessing the impairment of goodwill and intangible assets include the assumption the Company only has a single reporting unit, identifying whether events or changes in circumstances require an impairment assessment, estimating future cash flows, determining appropriate discount and growth rates and other assumptions. Changes in these estimates and assumptions could materially affect the determination of fair value as to whether an impairment exists and, if so, the amount of that impairment. The Company has not recognized any goodwill or intangible asset impairment charges in the years ended December 31, 2023 and 2022.

## Series A Voting Convertible Preferred Stock

In connection with the AxoBio Acquisition, the Company issued 4,243 shares of Series A Preferred Stock to former AxoBio stockholders. Based on the limited exception under ASC 480-10-S99-3A(3)(f) for equity instruments that are subject to a deemed liquidation provision if all of the holders of equally and more subordinated equity instruments of the entity would always be entitled to also receive the same form of consideration (for example, cash or shares) upon the occurrence of the event that gives rise to the redemption (that is, all subordinate classes would also be entitled to redeem), the Company determined that the Series A Preferred Stock should be classified as permanent equity.

#### Earnout Liability

In connection with the AxoBio Acquisition, the former stockholders of AxoBio are entitled to receive the Earnout, consisting of performance-based earnouts of up to \$9,000,000 in cash and up to \$66,000,000 in shares of Common Stock, based on the achievement of certain revenue targets and research and development milestones. In accordance with ASC 805, *Business Combinations* ("ASC 805"), the Earnout included in the purchase price of AxoBio at the Merger Closing Date and subsequently remeasured at each reporting date with changes in fair value recorded as a component of other (expense) income in the consolidated statements of operations. As of December 31, 2023, the Company determined that the performance-based targets would not be met and that the Earnout would not be payable. The Company recognized other income of \$13,482,292 in 2023 related to the change in the fair value of the earnout liability, which is included as a component of discontinued operations in the accompanying consolidated statements of operations.

## Revenue Recognition

The Company accounts for revenue in accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), on January 1, 2021, using the modified retrospective adoption method. Under ASC 606, revenues are recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for transferring those goods or services. Revenue is recognized based on the following five-step model:

- Identification of the contract with a customer
- Identification of the performance obligations in the contract
- Determination of the transaction price
- Allocation of the transaction price to the performance obligations in the contract
- Recognition of revenue when, or as, the Company satisfies a performance obligation

AxoBio sells its products principally to a specialty distributor (the "Customer") within the United States. This Customer subsequently resold AxoBio's products to healthcare providers throughout the United States. Revenues from product sales are recognized when the Customer obtains control of the product, which occurs at a point in time, typically upon delivery to the Customer's respective warehouse or designated location at a standard transaction price for the specific product sold. Such revenue is included as a component of discontinued operations in the accompanying statements of operations.

AxoBio has entered into service arrangements with this Customer to provide distinct services due to AxoBio having a limited workforce. Such services include distribution, credit risk, and marketing and sales services. The Company has assessed the consideration payable to this Customer as it relates to these service arrangements in accordance with ASC 606 and has concluded that the services being provided by this Customer are distinct, with the exception of the credit risk service fee, which was concluded to be a price concession. For those services that are deemed to be distinct, the Company has separately determined that the transaction price for the distribution and marketing services being provided by this Customer are at fair value. As such, in accordance with ASC 606, the distribution and marketing services are accounted for consistent with other services being provided by the Company's vendors and have not been recorded as an offset to the Company's revenues. The credit risk service fee is accounted for as consideration payable and as a reduction of the transaction price. The total amount of services accounted for as consideration payable and a reduction of transaction price totaled approximately \$440,784 from the date of the AxoBio Acquisition through December 31, 2023.

The Company has elected to apply the significant financing practical expedient, as allowed under ASC 606. As a result, the Company does not adjust the promised amount of consideration in a customer contract for the effects of a significant financing component when the period of time between when we transfer a promised good or service to a customer and when the customer pays for the good or service will be one year or less. The Company has standard payment terms that generally require payment within approximately 60-120 days. The Company had no material contract assets, contract liabilities, or deferred contract costs recorded as of December 31, 2023 and 2022. The Company expenses costs to obtain a contract as incurred when the amortization period is less than one year. All of the Company's revenue in 2023 was attributable to AxoBio and is reported as a component of discontinued operations in the accompanying consolidated statements of operations.

#### Cost of Revenue

Cost of revenue is comprised of purchase costs of our products, third-party logistics and distribution costs, including packaging, freight, transportation, shipping and handling costs, and inventory adjustments due to expiring products, if any. All of the Company's cost of revenues revenue was attributable to AxoBio, and, accordingly, reported as a component of discontinued operations in the accompanying consolidated statements of operations.

## Selling and Marketing Expenses

Selling and marketing expenses relate to AxoBio and consist primarily of advertising expenses, commissions and freight expenses, and the distribution and marketing expenses described previously in the revenue recognition policies. Sales and marketing expenses were \$6,829,520 from the date the AxoBio was acquired through December 31, 2023. These expenses are reported as a component of discontinued operations in the accompanying consolidated statements of operations.

## Research and Development Expenses

Research and development expenses are expensed as incurred and consist principally of internal and external costs, which include the cost of patent licenses, contract research services, laboratory supplies and development and manufacture of preclinical compounds and consumables for clinical trials and preclinical testing.

## Restructuring Charges

The Company has refocused its research and development efforts on aesthetic products that have near-term commercial potential and have reprioritized further development and ceased clinical studies of product candidates that will take more than a year to commercialize. Restructuring charges related to this strategic realignment of the Company's operations consists of severance from the termination of employees in non-core areas or overlapping business functions. As of December 31, 2023, \$452,579 of such severance remains unpaid (see Note 7).

#### Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as income tax expense. There were no unrecognized tax benefits and no amounts accrued for interest and penalties as of

December 31, 2023 and 2022. The Company is currently not aware of any issues under review that could result in significant payments, accruals, or material deviation from its position. The Company is subject to income tax examinations by major taxing authorities for tax years ended 2019 to 2022.

## Net Loss Per Share

Under ASC 260, Earnings per Share, the Company is required to apply the two-class method to compute earnings per share ("EPS"). Under the two-class method both basic and diluted EPS are calculated for each class of common stock and participating security considering both dividends declared (or accumulated) and participation rights in undistributed earnings. The two-class method results in an allocation of all undistributed earnings as if all those earnings were distributed. Considering the Company has generated losses in each reporting period since its inception through December 31, 2023, the Company also considered the guidance related to the allocation of the undistributed losses under the two-class method. The contractual rights and obligations of the shares of Preferred Stock and the Company's warrants were evaluated to determine if they have an obligation to share in the losses of the Company. As there is no obligation for the holders of Preferred Stock or the holders of the Company's warrants to fund the losses of the Company nor is the contractual principal or redemption amount of the preferred stock shares or the warrants reduced as a result of losses incurred by the Company, under the two-class method, the undistributed losses are allocated entirely to the Common Stock. Earnings per share information has been retrospectively adjusted to reflect the Business Combination ratio applied to Legacy Carmell's historical number of shares outstanding. Shares of Alpha are considered issued for EPS purposes as of the date of the Business Combination.

The Company computes basic loss per share by dividing the loss attributable to holders of Common Stock for the period by the weighted average number of shares of Common Stock outstanding during the period. The Company's warrants, options, preferred stock, and convertible notes could, potentially, be exercised or converted into Common Stock and then share in the earnings of the Company. However, these convertible instruments, warrants, and options were excluded when calculating diluted loss per share because such inclusion would be anti-dilutive for the periods presented. As a result, diluted loss per share is the same as basic loss per share for the periods presented.

Potentially dilutive securities, which are not included in diluted weighted average shares outstanding for the periods ended December 31, 2023 and 2022, consist of the following (in common stock equivalents):

	December 31,			
	2023	2022		
Series A Preferred Stock (if converted)	4,243,000	_		
Stock Options	1,689,765	2,235,313		
Public Warrants	4,638,454	3,870,524		
Series A Preferred Stock (if converted)		2,010,728		
Series B Preferred Stock (if converted)	_	2,817,886		
Series C-1 Preferred Stock (if converted)		89,264		
Series C-2 Preferred Stock (if converted)	_	5,857,512		
Preferred Stock Warrants		164,894		
Convertible Notes (if converted)		777,062		
Total	10,571,219	17,823,183		

## Stock-Based Compensation

The Company applies the provisions of ASC 718, *Compensation-Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all stock-based awards made to employees, including employee stock options, in the consolidated statements of operations.

For stock options issued to employees and members of the Company's Board of Directors (the "Board") for their services, the Company estimates each option's grant-date fair value using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the Common Stock consistent with the expected life of the option, risk-free interest rates, and expected dividend yields of the Common Stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, generally the vesting term. Forfeitures are recorded as incurred instead of estimated at the time of grant and revised.

Under Accounting Standards Update ("ASU") 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Non-Employee Share-Based Payment Accounting, the Company accounts for stock options issued to non-employees for their services in accordance with ASC 718. The Company uses valuation methods and assumptions to value the stock options that are in line with the process for valuing employee stock options noted above.

#### Leases

The Company adopted ASC 842, *Leases*, as amended, on January 1, 2020 ("ASC 842"). The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease.

The Company's leases consist of leaseholds on office space. The Company determines if an arrangement contains a lease at inception as defined by ASC 842. To meet the definition of a lease under ASC 842, the contractual arrangement must convey to the Company the right to control the use of an identifiable asset for a period of time in exchange for consideration. Right of Use ("ROU") assets represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term.

#### **Concentrations**

For the year ended December 31, 2023, one customer accounted for 100% of AxoBio's revenues. In addition, this customer accounted for 100% of accounts receivable at December 31, 2023. AxoBio's human amnion allograft product made up 100% of revenue for the year ended December 31, 2023. For the year ended December 31, 2023, 100% of AxoBio's human amnion allograft product was purchased from Pinnacle Transplant Technologies, LLC.

Fair Value Measurements and Fair Value of Financial Instruments

The Company categorizes its assets and liabilities that are valued at fair value on a recurring basis into a three-level fair value hierarchy in accordance with GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy gives the highest priority to quoted prices in active markets for identical assets and liabilities (Level 1) and lowest priority to unobservable inputs (Level 3). The carrying value of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, deferred consideration payable and related party loans payable approximate fair value because of the short-term maturity of such instruments.

Level 1 - Inputs are unadjusted quoted prices in active markets for identical assets or liabilities available at the measurement date.

Level 2 - Inputs are unadjusted quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, inputs other than quoted prices that are observable, and inputs derived from or corroborated by observable market data.

Level 3 - Inputs are unobservable inputs that reflect the reporting entity's assumptions on the assumptions the market participants would use to price the asset or liability based on the best available information.

Other financial assets and liabilities as of December 31, 2023 and 2022 are categorized based on a hierarchy of inputs as follows:

		<b>December 31, 2023</b>			<b>December 31, 2022</b>				Fair Value
		Carrying		Carrying Estimated Carrying		Estimated		Input	
		Value	F	air Value		Value	Fa	ir Value	Hierarchy
Forward purchase agreement	\$	5,700,451	\$	5,700,451	\$	_	\$	_	Level 3
SBA Loan		1,505,070		1,498,000					Level 2
Derivative liabilities		_		_		826,980		826,980	Level 3

Changes in the fair value of Level 3 financial assets and liabilities for the year ended December 31, 2023 are as follows:

		Fair Value Measurements Using Significant Unobservable Inputs (Level 3)							
	Forward Purchase Agreement		erivative iabilities	Earnout Liabilities					
Balance, beginning of year	<u> </u>	\$	826,980	\$	_				
Initial recognition	15,968,581			1.	3,482,292				
Change in fair value	_(10,268,130)		(826,980)		38,093				
Balance, end of period	\$ 5,700,451	\$		\$ 1.	3,520,385				

The Forward Purchase Agreement was accounted for at fair value as a financial instrument in the scope of ASC 480, *Distinguishing Liabilities from Equity*, and resulted in an asset at the Closing Date. The fair value of the Company's position under the Forward Purchase Agreement was calculated using the Call/Put Option Pricing Model. The assumptions incorporated into the valuation model as of the Closing Date of the Business Combination included the termination fee of \$0.50 per share, the debt rate of 14.35% and the term of one year. As of December 31, 2023, the assumptions incorporated into the valuation model included the share price of \$3.81, the termination fee of \$0.50 per share, the debt rate of 12.95% and the term of 0.54 years.

The fair value of the embedded derivatives in the convertible notes as of December 31, 2022 was valued using a Monte-Carlo model and was based upon the following management assumptions:

	December 31, 2022
Stock price	\$ 2.60
Expected term (years)	0.04
Volatility	55.1%
Risk-free interest rate	4.38%
Probability of Qualified Financing or IPO	50.00%
Probability of a Change in Control Event	10.00%

The December 31, 2022 stock price was derived from a 409A valuation. Volatility was determined from the historical volatility of comparable public companies over the expected terms. The term was based on the maturity date of the note. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued. The probability of a Qualified Financing or IPO and a Change of Control Event were based on the Company's assessment of such an event occurring. The convertible notes related to the derivative liabilities were repaid during 2023.

## Recently Adopted Accounting Guidance

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments, or ASU 2016-13. The guidance is effective for fiscal years beginning after December 15, 2022. The Company adopted this standard on January 1, 2023, which had no material impact on the Company's consolidated financial statements.

## Recent Accounting Pronouncements

On September 30, 2022, the FASB issued ASU 2022-03, which (1) clarifies the guidance in ASC 820 on the fair value measurement of an equity security that is subject to a contractual sale restriction and (2) requires specific disclosures related to such equity security. The amendments in ASU 2022-03 are consistent with the principles of fair value measurement under which an entity is required to consider characteristics of an asset or liability if other market participants would also consider those characteristics when pricing the asset or liability. Specifically, the ASU clarifies that an entity should apply these fair value measurement principles to equity securities subject to contractual sale restrictions. The Company does not believe that, if adopted, ASU 2022-03 would have a material effect on the Company's financial statements.

#### **NOTE 3 — BUSINESS COMBINATIONS**

#### AxoBio Acquisition

The AxoBio Acquisition is reflected in the consolidated financial statements under the acquisition method of accounting in accordance with ASC 805, with the Company treated as the accounting and legal acquirer in the AxoBio Acquisition. It was determined that AxoBio is a variable interest entity, as AxoBio's total equity at risk is not sufficient to permit AxoBio to finance its activities without additional subordinated financial support, with the Company being the primary beneficiary. In accordance with ASC 805, the Company recorded AxoBio's assets and liabilities at fair value. For purposes of estimating the fair value, where applicable, of the assets acquired and liabilities assumed as reflected in the consolidated financial information, the Company has applied the guidance in ASC 820, Fair Value Measurements and Disclosures ("ASC 820"), which establishes a framework for measuring fair value in acquisitions. In accordance with ASC 820, fair value is an exit price and is defined as "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date." Under ASC 805, acquisition-related transaction costs are not included as components of consideration transferred but are accounted for as expenses in the period in which the costs are incurred. The fair value of the purchase consideration transferred in the AxoBio Acquisition was as follows:

Common Stock - 3,845,337 shares	\$ 11,270,683
Series A Convertible Voting Preferred Stock - 4,243 shares	10,382,107
Earnout	13,482,292
Deferred Consideration	8,000,000
Total estimated value of consideration transferred	\$ 43,135,082

The fair value of the Series A Preferred Stock was estimated at \$2,447 per share, using the put option model, based on the market value of the Common Stock at the Merger Closing Date, conversion rate, projected conversion term, and estimated discount for lack of marketability. Deferred consideration is related to the Closing Cash Consideration of \$8,000,000, that was payable upon delivery of the AxoBio 2022 audited financial statements. The 2022 audited financial statements were delivered in October 2023 and as such, the cash consideration was payable at December 31, 2023.

In connection with the AxoBio Acquisition the former stockholders of AxoBio were entitled to receive payment of the Earnout consisting of up to \$9,000,000 in cash and up to \$66,000,000 in shares of Common Stock, subject to the achievement of certain revenue targets and research and development milestones. In accordance with ASC 815-40, as the Earnout was not indexed to the Common Stock, it was accounted for as a liability at the Merger Closing Date and is subsequently remeasured at each reporting date with changes in fair value recorded as a component of in discontinued operations in the consolidated statements of operations.

The fair value of the Earnout was estimated as of the Merger Closing Date using (1) the probabilities of success and estimated dates of milestone achievements in relation to the research and development milestones, and (2) probability-adjusted revenue scenarios in relation to the revenue targets.

The Earnout liability is categorized as a Level 3 fair value measurement (see Fair Value Measurements accounting policy described in Note 2) because the Company estimated projections utilizing unobservable inputs. Contingent earnout payments involve certain assumptions requiring significant judgment and actual results can differ from assumed and estimated amounts.

The total purchase consideration transferred in the AxoBio Acquisition has been allocated to the net assets acquired and liabilities assumed based on their fair values at the acquisition date. The transaction costs related to this acquisition of approximately \$1,300,000 were expensed and included in the transaction related expenses on the consolidated statements of operations.

The allocation of the purchase price is as follows:

Total estimated value of consideration transferred	\$ 43,135,082
Cash and cash equivalents	662,997
Accounts receivable	18,296,000
Prepaid expenses	170,604
Inventories	10,600,000
Property and equipment	81,846
Intangible assets	23,260,000
Total assets	53,071,447
Accounts payable	12,767,909
Accrued interest	146,829
Other accrued expenses	1,390,278
Loan payable	1,498,000
Related party loans	5,610,000
Deferred tax liabilities	7,711,627
Net assets to be acquired	23,946,804
Goodwill	\$ 19,188,278

The Company estimated the fair value of the acquired inventories based on the selling price less costs to sell and recorded the fair value step-up of approximately \$8,200,000 at the Merger Closing Date. The fair value step-up is amortized over the expected realization term of one year from the Merger Closing Date.

The acquired loan payable of AxoBio was adjusted down to its fair value by \$502,000 due to the more favorable than the market interest rate. This fair value step down is amortized over the term of loan payable as a credit to the interest expense.

The intangible assets include trade names, customer contracts and intellectual property. The intangible assets were valued using a discounted cash flow model. The estimated fair value of the customer contracts as of the acquisition date was determined based on the projected future profits from the contracts, discounted to present value, and the likelihood of contract renewals at the end of each contract term. The estimated fair value of the intellectual property as of the acquisition date was determined based on the estimated license royalty rates, the present value of future cash flows from the intellectual property, and the expected useful life of 7 years. The estimated fair value of the trade name was determined based on the estimated royalty rates for the use of the trade name, the projected revenues attributable to the trade name discounted to present value and the expected useful life of 7 years. The goodwill and other intangible assets associated with the AxoBio Acquisition are not deductible for U.S. tax purposes.

The Company determined that the AxoBio Acquisition was deemed significant to the Company in accordance with Rule 3-05 of Regulation S-X. As required by ASC 805, *Business Combinations*, the following unaudited pro forma statements of operations for the year ended December 31, 2023 and 2022 give effect to the AxoBio Acquisition as if it had been completed on January 1, 2022. The unaudited pro forma financial information below is presented for illustrative purposes only and is not necessarily indicative of what the operating results actually would have been during the periods presented had the AxoBio Acquisition been completed during the periods presented. In addition, the unaudited pro forma financial information does not purport to project future operating results. The pro forma statements of operations do not fully reflect: (i) any anticipated synergies (or costs to achieve synergies) or (ii) the impact of non-recurring items directly related to the acquisition of AxoBio.

	 Year ended December 31,			
	2023		2022	
Revenue included in discontinued operations in the consolidated statements of operations	\$ 4,456,816	\$	-	
Add: AxoBio revenue not reflected in the consolidated statements of				
operations	26,020,319		39,896,998	
Unaudited pro forma revenue	\$ 30,477,135	\$	39,896,998	
	 Year ended I	<b>Dece</b> n	nber 31,	
	2023		2022	
Net loss from consolidated statements of operations	\$ (15,445,087)	\$	(9,051,334)	
Add: AxoBio net income (loss) not reflected in the consolidated				
statements of				
operations, less pro forma adjustments described below (1)	950,126		(7,949,016)	
Unaudited pro forma net loss	\$ (14,494,961)	\$	(17,000,350)	

(1) An adjustment to reflect additional amortization of \$1,700,000 and \$2,500,000 for the period from January 1, 2023 through the Merger Closing Date and the year ended December 31, 2022, respectively, that would have been charged assuming the fair value adjustments to intangible assets had been applied on January 1, 2022. The adjustment also reflects additional costs of goods sold of \$0 and \$8,200,000 for the year ended December 31, 2023 and 2022, respectively, that would have been charged assuming the fair value step up to inventories had been applied on January 1, 2022.

#### NOTE 4 — GOING CONCERN AND MANAGEMENT'S LIQUIDITY PLANS

As of December 31, 2023 and 2022, the Company had cash of \$2,912,461 and \$128,149, respectively. The Company's liquidity needs up to December 31, 2023 have been satisfied through debt and equity financing.

The Company had a net loss from continuing operations of \$16,205,252 and \$9,051,334 for the years ended December 31, 2023 and 2022, respectively. The Company had negative cash flows from operations of \$8,348,208 and \$3,428,707 for the years ended December 31, 2023 and 2022, respectively, and an accumulated deficit of \$58,503,401 and \$42,382,291 as of December 31, 2023 and December 31, 2022, respectively.

Due to its current liabilities and other potential liabilities, the cash available to the Company may not be sufficient to allow the Company to operate for at least 12 months from the date these financial statements are available for issuance. The Company may need to raise additional capital through equity or debt issuances. If the Company is unable to raise additional capital, it may be required to take additional measures to conserve liquidity, which could include, but not necessarily be limited to, curtailing operations and reducing payroll expenses. The Company cannot provide any assurance that new financing will be available to it on commercially acceptable terms, if at all.

These conditions raise substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

During the third quarter of 2023, the Company has significantly reduced its operating expenses going forward by terminating certain executives serving as part-time consultants and full-time employees in non-core areas or overlapping business functions. This workforce reduction is expected to result in \$2,000,000 to \$3,000,000 in annual savings. In addition, the Company has refocused its research and development efforts on aesthetic products that have near-term commercial potential and has reprioritized development and ceased clinical studies of product candidates that will take more than a year to commercialize. The Company is also exploring out-licensing of certain research and development programs to generate non-dilutive liquidity.

## NOTE 5 — PROPERTY AND EQUIPMENT

Property and equipment included in continuing operations consist of the following:

	December 31,						
		20	23		2022		
8				Discontinued Operations		ontinuing perations	
Lab equipment	\$	696,648	\$	216,210	\$	666,178	
Leasehold improvements		115,333				115,333	
Furniture and fixtures		3,580		30,057		3,579	
	-	815,561		246,267		785,090	
Less: accumulated depreciation		(622,715)		(182,883)		(530,116)	
Property and equipment, net	\$	192,846	\$	63,384	\$	254,974	

Depreciation expense included in continuing operations was \$92,598 and \$89,782 for the year ended December 31, 2023 and 2022, respectively. Depreciation expense included in discontinued operations was \$18,462 in 2023.

## NOTE 6 —GOODWILL AND INTANGIBLE ASSETS

The Company's goodwill relates to the AxoBio Acquisition. Goodwill represents the excess of the purchase price of the acquired business over the fair value of the underlying net tangible and intangible assets. The Company may record goodwill adjustments pursuant to changes in the preliminary valuations acquired during the measurement period, which is up to one year from the date of acquisition. The Company has determined, based on its organizational structure, that it had one reporting unit as of December 31, 2023. For the year ended December 31, 2023, the Company recognized \$19,188,278 in goodwill from the AxoBio Acquisition, which is classified as a component of assets available for sale in the accompanying consolidated balance sheets.

The Company's intangible assets primarily relate to the AxoBio Acquisition (see Note 3). Intangible assets acquired in connection with the AxoBio Acquisition were initially recorded at their estimated fair value as of the acquisition date. Intangible assets that have finite lives are amortized over their economic useful life. Amortization of intangibles related to AxoBio are included as a component of discontinued operations in the accompanying statements of operations.

Additionally, the Company capitalizes legal costs directly associated with the submission of Company patent applications. Gross patent costs of \$70,746 as of December 31, 2023 and 2022 are amortized on a straight-line basis over the patent term.

Intangible assets and the related accumulated amortization consist of the following at December 31, 2023:

Continuing operations:	Amortization Period	Gross Carrying Value		 cumulated ortization	_	Net Book Value
Patents	16 years	\$	70,746	\$ 46,559	<u>\$</u>	24,187
Discontinued operations:						
Customer contracts	20 years	\$	12,170,000	\$ 337,313	\$	11,832,687
Trade name	7 years		2,220,000	132,143		2,087,857
Intellectual property	7 years		8,870,000	527,976		8,342,024
		\$	23,260,000	\$ 997,432	\$	22,262,568

Intangible assets and the related accumulated amortization consist of the following at December 31, 2022:

	Amortization Period	Gross Carrying Value	Accumulated Amortization	Net Book Value
Continuing operations:				
Patents	16 years	\$70,746	\$42,044	\$28,702

Amortization expense included in loss from continuing operation in the accompanying statements of operations was approximately \$4,515 and \$4,516 for the years ended December 31, 2023 and 2022, respectively. Amortization expense included in income from discontinued operation in the accompanying statements of operations was \$997,432 for the year ended December 31, 2023.

Amortization expense related to the Company's intangible assets for future years is as follows:

	tinuing erations	iscontinued Operations
2024	\$ 4,528	\$ 2,648,741
2025	4,516	2,679,576
2026	4,516	2,715,903
2027	4,090	2,690,449
2028	2,451	2,622,896
Thereafter	4,086	 8,905,003
	\$ 24,187	\$ 22,262,568

#### NOTE 7— ACCRUED EXPENSES AND OTHER LIABILITIES

Accrued expenses and other liabilities consist of the following amounts:

	December 31,					
	2	023	2022			
	Continuing	Discontinued	Continuing			
	Operations	Operations	Operations			
Accrued compensation	\$ 790,332	\$ —	\$ 916,934			
Accrued severance	452,579					
Accrued stock-based compensation	48,698	_	_			
Other accrued expenses	303,825	468,652	27,639			
Accrued expenses and other liabilities	\$ 1,595,434	\$ 468,652	\$ 944,573			

Accrued compensation is a non-interest bearing liability for employee payroll outstanding as of December 31, 2023 and 2022. This includes compensation earned during the years 2019 to 2023.

#### NOTE 8 — DEBT

## U.S. Small Business Administration (SBA) Loan

As of the Merger Closing Date, AxoBio had an outstanding loan with the SBA with total principal and accrued interest outstanding of \$2,000,000 and \$113,476, respectively (the "SBA Loan"). Interest under the SBA Loan accrues at a simple interest rate of 3.75% annually on funds outstanding as of the anniversary date of the initial borrowing. A monthly payment in the amount of \$9,953 began in December 2023 and continues for a total of 30 years. As of December 31, 2023, there was outstanding principal and accrued interest of \$2,000,000 and \$134,961, respectively. As of December 31, 2023, there was unamortized debt discount of \$494,930. In connection with the AxoBio Acquisition, the SBA Loan was adjusted to fair value, which, excluding accrued interest, was determined to be \$1,498,000. The difference in the outstanding principal and fair value of \$502,000 was recorded as debt discount and is accreted over the remaining term of the loan using the effective interest method. From the acquisition date through December 31, 2023, the Company incurred interest expense and amortization of debt discount of \$31,438 and \$7,070, respectively. The SBA Loan and related accrued interest are classified as a component of assets available for sale in the accompanying balance sheets, and the related interest expense is classified as a component of discontinued operations in the accompanying statements of operations.

## Related Party Loans

As of the Merger Closing Date, AxoBio had several promissory notes outstanding to Burns Ventures, LLC (the "Burns Notes") with total principal outstanding of \$5,610,000. The owner of Burns Ventures LLC was a former stockholder of AxoBio. Interest on the Burns Notes is payable quarterly at a fixed interest rate of 7.00%. The Burns Notes require no monthly payments and are due in full at maturity date on December 31, 2024. As of December 31, 2023, the Burns Notes had outstanding principal and accrued interest of \$5,610,000 and \$98,982, respectively, and interest expense totaled \$164,611 for the year ended December 31, 2023. The Burns Notes and related accrued interest are classified as a component of assets available for sale in the accompanying balance sheet, and the related interest expense is classified as a component of discontinued operations in the accompanying statements of operations.

## 2023 Promissory Notes

During the year ended December 31, 2023, the Company received proceeds of \$848,500 from 26 zero coupon Promissory Notes (the "Notes"). Four of the Notes were from related parties and represented \$100,000 of the borrowings. The Notes have a maturity date of one year from the date of issuance. The principal of the Notes is due in full at maturity. All Notes had a proportionate number of warrants issued in connection with the issuance of the Notes. There were 16,489 Common Stock warrants issued in connection with these Notes with a fair value of \$55,062. The warrants vested immediately, have a term of 5 years, and exercise prices ranging from \$11.50 to \$14.30. The fair value of the warrants was recorded as debt discount and is amortized over the term of the loans using the effective interest method. As of December 31, 2023, there was \$19,549 of unamortized debt discount. Debt discount amortization during the year ended December 31, 2023, was \$33,513.

## Premium Financing

In July 2023, the Company entered into an agreement with a third party, whereby the Company financed \$1,011,480 of premiums on certain of its insurance policies. This financing agreement accrues interest at 8.99% and has a monthly payment of \$117,072, with the last payment due in April 2024. Principal outstanding on this loan was \$459,647 as of December 31, 2023 and interest expense totaled \$33,527 for the year ended December 31, 2023.

#### Series 1 Convertible Notes

The Company issued Series 1 convertible notes (the "Series 1 Convertible Notes") between July 9, 2018 and September 13, 2019, with an amended maturity date of July 9, 2023. The Series 1 Convertible Notes bore interest at 8%, had no monthly payments, and were due in full with a balloon payment on the maturity date. The Series 1 Convertible Notes contained an embedded conversion feature whereby the outstanding principal and accrued and unpaid interest are automatically convertible upon a qualified financing. The conversion feature of the Series 1 Convertible Notes met the definition of a derivative and was valued using the Monte Carlo model, with the fair value of the derivative recorded as a derivative liability (see Note 2) and debt discount at the time of issuance. On September 23, 2022, a qualified financing occurred, at which point all outstanding principal and accrued and unpaid interest were converted to shares of Series C-2 convertible preferred stock ("Series C-2 Preferred Stock"). The principal and interest converted was \$6,109,560 and \$1,829,865, respectively, which converted into 2,196,158 and 657,768 shares, respectively, at a ratio of \$2.78 per share. The fair value of the shares issued was \$15,595,283. The fair value of the derivative upon conversion was \$1,938,481. The Company incurred interest expense of \$356,196 and amortization of debt discount expense of \$0 during the year ended December 31, 2022. The shares of Series C-2 Preferred Stock were converted into Common Stock upon the closing of the Business Combination.

## Series 2 Convertible Notes

The Company issued Series 2 convertible notes (the "Series 2 Convertible Notes") between September 25, 2019 and December 31, 2021, all with a maturity date of September 24, 2022. The Series 2 Convertible Notes bore interest at 8%, had no monthly payments, and were due in full with a balloon payment on the maturity date. The Series 2 Convertible Notes contained an embedded conversion feature whereby the outstanding principal and accrued and unpaid interest were convertible upon a qualified financing. The conversion feature of the Series 2 Convertible Notes met the definition of a derivative and was valued using the Monte Carlo model, with the fair value of the derivative recorded as a derivative liability (see Note 2) and debt discount at the time of issuance. On September 23, 2022, a qualified financing occurred, at which point all outstanding principal and accrued and unpaid interest was converted into shares of Series C-2 Preferred Stock. The principal and interest converted was \$3,965,455 and \$629,920, respectively, which converted into 1,425,433 and 226,433 shares, respectively, at a ratio of \$2.78 per share. The fair value of the shares issued was \$5,717,377. The fair value of the derivative upon conversion was \$1,122,002. The Company incurred interest expense of \$222,906 and amortization of debt discount expense of \$1,099,770 during the year ended December 31, 2022. The debt discount at the time of conversion was \$57,921 which was written off as a loss on debt extinguishment. The shares of Series C-2 Preferred Stock were converted into Common Stock upon the closing of the Business Combination.

#### Other Convertible Note

The Company issued a convertible note to an economic development fund for \$50,000 on September 24, 2020. The note was non-interest bearing, had no monthly payments, and was due in full with a balloon payment on June 23, 2025. The note contained an embedded conversion feature whereby the note holder could convert the shares at a discount in the event of a Qualified Financing or a change in control event. This conversion feature met the definition of a derivative and was valued using the Monte Carlo model, with the fair value of the derivative being recorded as a derivative liability (see Note 2) and debt discount at the time of issuance. On September 23, 2022, a Qualified Financing under the convertible note occurred, at which point all outstanding principal was converted to shares of Series C-2 Preferred Stock. The principal converted was \$50,000, which converted into 21,118 shares at a ratio of \$2.37 per share. The fair value of the shares issued was \$73,092. The fair value of the derivative upon conversion was \$23,092. The debt discount at the time of conversion was \$47,872, which was written off as a loss on debt extinguishment. During the year ended December 31,

2022, there was \$1,206 of amortization of debt discount. The shares of Series C-2 Preferred Stock were converted into Common Stock upon the closing of the Business Combination.

## January 2022 Convertible Notes

On January 19, 2022, the Company issued two senior secured convertible notes (the "Convertible Notes") of \$1,111,111 each to two investors ("Holders"), due on January 19, 2023. The Convertible Notes bore interest at 10% (18% upon default). The Company was required to make monthly interest payments for the interest incurred and required monthly principal payments of \$158,730 beginning on July 19, 2022. The Convertible Notes were collateralized by all assets (including current and future intellectual property) of Legacy Carmell. The Convertible Notes were issued with a 10% discount and were subject to an 8% commission due to the underwriter. These fees were recorded as debt discount. In addition, each of the Holders received warrants to subscribe for and purchase up to 155,412 shares of Common Stock (the "Convertible Note Warrants"). Each Convertible Note Warrant is exercisable at a price of \$0.16 per warrant share and vested immediately and have a term of five years. The fair value of the Convertible Note Warrants at the time of issuance was \$409,483, which was recorded as debt discount. The Convertible Notes are convertible at the option of the Holders into shares of Common Stock at a fixed conversion price equal to the lesser of \$3.57 per share and a 25% discount to the price of the Common Stock in a Qualified Offering (as adjusted, the "Conversion Price"). In the event units consisting of Common Stock and warrants are issued in a Qualified Offering, the Convertible Notes are convertible into Common Stock and warrants. If, at any time while the Convertible Notes are outstanding, the Company sells or grants any option to purchase or sells or grants any right to reprice, or otherwise disposes of or issues (or announces any sale, grant or any option to purchase or other disposition), any Common Stock or Common Stock equivalents entitling any person to acquire shares of Common Stock at an effective price per share that is lower than the then Conversion Price (such lower price, the "Base Conversion Price"), then the Conversion Price shall be reduced to equal the Base Conversion Price. Such adjustments are to be made whenever such Common Stock or Common Stock equivalents are issued. Multiple events have triggered the down-round feature of the base conversion price. As of December 31, 2022, the Base Conversion Price was \$1.79.

The conversion feature within the Convertible Notes met the requirements to be treated as a derivative. Accordingly, the Company estimated the fair value of the Convertible Notes derivative using the Monte Carlo Method as of the date of issuance. The fair value of the derivative was determined to be \$1,110,459 at the time of issuance and was recorded as a liability with an offsetting amount recorded as a debt discount. The derivative is revalued at the end of each reporting period, and any change in fair value is recorded as a gain or loss in the consolidated statements of operations.

Proceeds from the sales of the Convertible Notes with Convertible Note Warrants were allocated to the two elements based on the relative fair value of the Convertible Notes without the warrants and the warrants themselves at the time of issuance. The total amount allocated to the Convertible Note Warrants was \$409,483 and accounted for as paid-in capital. The discount amount was calculated by determining the aggregate fair value of the warrants using the Black-Scholes Option Pricing Model.

On July 19, 2022, Carmell defaulted on the Convertible Notes. Under the terms of the Convertible Notes, upon an event of default, there would be a 25% increase to the outstanding principal, in addition to the interest rate increasing from 10% to 18%. Upon the event of default, the unamortized debt discount of \$958,899 was accelerated and expensed, and the 25% increase in outstanding principal of \$555,556 was recorded as interest expense in the consolidated statements of operations. For the year ended December 31, 2022, interest expense, including fees, on the Convertible Notes, excluding the 25% increase in the outstanding principal, was \$570,312. For the year ended December 31, 2023, interest expense on the Convertible Notes, as calculated under GAAP, totaled \$570,220, not accounting for the management of the Company's belief that no additional payments are due to the Holders.

## An Agreement Subsequent to the Notice of Acceleration

On November 2, 2022, Carmell received a letter ("Notice of Acceleration") from one of the Holders, notifying it of an Event of Default. Carmell and Alpha entered into an agreement with Puritan Partners LLC, one of the Holders ("Puritan"), in connection with the Notice of Acceleration on December 19, 2022. Pursuant to this agreement, Alpha and Carmell each represented and warranted to Puritan that (i) it intended to enter into the Business Combination, (ii) there would be no conditions to closing relating to Alpha or its affiliates delivering a certain amount of cash to the Company at closing of the Business Combination (the "Closing"), (iii) the only conditions to Closing of the Business Combination were as set forth in Sections 6.1 through Section 6.3 of the Business Combination Agreement, (iv) upon entering into such Business Combination Agreement, such parties would have a commitment letter from a third party to provide capital in an amount sufficient to the surviving company to the Business Combination to, among other things, repay all amounts due and owing at such time to Puritan at the Closing, (v) the equity valuation ascribed to Carmell in the Business Combination Agreement is \$150,000,000, and (vi) such Business Combination Agreement shall not place any restrictions on Puritan's ability to transfer any of its securities, including, without limitation, the shares underlying its Convertible Note Warrants. Carmell agreed it would not pay any other debtholder on account of interest or principal during the forbearance period.

Based on the representations and warranties, and agreements above and in consideration of Carmell's agreement to pay Puritan at the Closing (i) the outstanding principal amount, plus accrued interest, late fees and all other amounts then owed as specified in the Convertible Notes and (ii) 25,000 freely tradeable shares of Common Stock (not subject to lock-up or any other restrictions on transfer) at a price of \$10.00 per share (i.e., the price per share of Common Stock to the equity holders of Carmell in the Business Combination), Puritan withdrew and rescinded the Notice of Acceleration, and such Notice of Acceleration was deemed null and void and had no further force or effect. Puritan further agreed that, based on the representations and warranties, and agreements contained in such agreement, it shall not issue any further notices of acceleration or default notices under the Convertible Notes, seek repayment of any amounts due under the Convertible Notes, or seek to exercise any other remedies contained in the Convertible Notes and other related agreements in regard to non-payment of the notes from the Effective Date until the June 30, 2023.

On the closing of the Business Combination, the Company repaid \$2,649,874 to the Holders, which represented the original principal amount of the Convertible Notes plus accrued interest at a rate of 25%, which the Company believes is the maximum rate permissible under New York State usury laws. In addition, the Company issued Puritan 25,000 shares freely of tradeable Common Stock. Following the closing of the Business Combination, both Holders have provided notice to the Company demanding additional payment of principal and interest on the Convertible Notes in an approximate amount of \$600,000 per each Holder at the closing of the Business Combination with additional interest thereon. In the case of Puritan, following the Business Combination, Puritan alleged that the Business Combination constituted a "Fundamental Transaction" under the terms of the Convertible Note Warrants, resulting in a purported right for Puritan to require the Company to repurchase such Convertible Note Warrants at a purchase price equal to the Black-Scholes Value of the unexercised portion of such Convertible Note Warrants as of the closing of the Business Combination. Puritan calculated the cash amount of such repurchase to be \$1,914,123. The Company believes that this calculation is inaccurate. In the case of the other holder, that Holder demanded to be provided its share of the Convertible Note Warrants. Puritan has also asserted damages in connection with the timing of the issuance to it of 25,000 shares of freely tradeable common stock. The Company believes that it provided freely tradeable shares to Puritan at the same time as other Legacy Carmell shareholders. Puritan's total claims inclusive of the amounts paid at Closing Date exceed \$4,050,000 in connection with a loan for which the Company received \$1,000,000. Management of the Company believes that its obligations under the Convertible Notes and Convertible Note Warrants have been satisfied and that no additional payments are due to the Holders, and the Company has conveyed its position to the Holders. There can be no assurance that these or similar matters will not result in expensive arbitration, litigation or other dispute resolution, which may not be resolved in our favor and may adversely impact our financial condition (see Note 10).

Future Maturities of Debt

All of the Company's outstanding debt as of December 31, 2023 matures and is payable in 2024.

## NOTE 9— LEASES

The Company is a party to two office leases which expire on December 31, 2028. As of December 31, 2023, the weighted average remaining term is five years. The Company elected to not recognize ROU assets and lease liabilities arising from short-term leases (leases with initial terms of twelve months or less, which are deemed immaterial) on its balance sheets.

When measuring lease liabilities for leases that were classified as operating leases, the Company discounted lease payments using its estimated incremental borrowing rate at the later of lease inception or January 1, 2020 (the date of adoption). The weighted average incremental borrowing rate applied was 8%.

The following table presents net lease cost and other supplemental lease information:

	 December 31,				
	2023		2022		
Lease cost:	 				
Operating lease cost	\$ 27,675		\$ 201,400		
Short term lease cost	 <u> </u>		<u>—</u>		
Net lease cost	27,675		2,022		
Cash paid for operating lease liabilities	\$ (109,379)	\$	(204,930)		

As of December 31, 2023, the estimated future minimum lease payments, excluding non-lease components, are as follows:

	C	perating
Fiscal Year		Leases
2024	\$	204,930
2025		204,930
2026		204,930
2027		204,930
2028		204,930
Total future minimum annual lease payments		1,024,650
Less: Imputed interest		(176,799)
Present value of lease liabilities	\$	847,851

## NOTE 10 — COMMITMENTS AND CONTINGENCIES

## Exclusive License Agreement

On January 30, 2008, the Company and Carnegie Mellon University ("CMU") entered into a License Agreement, as amended by that certain Amendment No. 1 to License Agreement, dated as of July 19, 2011, as further amended by that certain Amendment No. 2 to License Agreement, dated as of February 8, 2016, as further amended by that certain Amendment No. 3 to License Agreement, dated as of February 27, 2020 and as further amended by that certain Amendment No. 4 to License Agreement, dated November 23, 2021 (collectively, the "Amended License Agreement"). The Amended License Agreement provides the Company an exclusive, worldwide right to use certain technology of CMU relating to biocompatible plasma-based plastics to make, have made, use, and otherwise dispose of licensed products and to create derivatives for the field of use. The Company is required to use its best efforts to effect the introduction of the licensed technology into the commercial market as soon as possible and meet certain milestones as stipulated within the Amended License Agreement. CMU retains the right to use any derivative technology developed by the Company due to its use of this technology and retains the intellectual property rights to the licensed technology, including patents, copyrights, and trademarks.

The Amended License Agreement is effective until January 30, 2028, or until the expiration of the last-to-expire patent relating to this technology, whichever comes later, unless otherwise terminated under another provision within the Amended License Agreement. Failure to perform in accordance with the agreed-upon milestones is grounds for CMU to terminate the Amended License Agreement prior to the expiration date. As a partial royalty for the license rights, the Company issued 66,913 shares of the Company's common stock to CMU. In addition, in 2008, the Company issued a warrant which was exercised in full in 2011 for 98,938 shares of common stock. Prior to a qualified initial public offering or a qualified sale, CMU has the right to subscribe for additional equity securities to maintain its then percentage of ownership in the Company. The Business Combination did not qualify as a qualified initial public offering or qualified sale under the Amended License Agreement.

Royalties payable by the Company to CMU are 2.07% of net sales, as defined in the Amended License Agreement. The Company is also required to pay CMU 25% of any sublicense fees received, due, and payable upon receipt of the sublicense fees by the Company. All payments due to CMU are due within sixty (60) days after the end of each fiscal quarter. All overdue payments bear interest at a rate equal to the Prime Rate (as defined in the Amended License Agreement) in effect at the date such amounts are due plus 4%. No royalties were accrued or paid during the years ended December 31, 2023 and 2022.

The Company is obligated to reimburse CMU for all patent expenses and fees incurred to date by CMU for the licensed technology at the earlier of (1) three years from the effective date; (2) the closing date of a change in control event; and (3) for international patents, from the start of expenses for patenting outside of the United States of America. There were no reimbursed expenses and no owed related to reimbursable expenses for the years ended December 31, 2023 and 2022.

#### Convertible Notes

As detailed in Note 8 - Debt, both Holders have provided notice to the Company demanding additional payment of principal and interest on the Convertible Notes in an approximate amount of \$600,000 per each Holder at the closing of the Business Combination with additional interest thereon. In the case of Puritan, following the Business Combination, Puritan alleged that the Business Combination constituted a "Fundamental Transaction" under the terms of the Convertible Note Warrants, resulting in a purported right for Puritan to require the Company to repurchase such Convertible Note Warrants at a purchase price equal to the Black-Scholes Value of the unexercised portion of such Convertible Note Warrants as of the closing of the Business Combination. Puritan calculated the cash amount of such repurchase to be \$1,914,123. The Company believes that this calculation is inaccurate. In the case of the other Holder, that Holder demanded to be provided its share of the Convertible Note Warrants. Puritan has also asserted damages in connection with the timing of the issuance to it of 25,000 shares of freely tradeable Common Stock. The Company believes that it provided freely

tradeable shares to Puritan at the same time as other Legacy Carmell stockholders. Puritan's total claims inclusive of the amounts paid at Closing date exceed \$4,050,000 in connection with a loan for which the Company received \$1,000,000. Management of the Company believes that its obligations under the Convertible Notes and Convertible Note Warrants have been satisfied and that no additional payments are due to the Holders, and the Company has conveyed its position to the Holders. As described in further detail below, Puritan has filed a complaint against the Company related to these allegations. There can be no assurance that these or similar matters will not result in further arbitration, litigation or other dispute resolution, which may not be resolved in our favor and may adversely impact our financial condition.

#### Puritan Litigation

On November 8, 2023, Puritan filed a complaint captioned Puritan Partners LLC v. Carmell Regen Med Corporation et al., No. 655566/2023 (New York Supreme Court, New York County) naming the Company as a defendant. In the complaint, Puritan asserts that the Company breached its obligations under the Convertible Notes and the Convertible Note Warrants. Puritan also asserts the Company did not timely comply with its obligations to provide Puritan with 25,000 freely tradeable Common Stock. Puritan asserts claims for declaratory judgment, breach of contract, conversion, foreclosure of its security interest, replevin, unjust enrichment, and indemnification, and seeks remedies including damages totaling \$2,725,000 through November 1, 2023, additional fees and interest thereafter, costs and attorney's fees, an order of foreclosure on its security interest, and other declaratory relief. The Company has moved to dismiss the complaint and intends to defend itself vigorously against this litigation. There can be no assurance that this matter will be resolved in the Company's favor, and an adverse outcome could have a material adverse effect on the Company's financial condition.

#### NOTE 11 — PROFIT-SHARING PLAN

The Company has 401(k) profit-sharing plans covering substantially all employees. The Company's discretionary profit-sharing contributions are determined annually by the Board. No discretionary profit-sharing contributions were made to the 401(k) profit-sharing plans during the years ended December 31, 2023 and 2022.

## NOTE 12 — MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY (DEFICIT)

#### Common Stock

On July 14, 2023, the Business Combination was consummated and the Company issued 12,053,517 shares of Common Stock to stockholders of Legacy Carmell. Immediately following the Business Combination, there were 19,236,305 shares of Common Stock outstanding. As of December 31, 2023, the Company's Third Amended and Restated Certificate of Incorporation, as amended at the Closing Date, authorized the Company to issue 250,000,000 shares of Common Stock.

#### Series A Voting Convertible Preferred Stock

In connection with the AxoBio Acquisition, the Company issued 4,243 shares of Series A Preferred Stock to former stockholders of AxoBio.

Automatic Conversion: The Series A Preferred Stock will be automatically converted into shares of Common Stock at a conversion rate of 1,000 shares of Common Stock for one share of Series A Preferred Stock on the tenth trading day following the announcement of the approval by Company's stockholders of the issuance of Common Stock upon conversion of the Series A Preferred Stock ("Requisite Approval"). If the Company's stockholders do not approve such conversion at the first meeting in which it is voted on by stockholders, the Company will submit issuance of Common Stock upon the conversion of the Series A Preferred Stock for the approval of the Company's stockholders at least semi-annually until such approval is obtained. As of December 31, 2023, the Requisite Approval has not been obtained.

*Voting:* Series A Preferred Stock has the same voting rights as holders of Common Stock in any such vote. The holders of the Series A Preferred Stock shall be entitled to a number of votes equal to the number of shares of Common Stock into which the Series A Preferred Stock is convertible. Unless and until the Company has obtained the Requisite Approval, the number of shares of Common Stock that shall be deemed issued upon conversion of the Series A Preferred Stock (for purposes of calculating the number of aggregate votes to which the holders of Series A Preferred Stock are entitled on an as-converted basis) will be equal to that number of shares of Common Stock equal to the Cap, which is the number of shares of Common Stock equal to 19.9% of the Company's outstanding Common Stock as of the issuance date of the Series A Preferred Stock.

*Dividends*: If and when declared by the Board, if the dividend is declared on Common Stock, the holders of Series A Preferred Stock will receive that dividend or distribution, on an as-if-converted basis, in the same form as dividends paid on shares of Common Stock.

Liquidation: Prior to the Requisite Approval, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, including a change of control transaction, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, the amount per share if such holders converted all of the Series A Preferred Stock into Common Stock.

## Convertible Preferred Stock

As of December 31, 2022 and immediately prior to the Business Combination, Legacy Carmell had outstanding Series A convertible preferred stock ("Series A Preferred Stock"), Series B convertible preferred stock ("Series B Preferred Stock"), Series C-1 convertible preferred stock ("Series C-1 Preferred Stock") and Series C-2 Preferred Stock, which are collectively referred to herein as "Preferred Stock."

As of December 31, 2022, Convertible Preferred Stock consisted of the following:

		<b>Issued and</b>	Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Carrying		Li	iquidation	Is	suance
	Authorized	Outstanding	Value		Value		Value		Value		Value		Value		Value		Value		Value		Value		Value		Value		P	reference		Price				
Series A convertible preferred stock	2,010,728	2,010,728	\$	7,714,336	\$	7,714,336	\$	2.19																										
Series B convertible preferred stock	2,893,515	2,824,881		7,025,434		7,025,434		2.49																										
Series C-1 convertible preferred stock	3,436,863	426,732		772,028		772,028		2.54																										
Series C-2 convertible preferred stock	6,011,960	5,857,512		15,904,275		15,904,275		2.15																										

Legacy Carmell Series A Preferred Stock, Series C-1 Preferred Stock, and Series C-2 Preferred Stock accrued cumulative dividends at a per annum rate of 7% calculated on the original issue price (the "Original Issue Price"). Such dividends accrue on each share of Preferred Stock commencing on the date of issuance. The Company accrued dividends of \$164,510, \$40,551, and \$470,962 for Legacy Carmell Series A Preferred Stock, Series C-1 Preferred Stock, and Series C-2 Preferred Stock for the period from January 1, 2023 to July 13, 2023. As of December 31, 2022, the Company has accrued dividends of \$3,254,803, \$9,470, and \$239,104 for Legacy Carmell Series A Preferred Stock, Series C-1 Preferred Stock, and Series C-2 Preferred Stock, respectively.

In connection with the Business Combination, all previously issued and outstanding Preferred Stock was converted into an equivalent number of shares of Common Stock on a one-for-one basis, then multiplied by the Exchange Ratio pursuant to the Business Combination Agreement.

#### 2023 Long-Term Incentive Plan

In July 2023, the stockholders of the Company approved the 2023 Long-Term Incentive Plan (the "2023 Plan"), which replaced the Amended and Restated 2009 Stock Incentive Plan of Legacy Carmell (the "2009 Plan"). No new awards are being made under the 2009 Plan. Under the 2023 Plan, the Board may grant awards of stock options, stock appreciation rights, restricted stock, restricted stock units or other stock-based awards to employees and other recipients as determined by the Board. The exercise price per share for an option granted to employees owning stock representing more than 10% of the Company at the time of the grant cannot be less than 110% of the fair market value. Incentive and non-qualified stock options granted to all persons shall be granted at a price no less than 100% of the fair market value and any price determined by the Board. Options expire no more than ten years after the date of the grant. Incentive stock options to employees owning more than 10% of the Company expire no more than five years after the date of grant. The vesting of stock options is determined by the Board. Generally, the options vest over a four-year period at a rate of 25% one year following the date of grant, with the remaining shares vesting equally on a monthly basis over the subsequent thirty-six months.

The maximum number of shares that may be issued under the 2023 Plan is the sum of: (i) 1,046,408, (ii) an annual increase on January 1, 2024 and each anniversary of such date prior to the termination of the 2023 Plan, equal to the lesser of (a) 4% of the outstanding shares of our Common Stock determined on a fully diluted basis as of the immediately preceding year-end and (b) such smaller number of shares as determined by the Board or compensation committee, and (iii) the shares of Common Stock subject to 2009 Plan awards, to the extent those shares are added into the 2023 Plan by operation of the recycling provisions described below.

The maximum number of shares of Common Stock that may be issued under the 2023 Plan through incentive stock options is 1,046,408, provided that this limit will automatically increase on January 1 of each year, for a period of not more than ten years, commencing on January 1, 2024 and ending on (and including) January 1, 2032, by an amount equal to the lesser of 1,500,000 shares or the number of shares added to the share pool as of such January 1, as described in clause (ii) of the preceding sentence. The following shares will be added (or added back) to the shares available for issuance under the 2023 Plan:

- Shares subject to 2009 Plan or 2023 Plan awards that expire, terminate or are canceled or forfeited for any reason after the effectiveness of the 2023 Plan;
- Shares that after the effectiveness of the 2023 Plan are withheld to satisfy the exercise price of an option issued under the 2009 Plan or 2023 Plan;

- Shares that after the effectiveness of the 2023 Plan are withheld to satisfy tax withholding obligations related to any award under the 2009 Plan or 2023 Plan; and
- Shares that after the effectiveness of the 2023 Plan are subject to a stock appreciation right that are not delivered on exercise or settlement.

However, the total number of shares underlying 2009 Plan awards that may be recycled into the 2023 Plan pursuant to the above-described rules will not exceed the number of shares underlying 2009 Plan awards as of the effective date of the 2023 Plan (as adjusted to reflect the Business Combination). Shares of Common Stock issued through the assumption or substitution of awards in connection with a future acquisition of another entity will not reduce the shares available for issuance under the 2023 Plan.

## Warrant and Option Valuation

The Company computes the fair value of warrants and options granted using the Black-Scholes option pricing model. The expected term used for warrants and options issued to non-employees is the contractual life, and the expected term used for options issued to employees and directors is the estimated period that options granted are expected to be outstanding. The Company utilizes the "simplified" method to develop an estimate of the expected term of "plain vanilla" grants for stock options. The Company utilizes an expected volatility figure based on a review of the historical volatilities over a period equivalent to the expected life of the instrument valued by similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued. The Company's stock price was derived from a 409A valuation prior to the Business Combination and market price for all options and warrants granted thereafter.

## Warrants Outstanding

During the year ended December 31, 2023, the Company issued 16,489 warrants in connection with notes payable (see Note 8). Also during 2023, the Company assumed the Public Warrants in conjunction with the Business Combination. Each whole Public Warrant has an exercise price of \$11.50 and a term of five years from the Closing Date. The following table presents information related to Common Stock warrants for the year ended December 31, 2023.

		Weighted Average			
	Number of	Weighted Average Exercise	Remaining Contractual Life in	Aggregate Intrinsic	
	Warrants	Price	<u>Years</u>	Value	
Outstanding and exercisable, December 31, 2022	644.980	\$ 2.08	5.03	\$	
	011,500	Ψ 2.00	5.05	Ψ	
Warrants issued	16,489	14.20	3.03	Ψ	
, ,	- ,		3.03	Ψ	

## Option Outstanding

A summary of the option activity during the year ended December 31, 2023 is presented below:

	Number of Options	Weighted Average Exercise Price		Weighted Average Remaining Life in Years	Aggregate Intrinsic Value	
Outstanding, December 31, 2022	2,235,313	\$	2.12	8.07	\$	1,083,492
Granted	1,504,638		2.92			
Exercised	(21,158)		1.94			
Expired/Cancelled	(2,029,028)		2.21			
Outstanding, December 31, 2023	1,689,765	\$	2.72	9.00	\$	1,850,397
Vested/Exercisable, December 31, 2023	283,438	\$	2.06	6.18	\$	496,063

The weighted average fair value of the options granted during the year ended December 31, 2023 was based on a Black Scholes option pricing model using the following assumptions:

Expected volatility	70% - 76%
Expected term of option	6.0 - 7.0
Range of risk-free interest rate	3.6% -3.8%
Dividend yield	0%

The Company recorded stock-based compensation expense for options of \$667,682 and \$609,891 for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, there was approximately \$2,597,602 of total unrecognized compensation expense related to unvested stock options, which will be recognized over the weighted average remaining vesting period of 3.08 years.

#### **NOTE 13 – OTHER RELATED PARTY TRANSACTIONS**

A former member of the Board holds investments in the Company through various venture capital firms. In addition, certain family members of the Company's former Chief Executive Officer invested in Series C-2 Preferred Stock, which was converted to Common Stock as of the Effective Time.

The Company uses OrthoEx for 3PL services. The former Chief Executive Officer of AxoBio, who is currently serving as an advisor to the Company, has an equity interest in OrthoEx and has a seat on OrthoEx's Board of Directors. The Company incurred \$41,752 of expenses from OrthoEx during the year ended December 31, 2023. As of December 31, 2023, the Company had a payable to this related party of \$8,650. The Company uses Ortho Spine Companies, LLC ("Ortho Spine") for various consulting and marketing services. Ortho Spine is owned by one of the advisors to the Company. The Company incurred \$79,167 of expenses from Ortho Spine for the year ended December 31, 2023. As of December 31, 2023, the Company had no payables to this related party.

#### **NOTE 14 – INCOME TAXES**

The Company accounts for income taxes under ASC 740-10, which provides for an asset and liability approach of accounting for income taxes. Under this approach, deferred tax assets and liabilities are recognized based on anticipated future tax consequences, using currently enacted tax laws, attributed to temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts calculated for income tax purposes. The Company's tax jurisdictions are Florida and Pennsylvania.

The components of the Company's income tax rate for the years ended December 31, 2023 and 2022 are as follows:

	Year Ended De	cember 31,
	2023	2022
U.S. federal statutory rate	21.0%	21.0%
Effects of:		
State taxes, net of federal benefit	<u> </u>	7.9%
Stock-based compensation	(4.0)%	(0.4)%
Research and development expenses, net	(3.5)%	(6.4)%
Capitalized transaction costs	(9.8)%	%
Loss on forward purchase agreement	13.7%	
Gain on loan forgiveness	<u> </u>	(2.5)%
Net operating loss true-up	<u> </u>	2.6%
Other	(3.8)%	(0.2)%
Valuation allowance	(13.6)%	(22.0)%
Effective rate		

Significant components of the Company's deferred tax assets as of December 31, 2023 and 2022 are summarized below.

	December 31,			1,
		2023		2022
Deferred income tax assets:				
Net operating losses	\$	8,775,098	\$	7,642,000
Accrued interest		1,845,473		747,000
Federal research and development tax credits		68,106		113,000
Amortization of research expense		635,669		585,000
Right of use asset		4,676		29,000
Non-qualified deferred compensation		404,327		263,000
Accrued compensation		357,171		271,000
Change in fair value of forward purchase agreement		2,485,388		
Capitalization of start-up costs		351,383		
Accrual to cash and other		548,665		_
Change in fair value of earnout liability		(3,353,181)		
Change in fair value of derivative liabilities		<del>_</del>		275,000
Gross deferred tax asset		12,122,775		9,925,000
Valuation allowance		(12,122,775)		(9,925,000)
Net deferred income tax assets	\$		\$	

As of December 31, 2023, the Company had approximately \$31.3 million of federal and \$30.9 million of state net operating loss carry forwards. Federal and state net operating loss carryforwards were approximately \$25.7 million and \$29.9 million, respectively, for the year ended December 31, 2022. The Company's federal net operating loss carry forwards consist of approximately \$8.2 million of pre 2018 net operating loss carryforwards, which expire after twenty years and begin to expire starting in 2028. The Company had approximately \$23.1 million of post 2017 net operating losses that carry forward indefinitely. Future utilization of the net operating loss carry forwards is subject to certain limitations under Section 382 of the Internal Revenue Code. In addition, the Company has approximately \$68,000 of federal research and development credit carryovers, which expire after twenty years and begin to expire starting in 2042. The Company utilized approximately \$56,000 of such credits for tax year 2023. Future realization of the credit carry forwards is subject to certain limitations under Section 383 of the Internal Revenue Code. The Company has not undertaken any formal research and development credit study to calculate its credits.

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of the deferred tax assets. The Company has established a valuation allowance against the net deferred tax asset due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, we have not reflected any benefit of such deferred tax assets in the accompanying financial statements. Our net deferred tax asset and valuation allowance increased by approximately \$2,198,000 and \$2,323,000 for the years ended December 31, 2023 and 2022, respectively.

The Company is subject to U.S. federal income tax examinations by tax authorities for all tax years since inception due to unexpired net operating loss carryforwards originating in and after that year. The Company may be subject to income tax examinations for the various state taxing authorities which vary by jurisdiction.

The Company has evaluated its income tax positions and has determined that it does not have any uncertain tax positions. The Company will recognize interest and penalties related to any uncertain tax positions through its income tax expense.

## **NOTE 15 – Discontinued Operations**

On March 20, 2024, the Company entered into the Purchase Agreement to sell AxoBio and closed on such sale on March 26, 2024 as detailed in Note 1. The assets and liabilities of AxoBio are classified as available for sale in the accompanying consolidated balance sheets and consist of the following:

	December 31,				
		2023		2022	
Assets available for sale					
Cash and cash equivalents	\$	804,277	\$		_
Accounts receivable, net		7,713,600			
Prepaid expenses		251,086			
Inventories		3,038,179			
Property and equipment, net		63,384			
Intangible assets, net		22,262,568			
Goodwill		19,188,278			
Total assets available for sale	\$	53,321,372	\$		
Liabilities available for sale					
Accounts payable	\$	8,520,243	\$		_
Accrued interest		134,961			
Accrued interest, related party		98,982			
Other accrued expenses		468,652			
Loans payable, current		1,505,070			_
Related party loans, current		5,610,000			
Earnout liability		8,000,000			
Deferred income taxes		5,536,923			
Total liabilities available for sale	\$	29,874,831	\$		

The significant components of discontinued operations in the accompanying consolidated statements of income are as follows:

	Year Ended December 31,			1,
		2023	2022	2
Revenue	\$	4,456,816	\$	_
Cost of sales		3,620,651		
Gross profit		836,165		
Operating expenses:				
Selling and marketing		6,829,520		_
Research and development		403,616		_
General and administrative		2,525,715		_
Depreciation and amortization		1,015,894		
Total operating expenses		10,774,745		<u> </u>
Loss from operations		(9,938,580)		
Other income (expense):				
Other income		7		_
Amortization of debt discount		(7,070)		
Interest expense, related party		(164,611)		_
Interest expense		(32,221)		_
Inventory write-down		(4,754,357)		_
Change in fair value of earnout liability		13,482,292		
Total other (expense) income		8,524,040		
Loss before income taxes		(1,414,540)		
Income tax benefit, deferred		2,174,705		
Discontinued operations, net	\$	760,165	\$	

# **NOTE 16 – Subsequent Events**

As more fully described in Note 1, the Company entered into the Purchase Agreement on March 20, 2024 to sell AxoBio to its former stockholders. The sale transaction contemplated by the Purchase Agreement closed on March 26, 2024.

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

None

#### Item 9A. Controls and Procedures.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

#### **Evaluation of Disclosure Controls and Procedures**

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2023. Based upon their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that during the period covered by this report, our disclosure controls and procedures were effective.

## Management's Report on Internal Control over Financial Reporting

As required by SEC rules and regulations implementing Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at December 31, 2023. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Based on our assessments and those criteria, management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

## Remediation Efforts to Address a Previously Identified Material Weakness in Internal Control over Financial Reporting

In 2022, our management concluded that our control around the interpretation and accounting for certain complex financial instruments we previously issued was not effectively designed or maintained as described in Item 9.A. of the Company's 2022 Form 10-K.

To address this material weakness, management has devoted, and plans to continue to devote, significant effort and resources to the remediation and improvement of its internal control over financial reporting and to enhance controls and improve internal communications within the Company and its financial reporting advisors. While we have processes to identify and appropriately apply applicable accounting requirements, we enhanced these processes to better evaluate our research and understanding of the nuances of the complex accounting standards that apply to our financial reporting requirements by utilizing the expertise of outside financial reporting advisors to support the Company in evaluating these transactions. With respect to the material weakness surrounding the completeness and accuracy of liabilities, we implemented additional review procedures to enable the Company to effectively search for and identify material unrecorded liabilities on a timely basis,

# Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### Item 9B. Other Information.

None

#### Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable

#### PART III

## Item 10. Directors, Executive Officers and Corporate Governance.

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report relates.

#### Item 11. Executive Compensation.

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report relates.

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

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report relates.

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

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report relates.

#### Item 14. Principal Accounting Fees and Services.

Incorporated by reference from the information in our Proxy Statement for our 2024 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report relates.

#### **PART IV**

#### Item 15. Exhibits and Financial Statement Schedules

- a) The following financial statements are included in this Annual Report on Form 10-K:
- (1) List of Financial Statements: The financial statements required by this item are listed in Item 8, "Financial Statements and Supplementary Data" herein.
- (2) List of Financial Statement Schedules: All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or notes thereto.
  - (3) List of Exhibits

Exhibit

## **Exhibit Index**

Exhibit Number 2.1†	<b>Description</b> Agreement and Plan of Merger, by and among Carmell Corporation, Aztec Merger Sub, Inc. and Axolotl Biologix, Inc., dated July 26, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 1, 2023).
2.2	First Amendment to Agreement and Plan of Merger, by and among Carmell Therapeutics Corporation, Aztec Merger Sub, Inc. and Axolotl Biologix, Inc., dated August 9, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 14, 2023).
2.3†	Business Combination Agreement, dated as of January 4, 2023, by and among Alpha Healthcare Acquisition Corp. III, Candy Merger Sub, Inc. and Carmell Therapeutics Corporation. (incorporated by reference to Annex A to the proxy statement/prospectus contained in the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
3.1	Third Amended and Restated Certificate of Incorporation of Carmell Therapeutics Corporation. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on July 20, 2023).
3.2	Amendment to Third Amended and Restated Certificate of Incorporation of Carmell Corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2023).
3.3	Bylaws of Carmell Therapeutics Corporation (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K, filed with the SEC on July 20, 2023).
4.1*	Description of Securities.
4.2	Warrant Agreement, dated July 26, 2021, by and between Alpha Healthcare Acquisition Corp. III and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2021).
4.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on August 14, 2023).
10.1†	Investor Rights and Lock-up Agreement, dated July 14, 2023, by and among Carmell Therapeutics Corporation (f/k/a Alpha Healthcare Acquisition Corp. III), and the parties listed as Investors thereto (incorporated by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2023).
10.2	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2023).
10.3+	2023 Equity Incentive Plan of Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.3 to Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).

- 10.4+\* Form of Grant Agreement under 2023 Equity Incentive Plan of Carmell Therapeutics Corporation
- License Agreement, dated January 30, 2008, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
- Amendment #1 to License Agreement, dated July 19, 2011, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on S-4/A, filed with the SEC on June 21, 2023).
- Amendment #2 to License Agreement, dated February 8, 2016, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on S-4/A, filed with the SEC on June 21, 2023).
- Amendment #3 to License Agreement, dated February 27, 2020, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
- Amendment #4 to License Agreement, dated November 23, 2021, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
- 10.10 Office Lease Agreement, dated March 27, 2017, by and between RJ Equities LP and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
- 10.11 Office Lease Agreement, dated March 21, 2019, by and between RJ Equities LP and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
- 10.12 First Amendment to Office Lease Agreement, dated March 21, 2019, by and between RJ Equities LP and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
- 10.13 10% Original Issue Discount Senior Secured Convertible Note Due January 19, 2023, by and between Carmell Therapeutics Corporation and Puritan Partners LLC (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
- 10.14 10% Original Issue Discount Senior Secured Convertible Note Due January 19, 2023, by and between Carmell Therapeutics Corporation and Verition Multi-Strategy Master Fund Ltd. (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on S-4/A filed with the SEC on June 21, 2023).
- 10.15+ Executive Employment Agreement between Carmell Corporation and Rajiv Shukla, dated December 29, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 5, 2024).
- Letter of Intent by and between Alpha Healthcare Acquisition Corp. III and the investor named therein related to Equity Line of Credit, dated as of May 5, 2023 (incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-4/A filed with the SEC on May 26, 2023).
- Form of Common Stock Purchase Agreement by and between Alpha Healthcare Acquisition Corp. III, Carmell Therapeutics Corporation and the investor named therein (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-4/A filed with the SEC on June 8, 2023).
- Forward Purchase Agreement, dated July 9, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 10, 2023).

- Non-Redemption Agreement, dated July 9, 2023 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 10, 2023).
- 14.1#\* Carmell Corporation Code of Business Conduct and Ethics
- 21.1\* Subsidiaries of Carmell Corporation.
- 31.1\* Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of Principal Financial Officer Pursuant to Rules` 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1\*\* Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2\*\* Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 97.1\* Carmell Corporation Compensation Recovery Policy

#### Exhibit 101:

- 101.INS Inline XBRL Instance Document the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
- 101.SCH Inline XBRL Taxonomy Extension Schema Document
- 101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF Inline XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB Inline XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase Document

#### \* Filed herewith

- \*\* This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, except to the extent specifically incorporated by reference into such filing.
- + Indicates a management contract or compensatory plan.
- # The Registrant's Code of Business Conduct and Ethics is posted to its corporate website, www.carmellcorp.com. A copy of the code can also be obtained by submitting a written request to the Registrant at 2403 Sidney Street, Suite 300, Pittsburgh, PA 15203 or by email to ethics@carmellcorp.com.
- † Annexes, schedules and exhibits to this Exhibit omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

#### Item 16. Form 10-K Summary

Not Applicable

#### **SIGNATURES**

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

## **Carmell Corporation**

Date: April 1, 2024 By: /s/ Rajiv Shukla

Name: Rajiv Shukla

Chief Executive Officer and Chairman

(Principal Executive Officer)

**Carmell Corporation** 

Date: April 1, 2024 By: /s/ Bryan J. Cassaday

Name: Bryan J. Cassaday Chief Financial Officer

(Principal Financial and Accounting Officer)

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

Name	Title	Date
/s/ Rajiv Shukla Rajiv Shukla	Chief Executive Officer and Chairman (Principal Executive Officer)	April 1, 2024
/s/ Bryan Cassaday Bryan Cassaday	Chief Financial Officer (Principal Financial and Accounting Officer)	April 1, 2024
/s/ David Anderson  David Anderson	Director	April 1, 2024
/s/ Scott Frisch Scott Frisch	Director	April 1, 2024
/s/ Kathryn Gregory Kathryn Gregory	Director	April 1, 2024
/s/ Gilles Spenlehauer Gilles Spenlehauer	Director	April 1, 2024
/s/ Patrick Sturgeon Patrick Sturgeon	Director	April 1, 2024
/s/ Richard Upton Richard Upton	Director	April 1, 2024



# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, DC 20549** 

# FORM 10-K/A

Amendment No. 1

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 

Commission File Number: 001-40228

# CARMELL CORPORATION

(Exact Name of Registrant as Specified in its Charter)

**Delaware** 

( State or other jurisdiction of incorporation or organization)

86-1645738 (I.R.S. Employer Identification No.)

2403 Sidney Street, Suite 300 Pittsburgh, Pennsylvania

(Address of principal executive offices)

15203

(Zip Code)

Registrant's telepho	ne number, including area	code: (412) 894-8248	
Securities registered pursuant to Section 12(b) of the	ne Act:	-	
Title of each class	Trading Symbol(s)	Name of each exchange on which registered	
Common Stock, par value \$0.0001 per share	CTCX	The Nasdaq Stock Market LLC	
Redeemable Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of \$11.50	CTCXW	The Nasdaq Stock Market LLC	
Indicate by check mark if the Registrant is a well-known seasoned issu	er, as defined in Rule 405 of the Secu	urities Act. YES □ NO 🗵	
Indicate by check mark if the Registrant is not required to file reports p	oursuant to Section 13 or 15(d) of the	Act. YES □ NO 🗵	
Indicate by check mark whether the Registrant: (1) has filed all reports months (or for such shorter period that the Registrant was required to f			-
Indicate by check mark whether the Registrant has submitted electroni of this chapter) during the preceding 12 months (or for such shorter per	3 3	1 0	405
Indicate by check mark whether the registrant is a large accelerated fil See the definitions of "large accelerated filer," "accelerated filer," "small states" accelerated filer, small states acc			iny.
Large accelerated filer □		Accelerated filer	
Non-accelerated filer		Smaller reporting company	$\boxtimes$
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.  $\square$ 

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

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  $\square$  NO  $\boxtimes$ 

The aggregate market value of the registrant's Class A Common Stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was approximately \$159.1 million, based on the closing price of the registrant's Class A Common Stock as reported on the Nasdaq Capital Market on such date. This determination of affiliate status is not a determination for other purposes.

The number of shares of the registrant's Common Stock outstanding as of April 24, 2024 was 20,730,559.

DOCUMENTS INCORPORATED BY REFERENCE

None.



# **Table of Contents**

		Page
Explanator	y Note	2
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	3
Item 11.	Executive Compensation	7
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	14
Item 13.	Certain Relationships and Related Transactions, and Director Independence	15
Item 14.	Principal Accounting Fees and Services	17
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	18

#### EXPLANATORY NOTE

Carmell Corporation (the "Company," "Carmell," "we," "us," or "our") is filing this Amendment No. 1 on Form 10-K/A (this "Amendment No. 1") to amend our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, originally filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024 (the "Original Form 10-K," together with Amendment No. 1, our "Annual Report"), to (i) include the information required by Items 10 through 14 of Part III of Form 10-K and (ii) delete the reference on the cover page of the Original Form 10-K to the incorporation by reference of portions of our definitive proxy statement for our 2024 annual meeting of stockholders (the "Annual Meeting") in Part III of such Original Form 10-K. The information required by Items 10 through 14 of Part III of Form 10-K was previously omitted from the Original Form 10-K in reliance on General Instruction G(3) to Form 10-K, which permits the information in the above-referenced items to be incorporated in the Form 10-K by reference to our definitive proxy statement if such proxy statement is filed no later than 120 days after our fiscal year-end. We are filing this Amendment No. 1 to provide the information required in Part III of Form 10-K because our definitive proxy statement for the Annual Meeting containing such information will not be filed with the SEC within 120 days after the end of the fiscal year covered by the Original Form 10-K.

In accordance with Rules 12b-15 and 13a-14(a) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we have also amended Item 15 of Part IV of the Original Form 10-K to include currently dated certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from our principal executive officer and principal financial officer. Because no financial statements have been included in this Amendment No. 1 and this Amendment No. 1 does not contain or amend any disclosure with respect to Items 307 and 308 of Regulation S-K, the corresponding certifications have been omitted. Similarly, because no financial statements have been included in this Amendment No. 1, certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 have been omitted.

Except as set forth above, no other Items of the Original Form 10-K have been amended or revised in this Amendment No. 1, and all such other Items shall be as set forth in such Original Form 10-K. Accordingly, this Amendment No. 1 should be read in conjunction with the Original Form 10-K and our other filings with the SEC. Certain capitalized terms used and not otherwise defined in this Amendment No. 1 have the meanings given to them in the Original Form 10-K.

#### PART III

## Item 10. Directors, Executive Officers and Corporate Governance.

#### **Directors**

The following table sets forth information concerning our directors as of April 24, 2024. The biographical description of each director includes the specific experience, qualifications, attributes and skills that our Board of Directors (the "Board") would expect to consider if it were making a conclusion currently as to whether such person should serve as a director.

Name	Age	Position
Rajiv Shukla	49	Chairman, Chief Executive Officer and Class III Director
David Anderson	71	Class I Director
Rich Upton	60	Class I Director
Kathryn Gregory	62	Class II Director
Scott Frisch	55	Class II Director
Gilles Spenlehauer	64	Class II Director
Patrick Sturgeon	47	Class III Director

Rajiv Shukla has been our Chairman and Chief Executive Officer since inception and has two decades of experience in buyouts, investments and operations in the healthcare industry. Mr. Shukla served as Chairman and Chief Executive Officer of Alpha Healthcare Acquisition Corp. ("AHAC"), a Nasdaq-listed special purpose acquisition company that raised \$100 million in its initial public offering in September 2020. In August 2021, AHAC successfully closed its initial business combination with Humacyte, Inc. ("Humacyte"), a clinical-stage biotechnology platform company developing universally implantable bioengineered human tissue at a commercial scale, together with a concurrent \$175 million private placement from several fundamental healthcare investors. Mr. Shukla served as Chairman and Chief Executive Officer of Constellation Alpha Capital Corp. ("CNAC"), a Nasdaq-listed special purpose acquisition company, from June 2017 to August 2019. CNAC raised \$144 million in proceeds from a Nasdaq initial public offering and successfully closed its initial business combination with DermTech, Inc., or DermTech, in August 2019. DermTech is a molecular dermatology company that develops and markets non-invasive diagnostic tests. The transaction was financed in part with proceeds from a private placement transaction with investors including RTW Investments, Farallon Capital, Victory RS Science and Technology Fund, Irwin Jacobs, RTW Investments and HLM Venture Partners. Mr. Shukla has served as Director of Humacyte since August 2021. From August 2019 to August 2022, Mr. Shukla served as an independent director on the board of directors of InflammX Therapeutics, formerly known as Ocunexus Therapeutics, a clinical-stage biotech company, From June 2013 to May 2015, Mr. Shukla served as Chief Executive Officer of Pipavav Defence & Offshore Engineering Company (now Reliance Naval and Engineering Ltd.), an Indian-listed shipbuilding and defense manufacturing company. In this role, he successfully implemented an extensive financial restructuring project and sold control to the Reliance ADA Group. Between 2008 and 2013, Mr. Shukla worked as an investor at ICICI Venture, Morgan Stanley Investment Management and Citi Venture Capital International. Throughout his career, Mr. Shukla has been involved in numerous investments in healthcare companies. As a private equity investor, Mr. Shukla was involved with numerous control and minority healthcare investments and served as a member of the board of directors of I-ven Medicare, a hospital roll-up platform comprising multiple control investments and significant minority stakes in tertiary care hospitals and outpatient treatment centers, Ranbaxy Fine Chemicals Ltd, a roll-up of specialty chemicals and animal health businesses, Swiss Bio, a U.S. based clinical CRO, Bharat Biotech, a vaccine company, three specialty pharma companies: Arch Pharmalabs, Malladi Drugs and Unimark Remedies. From 2001 to 2006, Mr. Shukla served as Senior Director at Pfizer, Inc. In this role, he played a key role in several acquisitions, including Pharmacia in 2003, Meridica in 2004, Vicuron Pharmaceuticals and Idun Pharmaceuticals in 2005, and Rinat Neuroscience in 2006. Mr. Shukla also led the operational integration of these organizations into Pfizer across multiple sites around the world. Mr. Shukla graduated from Harvard University with a Master's in Healthcare Management and Policy and received a Bachelor's in Pharmaceutics from the Indian Institute of Technology. We believe that Mr. Shukla is qualified to serve on our Board due to his extensive executive, operations, finance, and investment experience.

**David Anderson** has served as a member of Carmell's Board since July 2016. Mr. Anderson has been a successful entrepreneur in the orthopedic medical device field for over 25 years. He has led five orthopedic organizations: Orteq Sports Medicine (CEO), Osteotech (Executive VP), Bionx Implants (CEO), Replication Medical (Founder and Director), and Gentis (CEO). Mr. Anderson was a founder of Osteotech and was the founder and CEO of Bionx Implants which he grew through over 60 product approvals to over \$20 million in sales in less than three years. He was also part of the team that created Integra LifeSciences and has been an active Board member of multiple public medical technology companies. He has raised over \$350 million in venture capital, taken a company through the IPO route onto Nasdaq, and has been a part of multiple M&A transactions. Mr. Anderson received his B.S. in Chemical Engineering from Cornell University. We believe that Mr. Anderson is qualified to serve on our Board due to his extensive executive leadership experience.

**Rich Upton** has served as a member of the Board since April 2011. Mr. Upton is a General Partner at Harbor Light Capital Partners, a private investment firm seeking to invest in early-stage companies. Previously, he was the founder and President of Upton Advisors, LLC, a boutique investment bank serving middle-market and emerging healthcare companies throughout the United States. Mr. Upton has been advising companies since 1992, both as a senior healthcare investment banker for Salomon Brothers and later as an independent adviser. In addition to Carmell Therapeutics, Mr. Upton serves on the boards of Anuncia Medical (Chairman), Alcyone Therapeutics and Medicinal Genomics Corp, and previously served on the boards of Home Diagnostics, Inc. (NASDAQ: HDIX - acquired by Nipro Corporation), Castlewood Surgical and Courtagen Life Sciences. Mr. Upton currently serves on the investment committee of the Endowment for Health and served ten years on the investment committee of the New Hampshire Charitable Foundation. He is also the former Chairman of The Pine Hill Waldorf School. Mr. Upton received his M.B.A. degree from The Darden School at the University of Virginia and a dual B.A. degree in Economics and English from Amherst College. We believe that Mr. Upton is qualified to serve on our Board due to his experience as an investor and familiarity with the financial operations of a broad range of companies.

Kathryn Gregory joined the Board in 2021. Ms. Gregory has over 25 years of executive leadership experience in both startup and midsized biotechnology and pharmaceutical companies. Ms. Gregory has extensive experience in international business development, including corporate strategy, negotiations, mergers and acquisitions, alliance management and operational expertise in marketing, strategic sourcing and procurement. Ms. Gregory is currently Vice President and Head of Global Business Development at Antengene Corporation, a hematology and oncology company focused on innovative medicines for patients in the Asia Pacific Region and worldwide. Prior to Antengene, Ms. Gregory was Chief Business Officer of Aileron Therapeutics, a Boston-based oncology company. Previously, Ms. Gregory was President of KG BioPharma Consulting LLC, a strategic advisory company, where she assisted small and mid-size biopharma companies in a range of corporate strategy and business development activities. Prior to her consulting career, Ms. Gregory was Co-Founder and CEO of Seneb BioSciences, an early-stage, rare disease company that was sold to a mid-sized biotech firm in 2017. Earlier in her career, Ms. Gregory worked in senior roles in pharmaceutical and biotechnology companies, including Purdue Pharma, where she was responsible for business development transactions for new therapeutic indications. Prior to Purdue, Ms. Gregory was at Shire Pharmaceuticals and was responsible for business development transactions for the Neuroscience and Ophthalmology business units. Ms. Gregory received her M.B.A. from Pepperdine University and her B.A. from the University of California, Berkeley. We believe that Ms. Gregory is qualified to serve on our Board due to her extensive executive leadership experience.

Scott Frisch currently serves as Chief Operating Officer and Chief Financial Officer of AARP. AARP is the nation's largest nonprofit, nonpartisan organization focused on issues affecting more than 100 million people ages 50 and older. In this role, he leads AARP's operational and financial matters, including human resources, information technology, real estate and facilities management, as well as data and analytics performance management. Previously, Mr. Frisch served as Managing Director at Bank of America, Chief Financial Officer at Natixis Asset Management Services, and Assistant Controller at Putnam Investments. Mr. Frisch began his career at KPMG in an audit role. He graduated from Villanova University with a bachelor's in accounting. We believe that Mr. Frisch is qualified to serve on our Board due to his extensive finance and operations experience.

*Dr. Gilles Spenlehauer* currently serves as Scientific Director of SDTech Group, a chemical manufacturing company. Prior to this role, he spent 17 years at L'Oreal, the world's biggest cosmetics company, where he served in various leadership roles - most recently as Department Head of Science and Skills of the Future and as Worldwide Head of Advanced Research where he led a team of 700 scientists that contributed to numerous product innovations and were involved in scientific due diligence of acquisitions. Before L'Oreal, Dr. Spenlehauer served as Head of Pharmaceutical Sciences for Pfizer's R&D operations in the UK. He began his career as a Scientist at Rhone-Poulenc Rorer in Paris, France. He graduated with a PhD in Biopharmacy from the Paris-Sud University with a post-doctoral fellowship in peptides from Washington University in St. Louis. We believe that Dr. Spenlehauer is qualified to serve on our Board due to his extensive experience in the cosmetics and life sciences industries.

Patrick Sturgeon currently serves as a Managing Director at Brookline Capital Markets, a division of Arcadia Securities, LLC ("BCAC"), since March 2016 and previously served as our Chief Financial Officer from inception until June 2023, and has nearly two decades of experience with M&A and equity capital market transactions in the healthcare and other sectors. Mr. Sturgeon served as Chief Financial Officer of Brookline Capital Acquisition Corp., a Nasdaq-listed special purpose acquisition company that raised \$50 million in its initial public offering in January 2021 and successfully closed its initial business combination with Apexigen in August 2022. He has also served as a Managing Director at Brookline Capital Markets, a division of Arcadia Securities, LLC ("BCAC") since March 2016. At Brookline, Mr. Sturgeon focuses on mergers and acquisitions, public financing, private capital raising, secondary offerings, and capital markets. On the public financing front, he focuses on SPAC transactions, primarily underwritten initial public offerings and initial business combinations. From July 2013 to February 2016, Mr. Sturgeon served as a Managing Director at Axiom Capital Management. He worked at Freeman & Co. from October 2002 to November 2011, where he focused on mergers and acquisitions in the financial services sector. Mr. Sturgeon received his B.S. in Economics from the University of Massachusetts, Amherst and his M.B.A. in Finance from New York University. We believe that Mr. Sturgeon is qualified to serve on our Board due to his extensive operations, finance, and investment experience.

#### **Executive Officers**

The following table sets forth information regarding our executive officers as of April 24, 2024:

Name	Age	Position
Rajiv Shukla	49	Chairman, Chief Executive Officer and Class III Director
Bryan Cassaday	55	Chief Financial Officer

Rajiv Shukla serves as Carmell's Chief Executive Officer and Chairman. Information on Mr. Shukla is included above under "Directors."

Bryan Cassaday currently serves as Carmell's Chief Financial Officer and previously served as Carmell's Interim Chief Financial Officer from June 2023 to November 2023. Mr. Cassaday has over 30 years of experience serving in strategic financial leadership positions across multiple industries ranging in size from mid-size private-equity portfolio companies to large, publicly traded corporations. Prior to joining Carmell, Mr. Cassaday was the Controller for Nevakar, Inc., a commercial-stage biopharmaceutical with an extensive portfolio of products in the areas of ophthalmics and critical care injectables. In this role, Mr. Cassaday managed the accounting, finance, financial reporting, and planning functions. Prior to Nevakar, Mr. Cassaday was the Chief Financial Officer of Atalian Global Services from 2019 to 2020, Controller and Acting Chief Financial Officer of EMCOR Facilities Services from 2015 to 2019, and Controller of SeeChange Health from 2013 to 2015. From 1993 to 2013, Mr. Cassaday held accounting and finance leadership roles at Nationwide Financial, Prevail InfoWorks, Delaware Investments, and Delphi Financial Group. Mr. Cassaday began his career in Ernst & Young's assurance group, where he was a senior auditor from 1990 to 1993. Mr. Cassaday received his B.S. in Accounting from Drexel University and is a Certified Public Accountant and Chartered Global Management Accountant.

### Family Relationships and Certain Legal Proceedings

There are no family relationships between any of our directors or executive officers. There are no legal proceedings related to any of the directors or executive officers that must be disclosed pursuant to Item 401(f) of Regulation S-K.

#### **Delinquent Section 16(a) Reports**

Section 16(a) of the Exchange Act and regulations of the SEC thereunder require our directors, officers and persons who own more than 10% of our Common Stock, as well as certain affiliates of such persons, to file initial reports of their ownership of our Common Stock and subsequent reports of changes in such ownership with the SEC. Directors, officers and persons owning more than 10% of our Common Stock are required by SEC regulations to furnish us with copies of all Section 16(a) reports they file. Based solely on our review of the copies of such reports and amendments thereto received by us and written representations from these persons that no other reports were required, we believe that during the fiscal year ended December 31, 2023, our directors, officers and owners of more than 10% of our Common Stock complied with all applicable filing requirements, except:

- Randolph W. Hubbell filed one late Form 4 with respect to seven transactions;
- Rajiv Shukla filed three late Form 4s with respect to a total of ten transactions;
- Bryan Cassaday filed one late Form 4 with respect to one transaction;
- Each of David Anderson, Scott Frisch, Kathryn Gregory, Gilles Spenlehauer, and Patrick Sturgeon filed one late Form 4 with respect to two transactions, and
- Each of Gilles Spenlehauer and Scott M. Frisch filed a late Form 3.

## **Code of Ethics**

Our Board has adopted a Code of Ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The full text of our Code of Ethics is available on our website at https://carmellcosmetics.com/pages/investors.

We intend to disclose future amendments to certain provisions of our Code of Ethics, or waivers of certain provisions as they relate to our directors and executive officers, at the same location on our website or in public filings. The information on our website is not intended to form a part of or be incorporated by reference into this proxy statement.

#### **Identifying and Evaluating Director Nominees**

Our nominating and corporate governance committee is responsible for identifying individuals qualified to become members of our Board and ensuring that our Board has the requisite expertise and that its membership consists of persons with sufficiently diverse and independent backgrounds. Our nominating and corporate governance committee, in recommending director candidates for election to

our Board, is expected to consider candidates who, at a minimum, have high standards of personal and professional ethics and integrity, proven achievement and competence in the nominee's field and ability to exercise sound business judgment, skills that are complementary to those of the existing Board, the ability to assist and support management and make significant contributions to the Company's success, and an understanding of the fiduciary responsibilities that are required of a member of the Board and the commitment of time and energy to diligently carry out those responsibilities. In evaluating director candidates, our nominating and corporate governance committee also considers the following criteria:

- The current size and composition of the Board and the needs of the Board and the respective committees thereof;
- Such factors as character, integrity, professionalism, judgment, diversity, independence, skills, education, expertise, business acumen, business experience, length of service, understanding of the Company's business and industry, other commitments and the like (the committee evaluates these factors, among others, and does not assign any particular weight or priority to any of these factors);
- Whether the proposed director candidate has demonstrated notable or significant achievements in business, education or public service and possesses the requisite intelligence, education, experience and dedication to make a significant contribution to the Board and bring a range of skills, diverse perspectives and backgrounds to its deliberations;
- Whether the proposed director candidate, if elected, assists in achieving a mix of board members that represents a diversity of background and experience, inclusive of gender, race, ethnicity, age, gender identity, gender expression and sexual orientation;
   and
- Other factors that the committee considers appropriate.

Other than the foregoing, there are no stated minimum criteria for director nominees or factors required to be considered by our nominating and corporate governance committee in evaluating director nominees, although our nominating and corporate governance committee may also consider such other factors as it may deem, from time to time, to be in our and our stockholders' best interests. Our Board evaluates each individual in the context of the Board as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas. Although the nominating and corporate governance committee may consider whether nominees assist in achieving a mix of board members that represents a diversity of background and experience, we have no formal policy regarding board diversity.

Stockholders may recommend individuals to our nominating and corporate governance committee for consideration as potential director candidates by submitting the names of the recommended individuals, together with appropriate biographical information and background materials, to the nominating and corporate governance committee, c/o Carmell Corporation, 2403 Sidney Street, Suite 300, Pittsburgh, Pennsylvania 15203. In the event there is a vacancy, and assuming that appropriate biographical and background material has been provided on a timely basis, our nominating and corporate governance committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates submitted by others.

## **Audit Committee**

The current members of the audit committee are Messrs. David Anderson, Scott Frisch, and Patrick Sturgeon. Mr. Anderson chairs the audit committee. Under the Nasdaq listing rules and applicable SEC rules, the audit committee is required to have at least three members. The Nasdaq listing rules and Rule 10A-3 of the Exchange Act also require that the audit committee of a listed company be composed solely of independent directors for audit committee purposes. Each member of our audit committee qualifies as an independent director for audit committee purposes under applicable rules. Each of David Anderson, Scott Frisch, and Patrick Sturgeon is financially literate, and David Anderson qualifies as an "audit committee financial expert" as defined in applicable SEC rules. During the fiscal year ended December 31, 2023, the audit committee met three times. The Board adopted a written charter for the audit committee, which sets out the following functions and responsibilities of the audit committee. The audit committee charter is located at https://carmellcosmetics.com/pages/investors.

The audit committee's responsibilities include to:

- oversee the accounting and financial reporting processes of the Company and the audits of the Company's financial statements;
- oversee the Company's compliance with legal and regulatory requirements;
- oversee the performance of the Company's internal audit function;
- monitor compliance on a quarterly basis with the terms of our initial public offering;
- review and approve all payments made to our existing stockholders, executive officers or directors and their respective affiliates:
- take, or recommend that the Board take, appropriate action to oversee the qualifications, independence and performance of the Company's independent auditors;

- prepare the report required by the rules of the SEC to be included in the Company's annual proxy statement;
- appoint, retain, terminate, and determine the compensation of, and assess the independence of, our independent auditors;
- pre-approve audit and permissible non-audit services, and the terms of such services, to be provided by our independent auditors; and
- conduct an appropriate review of all related party transactions for potential conflict of interest situations on an ongoing basis and the approval of the audit committee shall be required for all such transactions.

## Item 11. Executive Compensation.

#### **Executive Compensation**

Our named executive officers, or NEOs, determined pursuant to Item 402 of Regulation S-K for the year ended December 31, 2023, consist of the following:

- Rajiv Shukla, our Chairman and Chief Executive Officer;
- Bryan Cassaday, our Chief Financial Officer;
- Randolph Hubbell, our former Chief Executive Officer and President;
- Donna Godward, our former Chief Quality Officer; and
- James Hart, our former Chief Medical Officer.

# 2023 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by and paid to our NEOs for services rendered to us in all capacities for the year ended December 31, 2023. In addition to serving as our Chief Executive Officer, Mr. Shukla serves as the Chairman of our Board but receives no additional compensation for his service in this role.

Name and Principal Position	Year	Salary (\$)	Option Awards (\$) <sup>(7)</sup>	Total (\$)
Rajiv Shukla Chairman and Chief Executive Officer	2023	146,094 (1)	911,441	1,057,535
Bryan Cassaday Chief Financial Officer	2023	130,852 (2)	214,508	345,360
Randolph Hubbell Former Chief Executive Officer	2023 2022	334,663 <sup>(3)</sup> 363,000 <sup>(4)</sup>		334,663 363,000
Donna Godward Former Chief Quality Officer	2023 2022	120,000 <sup>(5)</sup> 170,000 <sup>(6)</sup>	40,000	210,000
James Hart Former Chief Medical Officer	2023 2022	120,000 <sup>(5)</sup> 170,000 <sup>(6)</sup>	40,000	210,000

- (1) Mr. Shukla became our Chairman in July 2023 and our Chief Executive Officer in September 2023. The base salary amounts presented are prorated based on the 170 days in fiscal 2023 during which he was employed with us. Mr. Shukla's annual compensation is payable as follows: 75% in cash in accordance with the Company's standard payroll schedule and 25% payable quarterly in arrears in the form of fully vested shares of Common Stock based on the average daily price of the Common Stock for the quarter immediately preceding and ending on the date of grant. Please see the "Narrative Disclosure to the Summary Compensation Table" below for additional details regarding Mr. Shukla's compensation arrangement.
- (2) Mr. Cassaday was appointed as Interim Chief Financial Officer in June 2023. The base salary amounts presented are prorated based on the 190 days in fiscal 2023 during which he was employed with us.
- (3) Effective as of August 31, 2023, Mr. Hubbell resigned as the Company's Chief Executive Officer and President and as a member of the Board. The base salary amounts presented are prorated based on the 243 days in fiscal 2023 during which he was employed with us. On October 25, 2023, the Company and Mr. Hubbell entered into a separation agreement with respect to his compensation, providing for a cash payment of \$450,000 related to unpaid salary for 2022 and portions of 2023, less applicable tax withholding, and monthly cash severance payments equal to an aggregate of \$410,000 payable over a 12-month period. The separation agreement contained customary covenants and a release of claims and an acknowledgment by the Company and Mr. Hubbell as to the number of his vested stock options and the deadline for the exercise thereof. The deadline for such exercise has passed without the exercise of any such options.
- (4) This amount represents the base salary earned by Mr. Hubbell for service during 2022. A portion of that base salary was not paid during 2022 due to cash flow constraints. The following base salary for Mr. Hubbell was accrued but unpaid as of December 31, 2022: \$299,337. Carmell paid such amounts in connection with Mr. Hubbell's resignation effective as of August 31, 2023.

- (5) Effective as of August 31, 2023, Ms. Godward and Dr. Hart's consulting agreements were terminated. The amounts presented are prorated based on the 243 days in fiscal 2023 during which they were employed with us. In January 2024, the Company entered into a separation agreement with each of Ms. Godward and Dr. Hart with respect to their unpaid compensation, providing for a cash payment of \$210,000 each related to unpaid salary for portions of 2021, 2022 and 2023 during which they were employed by Carmell. The separation agreement contains customary covenants and release of claims. In addition, the deadline for the exercise of each of Ms. Godward and Dr. Hart's vested stock options passed during 2023 without the exercise of any such options.
- (6) This amount represents amounts earned by Ms. Godward and Dr. Hart for service during 2022. A portion of that base salary was not paid during 2022 due to cash flow constraints. The following consulting fees were accrued but unpaid for each of for Ms. Godward and Dr. Hart, respectively as of December 31, 2022 was \$95,000. In January 2024, Carmell paid such amounts in connection with Ms. Godward and Dr. Harts' resignations effective as of August 31, 2023.
- (7) Amounts shown in this column represent the aggregate grant date fair value of the stock options awarded to the NEOs in fiscal year 2022 and 2023. These values have been determined in accordance with FASB ASC Topic 718 using a Black-Scholes model. For a discussion of the assumptions and methodologies used to calculate the amounts referred to above, please see the discussion of option awards contained in Note 2-Summary of Significant Accounting Policies to Carmell's financial statements included in its Original Form 10-K. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by the NEOs upon the exercise of the stock options.

## Narrative Disclosure to the Summary Compensation Table

## Elements of Compensation

The compensation of our NEOs generally consists of base salary, annual cash bonus opportunities, long-term incentive compensation in the form of equity awards and other benefits, as described below.

#### 2023 Base Salaries

The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, responsibilities, and contributions. Each NEO's initial base compensation was specified in their employment agreement, as described below, and is reviewed (and, if applicable, adjusted) from time to time by our Board's compensation committee (the "Compensation Committee"). For 2023, the NEOs annualized base compensation was equal to \$425,000 for Rajiv Shukla and \$245,000 for Bryan Cassaday, \$410,000 for Randy Hubbell, \$180,000 for Donna Godward, and \$180,000 for James Hart. The amount for Mr. Hubbell reflects a 13% increase to his annual base salary rate in effect at the end of 2022 in order to align with market pay levels for executives with similar duties and responsibilities.

#### Annual Performance-Based Bonus

Our NEOs are eligible for a performance-based cash bonus opportunity expressed as a percentage of their respective annual base salary that can be achieved at a target level by meeting predetermined corporate and individual performance objectives. Mr. Shukla and Mr. Cassaday each have the opportunity to earn an annual bonus with a target of 50% and 20%, respectively, of their total base compensation in effect as of the end of the applicable year. The actual amount of such annual bonus paid is solely determined by our Compensation Committee based on the satisfactory achievement of corporate and/or personal objectives set by the committee. Our Compensation Committee determined not to pay the NEOs any performance-based cash bonuses for 2023 in order to conserve cash.

#### Long-Term Equity Awards

Carmell's equity-based incentive awards are designed to align its interests and the interests of its stockholders with those of its employees and consultants, including the NEOs. The Board or Compensation Committee approves equity-based grants. Mr. Shukla and Mr. Cassaday received options to purchase shares Common Stock in 2023. Such options vest over four years, with 25% of the option vesting on the one-year anniversary of the grant, with the remaining options vesting thereafter in equal monthly installments over a period of thirty-six (36) months. Vesting ceases immediately upon termination of employment or service for any reason, and any portion of this option that has not vested on or prior to the date of such termination is forfeited on such date. See "Outstanding Equity Awards at Fiscal Year-End" for more information regarding equity awards made in 2023 to the NEOs.

## Employment Agreements with Our NEOs

#### Rajiv Shukla

In December 2023, we entered into an employment agreement with Mr. Shukla. Pursuant to the agreement, Mr. Shukla will receive total annual compensation of \$425,000, which may be adjusted from time to time by the Compensation Committee. Mr. Shukla's annual compensation is payable as follows: 75% in cash in accordance with the Company's standard payroll schedule and 25% payable quarterly in arrears in the form of fully vested shares of Common Stock based on the average daily price of the Common Stock for the quarter

immediately preceding and ending on the date of grant. Mr. Shukla is also eligible to participate in our employee benefit plans that are generally available to other employees.

In addition, Mr. Shukla has the opportunity to earn an annual bonus with a target of 50% of his total annual compensation in effect at the end of the applicable year. The actual amount of such annual bonus paid is solely determined by our Compensation Committee based on the satisfactory achievement of corporate and/or personal objectives set by the committee. Such annual bonus, if any, will be paid as follows: 75% in cash and 25% in the form of fully vested shares of Common Stock based on the average daily price of the Common Stock for the quarter immediately preceding and ending on the date of grant.

The agreement also provides that Mr. Shukla is entitled to certain severance payments in connection with a termination of employment by Carmell without Cause (as defined in his employment agreement) or for Good Reason (as defined in his employment agreement) (each such termination, a "Qualifying Termination"), subject to his timely execution of a release of claims. If a Qualifying Termination occurs within three months prior or 18 months following a Change in Control (defined as a "Protected Period" in this employment agreement), Mr. Shukla would be entitled to receive monthly cash severance payments equal to one-twelfth of his annual salary for an 18-month period. If a Qualifying Termination occurs other than during the Protected Period, then Mr. Shukla would be entitled to receive such monthly cash severance payments for a 12-month period. In the event of a Qualifying Termination, Mr. Shukla would also be entitled to receive his compensation, including any bonus award already accrued, payment of the applicable monthly premium payable for COBRA continuation coverage for 12 months to the extent such premium exceeds the amount charged to active similarly-situated employees of the Company for the same coverage, and a Pro Rata Bonus (as defined in his employment agreement) based upon actual performance and pro-rated for the portion of the bonus period prior to termination. In the event that such a Qualifying Termination occurs during a Protected Period, Mr. Shukla would be entitled to receive his bonus at the target level, as well as accelerated vesting in full of all time-based equity awards, as more fully described in his employment agreement.

In connection with a termination of his employment for any other reason, Mr. Shukla would only be entitled to receive his compensation that has already accrued, provided that he would only be entitled to receive his accrued and unpaid bonus in connection with termination for death or disability.

Mr. Shukla's employment agreement also required him to enter into a restrictive covenants agreement that contains customary covenants, including with respect to certain confidentiality, non-competition and non-solicitation obligations.

#### Bryan Cassaday

In 2023, we entered into an employment agreement with Mr. Cassaday. Pursuant to the agreement, Mr. Cassaday will receive total annual compensation of \$245,000, which may be adjusted from time to time by the Compensation Committee. In addition, Mr. Cassaday has the opportunity to earn an annual bonus with a target of 20% of his total annual compensation in effect at the end of the applicable year and is eligible to participate in our employee benefit plans that are generally available to other employees. The actual amount of such annual bonus paid is solely determined by our Compensation Committee based on the satisfactory achievement of corporate and/or personal objectives set by the committee.

Under Mr. Cassaday's employment agreement, he is entitled to certain severance payments in connection with a termination of employment by the Company without Cause (as defined in his employment agreement) or by Mr. Cassaday for Good Reason (as defined in his employment agreement) (each such termination, a "Qualifying Termination"), subject to his timely execution of a release of claims. If a Qualifying Termination occurs within three months prior or 18 months following a Change in Control (defined as a "Protected Period" in his employment agreement), Mr. Cassaday would be entitled to receive monthly cash severance payments equal to one-twelfth of his annual salary for a six-month period. If a Qualifying Termination occurs other than during the Protected Period, then Mr. Cassaday would be entitled to receive such monthly cash severance payments for a nine-month period. In the event of a Qualifying Termination, Mr. Cassaday would also be entitled to receive his compensation, including any bonus award already accrued, payment of the applicable monthly premium payable for COBRA continuation coverage for six months to the extent such premium exceeds the monthly amount charged to active similarly-situated employees of the Company for the same coverage, and a Pro Rata Bonus (as defined in his employment agreement) based upon actual performance and pro-rated for the portion of the bonus period prior to termination. In the event that such a Qualifying Termination occurs during a Protected Period, Mr. Cassaday would be entitled to receive his bonus at the target level, as well as accelerated vesting in full of all time-based equity awards, as more fully described in the Employment Agreement.

In connection with a termination of his employment for any other reason, Mr. Cassaday would only be entitled to receive his compensation that has already accrued, provided that he would only be entitled to receive his accrued and unpaid bonus in connection with termination for death or disability.

Mr. Cassaday's employment agreement also required him to enter into a restrictive covenants agreement that contains customary covenants, including with respect to certain confidentiality, non-competition and non-solicitation obligations.

## Randolph Hubbell

Effective as of the closing of the Business Combination, Carmell entered into a new employment agreement with Mr. Hubbell, replacing the prior employment agreement, dated February 17, 2016, by and between Mr. Hubbell and the Company. Prior to Mr. Hubbell's resignation in August 2023, the new employment agreement provided for Mr. Hubbell's at-will employment and set forth an annual base salary of \$410,000, a target annual bonus opportunity at 50% of base salary, and eligibility to participate in our employee benefit plans that are generally available to other employees. In addition, Mr. Hubbell's new employment agreement provided that he may receive equity awards at time and on terms described by the compensation committee in its discretion.

Mr. Hubbell's new employment agreement also provided for severance benefits upon the termination of his employment. Based on the terms of the new employment agreement, Mr. Hubbell, upon his resignation in August 2023, would have been entitled to twelve (12) months' continuation of his base salary, which is being paid out monthly through September 2024.

Effective as of August 31, 2023, Mr. Hubbell resigned as the Company's Chief Executive Officer and President and as a member of the Board. On October 25, 2023, the Company and Mr. Hubbell entered into a separation agreement with respect to his compensation, providing for a lump sum cash payment of \$450,000, less applicable tax withholding and monthly cash severance payments equal to an aggregate of \$410,000 payable over a 12-month period. The separation agreement contains customary covenants and a release of claims and an acknowledgment by the Company and Mr. Hubbell as to the number of his vested stock options and the deadline for the exercise thereof. The deadline for such exercise has passed without the exercise of any such options.

#### Donna Godward

In December 2020, Carmell entered into an amended and restated consulting agreement with Ms. Godward to serve as Carmell's Chief Quality Officer, which set forth her monthly fee of \$15,000 for her consulting services as well as reimbursement of reasonable out-of-pocket expenses. Ms. Godward's consulting agreement also provided for the continued vesting of previously granted option awards in accordance with terms of each grant agreement (and in accordance with the 2009 Plan). Her agreement allowed for immediate termination by either party.

In September 2022, Carmell entered into a new consulting agreement with Ms. Godward. The new consulting agreement replaced her prior consulting agreement described above. The new consulting agreement generally provides for the same terms as Ms. Godward's prior consulting agreement, such as the same monthly fee of \$15,000 for approximately twenty (20) hours per week of services. The new consulting agreement provides for termination by either party with sixty (60) days advanced written notice. In the event of her termination, Carmell will pay Ms. Godward for all fees incurred through the date of termination. The new consulting agreement also includes restrictive covenant provisions, such as customary prohibitions against competition with us and solicitation of our customers and employees, both during her term and for twelve (12) months following any termination.

Ms. Godward's consulting contract was terminated effective August 31, 2023. In January 2024, the Company and Ms. Godward entered into a separation agreement with respect to her unpaid compensation, providing for a cash payment of \$210,000 related to unpaid salary for portions of 2021, 2022 and 2023 during which she was employed by Carmell. The separation agreement contains customary covenants and release of claims. In addition, the deadline for the exercise of Ms. Godward's vested stock options passed during 2023 without the exercise of any such options.

#### Dr. James Hart

In December 2020, Carmell entered into an amended and restated consulting agreement with Dr. Hart to serve as Carmell's Chief Medical Officer, which set forth his monthly fee of \$15,000 for his consulting services as well as reimbursement of reasonable out-of-pocket expenses. Dr. Hart's consulting agreement also provided for the continued vesting of previously granted option awards in accordance with terms of each grant agreement (and in accordance with the 2009 Plan). His agreement allowed for immediate termination by either party.

In September 2022, Carmell entered into a new consulting agreement with Dr. Hart. The new consulting agreement replaced his prior consulting agreement described above. The new consulting agreement generally provides for the same material terms as Dr. Hart's prior consulting agreement, such as the same monthly fee of \$15,000 for approximately twenty (20) hours per week of services. The new consulting agreement provides for termination by either party with sixty (60) days advanced written notice. In the event of his termination, Carmell will pay Dr. Hart for all fees incurred through the date of termination. The new consulting agreement also includes restrictive covenant provisions, such as customary prohibitions against competition with us and solicitation of our customers and employees, both during his term and for twelve (12) months following any termination.

Dr. Hart's consulting contract was terminated effective August 31, 2023. In January 2024, the Company and Dr. Hart entered into a separation agreement with respect to his unpaid compensation, providing for a cash payment of \$210,000 related to unpaid salary for portions of 2021, 2022 and 2023 during which he was employed by Carmell. The separation agreement contains customary covenants and release of claims. In addition, the deadline for the exercise of Dr. Hart's vested stock options passed during 2023 without the exercise of any such options.

#### **Business Combination**

Upon the closing of the Business Combination, each outstanding option to purchase common stock of the pre-combination operating company was converted into an option to purchase a number of shares of Common Stock equal to the number of shares of pre-combination operating company common stock subject to such option multiplied by the applicable exchange ratio in the Business Combination.

## Restrictive Covenant Agreement

Mr. Shukla, Mr. Cassaday, and Mr. Hubbell also entered into Restrictive Covenant Agreements, which include customary prohibitions against competition with Carmell and solicitation of Carmell's customers and employees, both during employment and for two (2) years following any cessation of employment. The Restrictive Covenant Agreement also includes standard provisions relating to the Company's intellectual property rights and prohibiting the executive from disclosing confidential information. Mr. Shukla, Mr. Cassaday, and Mr. Hubbell's employment agreements are conditioned on continued compliance with his Restrictive Covenant Agreement.

## Outstanding Equity Awards at 2023 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our NEOs as of December 31, 2023.

		Number of Securities Underlying						
		Unexercised						
	Unexercised Options Option							
	Vesting Start	Options	Unexercisable	Option Exercise	Option Exercise	Expiration		
Name	Date	Exercisable (#)	(#)	Price (\$/share)	Price (\$/share)	Date		
Rajiv Shukla	10/09/2023	_	426,878	2.88	2.88	10/09/1933		
Bryan Cassaday	07/26/2023	_	100,000	3.00	3.00	07/26/1933		
Randolph Hubbell	_	_	_	_	_	_		
Donna Godward	_	_	_	_	_	_		
James Hart	_	_	_	_	_	_		

<sup>(1)</sup> Options granted to Mr. Shukla and Mr. Cassaday in 2023 vest over four years, with 25% of the option vesting on the one-year anniversary of the grant, with the remaining options vesting thereafter in equal monthly installments over a period of thirty-six (36) months.

#### 2023 Long-Term Incentive Plan

In July 2023, the stockholders of the Company approved the 2023 Long-Term Incentive Plan (the "2023 Plan"), which replaced the Amended and Restated 2009 Stock Incentive Plan of Legacy Carmell (the "2009 Plan"). No new awards are being made under the 2009 Plan. Under the 2023 Plan, the Board may grant awards of stock options, stock appreciation rights, restricted stock, restricted stock units or other stock-based awards to employees and other recipients as determined by the Board. The exercise price per share for an option granted to employees owning stock representing more than 10% of the Company at the time of the grant cannot be less than 110% of the fair market value. Incentive and non-qualified stock options granted to all persons shall be granted at a price no less than 100% of the fair market value and any price determined by the Board. Options expire no more than ten years after the date of the grant. Incentive stock options to employees owning more than 10% of the Company expire no more than five years after the date of grant. The vesting of stock options is determined by the Board. Generally, the options vest over a four-year period at a rate of 25% one year following the date of grant, with the remaining shares vesting equally on a monthly basis over the subsequent thirty-six months.

The maximum number of shares that may be issued under the 2023 Plan is the sum of: (i) 1,046,408, (ii) an annual increase on January 1, 2024 and each anniversary of such date prior to the termination of the 2023 Plan, equal to the lesser of (a) 4% of the outstanding shares of our Common Stock determined on a fully diluted basis as of the immediately preceding year-end and (b) such smaller number of shares as determined by the Board or compensation committee, and (iii) the shares of Common Stock subject to 2009 Plan awards, to the extent those shares are added into the 2023 Plan by operation of the recycling provisions described below.

The maximum number of shares of Common Stock that may be issued under the 2023 Plan through incentive stock options is 1,046,408, provided that this limit will automatically increase on January 1 of each year for a period of not more than ten years, commencing on January 1, 2024 and ending on (and including) January 1, 2032, by an amount equal to the lesser of 1,500,000 shares or the number of shares added to the share pool as of such January 1, as described in clause (ii) of the preceding sentence. The following shares will be added (or added back) to the shares available for issuance under the 2023 Plan:

- Shares subject to 2009 Plan or 2023 Plan awards that expire, terminate or are canceled or forfeited for any reason after the effectiveness of the 2023 Plan;
- Shares that after the effectiveness of the 2023 Plan are withheld to satisfy the exercise price of an option issued under the 2009 Plan or 2023 Plan;
- Shares that after the effectiveness of the 2023 Plan are withheld to satisfy tax withholding obligations related to any award under the 2009 Plan or 2023 Plan; and
- Shares that after the effectiveness of the 2023 Plan are subject to a stock appreciation right that are not delivered on exercise or settlement.

However, the total number of shares underlying 2009 Plan awards that may be recycled into the 2023 Plan pursuant to the above-described rules will not exceed the number of shares underlying 2009 Plan awards as of the effective date of the 2023 Plan (as adjusted to reflect the Business Combination). Shares of Common Stock issued through the assumption or substitution of awards in connection with a future acquisition of another entity will not reduce the shares available for issuance under the 2023 Plan.

Under both the 2023 Plan and 2009 Plan, the Board and/or the Compensation Committee, at its discretion, may take such actions as it deems appropriate with respect to outstanding awards under the 2023 Plan and the 2009 Plan upon or in anticipation of a change in control (which includes certain merger, asset or stock transactions, certain changes in the Board composition and any other event deemed by the Board to constitute a change in control). Such actions may include (among other things) the acceleration of award vesting, the substitution of awards, the cancellation of unexercised or unvested awards and the redemption or cashout of awards. In the discretion of the Compensation Committee, any cash or other substitute consideration payable upon redemption or cashout of an award may be subjected to the same vesting terms that applied to the original award or earn-out, escrow, holdback or similar arrangements comparable to those applicable to stockholders in connection with the change in control.

#### **Indemnification Agreements**

We entered into indemnification agreements with each of our directors and executive officers. Each indemnification agreement provides for indemnification and advancements by us of certain expenses and costs relating to claims, suits or proceedings arising from his or her service to us or, at our request, service to other entities as officers or directors to the maximum extent permitted by applicable law.

#### 401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible employees, including our NEOs, with an opportunity to save for retirement on a tax-advantaged basis. Plan participants are able to defer eligible compensation subject to applicable annual limits established by the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder. Employees' pre-tax or Roth contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions. Carmell discretionary contributions to the plan are determined annually by the Board. No discretionary contributions were made to the 401(k) plan during the years ended December 31, 2023. Our 401(k) plan is intended to be qualified under Section 401(a) of the Code with our 401(k) plan's related trust intended to be tax-exempt under Section 501(a) of the Code.

#### **Health and Welfare Benefits**

Our NEOs are eligible to participate in our health and welfare plans that are generally available to all of our employees, including medical, dental and vision benefits, short-term and long-term disability insurance and life insurance. In fiscal 2023, we did not provide our NEOs with any material perquisites.

#### **Director Compensation**

## Non-Employee Director Compensation Policy

Directors who are not employees of the Company are eligible to receive compensation pursuant to our non-employee director compensation policy. Mr. Shukla, our Chairman and Chief Executive Officer, does not receive any compensation from us for his services on our Board.

Following the Business Combination on July 14, 2023, the Board adopted a non-employee director compensation policy retroactive to the date of the Business Combination, under which our non-employee directors are entitled to an annual retainer of \$50,000, which is paid in quarterly installments.

Our Board may, in its discretion, permit a non-employee director to elect to receive any portion of the annual cash retainer in the form of fully vested shares of Common Stock in lieu of cash. In addition, following the Business Combination, our non-employee directors receive one-time option grants, which are intended to provide equity compensation for board service for four years following the grant. All equity awards granted under the non-employee director compensation policy following the closing of the Business Combination are granted under, and subject to the terms of, our 2023 Plan.

We also reimburse non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending Board and committee meetings.

Prior to the Business Combination, we did not have a formal policy to provide any cash or equity compensation to our non-employee directors for their service on our Board or Board committees.

## Oversight of Non-Employee Director Compensation

Our non-employee director compensation is overseen by the compensation committee, which makes recommendations to our Board on the appropriate structure for our non-employee director compensation program and the appropriate amount of compensation to offer to our non-employee directors. Our Board is responsible for final approval of our non-employee director compensation program and the compensation paid to our non-employee directors.

## 2023 Director Compensation Table

The following table presents the total compensation for each person who served as a non-employee director of our Board during fiscal year 2023. Each of Mr. Shukla, our Chairman of the Board and Chief Executive Officer, and Mr. Hubbell, our former Chief Executive Officer, President, and director, did not receive any compensation from us for his service on the Board during the fiscal year ended December 31, 2023. Mr. Shukla's and Mr. Hubbell's compensation during the fiscal year 2023 for their service as executive officers of the Company is set forth above in "Executive Compensation—2023 Summary Compensation Table."

	Fees Earned or Paid in Cash	Option Awards	Total
Name	(\$)	<b>(\$)</b> <sup>(3)</sup>	(\$)
David Anderson	25,000	_	25,000
Scott Frisch (1)	12,500	155,394	167,894
Kathryn Gregory	25,000	_	25,000
Gilles Spenlehauer (1)	12,500	155,394	167,894
Patrick Sturgeon	25,000	155,394	180,394
Rich Upton	25,000	_	25,000
Randolph Hubbell (2)	<u> </u>	_	_
Steve Bariahtaris	_	_	_
Jaime Garza	<u> </u>	_	_
William Newlin	_	_	_

- (1) Scott Frisch and Gilles Spenlehauer were appointed as directors of the Company effective as of November 15, 2023. Each Mr. Frisch and Mr. Spenlehauer received pro rated non-employee director compensation for the quarter in which they joined the Board.
- (2) Each of William Newlin, Steve Bariahtaris, Jaime Garza and Randolph Hubbell resigned from their respective position as a director of the Company effective as of August 31, 2023, and did not receive compensation for their service as a director of the Company prior to such resignation.
- (3) As of December 31, 2023, our former non-employee directors held no outstanding stock awards and our current non-employee directors held unexercised stock options as follows:

**Number of Shares** of Common Stock Underlying Unexercised Name (1) **Options** David Anderson 76,878 Scott Frisch 76,878 Kathryn Gregory 76,878 Gilles Spenlehauer 76,878 Patrick Sturgeon 76,878 Rich Upton 76,878

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

## Equity Compensation Plan Information at 2023 Fiscal Year End

The following table sets forth information with respect to securities authorized for issuance under our equity compensation plans as of December 31, 2023:

			(c) Number of
	(a)		Securities
	Number of		Available for
	Securities	(b)	Future Issuance
	to be Issued	Weighted- Average	under Equity Compensation
	upon Exercise of	Exercise Price of	Plans (excluding
	Outstanding	Outstanding	securities reflected
Plan Category	Options (2)	Options <sup>(3)</sup>	in column (a) <sup>(4)</sup>
Equity Compensation Plans Approved by Security Holders (1)	886,936	\$2.99	1,591,933
Equity Compensation Plans Not Approved by Security Holders (5)	472,829	\$2.16	
Total	1,689,765	\$2.72	1,591,933

<sup>(1)</sup> Consists of the 2023 Plan. For more information regarding the 2023 Plan, see Note 12 to the consolidated financial statements in the Original Form 10-K.

## Security Ownership of Certain Beneficial Owners, Executive Officers and Directors

The following table sets forth certain information known to us regarding the beneficial ownership of Common Stock as of April 24, 2024 for each of our NEOs, directors, all executive officers and directors as a group and each person known by us to be the beneficial owner of more than 5% of the Common Stock. Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security. Under those rules, beneficial ownership includes securities that the individual or entity has the right to acquire, such as through the exercise of warrants or stock options or the vesting of restricted stock units, within 60 days of April 24, 2024. Shares subject to warrants or options that are currently exercisable or exercisable within 60 days of April 24, 2024 or subject to restricted stock units that vest within 60 days of April 24, 2024 are considered outstanding and beneficially owned by the person holding such warrants, options or restricted stock units for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as noted by footnote, and subject to community property laws where applicable, based on the information provided to us, we believe that the persons and entities named in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them. Unless otherwise noted, the business address of each of our directors and executive officers is c/o Carmell Corporation, 2403 Sidney Street, Suite 300, Pittsburgh, Pennsylvania 15203. The percentage of beneficial ownership of our shares of Common Stock is calculated based on 20,730,559 shares of Common Stock outstanding as of April 24, 2024.

<sup>(1)</sup> The outstanding stock awards held by Mr. Shukla as of December 31, 2023 are reported under the table under "Outstanding Equity Awards at 2023 Fiscal Year-End" above.

<sup>(2)</sup> Consists of outstanding stock options, each exercisable for one share of Common Stock.

<sup>(3)</sup> Represents the weighted average exercise price of outstanding stock options.

<sup>(4)</sup> Consists of shares of Common Stock that were available for future issuance under the 2023 Plan

<sup>(5)</sup> Consists of the 2009 Plan. As of the effective date of the 2023 Plan, no new awards were made under the 2009 Plan. For more information regarding the 2009 Plan, see Note 12 to the consolidated financial statements in the Original Form 10-K.

	Number of	
Name and Address of Beneficial Owners	Shares	% of Class
Directors and Executive Officers		
Rajiv Shukla (1)	4,298,434	21%
David Anderson (2)	73,551	*
Scott Frisch	5,381	*
Kathryn Gregory (3)	63,150	*
Gilles Spenlehauer	5,381	*
Patrick Sturgeon	6,727	*
Rich Upton (4) (5)	1,391,873	7%
Bryan Cassaday	1,940	*
Randolph W. Hubbell	<u> </u>	_
Donna Godward	37,296	*
James Hart	37,307	*
All Directors and Executive Officers as a Group (8 Individuals)	5,844,497	28%
Five Percent Holders		
Meteora Capital, LLC (6)	1,743,023	8%
Newlin Investment Company 1, LLC (7)	1,249,062	6%

<sup>\*</sup> Less than 1%

- (1) Includes 4,249,908 shares of Common Stock directly owned by AHAC Sponsor III LLC. Mr. Shukla, Chairman and Chief Executive Officer, is the managing member of AHAC Sponsor III LLC. By virtue of this relationship, Mr. Shukla may be deemed to share voting and investment power with respect to the shares held of record by AHAC Sponsor III LLC. Mr. Shukla disclaims any such beneficial ownership except to the extent of his pecuniary interest.
- (2) Includes 66,824 shares of Common Stock that may be acquired by Mr. Anderson pursuant to the exercise of stock options within 60 days of April 24, 2024.
- (3) Includes 56,423 shares of Common Stock that may be acquired by Ms. Gregory pursuant to the exercise of stock options within 60 days of April 24, 2024.
- (4) Includes 52,854 shares of Common Stock that may be acquired by Mr. Upton pursuant to the exercise of stock options within 60 days of April 24, 2024.
- (5) Includes 1,230,484 shares of Common Stock directly owned by Carmell Series of Harbor Light Direct Investment, LLC and 108,535 shares of Common Stock directly owned by Harbor Light Direct Investment, LP. The business address of the entities listed above is 91 Court Street, Keene, NH 03431. Mr. Upton, a member of the Board, is General Partner at Harbor Light Capital Partners, which is affiliated with the entities listed above. By virtue of this relationship, Mr. Upton may be deemed to share voting and investment power with respect to the shares held of record by the entities listed above. Mr. Upton disclaims any such beneficial ownership except to the extent of his pecuniary interest.
- (6) Includes 1,743,023 shares of Common Stock directly owned by Meteora Capital, LLC and certain funds and managed accounts to which Meteora Capital, LLC serves as investment manager. The business address of the Meteora Capital, LLC is 1200 N. Federal Hwy, #200, Boca Raton, FL 33432. Vic Mittal, who serves as the Managing Member of Meteora Capital, LLC, may be deemed to share voting and investment power with respect to the shares held of record by Meteora Capital, LLC.
- (7) Includes 1,249,062 shares of Common Stock directly owned by Newlin Investment Company 1, LLC. The business address of the Newlin Investment Company 1, LLC is 428 Beaver Street, 2nd Floor, Sewickley, PA 15143. Mr. Newlin, a former member of the Board, is Chairman and Founder of Newlin Investment Company, L.P. By virtue of this relationship, Mr. Newlin may be deemed to share voting and investment power with respect to the shares held of record by Newlin Investment Company, L.P. Mr. Newlin disclaims any such beneficial ownership except to the extent of his pecuniary interest.

## Change in Control

We are unaware of any contract or other arrangement the operation of which may at a subsequent date result in a change of control of the Company.

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

Other than compensation and employment-related arrangements, including those described under the sections entitled "*Executive Compensation*" and "*Director Compensation*" in Item 11 of this Amendment No. 1, and the transactions described below, since January 1, 2022, there has not been, and there is not currently proposed, any transaction or series of similar transactions to which:

- we were, or will be, a participant;
- the amount involved exceeded or will exceed \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years; and

• in which any director, executive officer, holder of 5% or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons had, or will have, a direct or indirect material interest.

## Investor Rights and Lock-up Agreement

On July 14, 2023, certain of the Carmell stockholders and investors entered into an agreement pursuant to which the parties (i) agreed not to effect any sale or distribution of any shares held by any of them during the agreed upon lock-up periods, (ii) were granted certain registration rights with respect to certain shares of securities held by them, and (iii) provided for certain provisions related to the Board, in each case, on the terms and subject to the conditions therein. Pursuant to this Investor Rights Agreement, AHAC Sponsor III LLC, a Delaware limited liability company, was granted certain rights to designate individuals for election to the Board.

#### Forward Purchase Agreement

On July 9, 2023, the Company (formerly known as Alpha Healthcare Acquisition Corp. III) and each of Meteora Special Opportunity Fund I, LP ("MSOF"), Meteora Capital Partners, LP ("MCP") and Meteora Select Trading Opportunities Master, LP ("MSTO") (with MCP, MSOF, and MSTO collectively as "Seller" or "Meteora") entered into a forward purchase agreement (the "Forward Purchase Agreement") for an OTC Equity Prepaid Forward Transaction. Pursuant to the terms of the Forward Purchase Agreement, at the closing of the Business Combination, the Sellers purchased directly from the redeeming shareholders of the Company 1,705,959 shares of Common Stock ("Recycled Shares") at \$10.279, which is the price equal to the redemption price at which holders of Common Stock were permitted to redeem their shares in connection with the Business Combination pursuant to Section 9.2(a) of the Company's Second Amended and Restated Certificate of Incorporation (such price, the "Initial Price").

In accordance with the terms of the Forward Purchase Agreement, the Sellers were paid an aggregate cash amount (the "Prepayment Amount") equal to (x) the product of (i) the Recycled Shares and (ii) the Initial Price, or \$17,535,632. The settlement date will be the earliest to occur of (a) the first anniversary of the Closing Date, (b) after the occurrence of (x) a Delisting Event or (y) a Registration Failure upon the date specified by Seller in a written notice delivered to Counterparty at Seller's discretion (which settlement date shall not be earlier than the date of such notice). The transaction will be settled via physical settlement. Any Shares not sold in accordance with the early termination provisions described below will incur a \$0.50 per share termination fee payable by the Combined Company to the Seller at settlement.

From time to time and on any date following the Business Combination (any such date, an "OET Date") and subject to the terms and conditions below, Seller may, in its absolute discretion, and so long as the daily volume-weighted average price ("VWAP Price") of the Shares is equal to or exceeds the Reset Price, terminate the transaction in whole or in part by providing written notice (an "OET Notice") in accordance with the terms of the Forward Purchase Agreement. The effect of an OET Notice given shall be to reduce the Number of Shares by the number of Terminated Shares specified in such OET Notice with effect as of the related OET Date. As of each OET Date, Counterparty shall be entitled to an amount from Seller, and the Seller shall pay to Counterparty an amount, equal to the product of (x) the number of Terminated Shares multiplied by (y) the Initial Price in respect of such OET Date.

The Reset Price is initially \$11.50 and subject to a \$11.50 floor (the "Reset Price Floor"). The Reset Price shall be adjusted on the first scheduled trading day of every week commencing with the first week following the seventh day after the closing of the Business Combination to be the lowest of (a) the then-current Reset Price and (b) the VWAP Price of the shares of the Counterparty's common stock of the prior week; provided that the Reset Price shall be no lower than \$11.50.

On July 9, 2023, in connection with the Forward Purchase Agreement, the Seller entered into a Non-Redemption Agreement with Alpha, pursuant to which the Seller agreed not to exercise redemption rights under the Charter with respect to an aggregate of 100,000 Shares.

## Related Party Loans

On acquisition, AxoBio had several promissory notes outstanding to Burns Ventures, LLC (the "Burns Notes") with total principal outstanding of \$5,610,000 as of December 31, 2023. The owner of Burns Ventures LLC was the former owner of AxoBio. Interest on the notes is payable quarterly at a fixed interest rate of 7.00%. The notes require no monthly payments and are due in full at the maturity date of December 31, 2024. Accrued interest for the related party loans as of December 31, 2023 was \$98,982, and interest expense incurred totaled \$164,611 for the year ended December 31, 2023.

## OrthoEx and Ortho Spine

The Company uses OrthoEx for 3PL services. The former Chief Executive Officer of AxoBio, who is currently serving as an advisor to the Company, has an equity interest in OrthoEx and is a member of OrthoEx's Board of Directors. The Company incurred \$41,752 of expenses from OrthoEx during the year ended December 31, 2023. As of December 31, 2023, the Company had a payable to this related

party of \$8,650. The Company uses Ortho Spine Companies, LLC ("Ortho Spine") for various consulting and marketing services. Ortho Spine is owned by one of the advisors to the Company. The Company incurred \$79,167 of expenses from Ortho Spine for the year ended December 31, 2023. As of December 31, 2023, the Company had no payables to this related party.

## Registration Rights Agreement

We have entered into a registration rights agreement pursuant to which certain of Alpha's initial stockholders and their permitted transferees, if any, are entitled to certain registration rights with respect to the placement units, placement shares, the placement warrants, the securities issuable upon conversion of working capital loans (if any) and the shares of Common Stock issuable upon exercise of the foregoing and upon conversion of the founder shares.

#### **Independent Directors**

Applicable rules of Nasdaq require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. An "independent director" is defined generally as a person other than an officer or employee of the company or its subsidiaries or any other individual having a relationship which, in the opinion of the Board, would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. Our Board has determined that Messrs. David Anderson, Scott Frisch, Kathryn Gregory, Gilles Spenlehauer, Patrick Sturgeon, and Rich Upton are independent as that term is defined in applicable Nasdaq and SEC rules. In making its determinations, our Board has concluded that none of these directors has an employment, business, family or other relationship which, in the opinion of our Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. We expect that our independent directors will meet in executive session (without the participation of executive officers or other non-independent directors) at least two <sup>1</sup>times each year.

## Item 14. Principal Accounting Fees and Services.

The following is a summary and description of fees incurred by Adeptus Partners, LLC (PCAOB ID: 3686) located in Ocean, New Jersey for the fiscal years ended December 31, 2023 and 2022.

	Year ended December 31,		Year ended December 31,	
Fee Category	 2023		2022	
Audit Fees (1)	\$ 167,000	\$	172,000	
Total	\$ 167,000	\$	172,000	

(1) Consists of fees for services related to the audit of the Company's consolidated financial statements, quarterly reviews of the Company's unaudited interim consolidated financial statements, and consultation on significant accounting matters.

# **Pre-Approval Policies and Procedures**

The audit committee's charter provides that the audit committee will pre-approve all auditing services and permitted non-audit services (including the fees and terms thereof) to be performed for the Company by its independent registered public accounting firm, as required by the applicable rules promulgated pursuant to the Exchange Act, subject to exceptions described in the Exchange Act, which are approved by the audit committee before the completion of the audit. The audit committee may delegate authority to one or more members of the audit committee, including the authority to grant pre-approvals of audit and permitted non-audit services, provided that decisions of such chair of the audit committee to grant pre-approvals are presented to the full audit committee at its next scheduled meeting.

#### PART IV

#### Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K:

## 1. Consolidated Financial Statements:

Incorporated by reference to Item 15(a)(1) of the Original Form 10-K.

#### 2. Financial Statement Schedules:

Incorporated by reference to Item 15(a)(2) of the Original Form 10-K.

#### 3. Exhibits:

10.1†

10.2

#### **Exhibit Index**

Exhibit	
Number 2.1†	Agreement and Plan of Merger, by and among Carmell Corporation, Aztec Merger Sub, Inc. and Axolotl Biologix, Inc., dated July 26, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 1, 2023).
2.2	First Amendment to Agreement and Plan of Merger, by and among Carmell Therapeutics Corporation, Aztec Merger Sub, Inc. and Axolotl Biologix, Inc., dated August 9, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 14, 2023).
2.3†	Business Combination Agreement, dated as of January 4, 2023, by and among Alpha Healthcare Acquisition Corp. III, Candy Merger Sub, Inc. and Carmell Therapeutics Corporation. (incorporated by reference to Annex A to the proxy statement/prospectus contained in the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
3.1	Third Amended and Restated Certificate of Incorporation of Carmell Therapeutics Corporation. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on July 20, 2023).
3.2	Amendment to Third Amended and Restated Certificate of Incorporation of Carmell Corporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2023).
3.3	Bylaws of Carmell Therapeutics Corporation (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on July 29, 2021).
4.1	Description of Securities (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024).
4.2	Warrant Agreement, dated July 26, 2021, by and between Alpha Healthcare Acquisition Corp. III and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 29, 2021).
4.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on August 14, 2023).

18

the Company's Quarterly Report on Form 10-Q filed with the SEC on August 14, 2023).

10-Q filed with the SEC on August 14, 2023).

Investor Rights and Lock-up Agreement, dated July 14, 2023, by and among Carmell Therapeutics Corporation (f/k/a Alpha Healthcare Acquisition Corp. III), and the parties listed as Investors thereto (incorporated by reference to Exhibit 10.6 to

Form of Indemnification Agreement (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form

- 10.3+ 2023 Equity Incentive Plan of Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.3 to Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- Form of Grant Agreement under 2023 Equity Incentive Plan of Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.4 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024).
- License Agreement, dated January 30, 2008, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- Amendment #1 to the License Agreement, dated July 19, 2011, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on S-4/A, filed with the SEC on June 23, 2023).
- Amendment #2 to the License Agreement, dated February 8, 2016, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on S-4/A, filed with the SEC on June 23, 2023).
- Amendment #3 to the License Agreement, dated February 27, 2020, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- Amendment #4 to the License Agreement, dated November 23, 2021, by and between Carnegie Mellon University and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.9 to the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- Office Lease Agreement, dated March 27, 2017, by and between RJ Equities LP and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.18 to the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- Office Lease Agreement, dated March 21, 2019, by and between RJ Equities LP and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.19 to the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- First Amendment to Office Lease Agreement, dated March 21, 2019, by and between RJ Equities LP and Carmell Therapeutics Corporation (incorporated by reference to Exhibit 10.20 to the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- 10.13 10% Original Issue Discount Senior Secured Convertible Note Due January 19, 2023, by and between Carmell Therapeutics Corporation and Puritan Partners LLC (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- 10.14 10% Original Issue Discount Senior Secured Convertible Note Due January 19, 2023, by and between Carmell Therapeutics Corporation and Verition Multi-Strategy Master Fund Ltd. (incorporated by reference to Exhibit 10.22 to the Company's Registration Statement on S-4/A filed with the SEC on June 23, 2023).
- 10.15+ Executive Employment Agreement between Carmell Corporation and Rajiv Shukla, dated December 29, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on January 5, 2024).
- Letter of Intent by and between Alpha Healthcare Acquisition Corp. III and the investor named therein related to Equity Line of Credit, dated as of May 5, 2023 (incorporated by reference to Exhibit 10.32 to the Company's Registration Statement on Form S-4/A filed with the SEC on May 26, 2023).
- Form of Common Stock Purchase Agreement by and between Alpha Healthcare Acquisition Corp. III, Carmell Therapeutics Corporation and the investor named therein (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-4/A filed with the SEC on June 8, 2023).

- Forward Purchase Agreement, dated July 9, 2023 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 10, 2023).
- Non-Redemption Agreement, dated July 9, 2023 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on July 10, 2023).
- 14.1# Carmell Corporation Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024).
- Subsidiaries of Carmell Corporation (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024).
- 31.1\* Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2\* Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (incorporated by reference to Exhibit 31.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024).
- Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (incorporated by reference to Exhibit 31.2 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024).
- 32.1\*\* Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (incorporated by reference to Exhibit 32.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024).
- 32.2\*\* Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (incorporated by reference to Exhibit 32.2 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024).
- Orporation Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on April 1, 2024)
- 101.INS Inline XBRL Instance Document the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
- 101.SCH Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents
- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### \* Filed herewith

- \*\* This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, except to the extent specifically incorporated by reference into such filing.
- + Indicates a management contract or compensatory plan.
- # The Compnay's Code of Business Conduct and Ethics is posted to its corporate website, www.carmellcorp.com. A copy of the code can also be obtained by submitting a written request to the Company at 2403 Sidney Street, Suite 300, Pittsburgh, PA 15203 or by email to ethics@carmellcorp.com.
- † Annexes, schedules and exhibits to this Exhibit omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

#### **SIGNATURES**

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

## **Carmell Corporation**

Date: April 29, 2024 By: /s/ Rajiv Shukla

Name: Rajiv Shukla

Chief Executive Officer and Chairman

(Principal Executive Officer)

**Carmell Corporation** 

Date: April 29, 2024 By: /s/ Bryan J. Cassaday

Name: Bryan J. Cassaday Chief Financial Officer

(Principal Financial and Accounting Officer)

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

Name	Title	Date
/s/ Rajiv Shukla Rajiv Shukla	Chief Executive Officer and Chairman (Principal Executive Officer)	April 29, 2024
/s/ Bryan Cassaday Bryan Cassaday	Chief Financial Officer (Principal Financial and Accounting Officer)	April 29, 2024
/s/ David Anderson  David Anderson	Director	April 29, 2024
/s/ Scott Frisch Scott Frisch	Director	April 29, 2024
/s/ Kathryn Gregory Kathryn Gregory	Director	April 29, 2024
/s/ Gilles Spenlehauer Gilles Spenlehauer	Director	April 29, 2024
/s/ Patrick Sturgeon Patrick Sturgeon	Director	April 29, 2024
/s/ Richard Upton Richard Upton	Director	April 29, 2024