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DELTA REPORT

10-K

CELZ - CREATIVE MEDICAL TECHNOLO

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	1446
CHANGES	224
DELETIONS	564
ADDITIONS	658

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

FORM 10-K

(Mark One)

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

For the fiscal year ended **December 31, 2022 2023**

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

For the transition period from _____ to _____

Commission File Number: 000-53500

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.

(Exact name of Registrant as specified in its charter)

Nevada	**87-0622284**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
211 E Osborn Road, Phoenix, AZ	**85012**
(Address of principal executive offices)	(Zip Code)

Issuer's telephone number, including area code: **(480) 399-2822**

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	CELZ	The NASDAQ Stock Market LLC

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing

requirements for the past 90 days. Yes ☒ No ☐

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

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

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

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

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

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

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

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

As of June 30, 2022 June 30, 2023, the aggregate market value of the registrant’s common stock held by non-affiliates was $6,193,548 $6,633,274 based on the closing price on the over-the-counter NASDAQ market of such common stock on such date.

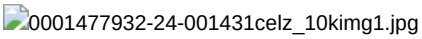
As of March 31, 2023 March 22, 2024, there were 14,076,238 1,356,626 shares of the registrant’s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s definitive proxy statement for the registrant’s 2023 Annual Meeting of Stockholders which will be filed with the Commission no later than 120 days after the registrant’s fiscal year ended December 31, 2022 December 31, 2023, are incorporated by reference into Part III of this report.

DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

The information contained in this Annual Report on Form 10-K contains certain forward-looking statements. All statements other than statements of historical facts contained or incorporated by reference in this Annual Report, including statements regarding our future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “will,” “may,” “future,” “plan,” “intend” and “expect” and similar expressions generally identify forward-looking statements. These forward-looking statements are not guarantees and are subject to known and unknown risks, uncertainties and assumptions 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. Although we believe that our plans, intentions and expectations reflected in the forward-looking statements are reasonable, we cannot be sure that they will be achieved. Particular uncertainties that could cause our actual results to be materially different than those expressed in our forward-looking statements include: our history of losses; our inability to receive regulatory approval for our products; later discovery of previously unknown problems; reliance on third parties; competition between us and other companies in the industry; delays in the development of products; our ability to raise additional capital; continued services of our executive management team; and statements of assumption underlying any of the foregoing, as well as other factors set forth under the caption **“Risk Factors”**. All subsequent written and oral forward-looking statements attributable to us, or persons acting on our behalf, are expressly qualified in their entirety by the foregoing. Except as required by law, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.



ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2022 December 31, 2023

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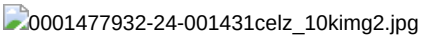
Item 1. Business

Overview

We are a commercial stage biotechnology company dedicated to the advancement of identifying and translating novel biological therapeutics in the fields of immunotherapy, endocrinology, urology, neurology and orthopedics. Our platforms, therapies and products include the following:



Our subsidiary, Creative Medical Technologies, Inc. (“CMT”), was originally created to monetize U.S. Patent No. 8,372,797 and related intellectual property related to the treatment of erectile dysfunction (“ED”), which it acquired in February 2016. Subsequently, we have expanded our development and acquisition of intellectual property beyond urology to include therapeutic treatments utilizing “re-programmed” stem cells, and the treatment of neurologic disorders, lower back pain, Type-1 diabetes, and heart, liver, kidney, and other diseases using various types of stem cells through our ImmCelz, Inc., StemSpine, Inc. and AlloCelz LLC subsidiaries. However, neither ImmCelz Inc., nor AlloCelz LLC have commenced commercial activities.

We currently conduct substantially all of our commercial operations through CMT, which markets and sells our CaverStem® and FemCelz® disposable kits utilized by physicians to perform autologous procedures that treat erectile dysfunction and female sexual dysfunction, respectively. Our CaverStem® and FemCelz® kits are currently available through physicians at eight locations in the United States.

In 2020, through our ImmCelz Inc. subsidiary, we began developing treatments under our ImmCelz® platform (CELZ-100), that utilize a patient's own extracted immune cells that are then "reprogrammed/supercharged" by culturing them outside the patient's body with optimized cell-free factors. The immune cells are then re-injected into the patient from whom they were extracted. We believe this process endows the immune cells with regenerative properties that may be suitable for (or "supercharges" them) providing them with the treatment of ability to treat multiple indications. We have validated this ability through the third-party studies described below that were independently conducted on selected human donor patient cells for accuracy and reproducibility. In contrast to other stem cell-based approaches, the immune cells are significantly smaller in size than stem cells and are believed to more effectively penetrate areas of the damaged tissues and induce regeneration.

In March 2022 2023, we contracted reported the following results of independent studies:

- ImmCelz® (CELZ-100) platform required 75% fewer donor patient cells compared to industry standard.
- The purity of the final ImmCelz® (CELZ-100) product was greater than 95% compared to the industry standard of greater than 80%.
- ImmCelz® (CELZ-100) demonstrated a greater than 200% reduction in functional suppression of effector T cells, which are a critical concern for patients with autoimmune issues, while still possessing a high number of functional T regulatory cells.
- The ability to verify repeated potency of the final ImmCelz®(CELZ-100) product.

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We believe these results show that we will be able to substantially reduce production costs, while allowing for the manufacture of the best clinical product for patients with The University of Miami immune disorders, which will enable us to accelerate our clinical applications and the Diabetes Research Institute encourage potential collaborations with respect to further develop, test and manufacture our ImmCelz technology. Results, products and all intellectual property related to this work is owned by the Company. ImmCelz® platform.

In June 2022, we signed an agreement with Greenstone Biosciences Inc. ("Greenstone") for the development of a human induced pluripotent stem cell (iPSC) pipeline for our ImmCelz® platform. This project was identified as iPScelz™. The efforts by Greenstone Biosciences Inc. are expected to complement and expand our current work on novel therapeutic cell lines. All data, products In May 2023, we announced that we had received confirmation that Greenstone had successfully developed a human induced pluripotent stem cell (iPSC). We estimate that the development of this cell line will save the Company two to three years in research and intellectual property related to this work is owned development time along with associated expenses. The final iPScelz™ results in a viral-free cell line which has great potential for differentiation into therapeutic biologics both for the cellular and cell-free programs along with targeted drug discovery. Greenstone's developments were confirmed by the Company. an independent, industry-leading research firm.

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In October 2022, we announced the development of our AlloStem™ Clinical Cell Line (CELZ-200), a proprietary allogenic cell line which includes a Master Cell Bank and a Drug Master File which we intend to submit to the U.S. Food and Drug Administration (the "FDA") for registration. File. We believe we will able to use this cell line for many of our programs, including our ImmCelz® ImmCelz® immunotherapy platform for multiple diseases, OvaStem® OvaStem® for Premature Ovarian Failure, CELZ-201 for Type 1 diabetes, StemSpine® for lower back pain, I Diabetes (CELZ-201 CREATE-1), AlloStemSpine® Chronic Lower Back Pain (CELZ-201 ADAPT), and IPScelz ™ perinatal IPScelz™ inducible pluripotent stem cell program in ongoing development with Greenstone Biosciences. Greenstone.

In November 2022, we announced that the FDA had cleared the Company's AlloStem™ (CELZ-201) Type I Diabetes (CELZ-201 CREATE-1) Investigational New Drug (IND) application for the treatment of Type 1 Diabetes utilizing our AlloStem™ Clinical Cell Line, which will allow us to begin a Phase I/II clinical trial. The primary objective of the study (CELZ-201) will be to evaluate AlloStem™ CELZ-201 treatment in patients with newly diagnosed Type 1 Diabetes. The trial has also received Institutional Board Review (IRB) approval for the trial to proceed as well as approval of the patient recruitment material. Patient recruitment is expected to begin was initiated in September 2023.

In addition February 2023, the Company reported positive three-year follow-up data for its StemSpine® pilot study. The three-year data demonstrates continued efficacy of the StemSpine® procedure for treating chronic lower back pain without any serious adverse effects reported.

In March 2023, the Company announced that it filed an application with the FDA to our clinical research efforts, receive Orphan Drug Designation ("ODD") for the treatment of Brittle Type 1 Diabetes using its ImmCelz® (CELZ-100) platform. The FDA has responded to the ODD filing with additional clarification requests, which we are currently seeking to expand the commercial sale and use of our CaverStem® and FemCelz® products by physicians in the United States. process of responding.

In April 2023, the Company reported positive one-year follow-up data and significant efficacy using CELZ-001 to treat patients with Type 2 Diabetes. There were no safety concerns related to CELZ-001 at one year follow-up utilizing the same infusion procedure as in the currently U.S. FDA cleared Type I Diabetes (CELZ-201 CREATE-1) clinical trial. There were 30 patients in the study, 15 who received CELZ-001 and the rest received optimized medical therapy. At one year, there was an overall efficacy of 93% in the treated patients demonstrating at least a 50% reduction in insulin requirement.

In September 2023, the Company received FDA clearance to initiate a Phase I/II clinical trial of AlloStemSpine® Chronic Lower Back Pain (CELZ-201 ADAPT) using AlloStem™ (CELZ-201-DDT) for the treatment of lower back pain. The first in country study, which will enroll 30 individuals suffering from chronic lower back pain, is designed to evaluate the safety, efficacy, and tolerability of AlloStem™ (CELZ-201-DDT). The minimally invasive procedure uses ultrasound for the targeted delivery of the cell product, and thus prevents radiation exposure to the patient or the injecting physician. This trial, protected by issued patents, is a huge milestone for the Company and for patients suffering from this debilitating problem and their need for opioids for pain.

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In October, 2023 the Company filed for and received approval from an institutional review board (IRB) to proceed with the Phase I/II clinical trial. The clinical trial is registered on www.clinicaltrials.gov. We are currently vetting Contract Research Organizations for a planned trial enrollment commencing in early 2024.

We were incorporated on December 3, 1998, in the State of Nevada under the name Jolley Marketing, Inc. On May 18, 2016, we completed a reverse merger transaction under which Creative Medical Technologies, Inc. became our wholly owned subsidiary. In connection with this merger, we changed our name to Creative Medical Technologies Holdings, Inc. to reflect our current business.

On December 7, 2021 May 3, 2022, we received gross proceeds the Company completed the sale of $16,003,750, before deducting underwriting discounts and commissions of seven percent (7%) and offering expenses, upon the closing of a public offering of 3,875,000 (i) 299,167 shares of our common stock, and accompanying warrants to purchase 3,875,000 shares of common stock at an exercise price of $4.13 per share ("Warrants"), at a combined public offering price to the public of $4.13 per share of common stock and related Warrant. We used a portion of the net proceeds of the offering to (i) redeem 15% Original Issue Discount Senior Notes in the aggregate outstanding amount of $5,146,176, and (ii) repurchase Series A Preferred Stock from our Chief Executive Officer for an aggregate purchase price of approximately $195,000. We intend to use the remaining proceeds from the offering to (i) hire marketing and sales personnel to support sales of our CaverStem® and FemCelz® products, (ii) proceed with a clinical study of 100 patients intended to support the safety and efficacy of our StemSpine® Regenerative Stem Cell Procedure for Treatment of Degenerative Disc Disease, (iii) conduct a Phase I clinical trial for the treatment of stroke utilizing our ImmCelz™ technology, (iv) continue to develop other products and therapies, and (v) fund working capital and general corporate purposes using any remaining amounts.

On May 3, 2022 we received gross proceeds of $17,000,000, before deducting placement agent fees and expenses, upon the closing of an unregistered sale of equity securities of (i) 2,991,669 shares of our common stock, and pre-funded warrants to purchase 4,563,887 456,389 shares of common stock (the "Pre-Funded Warrants"), and (ii) accompanying warrants to purchase 15,111,112 1,511,112 shares of common stock at an exercise price of $2.00 per share (" (the "Common Warrants"), at a combined offering price of $2.25 $22.50 per share of common stock/Pre-Funded Warrant and related Common Warrant, to a group of institutional investors (the "Purchasers"). , pursuant to a Securities Purchase Agreement between the Company and the Purchasers dated as of April 28, 2022 (the "Purchase Agreement"), resulting in gross proceeds to the Company of approximately

$17,000,000. The transaction was effected pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended and Rule 506(b) promulgated thereunder.

The Common Warrants have a five-year term, and an exercise price of $2.00 $20.00 per share. The Pre-Funded Warrants do did not expire have an expiration date and had an exercise price of $0.0001 $0.001 per share. As of December 31, 2023, all of the Pre-Funded Warrants had been exercised.

The Pre-Funded Warrants were classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, did not embody an obligation for the Company to repurchase its shares, and permitted the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Pre-Funded Warrants did not provide any guarantee of value or return.

Roth Capital Partners ("Roth") acted as sole placement agent for the offering. We The Company paid Roth a placement agent fee in the amount of $1,360,000 and issued Roth a warrant to purchase 1,133,333 113,334 shares of common stock Common Stock with the same terms as the Common Warrants issued to the Purchasers. Pursuant to the Purchase Agreement, the Company and the Purchasers entered into a Registration Rights Agreement, pursuant to which the Company agreed to file a registration statement with the Securities and Exchange Commission to register the resale of the shares of Common Stock issued in the offering and the shares of Common Stock underlying the Common Warrants and Pre-Funded Warrants. On May 10, 2022, we filed a Form S-3 registration statement to register the shares, common stock, Warrants and Pre-Funded Warrants for resale. The registration went effective on May 19, 2022, fulfilling our contractual obligation. In addition, the Company's directors and officers entered into Lock-Up Agreements under which they agreed not to sell any of their securities of the Company until 90 days following after the earliest of (i) the effective date of the Registration Statement, and (ii) the date all of the securities issued in the offering have been sold under Rule 144, or may be sold under Rule 144 without the Company being in compliance with the current public information requirement under such rule, and without any volume limitation. From June through July 2022, all of the Pre-Funded Warrants were exercised for shares of common stock.

Our principal executive offices are located at 211 E Osborn Road, Phoenix, AZ 85012.

Our Products

AlloStem™ (CELZ-201-DDT) - Allogenic Human Perinatal Tissue Derived Cell Program (Clinical Phase)

AlloStem™ (CELZ-201-DDT) leverages a unique approach to harnessing the power of Perinatal Tissue Derived Cells® (PRDC) to multi-potentialities, including self-renewal ability, low antigenicity, reduced toxicity, and large-scale clinical expansion. Drug Master Files, registered with the FDA, are a highly valuable tool in cross referencing data in Orphan Drug Development of interventional drug products, Investigational New Drug Development and Investigational Device Exemptions to the FDA. Drug Master Files do not expire and are utilized by many pharmaceutical and biotechnology giants as well as many other industries for their products, dating back to the 1940s, Additionally, the treatment does not require people to take immunosuppressant drugs, minimizing the risk for various side effects. We believe AlloStem™ (CELZ-201-DDT) has the following additional benefits and characteristics:

- Immediately available, scalable "Universal" recipient product
- Immunomodulatory properties to help treat immune and endocrine based disorders
- Supports ImmCelz® (CELZ-100), Alova®, Type I Diabetes (CELZ-201 CREAT-1) and AlloStemSpine® Chronic Lower Back Pain (CELZ-201 ADAPT) programs and others
- Supports FDA cleared clinical trials for rapid translation
- Designated and proprietary Master Cell Bank and Drug Master File for US FDA
- 8 billion manufactured and validated cells available for clinical trials and further research

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Our Products*ImmCelz™ (CELZ-100) - Personalized Supercharged Immune Therapy Platform (Pre-Clinical Trials*)

We are developing our ImmCelz™ (CELZ-100) technology for the treatment of multiple indications.

ImmCelz™ (CELZ-100) utilizes a patient's own extracted immune cells that are then "reprogrammed" by culturing them outside the patient's body with optimized secreted factors. The immune cells are then re-injected into the patient from whom they were extracted. In contrast with other stem cell-based approaches, the immune cells are significantly smaller in size than stem cells and are believed to more effectively penetrate areas of the damaged tissues and induce regeneration.

Unlike our CaverStem®, FemCelz® and StemSpine® procedures, because the patient's cells are reprogrammed/supercharged prior to reinjection, we will require FDA approval before we can market or sell products that use our ImmCelz™ (CELZ-100) technology.

We developed ImmCelz™ (CELZ-100) initially using co-culture techniques which have now been advanced to a cell-free culture system. We have also utilized certain cell-free factors pursuant to a license agreement we entered into with Jadi Cell LLC, which is owned and controlled by Dr. Patel, a former director of the Company. We have been granted the right to exploit Jadi Cell's patent rights (including U.S. Patent Number 9,803,176 and similar patents issued by other countries) and proprietary know how in connection with the enhancement of autologous cells. However, based on our current development of the ImmCelz™ (CELZ-100) platform, we have engineered the next generation of cell-free secreted factors which are independent of the Jadi Cell LLC license. We continue to have the previously licensed platform from Jadi Cells LLC for the first generation ImmCelz™ (CELZ-100).

Type I Diabetes (CELZ-201 CREATE-1) – Type I Diabetes

The proposed study is a Phase I/IIa randomized, controlled clinical trial to evaluate CELZ-201 therapy as an intervention for the treatment of recent onset Type 1 Diabetes. The objective is to determine the safety and efficacy of CELZ-201 administration, based on the timing and dose of CELZ-201 treatment. Subjects who meet eligibility criteria will be randomized to treatment or control groups, in a 2:1 ratio. Subjects in the Group I (Treatment Group, n=12) will receive standard of care for type 1 diabetes and CELZ-201 within 1 month from enrollment (within 180 days of diagnosis). Subjects in Group II (Control Arm, n=6) and will receive enhanced standard of care for type 1 diabetes.

AlloStemSpine*® Chronic Lower Back Pain *(CELZ 201 ADAPT)

This study is a double-blinded, randomized, placebo-controlled, dose escalation Phase 1/2a study. The objective is to determine the safety, tolerability, and efficacy of CELZ-201-DDT administered as an intramuscular injection for the treatment of lower back pain in patients with Degenerative Disc Disease. Subjects who meet all criteria for inclusion will be enrolled and randomized into either low, medium or high dose of CELZ-201-DDT versus Placebo, with a total of 30 subjects enrolled. Each dosing cohort will contain ten subjects (n=10), with eight subjects (n=8) receiving the investigational product and two subjects (n=2) randomized to receive placebo. Each subject will receive six paraspinal intramuscular injections (three injections per side) of either CELZ-201-DDT or placebo into the lumbar musculature under direct ultrasound guidance.

Alova

The Alova program utilizes the AlloStem™ platform to treat infertility as a result of premature ovarian failure.

CaverStem® - Erectile Dysfunction Treatment

CaverStem® is a clinically proven, patented procedure (U.S. Patent No. 8,372,797) that utilizes a patient's own stem cells to treat erectile dysfunction (ED). The procedure has been demonstrated safe and effective in clinical trials and is geared to the estimated nine million men in the United States that suffer from ED and do not respond to PDE5 inhibitors in drugs such as Viagra and Cialis due to damage to smooth muscle and blood vessels.

Our CaverStem® stem cell treatment consists of a one-hour out-patient visit in a physician's office. The physician harvests a patient's stem cells from bone marrow in the hip using a local anesthetic. The extraction device is designed to harvest only the stem cells, while filtering out the red blood cells, thereby eliminating the need for any centrifugation. The stem cells are then injected into the patient's corpus cavernosum (erectile tissue) to stimulate muscle and blood vessel regeneration. Clinical research data concludes that our CaverStem® treatment results in a marked increase in duration and frequency of erections and the ability to sustain erections until orgasm, with no known treatment-associated adverse events.

We generate revenues through the sale of disposable bone marrow aspiration kits to physicians who use the kits to perform the CaverStem® procedure. We contract with physicians to purchase kits and, in turn, provide exclusivity in their market through our patent protection, marketing support and training.

Our CaverStem® technology is protected by U.S. Patent No. 8,372,797, entitled “Treatment of Erectile Dysfunction by Stem Cell Therapy” which was issued to CMH by the United States Patent and Trademark Office (“USPTO”) on February 12, 2013. We acquired this patent and related know-how and technology from CMH in May 2016. CaverStem® is also a U.S. registered trademark (Reg. No. 5716528).

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In August 2017, we completed recruitment on a clinical trial of the CaverStem® procedure conducted by the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. Following completion of recruitment and treatment of the study subjects, an independent Institutional Review Board (IRB) overseeing the study validated the procedure as safe. In the same time frame, other worldwide, peer-reviewed and published clinical trials using the same procedure validated the efficacy of the ED treatment. As a result of these two developments, management concluded the CaverStem® procedure is both safe and effective and commenced marketing activities in November of 2017. From November 2017, through September 2020, the data from 40 patients in the clinical trial was combined with data from a 100-patient clinical registry and analyzed. The results were then submitted to the Journal of Translational Medicine for peer-review and publication and subsequently published in its January 2020 edition. The peer-reviewed results validated 100% safety and 85% efficacy of the CaverStem® procedure. This marked the largest ever study of the safety and efficacy of bone marrow stem cells used to treat erectile dysfunction.

FemCelz® - Female Sexual Function Treatment

In September 2018, we launched our proprietary FemCelz® procedure for the treatment of the loss of genital sensitivity and dryness experienced by women. The FemCelz® procedure uses the patient’s own stem cells to improve female sexual function, and is similar to the CaverStem® procedure. Management has determined that FemCelz® is exempt from the FDA premarket review and approval process under Section 361 of the PHS Act, as the procedure involves the autologous treatment of a patient with her own cells during the same surgical procedure without intervening processing steps.

Our FemCelz® stem cell treatment consists of a one-hour out-patient visit in a physician’s office. The physician harvests a patient’s stem cells from bone marrow in the hip using a local anesthetic. The extraction device is designed to harvest only the stem cells, while filtering out the red blood cells, thereby eliminating the need for any centrifugation. The cells are then injected into the pubocervical fascia (peri-G-spot), skene’s glands, and around the peri-clitoral to stimulate muscle and blood vessel regeneration.

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We generate revenues through the sale of disposable bone marrow aspiration kits to physicians who use the kits to perform the FemCelz® procedure. We contract with physicians to purchase kits and, in turn, provide exclusivity in their market through our patent protection, marketing support and training. However, to date, we have generated no revenues from this treatment.

FemCelz® is a U.S. registered trademark (Reg. No. 6107881).

StemSpine® - Regenerative Stem Cell Procedure for the Treatment of Degenerative Disc Disease (Clinical Trials)

Our StemSpine® procedure uses the patient’s own stem cells to reverse the effects of atherosclerosis and treat chronic lower back pain. A recent study reported that an estimated 2.6 million patients in the U.S. will have suffered from degenerative disc disease in 2021, with the number increasing to close to four million patients in 2028.

Management has determined that StemSpine® is exempt from the FDA premarket review and approval process under Section 361 of the PHS Act, as the procedure involves the autologous treatment of a patient with his or her own cells during the same surgical procedure

without intervening processing steps.

Our StemSpine® stem cell treatment consists of a one-hour out-patient visit in a physician's office. The physician harvests a patient's stem cells from bone marrow in the hip using a local anesthetic. The extraction device is designed to harvest only the stem cells, while filtering out the red blood cells, thereby eliminating the need for any centrifugation. The cells are then administered into muscles surrounding the area of lower back pain, such as the psoas major muscle to stimulate blood vessel regeneration. New blood vessels increase circulation around the disc and thus stimulates regeneration of the disc.

Lower back pain is the single leading cause of disability worldwide, affecting mobility, functionality, and the emotional state. To date, treatment options have ranged from prescription medication, to physical therapy and even acupuncture. Unfortunately, in patients whose lower back pain originates from disc degeneration, existing approved treatments do not address the underlying cause, but only symptoms.

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Recent U.S. clinical trials using stem cells administered directly into the disc have shown promise in regenerating injured discs, and by this means reducing pain in some patients. Companies such as Mesoblast Limited have patient follow-ups as long as three years post injection and show some degree of pain reduction and disc regeneration without adverse effects.

A significant number of patients suffering from lower back pain have deficient circulation in the areas surrounding the discs, which is believed by some to be the initial cause of disc degeneration. Our StemSpine® technology utilizes biologicals to stimulate a process termed angiogenesis, which overcomes the deficient circulation causing disc degeneration.

In May 2017, we formed StemSpine, LLC for the purpose of using stem cells to treat back pain under a patent we acquired from CMH. In June 2017, we filed an additional patent application covering the synergy between intradiscal stem cell injection subsequent to stimulation of perispinal angiogenesis.

In October 2019, we announced the successful completion of a pilot study of 15 patients with over 12 months of data showing safety and efficacy. Evaluation of patients at 30, 60 90, 180, and 360 days revealed significant improvement in mobility and reduction in pain score. The mean pain score (on a scale of 1 to 10, with 10 being most severe), changed from 8.9 at baseline to 4.3 at 30 days, and sustained to 1.8 at 6 months and 1.3 at 12 months, with a gradual reduction in overall pain medication utilization guided by patients' healthcare teams. No serious adverse effects were noted, with some short-term bruising in two patients at the harvest site. No long-term adverse events were reported related to the procedure.

On February 14, 2023, we announced positive three-year follow-up data for the Company's StemSpine® pilot study. The three-year data demonstrate continued efficacy of the StemSpine® procedure for treating chronic lower back pain without any serious adverse effects reported. There were no safety related concerns at up to three years, and the StemSpine® procedure resulted in a continued efficacy rate of 87% of patients that participated in the pilot study. No patients required re-dosage or surgical intervention since the last follow-up at two years.

StemSpine® is a U.S. registered trademark (Reg. No. 5997521).

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***ImmCelz™ - Personalized Supercharged Immune Therapy (Pre-Clinical Trials*)**

We are developing our ImmCelz™ technology for the treatment of multiple indications.

ImmCelz™ utilizes a patient's own extracted immune cells that are then "reprogrammed" by culturing them outside the patient's body with optimized secreted factors. The immune cells are then re-injected into the patient from whom they were extracted. In contrast with other stem cell-based approaches, the immune cells are significantly smaller in size than stem cells and are believed to more effectively penetrate areas of the damaged tissues and induce regeneration.

Unlike our CaverStem®, FemCelz® and StemSpine® procedures, because the patient's cells are reprogrammed/supercharged prior to reinjection, we will require FDA approval before we can market or sell ImmCelz™.

We developed ImmCelz™ initially using co-culture techniques which have now been advanced to a cell-free culture system. We have also utilized certain cell-free factors pursuant to a license agreement we entered into with Jadi Cell LLC, which is owned and controlled by Dr. Patel. We have been granted the right to exploit Jadi Cell's patent rights (including U.S. Patent Number 9,803,176 and similar patents issued by other countries) and proprietary know how in connection with the enhancement of autologous cells. However, based on our current development of the ImmCelz™ platform, we have engineered the next generation of cell-free secreted factors which are independent of the Jadi Cell LLC license. We continue to have the previously licensed platform from Jadi Cells LLC for the first generation ImmCelz™.

We have filed an application with the USPTO to trademark ImmCelz™ (Ser. No. 88829362).

OvaStem™ - Stem Cell Therapy for Premature Ovarian Failure

We are developing our OvaStem™ technology for the treatment of female infertility. Our treatment is intended to treat women suffering from infertility induced by factors such as chemotherapy and other non-natural causes, as well as age-associated infertility, and infertility with unexplained causes. In these cases, IVF treatment may not be appropriate as the woman's ovaries are not able to generate eggs capable of being fertilized. Studies have shown that the introduction of stem cells into dysfunctional ovaries induce fertility, reduce ovarian fibrosis, accelerate maturation of immature oocytes, and restore growth factor production damaged by aging and cancer interventions. Accordingly, we believe that our OvaStem™ procedure may be a suitable treatment for these women with damaged ovaries.

The OvaStem™ stem cell treatment will consist of a one-hour out-patient visit in a physician's office. The physician will harvest a patient's stem cells from bone marrow in the hip using a local anesthetic. The extraction device will harvest only the stem cells, while filtering out the red blood cells, thereby eliminating the need for any centrifugation. The cells would then be administered into the dysfunctional ovaries.

Like our CaverStem® and FemCelz® procedures, because OvaStem™ will utilize a patient's own extracted immune cells, management has determined that OvaStem™ will be exempt from the FDA premarket review and approval process under Section 361 of the PHS Act, as the procedure involves the autologous treatment of a patient with her own cells during the same surgical procedure without intervening processing steps.

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On July 28, 2022, we announced positive three-year follow up data for the Company's OvaStem® pilot study. The data shows significant efficacy of the OvaStem® procedure for the treatment of medical refractory Primary Ovarian Insufficiency (POI) without any serious adverse effects and the successful birth of healthy babies.

Other Products and Services

Additional Indications

We are also exploring the use of our technologies and/or have filed patents covering treatments for

- Preventing the rejection of transplanted organs
- Kidney failure
- Liver failure
- Type 1 Diabetes
- Heart attack
- Parkinson's Disease

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Marketing

We market our CaverStem® and FemCelz® procedures using a multifaceted marketing approach that includes:

- A robust web site for each of these products (CaverStem.com and FemCelz.com) designed to attract and educate both physicians and patients
- Publishing results of clinical studies demonstrating the efficacy of our products and therapies, and building clinical registries accessible to medical professionals that include the results of such studies
- Online advertising
- Social Media – Twitter, Facebook
- In-office flyers and banners
- Patient testimonials
- Informative videos

The first product we marketed was the CaverStem® procedure to treat erectile dysfunction, which was initiated in November 2017. We subsequently initiated marketing of FemCelz® in March 2020. The two procedures are now offered in the following eight markets:

- Arkansas – Martinsburg
- California
  - Roseville
  - San Francisco
- Florida – Orlando
- Ohio - Dublin
- Texas
  - Austin
  - San Antonio
- West Virginia - Fayetteville

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To-date, we have recruited physicians by partnering with independent sales representatives who represent the Company to physicians across the United States and Europe. States. Going forward, management plans to continue to partner with independent sales representatives.

Intellectual Property

We have developed and acquired a robust intellectual property portfolio related to the utilization of stem cells to improve patient lives in the areas of urology, neurology, and orthopedics. Our patent portfolio is currently composed of four issued patents and ten fifty pending patent applications filed in the United States with the USPTO as follows:

Issued Patents

Title	Application Number	Application Filing Date	Patent Number
Treatment of Erectile Dysfunction by Stem Cell Therapy	12305589	06/22/2007	8,372,797
Treatment Of Disc Degenerative Disease	12301597	09/30/2009	9,598,673
Methods For Treatment Of Premature Ovarian Failure And Ovarian Aging Using Regenerative Cells	15652213	07/17/2017	10,792,310
Paraspinal Perfusion by Administration of T regulatory Cells Alone or in Combination with Angiogenic Cell Therapies	16009982	06/15/2018	10,842,815

Pending Patent Applications

Area	Application/Patent #	Description
Immunology	15/617,813	Adipose Derived Immunomodulatory Cells for Immunotherapy of Recurrent Spontaneous Abortions
Immunology	*10,792,310*	Methods for Treatment of Premature Ovarian Failure and Ovarian Aging Using Regenerative Cells
Immunology	15/702,735	Inducing and Accelerating Post-stroke Recovery by Administration of Amniotic Fluid Derived Stem Cells
Immunology	15/987,739	Generation of Autologous Immune Modulatory Cells for Treatment of Neurological Conditions
Immunology	63/123,380	Induction of Infectious Tolerance by Ex Vivo Reprogrammed Immune Cells
Immunology	63/248,324	Suppression of Diabetes Using Exosomes From Stem Cell Programmed Myeloid Cells
Immunology	63/270,678	Regenerative T Regulatory Cells
Immunology	63/297,876	Chimeric Antigen Receptor Regenerative Gamma Delta T Cells
Immunology	63/297,883	Regenerative Car-T Cells
Immunology	63/302,228	Regenerative Cell Therapy for Viral Induced Sexual Dysfunction
Immunology	63/313,313	Methods for Quantifying Potency of Regenerative Immunotherapies
StemSpine	63/331,179	Enhancement of Cartilage Regenerative Activity of Stem Cell Populations Based on Reduction of Intra-articular Cellular Material
StemSpine	63/331,183	Enhancement of Stem Cell Therapy for Cartilage Degeneration by Anti-oxidant Pre-conditioning
Immunology	63/331,186	Treatment of Cartilage Degeneration Using Treatment of Cartilage Degeneration Using Myeloid Suppressor Cells and Exosomes Derived Thereof
Immunology	63/338,416	Cytokine Based Assessment of Recipient Ability to Respond to Stem Cell Therapy for Cartilage Regeneration

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Pending Patent Applications

Area	Application/Patent #	Description
Endocrinology	63/338,417	Prevention of Menopause Associated Osteoporosis by Intra-ovarian Administration of Regenerative Cells
Immunology	63395252 63/340,447	Prevention and Treatment Stimulation of Reproductive Failure by Regenerative Ovarian Function Subsequent to Chemotherapy and/or Radiation Therapy Using Natural Killer Cells and Adjuvants
Immunology	63351330 63/340,450	Protection from Ovarian Failure by Low Dose Interleukin-2 Administration
Immunology	63/340,454	Immunological Enhancement of Stem Cell Activity in Treatment of Ovarian Failure
Immunology	63/340,828	Exosome Based Assays for Determining Candidates for Osteoarthritis Stem Cell Therapy
Immunology	63/343,832	Cytokine Primed Regenerative Cells for Treatment of Ovarian Failure
Immunology	63/343,841	Degenerating Ovarian Microenvironment Resistant Mesenchymal Stem Cells
Immunology	63/343,846	Repair of Ovarian Damage and Dampening of Inflammatory Microenvironment by Administration of Monisytic-Granulocytic Progenitors with Immunomodulatory Activities
Immunology	63/349,297	Gene Therapeutics for Enhancement/Restoration of Endometrial Function
Endocrinology	63/349,976	Cellular Regenerative Therapeutics for Enhancement/Restoration of Endometrial Function
Immunology	63/351,330	Generation of Conditioned Media from Inducible Pluripotent Stem Cell Derived Endothelial Endothelian Progenitor Cells
Immunology	63389091	Overcoming TNF-alpha Blockade Resistance in Rheumatoid Arthritis by Regenerative T Regulatory Cell Therapy
Immunology	63248324	Suppression of Diabetes Using Exosomes from Stem Cell Programmed Myeloid Cells
Immunology	63270678	Regenerative T Regulatory Cells
Immunology	63351330 63/351,332	Generation of Conditioned Media from Inducible Pluripotent Stem Cell Derived Mesenchymal Stem Cells
Immunology	63297883 63/353,011	Inducible Pluripotent Stem Cell Derived Regenerative CAR-T T Cells
Immunology	63123380 63/389,091	Induction of Infectious Tolerance Overcoming TNF-Alpha Blockade Resistance in Rheumatoid Arthritis by Ex Vivo Reprogrammed Immune Cells Regenerative T Regulatory Cell Therapy
Immunology	63395836 63/390,759	Treatment of Limb Ischemia by Bone Marrow Stem Cells and Modification of Diseased Microenvironment
Immunology	63/391,865	Potentiation of Bone Marrow Cell Activity by Co-administration with Oxytocin
Immunology	63/395,252	Prevention and Treatment of Reproductive Failure by Regenerative Cells and Adjuvants
StemSpine	63/395,834	Prevention of Space Travel Associated Bone Density Loss by Regenerative Cell Populations
Immunology	63/395,836	Prevention and Treatment of Hair Loss
Endocrinology Immunology	63338417 63/395,839	Prophylaxis and Treatment of Orthopox Viruses Using Regenerative Cells and Products Thereof
Immunology	63/414,823	Treatment of Diabetes by Enhancement of Pancreatic Islet Engraftment Through Regenerative Immune Modulation
Immunology	63/455,965	Artificial Intelligence Systems and Processes for In Silico Discovery of Immune Modulators and T Regulatory Cell Screening Methodologies
Immunology	63/458,423	Artificial Intelligence Guided Production of Cells and Organs from Pluripotent Stem Cells

Immunology	63/460,543	Three-Dimensional Printing of Organs, Organoids, and Chimeric Immuno-Evasive Organs
Immunology	63/463,993	Artificial Intelligence Enhanced Real Time Biological Optimization and Health Monitoring for Space Travel
Immunology	63/465,616	Induction of Antigen Specific Immunological Tolerance Using Inducible Pluripotent Stem Cell Derived Veto Cells
Immunology	63/510,877	Enhanced Mobility of Inducible Pluripotent Stem Cell Derived T Regulatory Cells
Immunology	63/514,240	Creation of Inducible Pluripotent Stem Cell Derived T Regulatory Cells by In Vitro Recapitulation of Thymic Development
Immunology	63/518,386	Treatment of Spinal Cord Injury with T Regulatory Cells
Immunology	63/518,424	Prevention of Menopause Associated Osteoporosis Immunological Rejection Using Mesenchymal Stem Cells and Derivatives Thereof
Endocrinology	63/580,657	In Vitro and In Vivo Generation of Insulin Producing Cells
Immunology	63/580,669	Orthopedic Regeneration by Intra-ovarian Administration of Regenerative Inducible Pluripotent Stem Cell Derived Mesenchymal Stem Cells
Endocrinology	63349976 63/588,034	Cellular Regenerative Therapeutics for Enhancement/Restoration of Endometrial Function
Immunology	10,792,310	Methods for Treatment of Premature Ovarian Failure Lower Back Pain and Ovarian Aging Disc Degenerative Disease Using Regenerative Inducible Pluripotent Stem Cell Derived Mesenchymal Stem Cells and T Regulatory Cells
Endocrinology	16759671 16/759,671	Augmentation of Fertility by Platelet Rich Plasma
Immunology	63343846 18/183,900	Repair of Ovarian Damage and Dampening of Inflammatory Microenvironment by Administration of Monocytic-Granulocytic Progenitors with Immune Modulatory Activities
Immunology	63340454	Immunological Enhancement of Stem Cell Activity in Treatment of Ovarian Failure
Immunology	63340450	Protection from Ovarian Failure by Low Dose Interleukin-2 Administration
Immunology	63340447	Stimulation of Ovarian Function Subsequent to Chemotherapy
Immunology	63343832	Cytokine Primed Therapeutic Regenerative Cells for Treatment of Ovarian Failure
Immunology	63343841	Degenerating Ovarian Microenvironment Resistant Mesenchymal Stem Cells
Immunology	15617813	Adipose Derived Immunotherapy of Recurrent Spontaneous Abortion
Immunology	63349297	Gene Therapeutics for Enhancement/Restoration of Endometrial Function
Immunology	15702735	Inducing and Accelerating Post-Stroke Recovery by Administration of Amniotic Fluid Derived Stem Cells
Immunology	15987739	Generation of Autologous Immune Modulatory Cells for Treatment of Neurological Conditions
Immunology	63313313	Methods for Quantifying Potency of Regenerative Immunotherapies

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Patent Purchase and License Agreements

Lower Back Pain Patent Purchase. We acquired U.S. Patent No. 9,598,673 covering the use of various stem cells for the treatment of lower back pain from our affiliate CMH pursuant to a Patent Purchase Agreement dated May 17, 2017, which was amended in November

2017. The inventors of the patent were Thomas Ichim, PhD and Amit Patel, MD, former directors of ours, and Annette Marleau, PhD. As amended, the Patent Purchase Agreement includes the following terms:

- We were required to pay CMH $100,000 within 30 days of demand as an initial payment.
- Upon the determination to pursue the technology via use of autologous cells, we were required to pay CMH:
  - $100,000 upon the signing agreement with a university for the initiation of an IRB clinical trial.
  - $200,000, upon completion of the IRB clinical trial.
  - $300,000 in the event we commercialize the technology via use of autologous cells by a physician without a clinical trial.
- In the event we determine to pursue the technology via use of allogenic cells, we are required to pay CMH:
  - $100,000 upon filing an IND with the FDA.
  - $200,000 upon dosing of the first patient in a Phase 1-2 clinical trial.
  - $400,000 upon dosing the first patient in a Phase 3 clinical trial.
- Each payment may be made in cash or shares of our common at a discount of 30% to the recent trading price.
- In the event our shares of common stock trade below $0.01 per share for two or more consecutive trading days, the number of any shares issuable as payment doubles.
- For a period of five years from the date of the first sale of any product derived from the patent, we are required to make royalty payments of 5% from gross sales of products, and 50% of sale price or ongoing payments from third parties for licenses granted under the patent to third parties.

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The Company paid CMH the $100,000 obligation of the initial payment due under this agreement, by a $50,000 cash payment and the issuance of 6,667 667 shares of common stock on December 12, 2020. On December 31, 2020, following our the Company's announcement with respect to the clinical commercialization of the StemSpine technology, we the Company paid CMH $50,000 of the $300,000 obligation due under this agreement through the issuance of 133 14 shares of common stock. On September 30, 2021, we the Company paid CMH an additional $40,000 of the $300,000 obligation due under this agreement through the issuance of 84,656 8,466 shares of common stock, and in January 2021 we the Company paid CMH an additional $50,000 of the $300,000 obligation due under this agreement through the issuance of 89,286 8,929 shares of common stock. The remaining portion of the $300,000 obligation has been was paid in cash. cash in 2020. In August 2023, the Company paid CMH $100,000 related to the filing of an IND with the FDA per the terms of the agreement.

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ImmCelz™ License. (CELZ-100) *- On December 28, 2020, we ImmCelz, Inc. ("ImmCelz"), a newly formed Nevada corporation and wholly owned subsidiary of the Company, entered into a patent license agreement Patent License Agreement dated December 28, 2020 (the "Agreement"), with Jadi Cell, LLC, LLC. ("Jadi"), a company owned and controlled by Dr. Amit Patel, a former director of ours. the Company. The agreement provides us with an exclusive, worldwide license Agreement grants to ImmCelz™ the patent rights under U.S. Patent No. Patent# 9,803,176 B2, "Methods and compositions for the clinical derivation of an allogenic cell and therapeutic uses" and the. The contract grants ImmCelz™ access to proprietary process of expanding the master cell bank of Jadi Cell LLC, as currently practiced by Licensor, and as documented in the field of enhancing standard*

operating procedures (SOPs) and other written documentation to augment autologous cells. The terms of the agreement includes the following terms: are as follows:

- We were required to Licensee shall pay an initial Licensor a license fee of $250,000 either (the "Upfront Royalty"), which can also be paid in cash or shares of our common CELZ stock at a discount of 25% of the closing price of our common stock $0.0037, which is based on the date of the agreement. this agreement

- Within thirty (30) days of the end of each calendar quarter we are required to during the term of this Agreement, Licensee will pay Jadi Cell Licensor five percent (5%) of the net income we generate from Net Income of ImmCelz™, during such calendar quarter. quarter (the "Continuing Royalty")

- If we sell in one or dispose a series of related transactions, of all or substantially all of the ImmCelz™ business we or assets of Licensee ImmCelz, Inc. ("Sale of Assets") will result in a one-time ten-percent allocation to the licensor, the Continuing Royalty will be required to pay Jadi Cell ten calculated at five percent (5%) of the proceeds Net Income of Licensee in any calendar quarter in which the sale.
- The agreement may only be terminated by Jadi Cell if we are Net Income in material breach such calendar quarter reflects the receipt of the agreement, in the event any consideration from such Sale of our bankruptcy, if we cease to engage in the ImmCelz™ business or if we challenge the validity of the patent rights granted to us under the agreement.
  Assets.

To date, we have the Company has not made any payments to Jadi Cell under this agreement, other than the $250,000 initial license fee, which we was paid by the issuance of 180,180 18,018 shares of common stock to Jadi Cell in February 2022.

Trademarks

We have obtained trademark registration for CaverStem®, StemSpine®, AlloStemSpine® and FemCelz®, and have trademark applications pending for ImmCelz™, OvaStem™, iPScelz™, AlloStem™, AlloStem Perinatal Tissue Derived Cells™, and Alova™.

Competition

We compete with many pharmaceutical, biotechnology and medical device companies, as well as other private and public stem cell companies involved in the development and commercialization of cell-based medical technologies and therapies. Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. We cannot forecast when or if these companies are likely to bring their products and therapies to market in competition with our products and therapies or those that we are pursuing. Regenerative medicine is rapidly progressing, in large part through the development of cell-based therapies or devices designed to isolate cells from human tissues. Most efforts involve cell sources, such as bone marrow, adipose tissue, embryonic and fetal tissue, umbilical cord and peripheral blood and skeletal muscle.

While there are a number of public and private companies that market and sell treatments for erectile dysfunction, our CaverStem® procedure is targeted at men who, due to damage to the blood vessels and smooth muscle tissue in the penis, do not respond to PDE5 inhibitors such as Viagra or Cialis. For these men, the only widely available treatment is invasive, non-reversible rod or pump implantation into the penis, or the painful injection into the penis of drugs containing alprostadil. Currently, we believe there are fewer than a dozen private clinics in the U.S. that offer autologous stem cell treatments for erectile dysfunction. None of these firms is believed to have filed for patent protection or conducted clinical trials using bone marrow to validate safety and efficacy as we have.

Similarly, while there are many treatments available for female sexual dysfunction, we are not aware of any competitor for our FemCelz® procedure that uses or proposes to use autological stem cells to treat female sexual dysfunction, nor are we aware of any potential competitor for OvaStem™ that uses or proposes to use autologous stem cells to treat women with damaged ovaries who do not respond to available medications.

Companies working in the area of regenerative medicine with regard to the disc and spine include, among others, Mesoblast, SpinalCyte, Longeveron, BioRestorative Therapies, DiscGenics and Isto Biologics. DiscGenics. Companies working in the area of regenerative medicine to treat stroke victims include Athersys, Inc., among others, although our competitors' treatments are injected back pain inject into the disc, and our treatment is injected around the disc.

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Government Regulation

U.S. Government Regulation

The health care industry is highly regulated in the United States. The federal government, through various departments and agencies, state and local governments, and private third-party accreditation organizations, regulate and monitor the health care industry, associated products, and operations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, approval, manufacture, distribution, and marketing of medical products, including drugs, biologics, and medical devices. These agencies and other federal, state, and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of medical products. The following is a general overview of the laws and regulations pertaining to our business.

FDA Regulation of Stem Cell Treatment and Products

The FDA regulates the manufacture of human stem cell treatments and associated products under the authority of the Public Health Service Act (or PHS Act), and the Federal Food, Drug, and Cosmetic Act (or FDCA). Stem cells can be regulated under the FDA's Human Cells, Tissues, and Cellular and Tissue-Based Products Regulations, referred to as HCT/Ps, or may also be subject to the FDA's drug, biologic, or medical device regulations, each as discussed below.

Human Cells, Tissues, and Cellular and Tissue-Based Products Regulation

Under Section 361 of the PHS Act, the FDA issued specific regulations governing the use of HCT/Ps in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations, or CFR, or the HCT/P Regulations, the FDA established a unified registration and listing system for establishments that manufacture and process HCT/Ps. The regulations also include provisions pertaining to donor eligibility determinations; current good tissue practices covering all stages of production, including harvesting, processing, manufacture, storage, labeling, packaging, and distribution; and other procedures to prevent the introduction, transmission, and spread of communicable diseases.

The HCT/P Regulations define HCT/Ps as articles "containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient." The HCT/P Regulations strictly constrain the types of products that may be regulated solely as an HCT/P. Factors considered include the degree of manipulation, whether the product is intended for a homologous function, whether the product has been combined with noncellular or non-tissue components, and the product's effect or dependence on the body's metabolic function. In those instances where cells, tissues, and cellular and tissue-based products have been only minimally manipulated, are intended strictly for homologous use, have not been combined with noncellular or nontissue substances, and do not depend on or have any effect on the body's metabolism, the manufacturer is only required to register with the FDA, submit a list of manufactured products, and adopt and implement procedures

for the control of communicable diseases. If one or more of the above factors has been exceeded, the product would be regulated as a drug, biological product, or medical device rather than an HCT/P.

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In addition, pursuant to the "Same Surgical Procedure Exception" under Section 1271.15(b) of the HCT/P Regulations, the FDA has provided guidance that exempts HCT/Ps from Section 361 of the PHS Act where autologous cells are removed from an individual and implanted into the same individual during a single surgical procedure without intervening processing steps. The FDA's rationale is that this type of procedure raises no additional risks beyond that typically associated with surgery. Management has determined that our CaverStem® and FemCelz® procedures and therapies are exempt from the FDA premarket review and approval process and other HCT/P Regulations under the Same Surgical Procedure Exception, and that our StemSpine® and OvaStem™ procedures and therapies will be similarly exempt. Conversely, because our ImmCelz™ therapy will treat a patient's stem cells with Jadi Cells before being injected back into the patient, we will need to obtain FDA regulatory approval for ImmCelz™ in the same manner as a standard drug, as described below.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions including public warning letters, fines, consent decrees, orders of retention, recall or destruction of product, orders to cease manufacturing, and criminal prosecution. If any of these events were to occur, it could materially adversely affect us.

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Drug and Biological Product Regulation

An HCT/P product that does not meet the criteria for being solely regulated under Section 361 of the PHS Act will be regulated as a drug, device or biological product under the FDCA and/or Section 351 of the PHS Act, and applicable FDA regulations. The FDA has broad regulatory authority over drugs and biologics marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, effectiveness, labeling, storage, recordkeeping, promotion, distribution, and production of drugs and biological products. The FDA also regulates the export of drugs and biological products manufactured in the United States to international markets in certain situations.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practice (or GLP), or other applicable regulations;
- submission of an IND, which allows clinical trials to begin unless the FDA objects within 30 days;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use or uses conducted in accordance with FDA regulations and Good Clinical Practices (or GCP), which are international ethical and scientific quality standards meant to ensure that the rights, safety and well-being of trial participants are protected and that the integrity of the data is maintained;
- registration of clinical trials of FDA-regulated products and certain clinical trial information;

- preparation and submission to the FDA of a new drug application (or NDA), in the case of a drug or biologics license application (or BLA) in the case of a biologic;

- review of the product by an FDA advisory committee, where appropriate or if applicable;

- satisfactory completion of pre-approval inspection of manufacturing facilities and clinical trial sites at which the product, or components thereof, are produced to assess compliance with Good Manufacturing Practice, or cGMP, requirements and of selected clinical trial sites to assess compliance with GCP requirements; and

- FDA approval of an NDA or BLA which must occur before a drug or biologic can be marketed or sold.

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Approval of an NDA requires a showing that the drug is safe and effective for its intended use and that the methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity. To obtain a BLA, a manufacturer must show that the proposed product is safe, pure, and potent and that the facility in which the product is manufactured, processed, packed, or held meets established quality control standards.

For purposes of an NDA or BLA approval by the FDA, human clinical trials are typically conducted in the following phases (which may overlap):

- Phase 1: The investigational product is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution, and excretion. These trials may also provide early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

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- Phase 2: These clinical trials are conducted in a limited number of human subjects in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the investigational product for specific targeted diseases and to determine dosage tolerance and dosage levels. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

- Phase 3: Phase 3 clinical trials are undertaken after Phase 2 clinical trials demonstrate that a dosage range of the investigational product appears effective and has a tolerable safety profile. The Phase 2 clinical trials must also provide sufficient information for the design of Phase 3 clinical trials. Phase 3 clinical trials are conducted to provide statistically significant evidence of clinical efficacy and to further test for safety risks in an expanded human subject population at multiple clinical trial sites. These clinical trials are intended to further evaluate dosage, effectiveness, and safety, to establish the overall benefit-risk profile of the investigational product and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of an investigational drug or biologic.

All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any

specified period, or at all. These government regulations may delay or prevent approval of product candidates for a considerable period of time and impose costly procedures upon our business operations.

The FDA may require, or companies may pursue, additional clinical trials, referred to as Phase 4 clinical trials, after a product is approved. Such trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA, or an NDA or BLA supplement, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs.

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Drug and biological products must also comply with applicable requirements, including monitoring and recordkeeping activities, manufacturing requirements, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling, or off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may, in their independent professional medical judgment, prescribe legally available drugs for off-label uses, manufacturers typically may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling, or changes of the site of manufacture, are often subject to the approval of the FDA and other regulators, who may or may not grant approval or may include a lengthy review process.

In the event that the FDA does not regulate our product candidates in the United States solely under the HCT/P regulation, our products and activities could be regulated as drug or biological products under the FDCA. If regulated as drug or biological products, we will need to expend significant resources to ensure regulatory compliance. If an IND and NDA or BLA are required for any of our product candidates, there is no assurance as to whether or when we will receive FDA approval of the product candidate. The process of designing, conducting, compiling, and submitting the non-clinical and clinical studies required for NDA or BLA approval is time-consuming, expensive, and unpredictable. The process can take many years, depending on the product and the FDA's requirements.

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In addition, even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution or use, or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product, including safety labeling or imposition of a Risk Evaluation and Mitigation Strategy, or REMS, the requirement to conduct post-market studies or clinical trials or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our products, or obtaining approval but for significantly limited use, would harm our business. Further, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our

products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

FDA Expedited Review Programs

The FDA is authorized to expedite the review of NDAs and BLAs in several ways. Under the Fast Track program, the sponsor of a drug or biologic product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Drug and biologic products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied.

In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track NDA or BLA before the application is complete, a process known as rolling review.

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Any product submitted to the FDA for marketing, including under a Fast Track program, may also be eligible for the following other types of FDA programs intended to expedite development and review:

- Breakthrough therapy designation. To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative, and cross-disciplinary review, and rolling review.

- Priority review. A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA aims to complete its review of priority review applications within six months as opposed to ten months for standard review.

- Accelerated approval. Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

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Fast Track designation, breakthrough therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Further, with the passage of the 21st Century Cures Act, or the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine advanced therapy, or RMAT (which may include a cell therapy), that is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. The benefits of a RMAT designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Medical Device Regulation

The FDA also has broad authority over the regulation of medical devices marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, promotion, distribution, and production of medical devices. The FDA also regulates the export of medical devices manufactured in the United States to international markets.

Under the FDCA, medical devices are classified into one of three classes, Class I, Class II, or Class III, depending upon the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness. Class I devices are subject to the lowest degree of regulatory scrutiny because they are considered low risk devices and need only comply with the FDA's General Controls. The General Controls include compliance with the registration, listing, adverse event reporting requirements, and applicable portions of the Quality System Regulation as well as the general misbranding and adulteration prohibitions.

Class II devices are subject to the General Controls as well as certain Special Controls such as 510(k) premarket notification. Class III devices are subject to the highest degree of regulatory scrutiny and typically include life supporting and life sustaining devices and implants. They are subject to the General Controls and Special Controls that include a premarket approval application, or PMA. "New" devices are automatically regulated as Class III devices unless they are shown to be low risk, in which case they may be subject to de novo review to be moved to Class I or Class II. Clinical research of an investigational device is subject to the FDA's Investigational Device Exemption, or IDE, regulations. Nonsignificant risk devices are subject to abbreviated requirements that do not require a submission to the FDA but must have Institutional Review Board (IRB) approval and comply with other requirements pertaining to informed consent, labeling, recordkeeping, reporting, and monitoring. Significant risk devices require the submission of an IDE application to the FDA and the FDA's approval of the IDE application.

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The FDA premarket clearance and approval process can be lengthy, expensive, and uncertain. It generally takes three to twelve months from submission to obtain 510(k) premarket clearance, although it may take longer. Approval of a PMA could take one to four years, or more, from the time the application is submitted and there is no guarantee of ultimate clearance or approval. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA. In addition, modifications or enhancements of products that could affect the safety or effectiveness or effect a major change in the intended use of a device that was either cleared through the 510(k) process or approved through the PMA process may require further FDA review through new 510(k) or PMA submissions.

In the event we develop processes, products or services which qualify as medical devices subject to FDA regulation, we intend to comply with such regulations. If the FDA determines that our products are regulated as medical devices and we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, application integrity proceedings, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

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Current Good Manufacturing Practices and other FDA Regulations of Cellular Therapy Products

Products that fall outside of the HCT/P regulations and are regulated as drugs, biological products, or devices must comply with applicable cGMP regulations. These cGMPs and related quality standards are designed to ensure the products that are processed at a facility meet the FDA's applicable requirements for identity, strength, quality, sterility, purity, and safety. In the event that our domestic United States operations are subject to the FDA's drug, biological product, or device regulations, we intend to comply with the applicable cGMPs and quality regulations.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

Health Insurance Portability and Accountability Act—Protection of Patient Health Information

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information on certain types of individuals and organizations. In addition, certain state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts. Further, we may need to also comply with additional federal or state privacy laws and regulations that may apply to certain diagnoses, such as HIV/AIDS, to the extent that they apply to us.

The Department of Health and Human Services, or HHS, through its Office for Civil Rights, investigates breach reports and determines whether administrative or technical modifications are required and whether civil or criminal sanctions should be imposed. Companies failing to comply with HIPAA and the implementing regulations may also be subject to civil money penalties or in the case of knowing violations, potential criminal penalties, including monetary fines, imprisonment, or both. In some cases, the State Attorneys General may seek enforcement and appropriate sanctions in federal court.

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Other Applicable U.S. Laws

In addition to the above-described regulation by United States federal and state government, the following are other federal and state laws and regulations that could directly or indirectly affect our ability to operate the business:

- state and local licensure, registration, and regulation of the development of pharmaceuticals and biologics;
- state and local licensure of medical professionals;
- state statutes and regulations related to the corporate practice of medicine;
- other laws and regulations administered by the FDA;

- other laws and regulations administered by HHS;
- state and local laws and regulations governing human subject research and clinical trials;

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- the federal physician self-referral prohibition, also known as Stark Law, and any state equivalents to Stark Law;
- the federal False Claims Act, or FCA;
- the federal Anti-Kickback Statute, or AKS, and any state equivalent statutes and regulations;
- federal and state coverage and reimbursement laws and regulations;
- state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;
- Occupational Safety and Health Administration, or OSHA, regulations, and requirements;
- the Physician Payments Sunshine Act (in the event that our products are classified as drugs, biologics, devices, or medical supplies and are reimbursed by Medicare, Medicaid, or the Children's Health Insurance Program);
- state and other federal laws addressing the privacy of health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare professionals and other potential referral sources, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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Violation of any of the laws described above or any other governmental laws and regulations may result in penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs and imprisonment. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products.

Foreign Government Regulation

In general, we will need to comply with the government regulations of each individual country in which our products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States.

Due to the fact that there are new and emerging cell therapy regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not always precisely understood for each country, creating greater uncertainty for the international regulatory process. Furthermore, government regulations can change with little to no notice and may result in up-regulation of our product(s), thereby creating a greater regulatory burden for our cell processing technology products. We have not yet thoroughly explored the applicable laws and regulations that we will need to comply with in foreign jurisdictions. It is possible that we may not be permitted to expand our business into one or more foreign jurisdictions.

Employees

We currently employ four people on a full-time basis and multiple consultants on a part-time basis. None of our employees belong to a union. We believe relations with our employees are good.

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Research and Development

Research and development expenses for the year ended December 31, 2022 December 31, 2023, totaled $6,268,854. $1,970,639. This reflects expenses associated with the acquisition of research tools associated with the development of our drug master file, laboratory research in preparation of our master cell bank submittal to the FDA, the approval of our FDA application for a Type I Diabetes Phase I/II and Lower Back Pain Phase I/II clinical trial, trials, the manufacturing and testing of our ImmCelz™ cell line, and the development of our iPSC cell line in partnership with Greenstone Biosciences Inc. Research and development expenses for the year ended December 31, 2021 December 31, 2022 totaled $109,180. $6,268,854.

Item 1A. Risk Factors

RISK FACTORS

Risks Related to our Financial Position and Capital Needs

We have incurred recent losses and our future profitability is uncertain.

We have incurred an operating loss of approximately $10.2 million $5.6 million for the year ended December 31, 2022 December 31, 2023, and a loss of approximately $3.1 million $10.0 million (which included a $5.0 million investment for the research tools referenced in Note 3) for the year ended December 31, 2021 December 31, 2022, respectively. We expect our operating losses to continue until such time, if ever, that product sales, licensing fees, royalties and other sources generate sufficient revenue to fund our operations. We cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

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Even with the proceeds from our recent securities offerings, we will need additional capital to fund our operations as planned.

For the year ended December 31, 2022 December 31, 2023, our operations used approximately $7.8 million $8.0 million in cash. Cash used in operations consisted primarily of cash on hand and cash raised in our December 2021 public offering and our May 2022 private offering. At December 31, 2022 December 31, 2023, we had a combined cash, and certificates of deposit and short-term U.S. Treasuries balance of approximately $18.4

million $10.0 million. Although we generated gross proceeds in excess of $30 million from our 2021 and 2022 securities offerings, we will need additional capital to maintain our operations, continue our research and development programs, conduct clinical trials, seek regulatory approvals and manufacture and market our products. We will seek such additional funds through public or private equity or debt financings and other sources. We cannot be certain that adequate additional funding will be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations, we may be required to reduce the scope of or eliminate our research and development programs, delay our clinical trials and the ability to seek regulatory approvals, downsize our general and administrative infrastructure, or seek alternative measures to avoid insolvency. If we raise additional funds through future offerings of shares of our common stock or other securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Future offerings could also have a material and adverse effect on the price of our common stock.

We have generated minimal revenues from our products. We will not achieve profitability unless we generate increased revenues from our current or proposed products or therapies.

Revenues generated from sales of our CaverStem® and FemCelz® kits were only $88,600 $9,000 and $87,754 $88,600 for the years ended December 31, 2022 December 31, 2023, and December 31, 2021 December 31, 2022, respectively. To sustain our operating costs and generate profits, we will need to significantly increase revenues from our CaverStem® and FemCelz® products or from our other products or therapies that have not yet been commercialized.

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We expect to continue to incur significant financial losses in the future as we seek to proceed with our CELZ-201 Type I Diabetes (CELZ-201 CREATE-1) clinical trial, our AlloStemSpine® Chronic Lower Back Pain (CELZ-201 ADAPT) clinical trial, and our other planned clinical trials.

We have received the necessary regulatory approval for our CELZ-201 Type I diabetes Diabetes (CELZ-201 CREATE-1) clinical trial and our AlloStemSpine® Chronic Lower Back Pain (CELZ-202 ADAPT) clinical trial. In addition, we are investing significant resources to submit our drug master file to the FDA, further develop developing our cell platforms, and file INDs for additional indications that utilize our cell platforms. We anticipate that our expenses will increase substantially as we:

- initiate, conduct, and complete ongoing, anticipated, or future preclinical studies and clinical trials for our current and future product candidates;
- seek marketing approvals for product candidates that successfully complete clinical trials; and
- establish a sales, marketing, and distribution infrastructure to commercialize products for which we may obtain marketing approval.

Risks Related to Product Development, Regulatory Approval and Commercialization

Our product candidates' commercial viability remains subject to current and future preclinical studies, clinical trials, regulatory approvals, and the risks generally inherent in the development of biopharmaceutical products. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.

In the near term, failure to successfully advance the development of our proposed products may have a material adverse effect on us. To date, other than limited sales generated from our CaverStem® and FemCelz® products, we have not successfully developed or commercially marketed, distributed, or sold any product candidate. The success of our business may depend upon our ability to successfully advance the development of our current and future product candidates through preclinical studies and clinical trials, where applicable, have the

product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have the product candidates successfully commercialized by us or a commercial partner. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will receive the necessary approvals from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates.

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We may not be successful in our commercialization efforts for our proposed products and therapies, which may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

To the extent we possess or obtain the necessary regulatory approval for our proposed products and therapies, we still may not be successful in our commercialization efforts or in gaining sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. Market acceptance will require us to build and maintain strong relationships with healthcare professionals that treat the indications our therapies are intended to address. A failure to build or maintain these important relationships with these healthcare professionals and treatment centers could result in lower market acceptance. Our efforts to educate physicians, patients, third-party payors, and others in the medical community on the benefits of our products and therapies may require significant resources and may never be successful. The degree of market acceptance of our products and therapies will depend on a number of factors, including:

- their efficacy;
- limitations or warnings or any restrictions on use, and the prevalence and severity of any side effects;
- the availability and efficacy of alternative treatments;
- the effectiveness of sales and marketing efforts and the strength of marketing and distribution support;
- their cost-effectiveness compared to alternative therapies; and
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

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The results of our clinical trials may not support our product claims or may result in the discovery of adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that any regulatory authority whose approval we will require in order to market and sell our products in any territory will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that clinical trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including FDA approval. Our CaverStem® and FemCelz® products are exempt from the FDA premarket review and approval process as these autologous therapies involve treating the patient with his or her own cells. However, we will require FDA approval of CELZ-201 CREATE-1 for the treatment of Type I diabetes, AlloStemSpine (CELZ 201 – ADAPT) treatment for chronic lower back pain, and other indications. We have only limited experience in filing the applications necessary to gain regulatory approvals and have relied, and expect to continue to rely, in part, on consultants and third-party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of extensive non-clinical and clinical data and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. If third parties we rely on fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, our efforts to secure regulatory approval of our product candidates may be delayed or prove unsuccessful.

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Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We cannot predict whether we will encounter problems with any of our completed, ongoing, or planned clinical trials that will cause us or regulatory authorities to delay or suspend clinical trials or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials of CELZ-201 for the treatment of Type I diabetes Diabetes (CELZ-201 CREATE-1) and AlloStemSpine® Chronic Lower Back Pain (CELZ-201 ADAPT) will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing, and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;
- slower than anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;

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- unforeseen safety issues;
- uncertain dosing issues;
- an inability to monitor patients adequately during or after treatment; and
- problems with investigator or patient compliance with the trial protocols

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. We do not know whether any clinical trials we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market ImmCelz™(CELZ-100).

Our autologous products are currently not eligible for reimbursement from public or private insurers.

Currently, our CaverStem® and FemCelz® products and related medical procedures are paid for by patients and are not eligible for reimbursement from public or private insurers. As a general rule, reimbursement is available only for products and therapies that have been approved by the FDA. Our CaverStem® and FemCelz® products were exempt from the FDA premarket review and approval process as these autologous therapies involve treating the patient with his or her own cells. While we believe that the requirement that patients directly pay the cost for our CaverStem® and FemCelz® products and procedures make these procedures more attractive to doctors, these treatments are only available to patients that can afford to pay for them. Our success and the extent of our growth will depend in part on the extent to which reimbursement for the costs of our products and related treatments will be available from third party payers, such as public and private insurers and health systems.

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The pharmaceutical business is subject to increasing government regulation and reform, including with respect to price controls, reimbursement, and access to therapies, which could adversely affect our future revenues and profitability.

Our existing and proposed products may not be considered cost-effective, and third-party or government reimbursement might not be available or sufficient. Globally, governmental, and other third-party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U.S. to continue.

Our existing and proposed products are and will be subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and the implementation of U.S. health care reform legislation that is increasing these pricing pressures. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, instituted comprehensive health care reform, and includes provisions that, among other things, reduce and/or limit Medicare reimbursement, and impose new and/or increased taxes. The future of the Affordable Care Act and its constituent parts are uncertain at this time.

The continuing efforts of government and insurance companies, health maintenance organizations, and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers, and collaborative partners, as well as the availability of capital.

United States federal and state privacy laws, and equivalent laws of other nations, may increase our costs of operation and expose us to civil and criminal sanctions.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our collaborators to incur additional costs to achieve compliance, limit our competitiveness,

necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our collaborators' ability to process or use data in order to support the provision of our products, affect our or our collaborators' ability to offer our products in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities.

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We and our collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state personal information laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we knowingly use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

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Later discovery of previously unknown problems could limit our ability to market or sell our products or therapies and can expose us to product liability claims.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, warning letters, or holds on clinical trials;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials, or changes to product labeling requirements; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

Discovery of previously unknown problems or risks relating to our product could also subject us to potential liabilities through product liability claims.

If we do not obtain required approvals in other countries in which we aim to market our products, we will be limited in our ability to export or sell the products in those markets.

Our lack of experience in conducting clinical trials in foreign jurisdictions may negatively impact the approval process in those jurisdictions. If we are unable to obtain and maintain required approval from one or more foreign jurisdictions where we would like to sell our products or therapies, we will be unable to market products as intended, our international market opportunity will be limited, and our results of operations will be harmed.

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We rely in part on third parties for research and clinical trials for our products and therapies.

We rely on contract research organizations ("CROs"), academic institutions, corporate partners, and other third parties to assist us in managing, monitoring, and otherwise carrying out clinical trials and research activities. We rely or will rely heavily on these parties for the execution of our clinical studies and control only certain aspects of their activities. Accordingly, we may have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. Although we rely on these third parties to manage the data from clinical trials, we will be responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Our failure, or the failure of third parties on which we rely, to comply with the strict requirements relating to conducting, recording, and reporting the results of clinical trials, or to follow good clinical practices, may delay the regulatory approval process or cause us to fail to obtain regulatory approval for our proposed products and therapies.

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We currently have a very limited marketing and sales organization and may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products and therapies, we may not be able to generate sufficient revenues to support our operations.

Our current sales, marketing and distribution capabilities consist of independent contractors who promote the sale of our CaverStem® and FemCelz® products to medical doctors. To generate sufficient revenues to support our operations, we will have to seek collaborators, especially for marketing and sales outside of the United States or invest significant amounts of financial and management resources to develop internal sales, distribution, and marketing capabilities. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing, and distribution functions on acceptable financial terms, or at all. In addition, our product revenues, and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. Even if we determine to perform sales, marketing, and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by our product candidates that we may develop, in-license or acquire; and
- our direct sales and marketing efforts may not be successful.

We rely upon third parties for the manufacture of our CaverStem® and FemCelz® disposable kits and are dependent on their quality and effectiveness.

We rely upon third parties for the manufacture of our CaverStem® and FemCelz® disposable kits. The failure to achieve and maintain high manufacturing standards, or to detect or control anticipated or unanticipated manufacturing errors or the frequent occurrence of such errors, could result in cost overruns, product recalls or withdrawals, patient injury or death, and other problems that could seriously hurt our business.

We may be unable to compete effectively with marketed therapies or drugs targeting similar indications to our products and therapies.

We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any products that are safer, more effective, have fewer side effects or are less expensive than our products and therapies. These potential competitors may also compete with us in establishing clinical trial sites, and patient enrollment for clinical trials.

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Our business and operations would suffer in the event of computer system failures or security breaches.

In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, and proprietary business information. Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations, or CROs, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication, and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property and proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, the COVID-19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. 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 and the further development of our future product candidates could be delayed.

Our internal controls were inadequate in our most recent year.

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As a public company, our management is responsible for establishing and maintaining adequate internal control over financial reporting. In addition, we are required to include in our Annual Reports on Form 10-K, a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. As defined in Exchange Act Rule 13a-15(f), internal control over financial reporting is a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. As disclosed in Item 9A of this Annual Report on Form 10-K, management has concluded that our internal control over financial reporting was not effective for our year ended December 31, 2022, and has identified material weaknesses in our internal controls. Faulty judgments, simple errors or mistakes, or the failure of our personnel to adhere to established controls and procedures, may make it difficult for us to ensure that the objectives of the control system are met. A failure of our controls and procedures to detect material errors or fraud could seriously harm our business and results of operations.

We are subject to risks arising from the recent global outbreak of the COVID-19 coronavirus.

The recent outbreak of the COVID-19 coronavirus has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, CROs, suppliers, manufacturers and other partners may be prevented from conducting business activities for an indefinite period of time, including due to the spread of the disease or shutdowns that may be requested or mandated by governmental authorities. During 2021 and 2022, Another significant, outbreak of COVID-19, has resulted in significantly reduced revenues from our CaverStem® and FemCelz® products, as elective procedures in general have been greatly reduced throughout the United States during the pandemic. In addition, the continued spread of COVID-19 a communicable disease, could disrupt our clinical trials, supply chain and the manufacture or shipment of our products, and other related activities, which could have a material adverse effect on our business, financial condition and results of operations. COVID-19 has operations, and may also had have an adverse impact on global economic conditions which could impair our ability to raise capital when needed.

We are subject to risks arising from the wars in Ukraine and the Gaza Strip.

Although we believe we do not have any exposure to the wars in Ukraine and the Gaza Strip, we cannot predict how global supply chain activities, or the economy at large may be impacted by prolonged wars in those or other regions, or whether global conflicts, if any, may in the future adversely affect our results of operations.

Risks Related to Our Intellectual Property

We may not be able to protect our proprietary rights.

Our commercial success will depend in large part upon our ability to protect our proprietary rights. There is no assurance, for example, that any additional patents will be issued based on our or our pending applications or, if issued, that such patents will not become the subject of a re-examination, will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products and services incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products and services, duplicate any of our products and services, or design around any patents we obtain.

Our commercial success will also depend upon our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products, services or processes, obtain licenses, or cease certain activities. If we are required in the future to obtain any licenses from third parties for some of our products and/or services, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. United States and foreign patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using.

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In addition to patents, we rely on unpatented trade secrets and proprietary technological expertise, and confidentiality agreements with our partners, employees, advisors, vendors, and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Failure to obtain or maintain patent protection or to protect our trade secrets could have a substantial negative effect on our results of operations and financial condition.

We are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our product candidates.

There is a substantial amount of litigation over patent and other intellectual property rights in the biotechnology industry. Whether or not a product infringes a patent involves complex legal and factual considerations, the determination of which is often uncertain. Our competitors or other parties may assert that our product candidates and the methods employed may be covered by patents held by them. If any of our products infringes a valid patent, we could be prevented from manufacturing or selling such product unless we are able to obtain a license or able to redesign the product in such a manner as to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement, nor does a later redesign protect the Company from prior infringement.

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We may need to initiate lawsuits to protect or enforce our intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

In order to protect or enforce our intellectual property rights, we may need to initiate patent, trademark and related litigation against third parties, such as infringement suits or requests for injunctive relief. Our ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who we believe to be infringing its rights. Any lawsuits or administrative proceedings in patent offices that we initiate or that are initiated against us could be expensive, take significant time and divert our management's attention from other business concerns and the outcome of litigation to enforce our intellectual property rights in patents, trade secrets or trademarks is highly unpredictable. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, or adversely affect our ability to distribute any products that are subject to such litigation. In addition, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits or administrative proceedings that we initiate, and the damages or other remedies awarded, including attorney fees, if any, may not be commercially valuable.

Risks Related to Employee Matters

We are dependent on our executive officers, and we may not be able to pursue our current business strategy effectively if we lose them.

Our success to date has largely depended on the efforts and abilities of Timothy Warbington, our Chief Executive Officer and Don Dickerson, our Chief Financial Officer. Our ability to manage our operations and meet our business objectives could be adversely affected if, for any reason, such officers do not remain with us.

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Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) U.S. laws and regulations or those of foreign jurisdictions, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to our employees, but it is not always possible to identify and deter employee 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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If we fail to comply with the U.S. federal Anti-Kickback Statute and similar state and foreign country laws, we could be subject to criminal and civil penalties and exclusion from federally funded healthcare programs including the Medicare and Medicaid programs and equivalent third country programs, which would have a material adverse effect on our business and results of operations.

A provision of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, directly or indirectly, in cash or in kind, to induce or reward the referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable, in whole or in part, by Medicare, Medicaid or any other federal healthcare program. The federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute that apply to activity in those states, and some of these laws are even broader than the federal Anti-Kickback Statute in that their prohibitions may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the source of payment. Violations of the federal Anti-Kickback Statute may result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

While we believe our operations will be in compliance with the federal Anti-Kickback Statute and similar state laws, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti-Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

Risks Related To Our Common Stock

The market price of our common stock is highly volatile, and you could lose all or part of your investment.

The trading price of our common stock has been volatile. This volatility may prevent you from being able to sell your securities at or above the price you paid for your securities. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include:

- whether we achieve our anticipated corporate objectives;
- termination of lock-up agreements or other restrictions on the ability of our stockholders and other security holders to sell shares; and
- general economic or political conditions in the United States or elsewhere.

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In addition, the stock market in general, and the stock of clinical stage biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

If our shares of common stock are delisted from The Nasdaq Capital Market and become subject to the penny stock rules, it will be more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not maintain a listing on Nasdaq and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

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Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our securities.

On July 8, 2022, During 2023 we received effected a letter from The Nasdaq Stock Market stating that 1-for-10 reverse stock split in order to increase the Company was not in compliance with Nasdaq Listing Rule 5550(a)(2) because the closing bid trading price of our common stock was below and comply with NASDAQA's $1.00 per share for 30 consecutive business days. Pursuant to Nasdaq's Listing Rules, the Company had an initial 180-day grace period, until January 4, 2023, during which the Company could have regained compliance if the bid price of its common stock closed at $1.00 per share or more for a minimum of ten consecutive business days. The Company was eligible for an additional 180-day grace period if the Company met Nasdaq's initial listing standards (other than with respect to minimum bid price) for

The Nasdaq Capital Market. The Company applied for and received the additional 180-day grace period and now has until July 4, 2023, to meet the Nasdaq minimum bid price listing rule. The Company intends to actively monitor the bid price for its common stock and is considering available options to regain requirement. Although we are currently in compliance with the Nasdaq Nasdaq's minimum bid price requirement.

If requirement, if we again fail to satisfy the minimum bid rule when required, this or any other continued listing requirements of Nasdaq, requirement, Nasdaq may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

We will indemnify and hold harmless our officers and directors to the maximum extent permitted by Nevada law.

Our bylaws provide that we will indemnify and hold harmless our officers and directors against claims arising from our activities, to the maximum extent permitted by Nevada law. If we were called upon to perform under our indemnification agreement, then the portion of our assets expended for that purpose would reduce the amount otherwise available for our business.

Because we do not expect to pay dividends for the foreseeable future, investors seeking cash dividends should not purchase shares of common stock.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. Accordingly, investors seeking cash dividends should not purchase our shares.

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Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C Cybersecurity

Risk Management and Strategy

We periodically assess risks from cybersecurity threats, and monitor our information systems for potential vulnerabilities. However, to date, given the small size of our company and the nature of our operations, our reliance on information systems has been limited to the use of standard off-the-shelf software (such as Microsoft Office) and the use by our employees of standard personal computers. Accordingly, management has not implemented any formal process for assessing, identifying, and managing risks from cybersecurity threats.

Risks from cybersecurity threats have, to date, not materially affected us, our business strategy, results of operations or financial condition. We discuss how cybersecurity incidents could materially affect us in our risk factor disclosures in Item 1A of this Annual Report on Form 10-K.

Governance

As discussed above, given the nature of our current operations and our experience to date, we do not currently perceive cybersecurity as a particularly significant risk to our business. Accordingly, we have not tasked our Board of Directors with any additional cybersecurity oversight duties, or designated any committee of the Board of Directors to specifically oversee cybersecurity risks to our business.

Item 2. Properties

We do not currently own any real property. Our corporate office is located at 211 East Osborn Road, Phoenix, Arizona, which we lease on a month-to-month basis. Management believes that this space is adequate to meet our current and foreseeable needs.

Item 3. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business.

In October 2022, we terminated an employee for cause. Subsequent to the termination, in December 2022, the employee brought claims against us for breach of contract, wrongful termination and related claims in the Superior Court of the State California (Orange County). The parties have submitted the action for arbitration before JAMS, where it is now pending.

Item 4. Mine Safety Disclosures

Not Applicable.

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PART II – OTHER INFORMATION

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

On June 12, 2023, we announced that our Board of Directors authorized a share repurchase program for the repurchase of up to $2 million of our common stock (the "Repurchase Plan). Purchases under the Repurchase Plan commenced in August 2023. The following table provides information about our monthly share repurchases for the year ended December 31, 2023, which consisted solely of repurchases on the open market under the Repurchase Plan.

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 - July 31, 2023	-	$ -	0	$ 2,000,000
August 1 - August 31, 2023	11,500	4.57	11,500	1,947,462
September 1 - September 30, 2023	28,500	4.89	40,000	1,755,682
October 1 – October 31, 2023	6,500	4.68	46,500	1,725,269
November 1 – November 31, 2023	8,000	4.41	54,500	1,689,959
December 1 – December 31, 2023	3,000	4.48	57,500	1,676,510

Total	57,500	4.71

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

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "CELZ".

Holders

As of March 31, 2023 March 22, 2024, the number of holders of record of shares of common stock, excluding the number of beneficial owners whose securities are held in street name, was approximately 75.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock at any time in the foreseeable future. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our Board and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions, the terms of any future credit agreements and other factors that our Board may deem relevant.

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Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth as of the most recent fiscal year ended December 31, 2022 December 31, 2023, certain information with respect to compensation plans (including individual compensation arrangements) under which our common stock is authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and Rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) and (b)) (c)	Number of securities to be issued upon exercise of outstanding options, warrants and Rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) and (b)) (c)

Equity compensation plans approved by security holders	111,817 (1)	$	1.69	488,183 (1)	11,182 (1)	$	16.90	48,818 (1)
Equity compensation plans not approved by security holders	100,102 (2)	$	10.71	27 (3)	9,813 (2)	$	107.10	3 (3)
Total	211,919	$	5.67	376,393	20,995	$	56.70	48,821

(1) Represents 58,580 5,858 shares of common stock issuable to Timothy Warbington, the Company's Chief Executive Officer, under a ten-year option issued on February 9, 2022 with an exercise price of $1.69 $16.90 per share, and (x) 53,237 5,324 shares of common stock issuable to Donald Dickerson, the Company's Chief Financial Officer, under a ten-year option issued on February 9, 2022 with an exercise price of $1.69 $16.90 per share, and shares available for issuance under the Company's 2021 Equity Incentive Plan.

(2) Represents (i) 20,000 2,000 shares of common stock issuable to Donald Dickerson, the Company's Chief Financial Officer, under a ten-year warrant issued on December 28, 2020 with an exercise price of $2.00 $20.00 per share, (ii) 10,000 1,000 shares of common stock issuable to Donald Dickerson under a ten-year warrant issued on July 15, 2021 with an exercise price of $15.00 $150.00 per share, (iii) 20,000 2,000 shares of common stock issuable to Amit Patel, a former director of the Company, under a ten-year warrant issued on December 28, 2020 with an exercise price of $2.00 $20.00 per share, (iv) 10,000 1,000 shares of common stock issuable to Amit Patel under a ten-year warrant issued on July 15, 2021 with an exercise price of $15.00 $150.00 per share, (v) 10,000 1,000 shares of common stock issuable to Thomas Ichim, a former director of the Company, under a ten-year warrant issued on July 15, 2021 with an exercise price of $15.00 $150.00 per share, (vi) 28,020 2,802 shares of common stock issuable to various consultants of the Company under three-year warrant issued in April and May 2021 with an exercise price of $15.00 $150.00 per share; (vii) 95 10 shares of common stock issuable to a consultant of the Company under three-year warrant issued September 2020 with an exercise price of $1.45 $14.50 per share, and (viii) 7 shares 1 share of common stock issuable under options granted under the Company's 2016 Stock Incentive Plan.

(3) Represents 27 3 shares available under the Company's 2016 Stock Incentive Plan.

2021 Equity Incentive Plan

On September 6, 2021, the Company's Board of Directors, and holders of a majority of the voting power of the Company's stockholders approved the Company's 2021 Equity Incentive Plan (the "2021 Plan"). The essential features of the 2021 Plan are outlined below:

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Purpose. The 2021 Plan provides for the granting to our employees, officers, directors, consultants, and advisors of performance awards payable in shares of common stock, stock options (non-statutory and incentive), restricted stock awards, stock appreciation rights ("SARs"), restricted share units ("RSUs") and other stock-based awards. The purpose of the 2021 Plan is to secure for the Company and its stockholders the benefits arising from capital stock ownership by eligible participants who are expected to contribute to the Company's future growth and success. To date, we have not granted any awards under the 2021 Plan.

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Administration. The 2021 Plan is administered by the compensation committee of the Board (the "Committee"). Subject to the terms of the 2021 Plan, the Committee has the authority to determine the individuals to whom, and the time or times at which, awards are made, the size of each award, and the other terms and conditions of each award (which need not be identical across participants). The Committee also has the authority, subject to the express provisions of the 2021 Plan, to construe the respective agreements under the plan, proscribe, amend and rescind rules and regulations relating to the plan, accelerate or extend the dates options may be exercised or accelerate the vesting of other stock awards, and make all other determinations which are in the Committee's judgment necessary or desirable for the administration of the plan.

Stock Subject to 2021 Plan. Subject to certain adjustment provisions described below, the number of shares of common stock which are set aside and reserved for issuance under the 2021 Plan is 600,000 60,000 shares.

Eligible Participants. Subject to certain limitations, awards under the 2021 Plan may be granted to any employee, officer, director, consultant or advisor to the Company and its subsidiaries, provided that only employees of the Company and its subsidiaries may be granted ISOs under the 2021 Plan.

Plan Amendments and Termination. The Board may at any time, and from time to time, modify or amend the 2021 Plan in any respect, provided that without stockholder approval, no such modification or amendment may (i) modify the prohibitions against repricing in the 2021 Plan; (ii) materially increase benefits accruing to participants; (iii) increase the aggregate number of shares of common stock issued or issuable under the 2021 Plan; (iv) increase any limitation set forth in the 2021 Plan on the number of shares of common stock which may be issued or the aggregate value of awards which may be made, in respect of any type of award to any single participant during any specified period; (v) modify the eligibility requirements for participants in the 2021; or (vi) reduce the minimum exercise price or grant price as set forth in the 2021 Plan.

The Board may at any time suspend or terminate the Plan, provided that any such suspension or termination shall not adversely affect the rights of a participant under any stock award previously granted while the Plan is in effect except with the consent of the participant.

Transferability. Unless otherwise approved by the Committee, awards under the 2021 Plan are not assignable or transferable by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the life of the participant, shall be exercisable only by the participant.

Item 6. Selected Financial Data

As a Smaller Reporting Company, we are not required to furnish information under this Item 6.

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

*This Management's Discussion and Analysis of Financial Condition and Results of Operations, and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties. All forward-looking statements included in this Annual Report are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth in the section captioned "**Risk Factors**" in Annual Report. The following should be read in conjunction with our audited financial statements included elsewhere herein.*

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Overview

Overview

We are a commercial stage biotechnology company dedicated to the advancement of identifying and translating novel biological therapeutics in the fields of immunotherapy, endocrinology, urology, neurology and orthopedics. Our platforms, therapies and products include the following:

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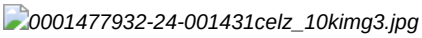

Our subsidiary, Creative Medical Technologies, Inc. ("CMT"), was originally created to monetize U.S. Patent No. 8,372,797 and related intellectual property related to the treatment of erectile dysfunction ("ED"), which it acquired in May February 2016. Subsequently, we have expanded our development and acquisition of intellectual property beyond urology to include therapeutic treatments utilizing "re-programmed" stem cells, and the treatment of neurologic disorders, lower back pain, Type-1 diabetes, and heart, liver, kidney, and other diseases using various types of stem cells through our ImmCelz, Inc., StemSpine, Inc. and AlloCelz LLC subsidiaries. However, neither ImmCelz Inc. nor AlloCelz LLC have commenced commercial activities.

We currently conduct substantially all of our commercial operations through CMT, which markets and sells our CaverStem® and FemCelz® disposable kits utilized by physicians to perform autologous procedures that treat erectile dysfunction and female sexual dysfunction, respectively. Our CaverStem® and FemCelz® kits are currently available through physicians at eight locations in the United States.

In 2020, through our ImmCelz Inc. subsidiary, we began developing treatments under our ImmCelz® platform (CELZ-100), that utilize a patient's own extracted immune cells that are then "reprogrammed/supercharged" by culturing them outside the patient's body with optimized cell-free factors. The immune cells are then re-injected into the patient from whom they were extracted. We believe this process endows the immune cells with regenerative properties that may be suitable for (or "supercharges" them) providing them with the treatment of ability to treat multiple indications. We have validated this ability through the third-party studies described below that were independently conducted on selected human donor patient cells for accuracy and reproducibility. In contrast to other stem cell-based approaches, the immune cells are significantly smaller in size than stem cells and are believed to more effectively penetrate areas of the damaged tissues and induce regeneration.

In June 2022, we signed an agreement with Greenstone Biosciences Inc. ("Greenstone") for the development of a human induced pluripotent stem cell (iPSC) pipeline for our ImmCelz® platform. This project was identified as iPScelz™. The efforts by Greenstone Biosciences Inc. are expected to complement and expand our current work on novel therapeutic cell lines. In May 2023, we announced that that we had received confirmation that Greenstone had successfully developed a human induced pluripotent stem cell (iPSC). We estimate that the development of this cell line will save the Company two to three years in research and development time along with associated expenses. The final iPScelz™ results in a viral-free cell line which has great potential for differentiation into therapeutic biologics both for the cellular and cell-free programs along with targeted drug discovery. Greenstone's developments were confirmed by an independent, industry-leading research firm.

In October 2022, we announced the development of our AlloStem™ Clinical Cell Line (CELZ-201), a proprietary allogenic cell line which includes a Master Cell Bank and a Drug Master File. We believe we will able to use this cell line for many of our programs, including our ImmCelz® immunotherapy platform for multiple diseases, OvaStem® for Premature Ovarian Failure, CELZ-201 for Type 1 diabetes, StemSpine® for lower back pain, I Diabetes (CELZ-201 CREATE-1), AlloStemSpine® Chronic Lower Back Pain (CELZ-201 ADAPT), and IPScelz ™ IPScelz™ inducible pluripotent stem cell program in ongoing development with Greenstone Biosciences.

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In November 2022, we announced that the FDA had cleared the Company's CELZ-201 Type I Diabetes (CELZ-201 CREATE-1) Investigational New Drug (IND) application for the treatment of Type 1 Diabetes utilizing our AlloStem™ (CELZ-201) Clinical Cell Line, which will allow us to begin a Phase I/II clinical trial. The primary objective of the study will be to evaluate CELZ-201 AlloStem™ (CELZ-201) in patients with newly diagnosed Type 1 Diabetes. The trial has also received Institutional Board Review (IRB) approval for the trial to proceed as well as approval of the patient recruitment material. Patient recruitment was initiated in September 2023.

In February 2023, the Company reported positive three-year follow-up data for its StemSpine® pilot study. The three-year data demonstrates continued efficacy of the StemSpine® procedure for treating chronic lower back pain without any serious adverse effects reported.

In March 2023, we reported the following results of independent studies:

- ImmCelz® (CELZ-100) platform required 75% fewer donor patient cells compared to industry standard.
- The purity of the final ImmCelz® (CELZ-100) product was greater than 95% compared to the industry standard of greater than 80%.
- ImmCelz® (CELZ-100) demonstrated a greater than 200% reduction in functional suppression of effector T cells, which are a critical concern for patients with autoimmune issues, while still possessing a high number of functional T regulatory cells.
- The ability to verify repeated potency of the final ImmCelz®(CELZ-100) product.

We believe these results show that we will be able to substantially reduce production costs, while allowing for the manufacture of the best clinical product for patients with immune disorders, which will enable us to accelerate our clinical applications and encourage potential collaborations with respect to our ImmCelz® platform.

In March 2023, the Company announced that it filed an application with the FDA to receive Orphan Drug Designation ("ODD") for the treatment of Brittle Type 1 Diabetes using its ImmCelz® (CELZ-100) platform. The FDA has responded to the ODD filing with additional clarification requests, which we are in the process of responding.

In April 2023, the Company reported positive one-year follow-up data and significant efficacy using AlloStem™ (CELZ-201) to treat patients with Type 2 Diabetes. There were no safety concerns related to AlloStem™ (CELZ-101) at one year follow-up utilizing the same infusion procedure as in the currently U.S. FDA cleared Type I Diabetes (CELZ-201 CREATE-1) clinical trial. There were 30 patients in the study, 15 who received AlloStem™ (CELZ-201) and the rest received optimized medical therapy. At one year, there was an overall efficacy of 93% in the treated patients demonstrating at least a 50% reduction in insulin requirement.

In September 2023, the Company received FDA clearance to initiate a Phase I/II clinical trial of AlloStemSpine® (CELZ-202 ADAPT) using AlloStem™ (CELZ-201-DDT) for the treatment of lower back pain. The study is expected designed to begin evaluate the safety, efficacy, and tolerability of AlloStem™ (CELZ-201-DDT). The study will enroll 30 individuals suffering from chronic lower back pain. Using an ultrasound guided, non-surgical procedure, AlloStem™ (CELZ-101-DDT) is injected in 2023. areas surrounding the diseased disc(s), thereby potentially repairing, remodeling, and improving the blood supply around the disc and lower back area, without exposing the patient to radiation or any other cell-based procedures. In October, 2023 we filed for and received approval from an institutional review board (IRB) to proceed with this trial.

In October, 2023 the Company filed for and received approval from an institutional review board (IRB) to proceed with the Phase I/II clinical trial. The clinical trial is registered on www.clinicaltrials.gov. We are currently vetting Contract Research Organizations for a planned trial enrollment commencing in early 2024.

In addition to our clinical research efforts, we are currently seeking to expand the commercial sale and use of our CaverStem® and FemCelz® products by physicians in the United States.

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Results of Operations – For the Year Ended December 31, 2022 December 31, 2023, and for the Year Ended December 31, 2021 December 31, 2022

Gross Revenue. We generated $88,600 $9,000 in gross revenue for the year ended December 31, 2022 December 31, 2023, in comparison with $87,754 for the comparable period a year ago. The increase of $846 or 1.0% is the result of lower revenue per unit offset by an increased number of unit sales. In the fourth quarter of 2021 we field tested an alternative sales and marketing program for CaverStem® whereby we marketed directly to the patient, collected the procedure fees from the patient and paid the physicians for their services. While this effort resulted in an increase in the number of procedures and gross revenues per procedure, gross margins were greatly reduced. As a result, in the first quarter of 2022, we reverted to our model of contracting with physicians, who resell our kits and bill their patients directly.

Cost of Goods Sold. We generated $28,491 in cost of goods sold for the year ended December 31, 2022, in comparison with $47,949 $88,600 for the comparable period a year ago. The decrease of $19,458 $79,600 or 40.6% 89.8% is due to a decrease in Caverstem sales. Management is currently re-evaluating the marketing strategy for the Caverstem® and FemCelz® products.We are exploring options to achieve market penetration and product profitability with a number of potential partners. However, there can be no assurance that the Company will be successful in that regard.

Cost of Goods Sold. We generated $3,600 in cost of goods sold for the year ended December 31, 2023, in comparison with $28,491 for the comparable period a year ago. The decrease of $24,891 or 87.4% is due to the effects of the business model change reduction in the fourth quarter of 2021 revenue as described above.

Gross Profit/(Loss)*. We generated $60,109 $5,400 in gross profit for the year ended December 31, 2022 December 31, 2023, in comparison with $39,805 $60,109 in gross profit for the comparable period a year ago. The increase decrease of $20,304 $54,709 or 51.0% 91.0% is due to the increased per-unit profit from moving off the temporary shift to a direct-to-patient model reduction in the fourth quarter of 2021. revenue.*

Selling, General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2022 December 31, 2023, totaled $3,943,543, $3,560,309, in comparison with $2,964,490 $3,943,543 for the comparable period a year ago. The increase decrease of 979,053, $383,234, or 33% 9.7% is primarily due to a net increase reductions of $810,513 in salaries and wages from both new hires and the transition of our CEO and CFO from being reimbursed via management fees for most of 2021 to full-time employees throughout 2022, an increase of $423,209 associated with director and officer insurance, an increase of $355,984 $259,080 in marketing expenses an increase of $264,623 as we re-evaluate the Caverstem® and FemCelz® marketing strategies, $341,079 in consulting services, $59,885 in Director and Officer insurance, and $53,457 in travel, offset by a decrease of $688,146 relating to an expense associated with an accrual related to a vendor dispute $308,589 in 2021, increased salaries and a reduction of $526,634 in stock-based compensation. wages.

Research and Development Expenses**. Research and development expenses for the years year ended December 31, 2022 December 31, 2023, totaled $6,268,854 $1,970,639 in comparison to $109,180 $6,268,854 for the comparable period a year ago. The increase decrease of $6,159,674 $4,298,215, or 5,641.8% 68.6% was due to expenses a $5,000,000 one-time expense associated with the acquisition of research tools and in 2022. This was offset by an increase of $661,785 associated with the development of a drug master file, laboratory research in preparation of our master cell bank submittal to the FDA, the approval of our FDA application for a Type I Diabetes Lower Back Pain (CELZ 202 – ADAPT) Phase I/II clinical trial, the manufacturing and testing of our ImmCelz™ cell line, and the development of our iPSC cell line in partnership with Greenstone Biosciences Inc.**

Operating Loss**. For the reasons stated above, our operating loss for the year ended December 31, 2022 December 31, 2023, was $10,244,372 $5,620,132 in comparison with $3,125,949 $10,244,372 for the comparable period a year ago.**

Other Income**. Other income for the year ended December 31, 2022 December 31, 2023, totaled $100,328 $333,558 in comparison with $22,337,717 $100,328 for the comparable period a year ago. The decreased increased income of $22,237,389 $233,230 or 99.6% 234.5%, is primarily due to a decrease of $26,030,549 in the in the fair value of derivative liabilities, a $585,601 decrease in the gain upon the extinguishment of convertible notes, offset by a $4,278,433 decrease in increased interest expense for the comparable period a year ago. In 2022, we had no outstanding promissory notes. In 2021 we incurred interest expense calculated rates on our promissory notes short-term CD's and we recorded the amortization of various debt discounts associated with our promissory notes. The discounts were the result of a combination of on-issuance discounts and fees, warrants issued with promissory notes, and derivative liabilities which are recorded due to the variability of the notes conversion price. The derivative liabilities were re-measured as of each reporting date. treasuries.**

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Net Income/Loss. For the reasons stated above, our net loss for the year ended December 31, 2022 December 31, 2023, was $10,144,044 $5,286,574 in comparison with income a loss of $19,211,768 $10,144,044 for the comparable period a year ago.

Amortization Expense*. We acquired a patent (U.S. Patent No. 8,372,797) from CMH on February 2, 2016, in exchange for shares of our restricted common stock valued at $100,000. The patent expires in 2026 and we have elected to amortize the patent over a ten-year period on a straight-line basis. On August 25, 2016, CMT entered into a License Agreement which grants it the exclusive right to all products derived from US Patent No.*

7,569,385 for multipotent amniotic fetal stem cells. Under the terms of the license agreement, CMT paid an initial license fee within 30 days of entering into the agreement. The patent expires in 2026 and we have elected to amortize the patent over a ten-year period on a straight-line basis. On May 17, 2017, CMT purchased U.S. Patent No. 9,598,673 covering use of various stem cells for treatment of lower back pain from CMH. Under the terms of the agreement, the Company was required to pay CMH $100,000. The agreement was modified in November 2017 to waive payment of the initial license fee, modify the fee structure, and add the ability to convert the outstanding payable balance into common shares. In November 2020, the Company announced the commercialization of the lower back procedure using a patient's own cells ("autologous"). This milestone triggered a milestone payment due from the Company to CMH in the amount of $300,000, which was subsequently paid. The patent expires in 2027, and we have elected to amortize the patent over a ten-year period on a straight-line basis. In December 2020, we entered into a Patent License Agreement with Jadi Cells, Inc. Execution of the contract triggered a milestone payment due from the Company to Jadi Cells, Inc. in the amount of $250,000, which was paid with shares of our common stock in February 2022. In August 2023, the Company paid CMH $100,000 related to the filing of an IND with the FDA per the terms of the agreement.We have elected to amortize the patent over a ten-year period on a straight-line basis.

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Amortization expense of $92,084 $94,584 was recorded for the year ended December 31, 2022 December 31, 2023, representing the amortization of the ED, multipotent amniotic fetal stem cell and lower back pain patents and the Jadi Cell patent license agreement based upon the remaining life of the patents and license agreement. There was $92,084 of amortization expense recorded for the period ended December 31, 2021 December 31, 2022.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our consolidated financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity capital expenditures or capital resources.

Liquidity and Capital Resources

As of December 31, 2022 December 31, 2023, we had $18,399,136 $9,899,504 of available cash and certificates of deposit and positive working capital of approximately $15,425,798. $9,899,504. In comparison, as of December 31, 2021 December 31, 2022, we had approximately $10,723,870 $18,399,136 of available cash and positive working capital of approximately $9,686,780. $15,425,798.

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On May 3, 2022 we received gross proceeds of $17,000,000, before deducting placement agent fees and expenses, upon the closing of an unregistered sale of equity securities of (i) 2,991,669 299,167 shares of our common stock and pre-funded warrants to purchase 4,563,887 456,389 shares of common stock (the "Pre-Funded Warrants"), and (ii) accompanying warrants to purchase 15,111,112 1,511,112 shares of common stock at an exercise price of $2.00 $20.00 per share ("Warrants"), and, at a combined offering price of $2.25 $22.50 per share of common stock/Pre-Funded Warrant and related Warrant to a group of institutional investors (the "Purchasers"). The Warrants have a five-year term, and an exercise price of $2.00 $20.00 per share. The Pre-Funded Warrants do not expire and had an exercise price of $0.0001 per share. Roth Capital Partners acted as sole placement agent for the offering. We paid Roth a placement agent fee in the amount of $1,360,000 and issued Roth a warrant to purchase 1,133,333 113,334 shares of common stock with the same terms as the common warrants issued to the purchasers. Pursuant to the Purchase Agreement, the Company and the Purchasers entered into a Registration Rights Agreement, pursuant to which the Company agreed to file a registration statement with the Securities and Exchange Commission to register the resale of the shares of Common Stock issued in the offering and the shares of Common Stock underlying the common stock, Warrants and Pre-Funded Warrants. On May 10, 2022, we filed a Form S-3 registration statement to register the shares, Common Warrants and Pre-Funded Warrants for resale. The registration went effective on May 19, 2022, fulfilling our contractual obligation. In addition, the Company's directors and officers entered into Lock-Up Agreements under which they agreed not to sell any of

their securities of the Company until 90 days following after the earliest of (i) the effective date of the Registration Statement, and (ii) the date all of the securities issued in the offering have been sold under Rule 144, or may be sold under Rule 144 without the Company being in compliance with the current public information requirement under such rule, and without any volume limitation. From June through July 2022, all of the Pre-Funded Warrants were exercised for shares of common stock.

On December 7, 2021, we sold an aggregate of 3,875,000 shares of our common stock and accompanying warrants to purchase 3,875,000 shares of common stock at an exercise price of $4.13 per share, at a combined public offering price to the public of $4.13 per share of common stock and related Warrant, pursuant to an Underwriting Agreement we entered into Roth Capital Partners, LLC. We received gross proceeds of $16,003,750, before deducting underwriting discounts and commissions of seven percent (7%) of the gross proceeds and offering expenses. We used a portion of the proceeds from the offering to (i) redeem our Bridge Notes described below, in the aggregate outstanding amount of $5,146,176, and (ii) repurchase the Company's Series A Preferred Stock from the Company's Chief Executive Officer for an aggregate purchase price of approximately $195,000.

In addition to our 2021 public offering and smaller private convertible note and preferred stock financing transactions we completed in the last two years, in August 2021, we completed the sale of 15% Original Issue Discount Senior Notes ("Bridge Notes") in the aggregate principal amount of $4,456,176. In connection with the sale of the Bridge Notes, holders of shares of our preferred stock issued earlier in 2021 exchanged such preferred stock for additional Bridge Notes in the aggregate principal amount of $690,000. We also issued to the purchasers of our Bridge Notes five-year warrants to purchase an aggregate of 363,046 shares of our common stock at an initial exercise price of $14.175 per share, subject to anti-dilution adjustment in the event of future sales of equity by us below the then exercise price, stock dividends, stock splits and other specified events.

Net Cash used in Operating Activities. We used cash in our operating activities due to our losses from operations. Net cash used in operating activities was $7,796,966 $8,027,885 for the year-ended ended December 30, 2022 December 30, 2023, in comparison to $2,215,782 $7,796,966 for the comparable period a year ago, an increase of $5,581,184 $230,919 or 252% 3.0%. The increase in cash used in operations was primarily related to an increase of $3,159,674 $661,785 in research-related cash outlays associated with the acquisition of research assets, personnel and laboratory research in preparation of our master cell bank submittal to the FDA, development, submittal and FDA clearance of our CELZ-201 AlloStemSpine® Chronic Lower Back Pain (CELZ-201 ADAPT) phase I/II clinical trial, continued efforts on our Type I Diabetes (CELZ-201CREATE-1) phase I/II clinical trial, the manufacturing and testing of our ImmCelz™ cell line, and the development of our iPSC cell line in partnership with Greenstone Biosciences Inc. In addition, there was a net increase of $810,513 in salaries and wages from both new hires and the transition of our CEO and CFO from being reimbursed via management fees for most of 2021 to full-time employees throughout 2022, an increase of $761,327 associated with cash outlays for director and officer insurance, an increase of $355,984 in marketing expenses, an increase of $283,642 in consulting services, and payments associated with a vendor dispute in 2021.

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Net Cash used in Investing Activities. Cash used in provided from investing activities was $3,445,185 for the year ended December 31, 2023, due to $3,558,426 in net certificate of deposit redemptions, offset a $100,000 payment on a patent purchase agreement. In comparison, we used $10,078,617 for the year ended December 31, 2022, related to the investment of $10,000,000 in certificates of deposit in comparison to $0 for the year ended December 31, 2021. 2022.

Net Cash from Financing Activities.

In the year ended December 31, 2023, we spent $270,953 on stock repurchases. In the year ended December 31, 2022, we received $15,471,775 in net proceeds from the sale of common stock and warrants in our May 2022 private offering. In the year ended December 31, 2021, we received $14,758,488 in net proceeds from the sale of common stock and warrants in our December 2021 public offering, along with $4,784,790 from the issuance of convertible debt, preferred stock, and short-term, non-convertible notes, and we spent $6,925,032 on re-payment of notes, redemption of preferred stock, and payment of debt issuance and offering costs. The $2,630,592 or 20% increase in cash flows from financing activities was primarily related to a $713,287 increase in net proceeds between our December 2021 and May 2022

offerings and a net reduction of $1,916,848 associated with retirement of convertible debt and other financing related expenses incurred in 2021.

We have continued to realize losses from operations. However, as a result of our December 2021 and May 2022 offerings, we believe we will have sufficient cash to meet our anticipated operating costs and capital expenditure requirements through at least March 2024. 2025. We anticipate that we will need to raise additional capital in the future to support our ongoing operations and continue our clinical trials. We expect to continue to raise additional capital through the sale of our securities from time to time for the foreseeable future to fund the development of our proposed products through clinical development, manufacturing, and commercialization. Our ability to obtain such additional capital will likely be subject to various factors, including our overall business performance and market conditions. There can be no guarantee that we will be successful in our ability to raise capital to fund future operational and development initiatives.

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Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles accepted in the United States. In connection with the preparation of our financial statements, we are required to make assumptions and estimates about future events and apply judgments that affect the reported amounts of assets, liabilities, revenue, expenses, and the related disclosures. We base our assumptions, estimates and judgments on historical experience, current trends, and other factors that management believes to be relevant at the time our consolidated financial statements are prepared. On a regular basis, we review the accounting policies, assumptions, estimates and judgments to ensure that our financial statements are presented fairly and in accordance with GAAP. However, because future events and their effects cannot be determined with certainty, actual results could differ from our assumptions and estimates, and such differences could be material.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As a Smaller Reporting Company, we are not required to furnish information under this Item 7A.

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Item 8. Financial Statements and Supplementary Data.

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Creative Medical Technology Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Creative Medical Technology Holdings, Inc. (the Company) as of December 31, 2022, December 31, 2023 and 2021, 2022, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2022 December 31, 2023, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022, December 31, 2023 and 2021, 2022, and the results of its consolidated operations and its cash flows for each of the years in the two-year period ended December 31, 2022 December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Material R&D Transaction Valuation and Disclosure of Stock-Based Compensation and Warrants

Description of the Matter Matter::

As discussed in Note 8 to 7 of the consolidated financial statements, the Company purchased has a set significant number of components referred to as "research tools" Warrants outstanding. The disclosure can be complex in December 2022, that was recorded as R&D expense in nature. Auditing the statement of operations. We note the transaction to be significant and required judgment on the part of management to determine the accounting treatment and disclosure. The transaction involved the purchase of tools that were created, in part, by a former director sufficiency of the Company. Because the transaction was significant, involved Company's disclosures can be complex, involves judgment, by management, and involved requires a former director thorough understanding of the Company, we identified this as a critical audit matter. award terms.

How We Addressed the Matter in Our AuditAudit:

We gained an understanding confirmed the number of registered warrants with the Company's transfer agent, we recalculated the converting power of the transaction and warrants after the parties involved by interviewing management and obtaining the signed agreement. We confirmed with third parties substantial details effects of the transaction, including speaking with the board of directors to ensure they had properly considered reverse stock split, and discussed with management. We obtained and considered a report, which was drafted by a third party researcher, that assessed the usefulness and value of the research tools acquired. Furthermore, we verified the credentials of the third party. Once we completed these procedures, we evaluated the accounting treatment and disclosure based on accounting guidance for R&D assets acquired and related party disclosures. adequacy of the disclosures in the Company's financial statements.

/s/ Haynie & Company

Haynie & Company
Salt Lake City, Utah
March 31, 2023 22, 2024

We have served as the Company's auditor since 2016.
PCAOB ID 0457 #457

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CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.	**CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.**

CONSOLIDATED BALANCE SHEETS			CONSOLIDATED BALANCE SHEETS	
	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
ASSETS				
CURRENT ASSETS				
Cash	$ 8,320,519	$ 10,723,870	$ 3,466,867	$ 8,320,519
Certificates of deposit	10,078,617	-		
Accounts receivable	-	2,485		
Investments			6,520,191	10,078,617
Inventory	10,194	10,866	6,594	10,194
Prepaids and other current assets	338,120	-	277,246	338,120
Total Current Assets	18,747,450	10,737,221	10,270,898	18,747,450
OTHER ASSETS				
Other assets	3,281	3,281	3,281	3,281
Licenses, net of amortization	435,595	527,679	441,011	435,595
TOTAL ASSETS	$ 19,186,326	$ 11,268,181	$ 10,715,190	$ 19,186,326
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES				
Accounts payable	$ 3,267,538	$ 761,862	$ 317,280	$ 3,267,538
Accrued expenses	39,920	24,385	39,920	39,920
Management fee and patent liabilities - related parties	-	250,000		
Advances from related party	14,194	14,194	14,194	14,194
Total Current Liabilities	3,321,652	1,050,441	371,394	3,321,652
TOTAL LIABILITIES	3,321,652	1,050,441	371,394	3,321,652
STOCKHOLDERS' EQUITY				
Common stock, $0.001 par value, 50,000,000 shares authorized; 14,076,246 and 6,338,872 issued and 14,076,238 and 6,338,864 outstanding at December 31, 2022 and 2021, respectively	14,077	6,339		
Common stock, $0.001 par value, 5,000,000 and 50,000,000 shares authorized; 1,431,126 and 1,407,625 issued and 1,373,626 and 1,407,624 outstanding at December 31, 2023 and 2022, respectively			1,431	1,407
Additional paid-in capital	69,662,455	53,879,215	69,711,749	69,675,125
Accumulated deficit	(53,811,858)	(43,667,814)	(59,098,432)	(53,811,858)
Treasury stock, at cost, 57,500 shares as of December 31, 2023			(270,952)	-
TOTAL STOCKHOLDERS' EQUITY	15,864,674	10,217,740	10,343,796	15,864,674

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 19,186,326	$ 11,268,181	$ 10,715,190	$ 19,186,326

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

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CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Revenues	$ 88,600	$ 87,754
Cost of revenues	28,491	47,949
Gross profit	60,109	39,805
OPERATING EXPENSES		
Research and development	6,268,854	109,180
Selling, general and administrative	3,943,543	2,964,490
Amortization of patent costs	92,084	92,084
TOTAL EXPENSES	10,304,481	3,165,754
Operating loss	(10,244,372)	(3,125,949)
OTHER INCOME		
Interest expense	-	(4,278,433)
Gain on extinguishment of convertible notes	-	585,601
Change in fair value of derivatives liabilities	-	26,030,549
Other income	100,328	-
Total other income	100,328	22,337,717
INCOME (LOSS) BEFORE PROVISION FOR INCOME TAXES	(10,144,044)	19,211,768
Provision for income taxes	-	-
NET INCOME (LOSS)	$ (10,144,044)	$ 19,211,768
BASIC NET INCOME (LOSS) PER SHARE	$ (0.93)	$ 7.37

DILUTED NET INCOME (LOSS) PER SHARE	$ (0.93)	$ 5.61
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING - BASIC	10,932,035	2,605,057
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING - DILUTED	10,932,035	3,248,619

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
Revenues	$ 9,000	$ 88,600
Cost of revenues	3,600	28,491
Gross profit	5,400	60,109
OPERATING EXPENSES		
Research and development	1,970,639	6,268,854
Selling, general and administrative	3,560,309	3,943,543
Amortization of patent costs	94,584	92,084
TOTAL EXPENSES	5,625,532	10,304,481
Operating loss	(5,620,132)	(10,244,372)
OTHER INCOME/(EXPENSE)		
Interest income	333,558	100,328
Total other income (expense)	333,558	100,328
LOSS BEFORE PROVISION FOR INCOME TAXES	(5,286,574)	(10,144,044)
Provision for income taxes	-	-
NET LOSS	$ (5,286,574)	$ (10,144,044)
NET LOSS PER SHARE - BASIC AND DILUTED	$ (3.76)	$ (9.28)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING - BASIC AND DILUTED	1,407,632	1,093,204

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

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CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ (10,144,044)	$ 19,211,768
Adjustments to reconcile net income (loss) to net cash from operating activities:		
Stock-based compensation	68,746	595,380
Amortization	92,084	92,084
Amortization of debt discounts	-	4,157,850
Change in fair value of derivatives liabilities	-	(26,030,549)
Increase in principal and accrued interest balances due to penalty provision	-	93,821
Gain on extinguishment of convertible notes	-	(585,601)
Changes in assets and liabilities:		
Accounts receivable	2,485	(2,485)
Inventory	672	(10,866)
Prepaids and other current assets	(338,120)	-
Accounts payable	2,505,676	410,963
Accrued expenses	15,535	20,635
Management fee payable	-	(168,782)
Net cash used in operating activities	(7,796,966)	(2,215,782)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of certificates of deposit	(10,078,617)	-
Net cash used in investing activities	(10,078,617)	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock and warrants, net of issuance costs ($1,487,964 and $1,111,665 respectively)	15,471,775	14,758,488
Proceeds from exercise of warrants	457	-
Proceeds from note payable	-	3,887,750
Payments on notes payable	-	(5,251,176)
Payment of debt issuance costs	-	(443,239)
Payment of deferred offering costs	-	(3,281)
Payment of offering costs	-	(105,180)
Preferred stock redemption	-	(196,751)
Proceeds from convertible notes payable	-	435,040

Proceeds from sale of preferred stock	-	462,000
Related party advances	-	223,394
Repayment of related party advances	-	(220,000)
Payments to settle convertible notes payable and warrants	-	(705,405)
Net cash provided by financing activities	15,472,232	12,841,640
NET INCREASE (DECREASE) IN CASH	(2,403,351)	10,625,858
BEGINNING CASH BALANCE	10,723,870	98,012
ENDING CASH BALANCE	$ 8,320,519	$ 10,723,870
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ -	$ 9,186
Cash payments for income taxes	$ -	$ -
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Accrued dividends on preferred stock	$ -	$ 27,725
Warrants issued with notes payable as a service fee	$ -	$ 2,097,629
Conversion of notes payable, accrued interest and derivative liabilities into common stock	$ -	$ 13,747,415
Conversion of management fees and patent liability into common stock	$ 250,000	$ 50,000
Discounts on convertible notes payable due to derivative liabilities	$ -	$ 134,640
Exchange of preferred stock for notes payable	$ -	$ 572,275
Warrants issued for ratchet provision adjustment	$ -	$ 989,346

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Additional Paid-in	Accumulated	Treasury	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	Stock	(Deficit)
December 31, 2021	633,886	$ 634	$ 53,884,920	(43,667,814)	$ -	$ 10,217,740
Issuance of common stock and accompanying warrants, net of issuance costs	299,167	299	15,471,476	-	-	15,471,775
Common stock issued for related party management and patent liabilities	18,182	18	249,982	-	-	250,000
Common Stock issued for warrant exercise	456,389	456	1	-	-	457
Stock-based compensation	-	-	68,746	-	-	68,746
Net loss	-	-	-	(10,144,044)	-	(10,144,044)

December 31, 2022	1,407,624	$ 1,407	$ 69,675,125	$ (53,811,858)	$ -	$ 15,864,674
Round-up shares issued in reverse stock split	23,502	24	(24)	-	-	-
Purchase of common stock	-	-	-	-	(270,952)	(270,952)
Stock-based compensation	-	-	36,648	-	-	36,648
Net loss	-	-	-	(5,286,574)	-	(5,286,574)
December 31, 2023	1,431,126	$ 1,431	$ 69,711,749	$ (59,098,432)	$ (270,952)	$ 10,343,796

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

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CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Series A Preferred Stock		Series B Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
December 31, 2020	3,000,000	3,000	-	-	-	-	1,537,074	1,537	22,082,689	(61,890,236)	(39,803,010)
Proceeds from sales of preferred stock	-	-	350	321,000	150	141,000	4,286	4	(4)	-	462,000
Common stock issued for related party management and patent liabilities	-	-	-	-	-	-	89,286	89	49,911	-	50,000

Proceeds from sales of common stock, net of issuance costs	-	-	-	-	-	-	3,875,000	3,875	14,754,613	-	14,758,488
Offering costs	-	-	-	-	-	-	-	-	(105,180)	-	(105,180)
Common stock issued for conversion of convertible notes, accrued interest and derivative liabilities	-	-	-	-	-	-	789,727	790	1,382,542	-	1,383,332
Relief of derivative liabilities	-	-	-	-	-	-	-	-	12,364,084	-	12,364,084
Dividends on preferred stock	-	-	-	-	-	-	-	-	(27,725)	-	(27,725)
Cashless exercise of warrants	-	-	-	-	-	-	37,870	38	(38)	-	-
Warrants issued with notes payable	-	-	-	-	-	-	-	-	2,097,629	-	2,097,629
Preferred stock redemption	(3,000,000)	(3,000)	(350)	(321,000)	(150)	(141,000)	-	-	(304,026)	-	(769,026)
Stock-based compensation	-	-	-	-	-	-	-	-	595,380	-	595,380
Differences in shares from reverse stock split	-	-	-	-	-	-	5,621	6	(6)	-	-

Revaluation of warrants related to ratchet provision adjustment	-	-	-	-	-	-	-	-	989,346	(989,346)	-
Net income	-	-	-	-	-	-	-	-	-	19,211,768	19,211,768
December 31, 2021	-	-	-	-	-	-	6,338,864	6,339	53,879,215	(43,667,814)	10,217,740
Issuance of common stock and accompanying warrants, net of issuance costs	-	-	-	-	-	-	2,991,669	2,992	15,468,783	-	15,471,775
Common stock issued for related party management and patent liabilities	-	-	-	-	-	-	181,818	182	249,818	-	250,000
Common Stock issued for warrant exercise	-	-	-	-	-	-	4,563,887	4,564	(4,107)	-	457
Stock-based compensation	-	-	-	-	-	-	-	-	68,746	-	68,746
Net loss	-	-	-	-	-	-	-	-	-	(10,144,044)	(10,144,044)
December 31, 2022	-	$ -	-	$ -	-	$ -	14,076,238	$ 14,077	$ 69,662,455	$ (53,811,858)	$ 15,864,674

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (5,286,574)	$ (10,144,044)
Adjustments to reconcile net loss to		
net cash used in operating activities:		
Stock-based compensation	36,648	68,746
Amortization	94,584	92,084
Unrealized gain on investments	(34,087)	
Changes in assets and liabilities:		
Accounts receivable	-	2,485
Inventory	3,600	672
Prepaids and other current assets	108,202	(338,120)
Accounts payable	(2,950,258)	2,505,676
Accrued expenses	-	15,535
Net cash used in operating activities	(8,027,885)	(7,796,966)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of investments	(22,854,815)	(10,078,617)
Redemptions of investments	26,400,000	-
Purchase of patents	(100,000)	-
Net cash provided by (used in) investing activities	3,445,185	(10,078,617)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock and warrants, net of issuance costs	-	15,471,775
Proceeds from exercise of warrants	-	457
Purchase of common stock	(270,952)	-
Net cash provided by financing activities	(270,952)	15,472,232
NET (DECREASE) IN CASH	(4,853,652)	(2,403,351)
BEGINNING CASH BALANCE	8,320,519	10,723,870
ENDING CASH BALANCE	$ 3,466,867	$ 8,320,519
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ -	$ -
Cash payments for income taxes	$ -	$ -
NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Conversion of management fees and patent liability into common stock	$ -	$ 250,000

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 – ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization - Creative Medical Technologies Holdings, Inc. (the "Company") is a commercial stage biotechnology company dedicated to the advancement of identifying and translating novel biological therapeutics in the fields of immunotherapy, endocrinology, urology, neurology and orthopedics. The Company was incorporated on December 3, 1998, in the State of Nevada under the name Jolley Marketing, Inc. On May 18, 2016, the Company closed a transaction which was accounted for as a recapitalization, reverse merger, under which Creative Medical Technologies, Inc., a Nevada corporation ("CMT") became the Company's wholly owned subsidiary, and Creative Medical Health, Inc. ("CMH"), which was CMT's sole stockholder prior to the merger, became the Company's principal stockholder. In connection with this merger, the Company changed its name to Creative Medical Technologies Holdings, Inc. to reflect its current business.

CMT was originally created on December 30, 2015 ("Inception"), as the urological arm of CMH to monetize a patent and related intellectual property related to the treatment of erectile dysfunction ("ED"), which it acquired from CMH in February 2016. Subsequently, the Company has expanded its development and acquisition of intellectual property beyond urology to include therapeutic treatments utilizing "re-programmed" stem cells, and the treatment of neurologic disorders, lower back pain, type I diabetes, and heart, liver, kidney, and other diseases using various types of stem cells through our ImmCelz, Inc., StemSpine, Inc. and AlloCelz LLC subsidiaries. However, neither ImmCelz Inc., StemSpine Inc. nor AlloCelz LLC have commenced commercial activities.

The Company currently conducts substantially all of its commercial operations through CMT, which markets and sells the Company's CaverStem® and FemCelz® disposable kits utilized by physicians to perform autologous procedures that treat erectile dysfunction and female sexual dysfunction, respectively.

In 2020, through the Company's ImmCelz Inc. subsidiary, the Company began developing treatments that utilize a patient's own extracted immune cells that are then "reprogrammed" by culturing them outside the patient's body with optimized stem cells. The immune cells are then re-injected into the patient from whom they were extracted. The Company believes this process endows the immune cells with regenerative properties that may be suitable for the treatment of multiple indications. In contrast to other stem cell-based approaches, the immune cells are significantly smaller in size than stem cells and are believed to more effectively penetrate areas of the damaged tissues and induce regeneration.

Risks and Uncertainties **- The Company has a limited operating history and has generated minimal revenues from its operations.**

On January 30, 2020, the World Health Organization declared The outbreak of the COVID-19 outbreak a "Public Health Emergency coronavirus has spread across the globe and is impacting worldwide economic activity. A pandemic, including COVID-19 or other public health epidemic, poses the risk that we or our employees, CROs, suppliers, manufacturers and other partners may be prevented from conducting business activities for an indefinite period of International Concern" and on March 10, 2020, declared it time, including due to be a pandemic. Actions taken around the world to help mitigate the spread of the disease or shutdowns that may be requested or mandated by governmental authorities. Another significant, outbreak of COVID-19, include restrictions a communicable disease, could disrupt our clinical trials, supply chain and the manufacture or shipment of our products, and other related activities, which

could have a material adverse effect on travel, our business, financial condition and quarantines in certain areas, results of operations, and forced closures for certain types of public places and businesses. The COVID-19 and actions taken to mitigate it have had and are expected to continue to may also have an adverse impact on the economies and financial markets of many countries, including the geographical area in global economic conditions which the Company operates. While it is unknown how long these conditions will last and what the complete financial effect will be could impair our ability to the company, to-date, the Company is experiencing a reduction in revenues due to the prioritization of medical resources to address the COVID-19 outbreak. In several of our markets, all non-essential (including elective) procedures have been placed on hold. While this has a negative financial impact to our revenues, there have been the same reductions to our costs. Additionally, since the Company maintains a minimal level of inventory and requires nearly all of its customers to pre-pay, there is no risk to receivables or inventory write-downs. The Company expects existing orders temporarily on hold and continued sales, training and patient treatments will resume once the physician's offices are back to being fully operational. raise capital when needed.

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The Company's business and operations are sensitive to general business and economic conditions in the U.S. and worldwide. These conditions include short-term and long-term interest rates, inflation, fluctuations in debt and equity capital markets and the general condition of the U.S. and world economy. A host of factors beyond the Company's control could cause fluctuations in these conditions, including the political environment and acts or threats of war or terrorism. Adverse developments in these general business and economic conditions, including through recession, downturn or otherwise, could have a material adverse effect on the Company's financial condition and the results of its operations.

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The Company has only recently started to generate generated minimal sales and we have has limited marketing and/or distribution capabilities. The Company has limited experience in developing, training, or managing a sales force and will incur substantial additional expenses if it decides to market any of its current and future products and services with an internal sales organization. Developing a marketing and sales force is also time-consuming and could delay the launch of its future products and services. In addition, the Company will compete with many companies that currently have extensive and well-funded marketing and sales operations. The Company's marketing and sales efforts may be unable to compete successfully against these companies. In addition, the Company has limited capital to devote to sales and marketing.

The Company's industry is characterized by rapid changes in technology and customer demands. As a result, the Company's products and services may quickly become obsolete and unmarketable. The Company's future success will depend on its ability to adapt to technological advances, anticipate customer demands, develop new products and services, and enhance the Company's current products and services on a timely and cost-effective basis. Further, the Company's products and services must remain competitive with those of other companies with substantially greater resources. The Company may experience technical or other difficulties that could delay or prevent the development, introduction or marketing of new products and services or enhanced versions of existing products and services. Also, the Company may not be able to adapt new or enhanced products and services to emerging industry standards, and the Company's new products and services may not be favorably received. In addition, the Company may not have the capital resources to further the development of existing and/or new ones.

Regarding the war between Russia and Ukraine, we have no direct exposure to those geographies. We cannot predict how global supply chain activities, or the economy at large may be impacted by a prolonged war in Ukraine global conflicts or sanctions imposed in response to the war, wars, or whether future conflicts, if any, may adversely affect our results of operations.

Use of Estimates – The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the balance sheet and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Basis of Presentation **– The consolidated financial statements and accompanying notes have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. In the opinion of the Company's management, the consolidated financial statements include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position for the periods presented.**

Concentration Risks **– The Federal Deposit Insurance Corporation insures cash deposits in most general bank accounts for up to $250,000 per institution. The Company maintains its cash balances at two four financial institutions. As of December 31, 2022 December 31, 2023, the Company's balance exceeded the limit at both three institutions.**

Cash Equivalents **– The Company classifies its highly liquid investments with maturities of three months or less at the date of purchase as cash equivalents. Management determines the appropriate classification of its investments at the time of purchase and reevaluates the designations of each investment as of the balance sheet date for each reporting period. The Company classifies its investments as either short-term or long-term based on each instrument's underlying contractual maturity date. Investments with maturities of less than 12 months are classified as short-term and those with maturities greater than 12 months are classified as long-term. The cost of investments sold is based upon the specific identification method. Investments include certificates of deposits and United States treasuries. As of December 31, 2023, the Company had an unearned gain of approximately $34,000 recorded within interest income on the accompanying statement of operations.**

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Inventories **– Inventories are valued on a cost basis. The cost of inventories is determined on a first-in, first-out basis.**

Fair Value of Financial Instrument – The Company's financial instruments consist of cash and cash equivalents, and payables. The carrying amount of cash and cash equivalents and payables approximates fair value because of the short-term nature of these items.

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Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. Fair value measurements are required to be disclosed by level within the following fair value hierarchy:

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

Level 2 – Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

Level 3 – Inputs lack observable market data to corroborate management's estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk

inherent in the inputs to the model.

When determining fair value, whenever possible the Company uses observable market data, and relies on unobservable inputs only when observable market data is not available. As of December 31, 2022 December 31, 2023, and 2021, 2022, the Company had no outstanding derivative liabilities.

***Intangible Assets* – Purchased intangible assets with finite lives are amortized over their respective estimated lives and reviewed for impairment whenever events or other changes in circumstances indicate that the carrying amount may not be recoverable. The impairment testing compares carrying values to fair values and, when appropriate, the carrying value of these assets is reduced to fair value. Impairment charges, if any, are recorded in the period in which the impairment is determined. The costs for intangible assets that are developed internally are expensed as incurred.**

Impairment – The Company records impairment losses when indicators of impairment are present and undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amount. Furthermore, the Company will make periodic assessments of technology and clinical testing to determine if it plans to continue to pursue the technology and if the license, patent, or other rights have value. To date no impairment has been recorded.

Derivative Liabilities *– A derivative is an instrument whose value is "derived" from an underlying instrument or index such as a future, forward, swap, option contract, or other financial instrument with similar characteristics, including certain derivative instruments embedded in other contracts and for hedging activities.*

As a matter of policy, the Company does not invest in separable financial derivatives or engage in hedging transactions. However, the Company entered into certain debt financing transactions in fiscal 2021, as disclosed in Notes 4 and 5, containing certain conversion features that resulted in the instruments being deemed derivatives. We evaluate the derivative instruments to properly classify such instruments within equity or as liabilities in our financial statements. Our policy is to settle instruments indexed to our common shares on a first-in-first-out basis.

The classification of a derivative instrument is reassessed at each reporting date. If the classification changes as a result of events during a reporting period, the instrument is reclassified as of the date of the event that caused the reclassification. There is no limit on the number of times a contract may be reclassified.
Instruments classified as derivative liabilities are remeasured using the Black-Scholes model at each reporting period (or upon reclassification), and the change in fair value is recorded on our consolidated statement of operations.
Revenue *- The Company recognizes revenues in accordance with Accounting Standards Codification ("ASC") 606, "Revenue from contracts with customers". Revenues are recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Deferred revenue represents amounts which still have yet to be earned.*

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The Company generates revenue from the sale of disposable stem cell concentration kits. Revenues are recognized when control of the promised goods or services are transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services, which is generally on delivery to the customer.

Payments received for which the earnings process is not yet complete are deferred. As of December 31, 2022 December 31, 2023, and 2021, 2022, the Company had $40,000 and $30,000 in deferred revenue respectively. revenue.

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Research and Development *- Research and development will continue to be a significant function of the Company. Research and development costs are expensed as incurred. Expenses in the accompanying financial statements include certain costs which are directly associated with the Company's two phase I/II clinical trials, research and development of the ImmCelz™, AlloStem™, and IPSCs™ technology platforms. ImmCelz™ is based upon re-programming T-regulatory cells with cell-free secreted factors. We are conducting laboratory research to validate the core technology and ability to achieve scalable production. These costs, which consist primarily of monies paid for research assets, outsourced research services, laboratory facility expenses, materials and supplies and compensation costs amounted to $1,970,639 for the year ended December 31, 2023. There was $6,268,854 in research costs for the year ended December 31, 2022. There was $109,180 in research costs for the period ended December 31, 2021.*

Stock-Based Compensation *– The Company accounts for its stock-based compensation in accordance with Accounting Standards Codification ("ASC") 718, Compensation - Stock Compensation. The Company accounts for all stock-based compensation using a fair-value method on the grant date and recognizes the fair value of each award as an expense over the requisite vesting period. The Company recognizes stock option forfeitures as they occur as there is insufficient historical data to accurately determine future forfeitures rates.*

Income Taxes *– The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred income taxes are recognized for differences between financial reporting and tax bases of assets and liabilities at the enacted statutory tax rates in effect for the years in which the temporary differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. The Company evaluates the realizability of deferred tax assets and valuation allowances are provided when necessary to reduce net deferred tax assets to the amounts expected to be realized.*

The Company recognizes a tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon settlement. The Company will recognize interest and penalties related to unrecognized tax benefits in the income tax provision in the accompanying statement of operations.

The Company calculates the current and deferred income tax provision based on estimates and assumptions that could differ from the actual results reflected in income tax returns filed in subsequent years. Adjustments based on filed income tax returns are recorded when identified. The amount of income taxes paid is subject to examination by U.S. federal and state tax authorities. The estimate of the potential outcome of any uncertain tax issue is subject to management's assessment of relevant risks, facts and circumstances existing at that time. To the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made.

Basic and Diluted Income (Loss) Per Share *– The Company follows Financial Accounting Standards Board ("FASB") ASC 260 Earnings per Share to account for earnings per share. Basic earnings per share ("EPS") calculations are determined by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted earnings per share calculations are determined by dividing net income by the weighted average number of common shares and dilutive common share equivalents outstanding. During loss periods when common stock equivalents, if any, are anti-dilutive they are not considered in the computation. During the year ended December 31, 2022 December 31, 2023, the Company had 111,824 11,183 options and 22,849,266 2,284,932 warrants to purchase common stock outstanding; however, the effects were anti-dilutive due to the net loss. The Company excluded 7 options and 6,604,819 warrants from the computation of diluted net income per share for During the year ended December 31, 2021 December 31, 2022, as their exercise prices were in excess of the average closing market price of the Company's Company had 11,183 options and 2,284,932 warrants to purchase common stock during that period. outstanding; however, the effects were anti-dilutive due to the net loss.*

On November 10, 2021 June 12, 2023, we effected a 1-for-500 1-for-10 reverse split of our authorized and issued and outstanding shares of common stock. All share references have been restated for this reverse split to the earliest period presented. As a result of the split, the authorized shares of the Company's common stock decreased to 50,000,000 5,000,000 shares.

***Recent Accounting Pronouncements** – The Company has reviewed all recently issued, but not yet adopted, accounting standards in order to determine their effects, if any, on its results of operation, financial position or cash flows. Based on that review, the Company believes that none of these pronouncements will have a significant effect on its financial statements.*

NOTE 2 – LICENSING AGREEMENTS

***ED Patent** – The Company acquired a patent from CMH, a related company on February 2, 2016, in exchange for 431,111 43,112 shares of CMTH restricted common stock valued at $100,000. CMH holds a significant amount of the Company's common stock. The patent expires in 2025 and the Company has elected to amortize the patent over a ten-year period on a straight-line basis. Amortization expense of $9,972 was recorded for the years ended December 31, 2022 December 31, 2023, and 2021. 2022. As of December 31, 2022 December 31, 2023, the carrying value of the patent was $31,016. $21,042. The Company expects to amortize $9,972 annually through 2026 related to the patent costs.*

***Multipotent Amniotic Fetal Stem Cells License Agreement** - On August 25, 2016, CMT entered into a License Agreement dated August 25, 2016, with a university. This license agreement grants to CMT the exclusive right to all products derived from a patent for use of multipotent amniotic fetal stem cells composition of matter throughout the world during the period ending on the expiration date of the longest-lived patent rights under the patent. The license agreement also permits CMT to grant sublicenses. Under the terms of the license agreement, CMT is required to diligently develop, manufacture, and sell any products licensed under the agreement. CMT paid the University an initial license fee within 30 days of entering into the agreement. CMT is also required to pay annual license maintenance fees on each anniversary date of the agreement, which maintenance fees would be credited toward any earned royalties for any given period. The License Agreement provides for payment of various milestone payments and earned royalties on the net sales of licensed products by CMT or any sub licensee. CMT is also required to reimburse the University for any future costs associated with maintaining the patent. CMT may terminate the license agreement for any reason upon 90 days' written notice and the University may terminate the agreement in the event CMT fails to meet its obligations set forth therein, unless the breach is cured within 30 days of the notice from the University specifying the breach. CMT is also obligated to indemnify the University against claims arising due to the exercise of the license by CMT or any sub licensee. As of December 31, 2022 December 31, 2023, no amounts are currently due to the University.*

The Company estimates that the patent expires in February 2026 and has elected to amortize the patent through the period of expiration on a straight-line basis. Amortization expense of $1,172 was recorded for the years ended December 31, 2022 December 31, 2023, and 2021. 2022. As of December 31, 2022 December 31, 2023, the carrying value of the patent was $3,205. $2,033. The Company expects to amortize approximately $1,172 annually through 2025 related to the patent costs.

***Lower Back Patent** – The Company, through its subsidiary StemSpine, LLC, acquired a patent from CMH, a related company, on May 17, 2017, covering the use of various stem cells for the treatment of lower back pain from pursuant to a Patent Purchase Agreement, which was amended in November 2017. As amended, the agreement provides the following:*

- The Company is required to pay CMH $100,000 within 30 days of demand as an initial payment.
- In the event the Company determines to pursue the technology via use of autologous cells, the Company will pay CMH:

  - $100,000 upon the signing agreement with a university for the initiation of an IRB clinical trial.

- o $200,000, upon completion of the IRB clinical trial.
- o $300,000 in the event we commercialize the technology via use of autologous cells by a physician without a clinical trial.

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- In the event the Company determines to pursue the technology via use of allogenic cells, the Company will pay CMH:
  - o $100,000 upon filing an IND with the FDA.
  - o $200,000 upon dosing of the first patient in a Phase 1-2 clinical trial.
  - o $400,000 upon dosing the first patient in a Phase 3 clinical trial.
- Payment may be made in cash or shares of our common at a discount of 30% to the lowest closing price within 20 business days prior to the conversion date.
- In the event the Company's shares of common stock trade below $0.01 per share for two or more consecutive trading days, the number of any shares issuable as payment doubles.
- For a period of five years from the date of the first sale of any product derived from the patent, the Company is required to make royalty payments of 5% from gross sales of products, and 50% of sale price or ongoing payments from third parties for licenses granted under the patent to third parties.

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The Company paid CMH the $100,000 obligation of the initial payment due under this agreement, by a $50,000 cash payment and the issuance of 6,667 667 shares of common stock on December 12, 2020. On December 31, 2020, following the Company's announcement with respect to the clinical commercialization of the StemSpine technology, the Company paid CMH $50,000 of the $300,000 obligation due under this agreement through the issuance of 133 14 shares of common stock. On September 30, 2021, the Company paid CMH an additional $40,000 of the $300,000 obligation due under this agreement through the issuance of 84,656 8,466 shares of common stock, and in January 2021 the Company paid CMH an additional $50,000 of the $300,000 obligation due under this agreement through the issuance of 89,286 8,929 shares of common stock. The remaining portion of the $300,000 obligation was paid in cash in 2020. In August 2023, the Company paid CMH $100,000 related to the filing of an IND with the FDA per the terms of the agreement.

The patent expires on May 19, 2027, and the Company has elected to amortize the patent over a ten-year period on a straight-line basis. Amortization expense of $10,000 was recorded for the years ended December 31, 2022 December 31, 2023, and 2021. 2022. As of December 31, 2022 December 31, 2023, the carrying value of the initial patent license was $45,000. $35,000. The Company expects to amortize approximately $10,000 annually through 2027 related to the patent costs.

The Company has elected to amortize the additional $300,000 $400,000 associated with the patent over a ten-year period on a straight-line basis. Amortization expense of $45,940 $48,440 was recorded for the years ended December 31, 2022 December 31, 2023, and 2021. 2022. As of December 31, 2022 December 31, 2023, the carrying value of the patent was $156,374. $207,936. The Company expects to amortize approximately $46,000 $56,000 annually through 2026 related to the patent costs.

***ImmCelz™** - On December 28, 2020, ImmCelz, Inc. ("ImmCelz"), a newly formed Nevada corporation and wholly owned subsidiary of the Company, entered into a Patent License Agreement dated December 28, 2020 (the "Agreement"), with Jadi Cell, LLC. ("Jadi"), a company controlled by Dr. Amit Patel, a former director of the Company. The Agreement grants to ImmCelz™ the patent rights under U.S. Patent# 9,803,176 B2, "Methods and compositions for the clinical derivation of an allogenic cell and therapeutic uses". The contract grants ImmCelz™ access to proprietary process of*

expanding the master cell bank of Jadi Cell LLC, as currently practiced by Licensor, and as documented in standard operating procedures (SOPs) and other written documentation to augment autologous cells. The terms of the agreement are as follows:

- Licensee shall pay Licensor a license fee of $250,000 (the "Upfront Royalty"), which can also be paid in CELZ stock at a discount of 25% of the closing price of $0.0037, which is based on the date of this agreement
- Within thirty (30) days of the end of each calendar quarter during the term of this Agreement, Licensee will pay Licensor five percent (5%) of the Net Income of ImmCelz™. during such calendar quarter (the "Continuing Royalty")
- in one or a series of related transactions, of all or substantially all of the business or assets of Licensee ImmCelz, Inc. ("Sale of Assets") will result in a one-time ten-percent allocation to the licensor, the Continuing Royalty will be calculated at five percent (5%) of the Net Income of Licensee in any calendar quarter in which the Net Income in such calendar quarter reflects the receipt of any consideration from such Sale of Assets.

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To date, the Company has not made any payments to Jadi Cell under this agreement, other than the $250,000 initial license fee, which was paid by the issuance of 180,180 18,018 shares of common stock to Jadi Cell in February 2022.

The Company has elected to amortize the patent over a ten-year period on a straight-line basis. Amortization expenses of $25,000 and $25,000 were recorded for the years ended December 31, 2022 December 31, 2023, and 2021. 2022. As of December 31, 2022 December 31, 2023, the carrying value of the patent was $200,000. $175,000. The Company expects to amortize approximately $25,000 annually through 2030 related to the patent costs.

As of December 31, 2022 December 31, 2023, future expected amortization of these assets is as follows:

For the year ended December 31,

2023	92,085	
2024	92,085	$ 102,085
2025	91,774	101,774
2026	54,650	64,650
2027	30,000	40,000
2028		35,000
Thereafter	75,002	97,502
Total	$ 435,595	$ 441,011

The following is a rollforward of the Company's licensing agreements for the year end December 31, 2022 December 31, 2023.

	Assets	Accumulated Amortization	Assets	Accumulated Amortization
Balances at December 31, 2021	$ 760,000	$ (232,321)		
Balances at December 31, 2022			$ 760,000	$ (324,405)
Addition of new assets		-	100,000	-

Amortization	-	(92,084)	-	(94,584)
Balances at December 31, 2022	$ 760,000	$ (324,405)		
Balances at December 31, 2023			$ 860,000	$ (418,989)

NOTE 3 – RELATED PARTY TRANSACTIONS

Management Reimbursement Agreement Narkeshyo Research Tools Purchase

On November 17, 2017 December 15, 2022, the Company entered into purchased a Management Reimbursement Agreement with CMH, set of components referred to as "research tools" for $5,000,000 from Narkeshyo LLC, an entity a related party whose directors former director and executive officers include the Company's officers and directors. Pursuant to this agreement, during 2019 and 2020, and until September 16, 2021, the Company reimbursed CMH an aggregate of $45,000 per month for the services of management and consultants employed by CMH (including the Company's Chief Executive Officer and Chief Financial Officer, and the Company's former directors Dr. Patel and Dr. Ichim). The agreement provided that at the option of CMH, the reimbursable amounts may be paid from time to time in shares of common stock current consultant of the Company at a price equal to a 30% discount is affiliated with, pursuant to the lowest closing price during the 20 trading days prior to time the notice is given. The terms of an Asset Purchase Agreement may be terminated by either party upon 30 days' prior written notice. This agreement was terminated effective September 15, 2021. At December 31, 2022, and 2021, between the Company owed no and Narkeshyo. Some of the acquired research tools were originally developed by the former director and current consultant. Under the terms of the agreement, the Company made an initial payment to Narkeshyo in the amount of $2,000,000 upon execution of the agreement, with the remaining amounts to CMH under this agreement. be paid at various times through March 15, 2023, which were made as scheduled. Upon execution of the agreement, the Company recorded $5,000,000 as research and development expenses.

Debt Settlement Agreement

On January 12, 2018, The vision and pipeline of the Company entered into a Debt Settlement Agreement is based on robust and thorough development of its biological platforms, therapies and products. This acquisition of the research tools aligned with Timothy Warbington, the Company's Chief Executive Officer, under which priority of advancing and augmenting its suite of cGMP (Current Good Manufacturing Practices) cellular therapy products. The Company believes that the Company issued 3,000,000 shares of super-voting Series A Preferred Stock acquired research tools will allow it to Mr. Warbington protect its intellectual property while complying with regulatory requirements, and accelerate product development. The information contained in exchange for the cancellation of $150,000 of debt owed by the Company research tools will not only be used to CMH, which CMH in turn was obligated to pay Mr. Warbington. The Series A Preferred Stock previously provided Mr. Warbington with substantial control over all matters subject to a vote of support and fast-track the Company's shareholders. Mr. Warbington surrendered the Series A Preferred Stock regulatory filings (such as IND, NDA, ANDA and export applications), but also, provide clinical and regulatory support to the Company in December 2021 immediately prior potential partners and collaborators without having to the closing of the Company's public offering in exchange for $150,000 plus 8% interest on such amount from January 2018 until the date of surrender. divulge trade secrets and know-how.

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A third-party analysis of this acquisition concluded it would accelerate development time by 3-5 years and result in a substantial reduction in the Company's research and development expenses over the long term.

The purchased tools included (but were not limited to):

- Toxicology
- Screening
- Preclinical Testing
- Assays
- Authorization

- Tools of Biological Transaction
- Tools of Intellectual Property

Jadi Cell License Agreement

On December 28, 2020, the Company entered into a patent license agreement with Jadi Cell, LLC, a company owned and controlled by Dr. Amit Patel, a former director of the Company. The agreement provides Company with an exclusive, worldwide license to U.S. Patent No. 9,803,176 "Methods and compositions for the clinical derivation of an allogenic cell and therapeutic uses" and the proprietary process of expanding the master cell bank of Jadi Cell LLC, in the field of enhancing autologous cells. The agreement is described in detail in Note 2 above. To date, the Company has not made any payments to Jadi Cell under this agreement, other than the $250,000 initial license fee, which was paid by the issuance of 180,180 18,018 shares of common stock to Jadi Cell in February 2022.

StemSpine Patent Purchase

The Company acquired U.S. Patent No. 9,598,673 covering the use of various stem cells for the treatment of lower back pain from its affiliate CMH pursuant to a Patent Purchase Agreement dated May 17, 2017, which was amended in November 2017. The inventors of the patent were Thomas Ichim, PhD and Amit Patel, MD, former directors of the Company, and Annette Marleau, PhD. The Patent Purchase Agreement is described in detail in Note 2 above. Pursuant to the Patent Purchase Agreement, the Company paid CMH the $100,000 obligation of the initial payment due under this agreement, by a $50,000 cash payment and the issuance of 6,667 667 shares of common stock on December 12, 2020. On December 31, 2020, following the Company's announcement with respect to the clinical commercialization of the StemSpine technology, the Company paid CMH $50,000 of the $300,000 obligation due under this agreement through the issuance of 133 14 shares of common stock. On September 30, 2021 the Company paid CMH an additional $40,000 of the $300,000 obligation due under this agreement through the issuance of 84,656 8,466 shares of common stock, and in January 2021 the Company paid CMH an additional $50,000 of the $300,000 obligation due under this agreement through the issuance of 89,286 8,929 shares of common stock. The remaining portion of the $300,000 obligation has been paid in cash.

Insider Loans

On May 28, 2021, Timothy Warbington, who is our CEO and Chairman; and Dr. Amit Patel, who was formerly a director of ours, advanced the Company $50,000 and $150,000 respectively. The two notes were repaid during the quarter ended September 30, 2021, did not have any conversion features, and bore interest at the rate of 5% per annum.

NOTE 4 – DEBT

On August 11, 2021, we completed the sale of 15% Original Issue Discount Senior Notes ("Bridge Notes") in the aggregate principal amount of $4,456,176 to a group of institutional investors (the "Purchasers"). In connection with the sale of the Bridge Notes, holders of our shares of Series B Preferred Stock and Series C Preferred Stock exchanged such preferred stock for additional Bridge Notes in the aggregate principal amount of $690,000. The Bridge Notes were set to mature on February 11, 2022, subject to the requirement that we redeem the Bridge Notes prior to such date with the net proceeds of any future offering of our securities. The Notes did not bear interest other than upon an event of default and were not convertible into the Company's common stock. In addition, the Notes were subject to covenants, events of defaults and other terms and conditions customary in transactions of this nature. The Company amortized the on-issuance discount and financing fees totaling $758,426 to interest expense with respect to these notes. The notes were repaid in full on December 6, 2021, following the completion of the Company's public offering (see Note 7).

The Company also issued to the purchasers of the Bridge Notes five-year warrants to purchase an aggregate of 363,046 shares of our common stock at an initial exercise price of $14.175 per share, subject to anti-dilution adjustments in the event of future sales of our equity below the then exercise price, stock dividends, stock splits and other specified events. These warrants were valued based on the Black-Scholes valuation model (see Note 5 for assumptions used), and then recorded as a discount to the Bridge Notes based on their relative fair value of approximately $1,846,000.

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Roth Capital Partners ("Roth"), acted as sole placement agent for the offering. Pursuant to terms of an engagement letter with Roth, the Company paid Roth a placement agent fee in the amount of $312,750. The Company also issued Roth a warrant to purchase 20,189 shares of common stock with

the same terms as the warrants issued to the Purchasers. These warrants were valued based on the Black-Scholes valuation model (see Note 5 for assumptions used), and then recorded as an additional discount in the amount of approximately $252,000 to the Bridge Notes.

The full amount of the discount on the Bridge Notes, including that arising from on-issuance discounts, fees and issuance costs, and warrants totaling approximately $3,299,000 was amortized to interest expense during the year ended December 31, 2021 as the notes were repaid in full on December 6, 2021 as noted above.

During 2021, we also issued $498,800 in convertible notes to accredited investors with net proceeds of $435,040, which were repaid in full during 2021. The notes were to mature during February and July of 2022 and bore interest rate of 8%. The notes were convertible into shares of the Company's common stock at conversion prices ranging from 60% to 71% of the average of the two lowest traded prices or the lowest trade price of the Company's common stock during the previous 15 trading days preceding the conversion date. The Company amortized the discount due to derivative liabilities and on-issuance discount totaling $443,905 to interest expense with respect to these notes.

On May 28, 2021, Mr. Timothy Warbington, who is our CEO and Chairman; and Dr. Amit Patel, who was formerly a director of ours, advanced the Company $50,000 and $150,000 respectively. The two notes were repaid during the quarter ended September 30, 2021, did not have any conversion features, and bore interest at the rate of 5% per annum.

On June 21, 2021, we issued a $105,000, non-convertible note to an accredited investor with net proceeds of $100,000. The note was repaid during the quarter ended September 30, 2021, did not have any conversion features, and bore interest at the rate of 10% per annum.

During the year ended December 31, 2021, the Company issued an aggregate of 789,727 shares upon the conversion of $1,383,332 of outstanding principal, interest and fees on outstanding notes, and 37,870 shares upon the cashless exercise of 43,167 warrants.

During 2022 there were no debt issuances.

As of December 31, 2022, and 2021, the Company had no outstanding loans.

NOTE 5 – DERIVATIVE LIABILITIES

In connection with convertible notes payable, the Company records derivative liabilities for the conversion feature. The derivative liabilities are valued on the date the convertible note payable become convertible and revalued at each reporting period. During 2021, the Company recorded initial derivative liabilities of $1,077,757 based upon the following Black-Scholes option pricing model average assumptions: an exercise price of $5.30 to $12.40 our stock price on the date of grant of $17.00 to $40.30, expected dividend yield of 0%, expected volatility of 75.03% to 98.14%, risk free interest rate of 0.10% and expected terms of 1.0 year. Upon initial valuation, the derivative liabilities exceeded the face values certain of the convertible notes payable by approximately $697,602, which was recorded as a day one loss in derivative liability.

In March 2021, the derivatives were re-valued at $2,275,578, producing a gain of $28,476,039 related to the change in fair market value of the derivative liabilities. The derivative liabilities were revalued using the Black-Scholes option pricing model with the following average assumptions: an exercise price of $0.0008 to 3.0900, our stock price on the date of valuation ($0.0332), expected dividend yield of 0%, expected volatility of 93.05% to 102.96%, risk-free interest rate of 0.07% to 0.35%, and expected terms ranging from 0.5 to 3.3 years.

In August 2021, we completed the sale of 15% Original Issue Discount Senior Notes ("Bridge Notes") in the aggregate principal amount of $4,456,176 to a group of institutional investors (the "Purchasers"). A portion of the proceeds were used to repay the principal, accrued interest, pre-payment fees and other premiums of all the outstanding convertible notes as well as all previously outstanding warrants with re-pricing and anti-dilutive features. The result was $0 in derivative liabilities as of December 31, 2021.

There was no derivative liability activity in 2022.

There were no derivative liabilities as of December 31, 2022 and 2021.

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NOTE 6 – STOCK-BASED COMPENSATION

On September 6, 2021, the Company's Board of Directors, and holders of a majority of the voting power of the Company's stockholders approved the Company's 2021 Equity Incentive Plan (the "2021 Plan") and reserved 600,000 60,000 shares of common stock for the issuance of awards thereunder. The 2021 Plan provides for the granting to our employees, officers, directors, consultants, and advisors of performance awards payable in shares of common stock, stock options (non-statutory and incentive), restricted stock awards, stock appreciation rights ("SARs"), restricted share units ("RSUs") and other stock-based awards. The purpose of the 2021 Plan is to secure for the Company and its stockholders the benefits arising from capital stock

ownership by eligible participants who are expected to contribute to the Company's future growth and success. As of December 31, 2022 December 31, 2023, 169,837 stock options to purchase 16,984common shares had been granted under the 2021 Plan.

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*The Company has also reserved 27 stock options to purchase 3 common shares under its 2016 Stock Incentive Plan (the "Prior Plan"). In July 2016, the Company granted 10-year options to one party under the Prior Plan for accepting appointment to the Company's scientific advisory board. The award consisted of options to purchase up to 7 shares **1** share of common stock at $13,125 $75,000 per share. The options are accounted for as non-employee stock options and thus revalued for reporting purposes at the end of each quarter. The Company does not expect to make any future awards under the Prior Plan.*

During 2022 2023 and 2021, 2022, the fair market value of the options was insignificant to the financial statements.

Since the expected life of the options was greater than the Company's historical stock information available, the Company determined the expected volatility based on price fluctuations of comparable public companies.

There were 111,817 options issued during the year ended December 31, 2022, and no options issued during the year ended December 31, 2021. year-ended December 31, 2023 and 11,182 options issued during the year-ended 2022.

Option activity for the years ended December 31, 2022 December 31, 2023, and 2021 2022 consists of the following:

	Stock Options	Weighted Average Exercise Price	Weighted Average Life Remaining	Stock Options	Weighted Average Exercise Price	Weighted Average Life Remaining
Outstanding, December 31, 2020	**7**	$ 7,500	5.64			
Issued	-	-	-			
Exercised	-	-	-			
Expired	-	-	-			
Outstanding, December 31, 2021	7	$ 7,500	4.64	1	$ 75,000	4.64
Issued	111,817	1.69	10.00	11,182	16.90	-
Exercised	-	-	-	-	-	-
Expired	-	-	-	-	-	-
Outstanding, December 31, 2022	111,824	$ 2.14	9.11	11,183	$ 83.96	9.11
Vested, December 31, 2022	55,915	$ 2.58	9.11			
Issued				-	-	-
Exercised				-	-	-
Expired				-	-	-
Outstanding, December 31, 2023				11,183	$ 83.96	8.11
Vested, December 31, 2023				7,735	$ 210.83	8.11

See Note 2 for discussion related to the issuance of common stock in connection with licensing agreements. See Note 4 and 5 for discussion regarding warrants issued with convertible notes payable. See Note 7 for warrants issued in connection with the December 2021 public our May 2022 private offering.

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In February 2022, we granted a total of 111,817 11,182 options to Timothy Warbington and Donald Dickerson at an exercise price of $1.69. $16.90. The value of the options was determined to be $145,525 based upon the Black-Scholes method, see variables used below. As of December 31, 2022 December 31, 2023, future estimated stock-based compensation expected to be recorded was estimated to be $104,164. $40,132.

	Inputs Used	Inputs Used
Annual dividend yield	$ -	$ -
Expected life (years)	6.5	6.5
Risk-free interest rate	0.81%	0.81%
Expected volatility	92.95%	92.95%
Common stock price	$ 1.69	$ 16.90

In July 2021, we granted a total See Note 2 for discussion related to the issuance of 30,000 warrants to three of our board members at that time, Dr. Ichim, Dr. Patel, and Donald Dickerson (Mr. Dickerson remains a board member) at an exercise price of $15.00. The value of the warrants was determined to be $383,612 based upon the Black-Scholes method, see variables used below. As of December 31, 2022, future estimated stock-based compensation expected to be recorded was estimated to be $0. common stock in connection with licensing agreements.

	Inputs Used
Annual dividend yield	$ -
Expected life (years)	3.0
Risk-free interest rate	1.13%
Expected volatility	93.09%
Common stock price	$ 15.00

See Note 7 for warrant rollforward. rollforward

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NOTE 7 – STOCKHOLDERS' EQUITY

May 2022 Private Offering

On May 3, 2022, the Company completed the sale of (i) 2,991,669 299,167 shares of common stock, and pre-funded warrants to purchase 4,563,887 456,389 shares of common stock (the "Pre-Funded Warrants"), and (ii) accompanying warrants to purchase 15,111,112 1,511,112 shares of common stock (the "Common Warrants"), at a combined offering price of $2.25 $22.50 per share of common stock/Pre-Funded Warrant and related Common Warrant, to a group of institutional investors (the "Purchasers"), pursuant to a Securities Purchase Agreement between the Company and the Purchasers dated as of April 28, 2022 (the "Purchase Agreement"), resulting in gross proceeds to the Company of approximately $17,000,000. The transaction was effected pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended and Rule 506(b) promulgated thereunder.

The Common Warrants have a five-year term, and an exercise price of $2.00 $20.00 per share. The Pre-Funded Warrants did not have an expiration date and had an exercise price of $0.0001 per share. As of December 31, 2022 December 31, 2023, all of the Pre-Funded Warrants had been exercised.

The Pre-Funded Warrants were classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, did not embody an obligation for the Company to repurchase its shares, and permitted the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Pre-Funded Warrants did not provide any guarantee of value or return.

Roth Capital Partners ("Roth") acted as sole placement agent for the offering. The Company paid Roth a placement agent fee in the amount of $1,360,000 and issued Roth a warrant to purchase 1,133,333 113,334 shares of Common Stock with the same terms as the Common Warrants issued to the Purchasers.

December 2021 Public Offering Share Repurchase Program

On December 7, 2021, we sold an aggregate June 12, 2023 the Company announced that its Board of 3,875,000 shares Directors has approved a share repurchase program. The program authorizes the Company to repurchase up to $2 million of our common stock and accompanying warrants to purchase 3,875,000 its shares of common stock, in the open market or through privately negotiated transactions, in accordance with applicable securities laws and other restrictions. The manner, timing and amount of any purchase will be based on an evaluation of market conditions, the Company's stock price and other factors. The program has no termination date, may be suspended or discontinued at an exercise price of $4.13 per share, at a combined public offering price to the public of $4.13 per share of common stock any time, and related Warrant, pursuant to an Underwriting Agreement we entered into with Roth Capital Partners, LLC. We received gross proceeds of $16,003,750, before deducting underwriting discounts and commissions of seven percent (7%) of the gross proceeds and offering expenses. As a result of the offering, the exercise price of our Warrants issued together with our Bridge Notes was reduced to the $4.13.

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Series B Convertible Preferred Stock Equity Financing

On February 11, 2021, the Board of Directors authorized the issuance of up to 350 shares of preferred stock, $0.001 par value per share, designated as Series B Convertible Preferred Stock. Each share of Preferred Stock had a par value of $0.001 per share and a stated value of $1,200. On February 12, 2021, does not obligate the Company issued 350 shares to acquire any particular number of the Series B Convertible Preferred Stock to BHP Capital, LLC ("BHP") for which $326,600 in proceeds were received by the Company. In connection with the closing, the Company issued BHP an additional 3,000 shares of common stock as stock. As-of December 31, 2023, 57,500 shares had been repurchased under this program for a service fee. The Company has accounted for the transaction with equity as the proceeds received was considered consideration for all securities issued. In August 2021, the preferred shares were redeemed at 120% of their stated value per the terms of their designations through the issuance of Bridge Notes as described in Note 4. On November 22, 2021, the Company filed a Certificate of Withdrawal of Designation of the Series B Convertible Preferred Stock with the State of Nevada.

Series C Convertible Preferred Stock Equity Financing

On March 30, 2021, the Board of Directors authorized the issuance of up to 150 shares of preferred stock, $0.001 par value per share, designated as Series C Convertible Preferred Stock. Each share of Preferred Stock had a par value of $0.001 per share and a stated value of $1,200. On March 30, 2021, the Company issued 150 shares of Series C Convertible Preferred Stock to Fourth Man, LLC ("FM") for a total purchase price of $150,000, or $1,000 per share, for which $141,049 in proceeds were received by the Company. In connection with the closing, the Company issued FM an additional 642,857 shares of common stock as a service fee. The Company has accounted for the transaction with equity as the proceeds received was considered consideration for all securities issued. In August 2021, the preferred shares were redeemed at 120% of their stated value per the terms of their designations through the issuance of Bridge Notes as described in Note 4. On November 22, 2021, the Company filed a Certificate of Withdrawal of Designation of the Series C Convertible Preferred Stock with the State of Nevada. $270,952.

Warrants

In connection with our May 2022 private offering, we issued pre-funded warrants to purchase 4,563,887 456,389 shares of common stock and accompanying warrants to purchase 16,244,445 1,624,446 shares of common stock at a price of $2.00 $20.00 per share.

During 2021, the Company granted ten-year warrants to three board members to purchase an aggregate of 30,000 shares of common stock at a price of $15.00 per share.

In connection with our August 2021 bridge financing, we issued five-year warrants to purchase 383,235 shares of common stock at an exercise price of $4.13 per share.

During April and May of 2021, the Company granted five-year warrants to various employees and scientific board members to purchase an aggregate of 28,020 shares of common stock at exercise prices varying from $14.00 to $15.00.

In connection with our December 2021 public offering, we issued five-year warrants to purchase 5,191,365 shares of common stock at an exercise price of $4.13 per share. In conjunction with the December 2021 public offering we also increased outstanding warrants associated with anti-dilution features of the August 2021 bridge financing to purchase 932,104 shares of common stock at an exercise price of $4.13.

For the year-ended 2021, there were 43,167 warrants converted into common shares through cashless conversions.

As of December 31, 2022, and 2021, warrants to purchase 22,969,266 and 6,604,820 shares of common stock were outstanding respectively.

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Assumptions used in calculating the fair value of the warrants issued in 2022 were as follows:

	Range of Inputs Used	Range of Inputs Used
Annual dividend yield	*$ -*	*$ -*
Expected life (years)	*5.0*	*5.0*
Risk-free interest rate	*0.81%*	*0.81%*
Expected volatility	*92.95%*	*92.95%*
Common stock price	*$ 1.83*	*$ 18.30*

Assumptions used in calculating the fair value As of the December 31, 2023, and 2022, warrants issued in 2021 to purchase 2,284,932 shares of common stock were as follows: outstanding.

	Range of Inputs Used
Annual dividend yield	$ -
Expected life (years)	2.7 to 10.0
Risk-free interest rate	0.23% to 1.26%
Expected volatility	92.93 to 98.81%
Common stock price	$ 1.68 to 17.00

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Warrant activity for the years ended December 31, 2022 December 31, 2023 and 2021 2022 consists of the following:

	Warrants	Weighted Average Exercise Price	Weighted Average Life Remaining
Outstanding, December 31, 2020	152,738	$ 2.85	2.47
Issued	5,632,621		
Exercises	(43,167)		
Anti-Dilution Modifications	932,104		
Forfeiture/Cancellations	(69,475)		-
Outstanding, December 31, 2021	6,604,821	$ 4.27	4.85
Issued	20,808,332		
Exercises	(4,563,887)		
Anti-Dilution Modifications	-		-
Forfeiture/Cancellations	-		-
Outstanding, December 31, 2022	22,849,266	$ 2.66	4.22

See Note 5 for discussion regarding anti-dilution and modifications related to warrants accounted for as derivative liabilities.

	Warrants	Weighted Average Exercise Price	Weighted Average Life Remaining
Outstanding, December 31, 2021	660,486	$ 42.70	4.85
Issued	2,080,835		
Exercises	(456,389)		
Anti-Dilution Modifications	-		
Forfeiture/Cancellations	-		
Outstanding, December 31, 2022	2,284,932	$ 26.59	4.22
Issued	-		
Exercises	-		
Anti-Dilution Modifications	-		
Forfeiture/Cancellations	-		
Outstanding, December 31, 2023	2,284,932	$ 26.59	3.22

See Note 2 for discussion related to the issuance of common stock in connection with licensing agreements.

See Note 3 for discussion related to the issuance of common stock to a related party for cash.

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NOTE 8 – SIGNIFICANT RESEARCH AND DEVELOPMENT PURCHASES

On December 15, 2022, the Company purchased a set of components referred to as "research tools" for $5,000,000 from Narkeshyo LLC, an entity a former director and current consultant of the Company is affiliated with, pursuant to the terms of an Asset Purchase Agreement between the Company and Narkeshyo. Some of the acquired research tools were originally developed by the former director and current consultant. Under the terms of the agreement, the Company made an initial payment to Narkeshyo in the amount of $2,000,000 upon execution of the agreement, with the remaining

amounts to be paid at various times through March 15, 2023, which were made as scheduled. Upon execution of the agreement, the Company recorded $5,000,000 as research and development expenses.

The vision and pipeline of the Company is based on robust and thorough development of its biological platforms, therapies and products. This acquisition of the research tools aligned with the Company's priority of advancing and augmenting its suite of cGMP (Current Good Manufacturing Practices) cellular therapy products. The Company believes that the acquired research tools will allow it to protect its intellectual property while complying with regulatory requirements, and accelerate product development. The information contained in the research tools will not only be used to support and fast-track the Company's regulatory filings (such as IND, NDA, ANDA and export applications), but also, provide clinical and regulatory support to potential partners and collaborators without having to divulge trade secrets and know-how.

A third-party analysis of this acquisition concluded it would accelerate development time by 3-5 years and result in a substantial reduction in the Company's research and development expenses over the long term.

The purchased tools included (but were not limited to):

- *Toxicology*
- *Screening*
- *Preclinical Testing*
- *Assays*
- *Authorization*
- *Tools of Biological Transaction*
- *Tools of Intellectual Property*

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NOTE 9 – INCOME TAXES

The provision for income tax expense consists of for the following at December 31, 2022 years ended December 31, 2023, and 2021: 2022:

	2022	2021	2023	2022
Income tax provision attributable to:				
Federal	*$ (2,096,475)*	*$ (325,596)*	*$ (1,082,622)*	*$ (2,096,475)*
State and local	*(582,461)*	*(90,460)*	*(300,783)*	*(582,461)*
Valuation allowance	*2,678,936*	*416,056*	*1,383,405*	*2,678,936*
Net provision for income tax	***$ -***	***$ -***	***$ -***	***$ -***

Deferred tax assets consist of the following at December 31, 2022 December 31, 2023, and 2021: 2022:

	2022	2021	2023	2022
Deferred tax asset attributable to:				
Net operating loss carryover	*$ 4,843,337*	*$ 2,097,315*	*$ 6,266,742*	*$ 4,843,337*
Accrued management fees, related party	*-*	*67,086*	*-*	*-*
Valuation allowance	*(4,843,337)*	*(2,164,401)*	*(6,266,742)*	*(4,843,337)*

Net deferred tax asset	$ -	$ -	$ -	$ -

The primary difference between the statutory federal rate and the Company's effective tax rate for the years ended December 31, 2022 December 31, 2023 and 2021 2022 was due to the 100% valuation allowance. The following is a reconciliation of the statutory federal rate and the Company's effective tax rate for the year ended December 31, 2022 December 31, 2023, and 2021: 2022:

	2022	2021	2023	2022
Tax at federal statutory rate	21.0%	21.0%	21.0%	21.0%
State, net of federal benefit	5.7%	(0.5)%	5.7%	5.7%
Change in temporary differences	(0.0)%	(0.0)%	(0.0)%	(0.0)%
Permanent differences	(0.3)%	(22.7)%	(0.4)%	(0.2)%
Valuation allowance	(26.4)%	2.2%	(26.2)%	(26.4)%
Provision for taxes	-	-	-	-

As of December 31, 2022 December 31, 2023 the Company had federal and state gross net operating loss carryforwards of approximately $18.0 million $23.5 million. The federal and state net operating losses and tax credits expire in years beginning in 2036. Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income may be limited. In general, an "ownership change" will occur if there is a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. To date, the Company hasn't experienced "ownership changes" under section 382 of the Code and comparable state tax laws. As of December 31, 2022 December 31, 2023, the Company estimates that none of the federal and state net operating losses will be limited under Section 382 of the Code.

As of December 31, 2022 December 31, 2023, and 2021, 2022, the Company maintained a full valuation allowance on its net deferred tax assets. The valuation allowance was determined in accordance with the provisions of ASC 740, Accounting for Income Taxes, which requires an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. Such assessment is required on a jurisdiction-by-jurisdiction basis. The Company's history of cumulative losses, along with expected future U.S. losses required that a full valuation allowance be recorded against all net deferred tax assets. The Company intends to maintain a full valuation allowance on net deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance.

The applicable federal and state rates used in calculating the deferred tax provision were 21.0% and 8.9%, respectively.

The Company files income tax returns in the U.S. and Arizona. All years presented remain subject to examination for U.S. federal and state purposes. The Company is not currently under examination in federal or state jurisdictions.

NOTE 10 – COMMITMENTS AND CONTINGENCIES

In October 2022, we terminated an employee for cause. Subsequent to the termination, in December 2022, the employee brought claims against us for breach of contract, wrongful termination and related claims in the Superior Court of the State California (Orange County). The parties have submitted the action for arbitration before JAMS, where it is now pending.

NOTE 11 – SUBSEQUENT EVENTS

Management has reviewed subsequent events through the date of the filing noting none.

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

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, our management evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2022 December 31, 2023.

*Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 15(d)-15(e) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were not effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and (ii) is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. The conclusion that our disclosure controls and procedures were not effective was due to the presence of material weaknesses in internal control over financial reporting, as that term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, which are described below.*

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of our company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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Management assessed our internal control over financial reporting as of December 31, 2022 December 31, 2023, the end of our fiscal year. Management based its assessment on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO 2013 Criteria). Management's assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on our assessment, management has concluded that our internal control over financial reporting was not effective, as of December 31, 2022 December 31, 2023, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Description of Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of a company's financial reporting. In connection with the preparation and audit of the Company's financial statements for the year ended the December 31, 2022, management identified the following deficiencies that alone or in combination, represent a material weaknesses in internal control over financial reporting, as follows:

- Previously, we failed to adequately disclose the transaction in which we purchased research tools for $5,000,000 from Narkeshyo LLC, an entity a former director and current consultant of the Company is affiliated with.

- During the year ended December 31, 2022, we did not sufficiently segregate the duties of our officers.

We intend to remediate the deficiencies described above, and take such other action as we deem appropriate to further strengthen our internal control over financial reporting. However, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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 of compliance with the policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2022 December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

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PART III

Item 10. Directors, Executive Officers, Promoters, Control Persons and Corporate Governance.

Information with respect to this item will be set forth in the Proxy Statement for the 2023 2024 Annual Meeting of Stockholders ("Proxy Statement") under the headings "Directors," "Executive Officers," "Delinquent Section 16 Reports" and "Corporate Governance" or an amendment to this Annual Report on Form 10-K ("Form 10-K/A"), and is incorporated herein by reference. The Proxy Statement or Form 10-K/A, as the case may be, will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation.

Information with respect to this item will be set forth in the Proxy Statement under the headings "Executive Compensation" and "Director Compensation," or the Form 10-K/A, and is incorporated herein by reference.

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

Information with respect to this item will be set forth in the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation—Securities Authorized for Issuance Under Equity Compensation Plans" or the Form 10-K/A, and is incorporated herein by reference.

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

Information with respect to this item will be set forth in the Proxy Statement under the headings "Related Party Transactions" and "Director Independence" and is incorporated herein by reference or the Form 10-K/A.

Item 14. Principal Accountant Fees and Services.

Information with respect to this item will be set forth in the Proxy Statement under the headings "Audit and Non-Audit Related Fees" and "Pre-Approval Policy" and is incorporated herein by reference or the Form 10-K/A.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

The following exhibits are included with this report:

Exhibits

3.1.1	Articles of Incorporation of Creative Medical Technology Holdings, Inc., a Nevada corporation (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2021).
3.1.2	Certificate of Designation of the Series A Preferred Stock of the Company (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 16, 2018).
3.1.3	Certificate of Amendment to Certificate of Designation of the Series A Preferred Stock Pursuant to NRS 78.1955, filed with the Secretary of State of the State of Nevada on March 11, 2021 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2021).
3.1.4	Certificate of Designation of the Series B Preferred Stock of the Company, filed March 30, 2021 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2021).
3.1.5	Certificate of Designation of the Series C Preferred Stock of the Company, filed March 30, 2021 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 2, 2021).
3.1.6	Certificate of Amendment to Articles of Incorporation Pursuant to NRS 78.385 and 78.390, as filed with the Secretary of State of the State of Nevada on November 2, 2021 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2021).
3.1.7	Certificate of Withdrawal of Certificate of Designation of Series B Convertible Preferred Stock, as filed with the Secretary of State of the State of Nevada on November 2, 2021 (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2021).
3.1.8	Certificate of Withdrawal of Certificate of Designation of Series C Convertible Preferred Stock, as filed with the Secretary of State of the State of Nevada on November 2, 2021 (incorporated by reference to Exhibit 3.3 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2021).
3.1.9	Certificate of Change Pursuant to NRS 78.209, as filed with the Secretary of State of the State of Nevada on November 8, 2021 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 9, 2021).
3.10	Certificate of Change Pursuant to NRS 78.209, as filed with the Secretary of State of the State of Nevada on June 1, 2023 (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2023).

3.2	Bylaws of Creative Medical Technology Holdings, Inc., a Nevada corporation (incorporated by reference to Exhibit 3.2 to the Company's Form 10 filed with the Securities and Exchange Commission on November 18, 2008).
4.1	Form of Public Warrant issued in December 7, 2021 public offering (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on November 23, 2021).
4.2	Underwriter's Warrant issued to Roth Capital Partners, LLC dated December 7, 2021 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2021).
4.3	Form of 15% Original Issue Discount Senior Note Due February 11, 2022 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 12, 2021).
4.4	Form of Common Stock Purchase Warrant issued under Securities Purchase Agreement dated as of August 9, 2021 between Creative Medical Technology Holdings, Inc. and the purchasers named therein (incorporated by reference to Exhibit 4.2 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 12, 2021).
4.5 4.4	Description of Registrant's Securities*

10.1	*Management Reimbursement Agreement dated November 17, 2017, between Creative Medical Technology Holdings, Inc. and Creative Medical Technologies, Inc. (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2021).*
10.2	*Patent Purchase Agreement dated May 17, 2017, between Creative Medical Technology Holdings, Inc. and Creative Medical Health, Inc. (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2021).*
10.3 10.2	*Amendment and Waiver to Patent Purchase Agreement dated November 14, 2017, between Creative Medical Technology Holdings, Inc. and Creative Medical Health, Inc. (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2021).*

10.4 10.3	*Agreement dated December 28, 2020, between Jadi Cell LLC and ImmCelz, Inc. (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on September 28, 2021).*
10.5 10.4	*Warrant Agency Agreement between Creative Medical Technology Holdings, Inc. and vStock Transfer LLC dated December 7, 2021 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2021).*
10.6† 10.5†	*2021 Equity Incentive Plan (incorporated by reference to Appendix B to the Company's Information Statement on Schedule 14C filed with the Securities and Exchange Commission on September 24, 2021).*
10.7† 10.6†	*Employment Agreement between Creative Medical Technology Holdings, Inc. and Timothy Warbington, dated as of February 9, 2022. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 11, 2022).*
10.8† 10.7†	*Employment Agreement between Creative Medical Technology Holdings, Inc. Company and Donald Dickerson, dated as of February 9, 2022. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 11, 2022).*
10.9 10.8	*Research Tools Purchase Agreement, dated December 15, 2022, between Creative Medical Technology Holdings, Inc and Narkeshyo LLC (incorporated by reference to Exhibit 10.9 of the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2023)*
21.1	*Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2021).*

31.1	*Rule 13a-14(a)/15d-14a(a) Certification of Principal Executive Officer**
31.2	*Rule 13a-14(a)/15d-14a(a) Certification of Principal Financial Officer**
32.1	*Section 1350 Certification of Principal Executive Officer **
32.2	*Section 1350 Certification of Principal Financial Officer **
101.INS	*Inline XBRL Instance 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*

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† Management contract or compensatory plan or arrangement.

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SIGNATURES

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

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.

Date: March 31, 2023 March 22, 2024

By: /s/ Timothy Warbington
Timothy Warbington, Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2023 March 22, 2024

By: /s/ Donald Dickerson
Donald Dickerson, Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

NAME	***TITLE***	***DATE***
/s/ Timothy Warbington *Timothy Warbington*	*Director & Chairman*	*March 31, 2023 22, 2024*
/s/ Donald Dickerson *Donald Dickerson*	*Director*	*March 31, 2023 22, 2024*

/s/ Michael H. Finger *Michael H. Finger*	*Director*	*March 31, 2023 22, 2024*
/s/ Susan Snow *Susan Snow*	*Director*	*March 31, 2023 22, 2024*
/s/ Bruce S. Urdang *Bruce S. Urdang*	*Director*	*March 31, 2023 22, 2024*

EXHIBIT 4.5

CREATIVE MEDICAL TECHNOLOGY HOLDINGS, INC.
DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

The following is a brief description of shares of capital stock of Creative Medical Technology Holdings, Inc. (the "Company," "we," "us," or "our"). The brief description is based upon our Articles of Incorporation (as amended, our "Articles of Incorporation"), our Bylaws (our "Bylaws"), and provisions of applicable Nevada law. This summary does not purport to be complete and is subject to, and qualified in its entirety by, the full text of our Articles of Incorporation and Bylaws, each of which is incorporated by reference as an exhibit to our Annual Report on Form 10-K.

Common Stock

We are authorized to issue 50,000,000 5,000,000 shares of Common Stock, $0.001 par value per share, of which 14,076,238 1,373,626 were outstanding as of December 31, 2022 December 31, 2023. Holders of shares of our Common Stock are entitled to one vote per share on all matters submitted to a vote of the stockholders and are not entitled to cumulative voting rights. Our shares of our Common Stock do not carry any preemptive, conversion or subscription rights, and there are no sinking fund or redemption provisions applicable to the shares of our Common Stock. Holders of our Common Stock are entitled to receive dividends and other distributions in cash, stock or property as may be declared by our Board of Directors from time to time out of our assets or funds legally available for dividends or other distributions, subject to dividend or distribution preferences that may be applicable to any then outstanding shares of preferred stock. In the event of our voluntary or involuntary liquidation, dissolution or winding up, holders of shares of our Common Stock are entitled to share ratably in the assets legally available for distribution to stockholders after payment of all debts and other liabilities and satisfaction of the liquidation preference, if any, granted to the holders of any preferred stock then outstanding. All outstanding shares of our Common Stock are fully paid and nonassessable.

Preferred Stock

We are authorized to issue 10,000,000 shares of preferred stock, $0.001 par value per share, none of which were issued or outstanding as of December 31, 2021. December 31, 2023 and 2022. Our certificate of incorporation authorizes our Board of Directors to establish one or more series of preferred stock (including convertible preferred stock). Unless required by law, the authorized shares of preferred stock will be available for issuance without further action by you. Our Board of Directors is able to determine, with respect to any series of preferred stock, the powers (including voting

powers), preferences and relative, participating, optional or other special rights, and the qualifications, limitations or restrictions thereof, including, without limitation:

- *the designation of the series;*
- *the number of shares of the series, which our Board of Directors may, except where otherwise provided in the preferred stock designation, increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares then outstanding);*
- *whether dividends, if any, will be cumulative or non-cumulative and the dividend rate of the series;*
- *the dates at which dividends, if any, will be payable;*
- *the redemption rights and price or prices, if any, for shares of the series;*
- *the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;*
- *the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding-up of our affairs;*
- *whether the shares of the series will be convertible into shares of any other class or series, or any other security, of the Company or any other corporation, and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates, any rate adjustments, the date or dates as of which the shares will be convertible and all other terms and conditions upon which the conversion may be made;*
- *restrictions on the issuance of shares of the same series or of any other class or series; and*
- *the voting rights, if any, of the holders of the series.*

We could issue a series of preferred stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our Common Stock might believe to be in their best interests or in which the holders of our Common Stock might receive a premium for your Common Stock over the market price of the Common Stock. Additionally, the issuance of preferred stock may adversely affect the holders of our Common Stock by restricting dividends on the Common Stock, diluting the voting power of the Common Stock or subordinating the liquidation rights of the Common Stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our Common Stock.

Nevada Anti-Takeover Statutes

The following provisions of the Nevada Revised Statutes ("NRS") could, if applicable, have the effect of discouraging takeovers of our company.

Transactions with Interested Stockholders. The NRS prohibits a publicly-traded Nevada company from engaging in any business combination with an interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless, prior to that date, the board of directors of the corporation approved either the business combination itself or the transaction that resulted in the stockholder becoming an interested stockholder.

An "interested stockholder" is defined as any entity or person beneficially owning, directly or indirectly, 10% or more of the outstanding voting stock of the corporation and any entity or person affiliated with, controlling, or controlled by any of these entities or persons. The definition of "business combination" is sufficiently broad to cover virtually any type of transaction that would allow a potential acquirer to use the corporation's assets to finance the acquisition or otherwise benefit its own interests rather than the interests of the corporation and its stockholders.

In addition, business combinations that are not approved and therefore take place after the three year waiting period may also be prohibited unless approved by the board of directors and stockholders or the price to be paid by the interested stockholder is equal to the highest of (i) the highest price per share paid by the interested stockholder within the 3 years immediately preceding the date of the announcement of the business combination or in the transaction in which he or she became an interested stockholder, whichever is higher; (ii) the market value per common share on the date of announcement of the business combination or the date the interested stockholder acquired the shares, whichever is higher; or (iii) if higher for the holders of preferred stock, the highest liquidation value of the preferred stock.

Acquisition of a Controlling Interest. The NRS contains provisions governing the acquisition of a "controlling interest" and provides generally that any person that acquires 20% or more of the outstanding voting shares of an "issuing corporation," defined as Nevada corporation that has 200 or more stockholders at least 100 of whom are Nevada residents (as set forth in the corporation's stock ledger); and does business in Nevada directly or through an affiliated corporation, may be denied voting rights with respect to the acquired shares, unless a majority of the disinterested stockholder of the corporation elects to restore such voting rights in whole or in part.

The statute focuses on the acquisition of a "controlling interest" defined as the ownership of outstanding shares sufficient, but for the control share law, to enable the acquiring person, directly or indirectly and individually or in association with others, to exercise (i) one-fifth or more, but less than one-third; (ii) one-third or more, but less than a majority; or (iii) a majority or more of the voting power of the corporation in the election of directors.

The question of whether or not to confer voting rights may only be considered once by the stockholders and once a decision is made, it cannot be revisited. In addition, unless a corporation's articles of incorporation or bylaws provide otherwise (i) acquired voting securities are redeemable in whole or in part by the issuing corporation at the average price paid for the securities within 30 days if the acquiring person has not given a timely information statement to the issuing corporation or if the stockholders vote not to grant voting rights to the acquiring person's securities; and (ii) if voting rights are granted to the acquiring person, then any stockholder who voted against the grant of voting rights may demand purchase from the issuing corporation, at fair value, of all or any portion of their securities.

The provisions of this section do not apply to acquisitions made pursuant to the laws of descent and distribution, the enforcement of a judgment, or the satisfaction of a security interest, or acquisitions made in connection with certain mergers or reorganizations.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is vStock Transfer, LLC. Its mailing address is 18 Lafayette Place, Woodmere, NY 11598, its telephone number is (212) 828-8436, and its facsimile number is (646) 536-3179.

EXHIBIT 10.9 10.8

EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Timothy Warbington, certify that:

1. *I have reviewed this Form 10-K for the year ended December 31, 2022 December 31, 2023, of Creative Medical Technology Holdings, Inc.;*

2. *Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;*

3. *Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;*

4. *The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:*

   a. *Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;*

   b. *Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;*

   c. *Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and*

   d. *Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and*

5. *The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):*

   a. *All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and*

   b. *Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.*

Date: March 31, 2023 March 22, 2024

/s/ Timothy Warbington

Timothy Warbington,
Chief Executive Officer
(Principal Executive Officer)
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EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Donald Dickerson, certify that:

1. *I have reviewed this Form 10-K for the year ended December 31, 2022 December 31, 2023, of Creative Medical Technology Holdings, Inc.;*

2. *Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;*

3. *Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;*

4. *The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:*

   a. *Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;*

   b. *Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;*

   c. *Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and*

   d. *Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and*

5. *The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):*

   a. *All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and*

   b. *Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.*

Date: March 31, 2023 March 22, 2024

/s/ Donald Dickerson

Donald Dickerson,
Chief Financial Officer
(Principal Financial and Accounting Officer)
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EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Creative Medical Technology Holdings, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022 December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned principal executive officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2023 March 22, 2024

/s/ Timothy Warbington

Timothy Warbington,
Chief Executive Officer
(Principal Executive Officer)
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EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Creative Medical Technology Holdings, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022 December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned principal financial officer of the Company, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2023 March 22, 2024

/s/ Donald Dickerson

Donald Dickerson,
Chief Financial Officer
(Principal Financial and Accounting Officer)

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