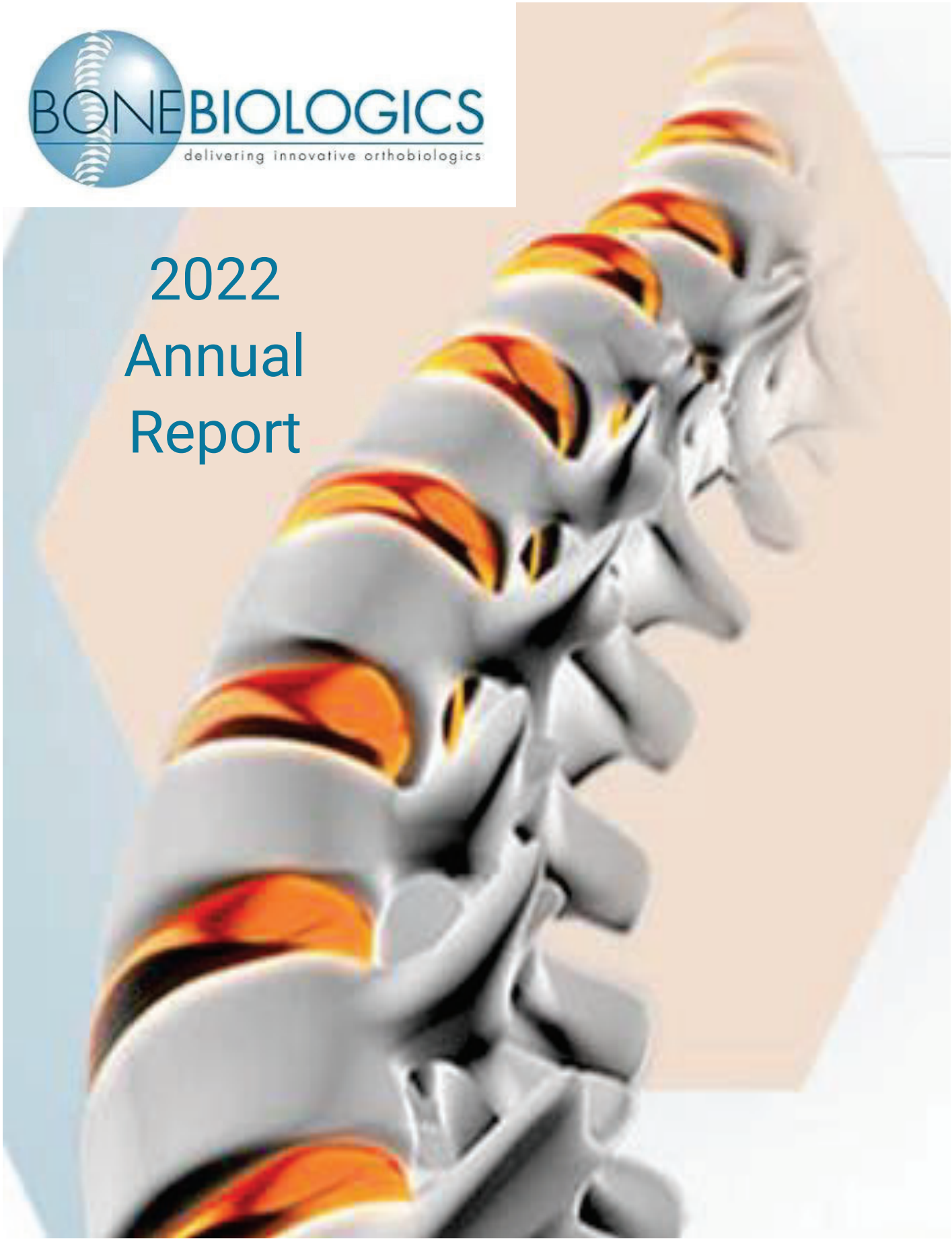
BONEBIOLOGICS

delivering innovative orthobiologics

2022 Annual Report



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

FORM 10-K

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

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

For the fiscal year ended: December 31, 2022

For the transition period from _____ to _____

Commission File Number: 001-40899

Bone Biologics Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

42-1743430
(I.R.S. Employer Identification No.)

2 Burlington Woods Drive, Ste 100, Burlington, MA 01803
(781) 552-4452

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, $0.001 par value per share	**BBLG**	**The Nasdaq Stock Market LLC**
Warrants to Purchase Common stock, $0.001 par value per share	**BBLGW**	**The Nasdaq Stock Market LLC**

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T 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 Company is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, 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 Company is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Approximate aggregate market value of registrant's common equity held by non-affiliates of the registrant at the close of business on June 30, 2022, was $4,403,460.

As of March 28, 2023, there were 16,702,912 shares of common stock, par value $0.001, outstanding.

Documents Incorporated by Reference

None.

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Cautionary Note on Forward-Looking Statements

This annual report on form 10-K ("Annual Report") contains forward-looking statements. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

All statements other than historical facts contained in this Annual Report, including statements regarding our future financial position, capital expenditures, cash flows, business strategy and plans and objectives of management for future operations are forward-looking statements. The words "anticipated," "believe," "expect," "plan," "intend," "seek," "estimate," "project," "could," "may," and similar expressions are intended to identify forward-looking statements. These statements include, among others, information regarding future operations, future capital expenditures, and future net cash flow. Such statements reflect our management's current views with respect to future events and financial performance and involve risks and uncertainties, including, without limitation, our ability to raise additional capital to fund our operations, obtaining Food and Drug Administration ("FDA") and other regulatory authorization to market our drug and biological products, successful completion of our clinical trials, our ability to achieve regulatory authorization to market our lead product NELL-1/DBM, our reliance on third party manufacturers for our drug products, market acceptance of our products, our dependence on licenses for certain of our products, our reliance on the expected growth in demand for our products, exposure to product liability and defect claims, development of a public trading market for our securities, and various other matters, many of which are beyond our control.

Should one or more of these risks or uncertainties occur, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated or otherwise indicated. Consequently, all of the forward-looking statements made in this Annual Report are qualified by these cautionary statements and accordingly there can be no assurances made with respect to the actual results or developments. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

Unless expressly indicated or the context requires otherwise, the terms "Company," "we," "us," and "our" in this document refer to Bone Biologics Corporation, a Delaware corporation, and, our wholly owned subsidiary, as defined under Part I, Item 1-"Business" in this Annual Report.

Glossary of Abbreviations and Defined Terms

Abbreviations

AIA or Leahy–Smith Act	The Leahy–Smith America Invents Act
ACA	Affordable Care Act
BMP	Bone Morphogenic Protein
CDMO	Contract Development and Manufacturing Organization
cGMP	current Good Manufacturing Practice
CRO	Contract Research Organization
DBM	Demineralized bone matrix is allograft bone that has had the inorganic mineral removed
DDD	Degenerative disc disease
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act of 2009
HREC	Human Research Ethics Committee
IDE	Investigational Device Exemption
IRB	Institutional Review Board
MTF	Musculoskeletal Transplant Foundation
NB1 Device	Product combination kit that includes vial of NELL-1 recombinant protein and demineralized bone matrix
NDA	New Drug Application
NELL-1	Neural epidermal growth factor-like 1 protein (NELL-1)
NOL	Net Operating Loss
ODI	Oswestry Disability Index
PMA	Pre-market approval
REMS	Risk Evaluation and Mitigation Strategies
rhBMP-2	Recombinant Bone Morphogenic Protein
rhNELL-1	Recombinant NELL-1
TLIF	Transforaminal lumbar interbody fusion
UCLA TDG	UCLA Technology Development Group on behalf of UC Regents
USPTO	The United States Patent and Trademark Office

Defined Terms

Alkaline phosphatase assay	Alkaline phosphatase is an enzyme that is found throughout your body. ALP blood tests measure the level of ALP in your blood that comes from your bones.
Athymic mouse model	A mouse that provides an experiment model for conducting research because it mounts no rejection response.
Demineralized Bone	Bone that has had the calcium removed.
Osteopromotive	A material that promotes the de novo formation of bone.
Osteostimulative	Stimulates bone growth.
Osteosynthetic	The reduction and fixation of a bone fracture with implantable devices.
Phylogenetically advanced spine model	Evolutionary advancement of spine systems that exist in large animal models.
Recombinant	Relating to or denoting an organism, cell, or genetic material formed by recombination.
Retrolisthesis	A medical condition in which a vertebra in the spine becomes displaced and moves forward or backward.
Spondylolisthesis	A spinal disorder in which one vertebra (spinal bone) slips onto the vertebra below it.

PART I

Item 1. *Business*

Company Overview

We are a medical device company that is currently focused on bone regeneration in spinal fusion using the recombinant human protein known as NELL-1. NELL-1 in combination with DBM, demineralized bone matrix, is an osteopromotive recombinant protein that provides target specific control over bone regeneration. The NELL-1 technology platform, has been licensed exclusively for worldwide applications to us through a technology transfer from the UCLA Technology Development Group on behalf of UC Regents ("UCLA TDG"). UCLA TDG and the Company received guidance from the FDA that NELL-1/DBM will be classified as a device/drug combination product with a pre-market approval filing ("PMA").

We were founded by University of California professors in collaboration with an Osaka University professor and a University of Southern California surgeon in 2004 as a privately-held company with proprietary, patented technology that has been validated in sheep and non-human primate models to facilitate bone growth. Our platform technology has application in delivering improved outcomes in the surgical specialties of spinal, orthopedic, general orthopedic, plastic reconstruction, neurosurgery, interventional radiology, and sports medicine. Lead product development and clinical studies are targeted on spinal fusion surgery, one of the larger segments in the orthopedic market.

We are a development stage entity. The production and marketing of our products and ongoing research and development activities will be subject to extensive regulation by numerous governmental authorities in the United States. Prior to marketing in the United States, any combination product developed by us must undergo rigorous preclinical (animal) and clinical (human) testing and an extensive regulatory approval process implemented by the FDA under the Food, Drug and Cosmetic Act. There can be no assurance that we will not encounter problems in clinical trials that will cause us or the FDA to delay or suspend the clinical trials.

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

Products

We have developed a stand-alone platform technology through significant laboratory and small and large animal research over more than ten years to generate the current applications across broad fields of use. The platform technology is our recombinant human protein, known as NELL-1, a proprietary skeletal specific growth factor which is a bone void filler. NELL-1 provides regulation over skeletal tissue formation and stem cell differentiation during bone regeneration. We obtained the platform technology pursuant to an exclusive license agreement with UCLA TDG.

We are currently focused on bone regeneration in lumbar spinal fusion, in keeping with our exclusive license agreement, using NELL-1 in combination with DBM, a demineralized bone matrix from Musculoskeletal Transplant Foundation ("MTF"). The NELL-1/DBM medical device is a combination product which is an osteopromotive recombinant protein that provides target specific control over bone regeneration. Leveraging the resources of investors and strategic partners, we have successfully surpassed four critical milestones:

- Demonstrating a successful small laboratory scale pilot run for the manufacturing of the recombinant NELL-1 protein in Chinese hamster ovary cells;
- Validation of protein dosing and efficacy in established large animal sheep models pilot study;
- Completed pivotal animal study; and
- Filed for a clinical trial outside the United States.

Our lead product is expected to be purified NELL-1 mixed with 510(k) cleared DBM Demineralized Bone Putty recommended for use in conjunction with applicable hardware consistent with the indication. The NELL-1/DBM Fusion Device will be comprised of a single dose vial of NELL-1 recombinant protein freeze dried onto DBM. A vial of NELL-1/DBM will be sold in a convenience kit with a diluent and a syringe of 510(k) cleared demineralized bone ("DBM Putty") produced by MTF. A delivery device will allow the surgeon to mix the reconstituted NELL-1 with the appropriate quantity of DBM Putty just prior to implantation.

The NELL-1/DBM Fusion Device is intended for use in lumbar spinal fusion and may have a variety of other spine and orthopedic applications.

While the product is initially targeted at the lumbar spine fusion market, in keeping with our exclusive license agreement, we believe NELL-1's novel set of characteristics, target specific mechanism of action, efficacy, safety and affordability position the product well for application in a variety of procedures including:

Spine Implants. This is the largest market for bone substitute product, representing greater than 70% of the total U.S. market according to Transparency Market Research. While use of the patient's own bone, also referred to as autograft, to enhance fusion of vertebral segments remains the optimal use for this type of treatment, complications associated with use of autograft bone including pain, increased surgical time and infection limit its use.

Non-Union Trauma Cases. While the majority of fractures heal without the need for osteosynthetic products, bone substitutes are used in complicated breaks where the bone does not mend naturally. Management believes that NELL-1 technology is expected to perform as well as other growth factors in this market.

Osteoporosis. The medical need to find a solution to counter a decrease in bone mass and density seen in women most frequently after menopause or a similar effect on astronauts in microgravity environments for an extended period is a major medical challenge. The systemic use of NELL-1 to stimulate bone regeneration throughout the body thereby increasing bone density could have a very significant impact on the treatment of osteoporosis.

UCLA's initial research was funded with approximately $18 million in resources from UCLA TDG and government grants. Since licensing the exclusive worldwide intellectual property rights from UCLA TDG, our continued development has been funded through capital raises. Our research and development expenses for the years ended December 31, 2022 and 2021 were $35,623 and $45,500, respectively. We anticipate that it will require approximately $15 million to complete first in man studies and an estimated additional $27 million to achieve FDA approval for a spine interbody fusion indication. These amounts are estimates based on data currently available to us, and are subject to many factors including the various risk factors discussed below under "*Risk Factors.*"

NELL-1's powerful specific bone and cartilage forming properties are derived from the ability of NELL-1 to only target cells that exhibit an activated "master switch" to develop into bone or cartilage. NELL-1 is a function specific recombinant human protein that has been proven in laboratory bench models to recapitulate normal human growth and development to provide control over bone and cartilage regeneration.

NELL-1 was isolated in 1996, and the first NELL-1 patent on bone regeneration was filed in 1999. Subsequent patents and continuations in part describing NELL-1 manufacturing, delivery, and cartilage regeneration were filed to further strengthen the patent portfolio.

Research & Publications

We believe our scientific evidence validates the many benefits of NELL-1. Currently there is a comprehensive database of more than 80 research publications and abstracts of preclinical studies with NELL-1 of which more than 45 are peer-reviewed publications.

We completed a preclinical study, which shows our rhNELL-1 growth factor effectively promotes bone formation in a phylogenetically advanced spine model. In addition, rhNELL-1 was shown to be well tolerated and there were no findings of inflammation.

Proposed Initial Clinical Application

The NELL-1/DBM Fusion Device will be indicated for spinal fusion procedures in skeletally mature patients with DDD at one level from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. The NELL-1/DBM Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach in conjunction with a cleared intervertebral body fusion device. Patients receiving the device should have had at least six months of non-operative treatment prior to treatment with the device. A cervical indication is currently under consideration. This indication for use would fill a current clinical gap, created by potentially dangerous inflammatory responses caused by commercially available catalytic bone growth agents, the subject of a Public Health Notification from the FDA on July 1, 2008 about life threatening complications associated with a recombinant human protein in cervical spine fusion. We do not expect our product to see the same adverse events with NELL-1/DBM as have been observed with other commercially available protein. We have performed a rat femoral onlay model to compare proinflammatory response of rhBMP-2 and NELL-1 within Helistate collagen sponges. While NELL-1 induced normal healing, rhBMP-2 induced significant amounts of swelling and histological evidence of intense inflammatory response.

Description of the DBM Putty to Be Used With Nell-1

The DBM Demineralized Bone Putty provided as part of the convenience kit with NELL-1/DBM is a Class II device. The common name is "Bone Void Filler Containing Human Demineralized Bone Matrix." The product is regulated under 21 C.F.R. §888.3045 Resorbable calcium salt bone void filler device, Product Codes MQV, GXP, and MBP. MTF is the manufacturer of the DBM Putty that was cleared by the FDA for spine indication in December 2006.

DBM Putty is a matrix composed of processed human cortical bone. Demineralized bone granules are mixed with sodium hyaluronate to form the DBM Putty. Every lot of final DBM Putty product is tested in an athymic mouse model or in an alkaline phosphatase assay, which has been shown to have a positive correlation with the athymic mouse model, to ensure osteostimulation.

Based upon extensive discussions with regulatory experts and a specific communication from the FDA in response to a submission of our plan under the Amended License Agreement between UCLA TDG and the Company, we believe the NELL-1/DBM Fusion Device will be regulated as a Class III medical device and will therefore require submission and approval of a pre-market approval ("PMA").

Our Business Strategy

Our business plan is to develop our target specific growth factor for bone regeneration that has demonstrated increases in the quantity and quality of bone, while displaying strong safety profile. Our spine fusion product focus entails advancing through clinical studies to achieve FDA approval for our target specific protein exhibiting efficacy and safety when compared to the gold standard for spine fusion (autografted). Continued capital funding is critical to facilitate the development of our Nell-1 technology through the clinical regulatory path.

Development of the Company

We were incorporated under the laws of the State of Delaware on October 18, 2007 as AFH Acquisition X, Inc. Pursuant to a Merger Agreement, dated September 19, 2014, by and among the Company, its wholly-owned subsidiary, Bone Biologics Acquisition Corp., a Delaware corporation ("Merger Sub"), and Bone Biologics, Inc. Merger Sub merged with and into Bone Biologics Inc., with Bone Biologics Inc. remaining as the surviving corporation in the merger. Upon the consummation of the merger, the separate existence of Merger Sub ceased. On September 22, 2014, the Company officially changed its name to "Bone Biologics Corporation" to more accurately reflect the nature of its business and Bone Biologics, Inc. became a wholly owned subsidiary of the Company. Bone Biologics, Inc. was incorporated in California on September 9, 2004.

Effective July 24, 2018, we implemented a reverse split of the common stock of the Company on a basis of 1 new common share for 10 old common shares.

Effective October 12, 2021, we implemented a reverse split of the common stock of the Company on a basis of 1 new common share for 2.5 old common shares.

UCLA TDG Exclusive License Agreement

Effective April 9, 2019, we entered into an Amended and Restated Exclusive License Agreement dated as of March 21, 2019 and amended through three sets of amendments (as so amended the "Amended License Agreement") with the UCLA TDG. The Amended License Agreement amends and restates the Amended and Restated Exclusive License Agreement, dated as of June 19, 2017 (the "2017 Agreement"). The 2017 Agreement amended and restated the Exclusive License Agreement, effective March 15, 2006, between the Company and UCLA TDG, as amended by ten amendments. Under the terms of the Amended License Agreement, the Regents have continued to grant us exclusive rights to develop and commercialize NELL-1 (the "Licensed Product") for spinal fusion by local administration, osteoporosis and trauma applications. The Licensed Product is a recombinant human protein growth factor that is essential for normal bone development.

We have agreed to pay an annual maintenance fee to UCLA TDG of $10,000 as well as pay certain royalties to UCLA TDG under the Amended License Agreement at the rate of 3.0% of net sales of licensed products or licensed methods. We must pay the royalties to UCLA TDG on a quarterly basis. Upon a first commercial sale, we also must pay a minimum annual royalty between $50,000 and $250,000, depending on the calendar year which is after the first commercial sale. If we are required to pay any third party any royalties as a result of us making use of UCLA TDG patents, then we may reduce the royalty owed to UCLA TDG by 0.333% for every percentage point paid to a third party. If we grant sublicense rights to a third party to use the UCLA TDG patent, then we will pay UCLA TDG 10% to 20% of the sublicensing income we receive from such sublicense.

We are obligated to make the following milestone payments to UCLA TDG for each Licensed Product or Licensed Method:

- $100,000 upon enrollment of the first subject in a Feasibility Study;
- $250,000 upon enrollment of the first subject in a Pivotal Study:
- $500,000 upon Pre-Market Approval of a Licensed Product or Licensed Method; and
- $1,000,000 upon the First Commercial Sale of a Licensed Product or Licensed Method.

We are also obligated pay to UCLA TDG a fee (the "Diligence Fee") of $8,000,000 upon the sale of any Licensed Product (the "Triggering Sale Date") in accordance with the payment schedule below:

- Due upon cumulative Net Sales equaling $50,000,000 following the Triggering Sale Date - $2,000,000;
- Due upon cumulative Net Sales equaling $100,000,000 following the Triggering Sale Date - $2,000,000; and
- Due upon cumulative Net Sales equaling $200,000,000 following the Triggering Sale Date - $4,000,000.

Our obligation to pay the Diligence Fee will survive termination or expiration of the agreement and we are prohibited from assigning, selling, or otherwise transferring any of its assets related to any Licensed Product unless our Diligence Fee obligation is assigned, sold, or transferred along with such assets, or unless we pay UCLA TDG the Diligence Fee within ten (10) days of such assignment, sale or other transfer of such rights to any Licensed Product.

We are also obligated to pay UCLA TDG a cash milestone payment within thirty (30) days of a Liquidity Event (including a Change of Control Transaction) and a payment election by UCLA TDG exercisable after December 22, 2016) such payment to equal the greater of:

- $500,000; or
- 2% of all proceeds in connection with a Change of Control Transaction.

As of December 31, 2022, none of the above milestones has been met.

We are obligated to diligently proceed with developing and commercializing licensed products under UCLA TDG patents set forth in the Amended License Agreement. UCLA TDG has the right to either terminate the license or reduce the license to a non-exclusive license if we do not meet certain diligence milestone deadlines set forth in the Amended License Agreement.

We must reimburse or pre-pay UCLA TDG for patent prosecution and maintenance costs incurred during the term of the Amended License Agreement. We have the right to bring infringement actions against third party infringers of the Amended License Agreement, UCLA TDG may join voluntarily, at its own expense, or, at our expense, be joined involuntarily to the action. We are required to indemnify UCLA TDG against any third party claims arising out of our exercise of the rights under the Amended License Agreement or any sublicense.

Competition

The orthobiologic and orthopedic industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on intellectual property. We face substantial competition from many different sources, including large and specialty orthopedic companies, biotechnology companies, academic research institutions and governmental agencies along with public and private research institutions.

Our business is in a very competitive and evolving field, that faces competition from large established orthopedic companies such as (but not limited to) Medtronic, Stryker, Zimmer-Biomet, and DePuy-Synthes that possess considerably more resources than Bone Biologics.

Our commercial opportunity could be reduced if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

The NELL-1 growth factor is mechanistically distinct from bone morphogenetic proteins ("BMPs") and can minimize complications associated with BMP therapies. The early proof of concept animal studies has shown the efficacy of NELL-1 combined with demineralized bone matrix as a novel bone graft material for interbody spine fusion.

Customers

The populations of interest include spine surgeons, and patients with a skeletal bone defect or bone-related condition in their spine, for which intervention is undertaken to correct such a defect. Spine surgeons and patients can choose to eliminate the need to perform a second painful surgery to obtain autograft harvest of hip bone for fusion procedures by utilizing various other types of biologics.

Most cases of lower back pain can be linked to a general cause such as muscle strain, injury, overuse, or can be attributed to a specific condition like herniated disc, degenerative disc disease, spondylolisthesis, spinal stenosis, or osteoarthritis.

Intellectual Property

We have an intellectual property portfolio that includes exclusive, worldwide licenses from UCLA TDG which we believe constitute a formidable barrier to entry.

Additional patent applications are currently in preparation. The intellectual property portfolio comprehensively covers NELL-1 manufacture, NELL-1 compositions and NELL-1 use in wide ranging clinical and diagnostic applications. We protect our proprietary technology through mechanisms including U.S. and foreign patent filings, trade secret protections, and collaboration agreements with domestic and international corporations, universities and research institutions. We are the exclusive licensee for the following nine (9) UCLA TDG issued patents:

U.S. Patent No.	Summary	Date Issued
7544486	NELL-1 Peptide Expression Systems	6/9/2009
7691607	Expression system of NELL-1 peptide	4/6/2010
7807787	NELL-1 Peptide	10/5/2010
7833968	Pharmaceutical compositions for treating or preventing bone conditions	11/16/2010
9447155	Isoform NELL-1 peptide	9/20/2016
9511115	Pharmaceutical compositions for treating or preventing bone conditions	12/6/2016
9598480	Recombinant NEL-like (NELL) protein production	3/21/2017
9974828	Isoform NELL-1 peptide	5/22/2018
10335458	Pharmaceutical compositions for treating or preventing bone conditions	7/2/2019

Government Regulation

The manufacturing and marketing of any product which we may formulate with our technologies as well as our related research and development activities are subject to regulation for safety, efficacy and quality by governmental authorities in the U.S. and other countries. We anticipate that these regulations will apply separately to each product. We believe that complying with these regulations will involve a considerable level of time, expense and uncertainty.

In the U.S., devices are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. Device development and approval within this regulatory framework is difficult to predict, requires a number of years and involves the expenditure of substantial resources. Moreover, ongoing legislation by U.S. Congress and rule making by the FDA presents an ever-changing landscape where we could be required to undertake additional activities before any governmental approval is granted allowing us to market our products. The steps required before a biological device may be marketed in the U.S. include:

- Laboratory and non-clinical tests for safety and small scale manufacturing of the agent;
- The submission to the FDA of an IDE which must become effective before human clinical trials can commence;
- Clinical trials to characterize the efficacy and safety of the product in the intended patient population;
- The submission of a PMA to the FDA; and
- FDA approval of the NDA or PMA prior to any commercial sale or shipment of the product.

In addition to obtaining FDA approval for each product, each manufacturing establishment must be registered with, and approved by, the FDA. Moreover, manufacturing establishments are subject to biennial inspections by the FDA and must comply with the FDA's current Good Manufacturing Practice **"cGMP"** for products, drugs and devices.

Non-clinical Trials

Non-clinical testing includes laboratory evaluation of chemistry and formulation as well as tissue culture and animal studies to assess the safety and potential efficacy of the product. Non-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding good laboratory practices. Non-clinical testing is inherently risky and the results can be unpredictable or difficult to interpret. The results of non-clinical testing are submitted to the FDA as part of an IDE and are reviewed by the FDA prior to the commencement of clinical trials. Unless the FDA objects to an IDE, clinical studies may begin 30 days after the IDE is submitted. We have relied and intend to continue to rely on third-party contractors to perform non-clinical trials.

Clinical Trials

Our pilot clinical study which is planned for late 2023, will evaluate the safety and effectiveness of NB1 in adult subjects with spinal degenerative disc disease ("DDD") at one level from L2-S1, who may also have up to Grade 1 spondylolisthesis or Grade 1 retrolisthesis at the involved level who undergo transforaminal lumbar interbody fusion ("TLIF"). The multi-center, prospective, randomized trial will consist of 30 patients in Australia, with the primary end-point being fusion success at 12 months and change from baseline in the ODI ("Oswestry Disability Index") pain score.

Our clinical, and regulatory strategy involves a well-established pathway to success. We intend to use the pilot clinical study data from Australia to enable our larger U.S. pivotal clinical study, prior to an FDA PMA submission

Clinical trials involve the administration of the investigational product to healthy volunteers or to patients under the supervision of a qualified investigator. Clinical trials must be conducted in accordance with good clinical practices under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA prior to its conduct. Further, each clinical study must be conducted under the auspices of an independent institutional review board. The institutional review board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. The drug product used in clinical trials must be manufactured according to the FDA's current Good Manufacturing Practices.

Clinical trials under IDE regulations are typically conducted in two sequential trials. In the Pilot trial, the initial introduction of the product into healthy human subjects, the drug is tested for safety (adverse side effects), absorption, metabolism, bio-distribution, excretion, food and drug interactions, abuse as well as limited measures of pharmacologic effect and proof of principle that involves studies in a limited patient population in order to:

- assess the potential efficacy of the product for specific, targeted indications;
- demonstrate efficacy in a limited patient population;
- identify the range of doses likely to be effective for the indication; and
- identify possible adverse events and safety risks.

When there is evidence that the product may be effective and has an acceptable safety profile in pilot evaluations, pivotal trials are undertaken to establish and confirm the clinical efficacy and establish the safety profile of the product within a larger population at geographically dispersed clinical study sites. Pivotal trials frequently involve randomized controlled trials and, whenever possible, studies are conducted in a manner so that neither the patient nor the investigator knows what treatment is being administered. The Company, the IRB or the FDA, may suspend clinical trials at any time if it is believed that the individuals participating in such trials are being exposed to unacceptable health risks. We intend to rely upon third-party contractors to advise and assist us in the preparation of our IDEs and the conduct of clinical trials that will be conducted under the IDEs.

Premarket Approval and FDA Approval Process

The results of the manufacturing process, development work, non-clinical studies and clinical studies are submitted to the FDA in the form of a PMA prior to marketing and selling the product. The testing and approval process is likely to require substantial time and effort. In addition to the results of non-clinical and clinical testing, the PMA applicant must submit detailed information about chemistry, manufacturing and controls that will describe how the product is made and tested through the manufacturing process.

The PMA review process involves FDA investigation into the details of the manufacturing process, as well as the design and analysis of each of the non-clinical and clinical studies. This review includes inspection of the manufacturing facility, the data recording process for the clinical studies, the record keeping at a sample of clinical trial sites and a thorough review of the data collected and analyzed for each non-clinical and clinical study. Through this investigation, the FDA reaches a decision about the risk-benefit profile of a product candidate. If the benefit is worth the risk, the FDA begins negotiating with the company about the content of an acceptable package insert and associated Risk Evaluation and Mitigation Strategies ("REMS"), if required.

The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Consequently, there is a risk that approval may not be granted on a timely basis, if at all. The FDA may deny a PMA if applicable regulatory criteria are not satisfied, require additional testing or information or require post-marketing testing (Phase 4) and surveillance to monitor the safety of a company's product if it does not believe the PMA contains adequate evidence of the safety and efficacy of the product. Moreover, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or health problems are identified that would alter the risk-benefit analysis for the product. Post-approval studies may be conducted to explore the use of the product for new indications or populations such as pediatrics.

Among the conditions for PMA approval is the requirement that any prospective manufacturer's quality control and manufacturing procedures conform to the FDA's Good Manufacturing Practices and the specifications approved in the PMA. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of product and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, also are subject to inspections by or under the authority of the FDA and by other federal, state or local agencies. Additionally, in the event of non-compliance, FDA may issue warning letters and/or seek criminal and civil penalties, enjoin manufacture, seize product or revoke approval.

International Approval

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the medical product in such countries. The requirements governing the conduct of clinical trials and product approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country at this time has its own procedures and requirements.

Other Regulation

In addition to regulations enforced by the FDA, we are also subject to U.S. regulation under the Controlled Substances Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state, local or similar foreign regulations. Our research and development may involve the controlled use of hazardous materials, chemicals and radioactive compounds. Although we believe that its safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of any accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Employees and Human Capital

As of the date hereof, we have two (2) full-time employees. We have relied and plan on continuing to rely on independent organizations, advisors and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. Such services may not always be available to us on a timely basis or at costs that we can afford. Our future performance will depend in part on our ability to successfully integrate newly hired officers and to engage and retain consultants, as well as our ability to develop an effective working relationship with our management and consultants.

Item 1A. ***Risk Factors***

The following factors, as well as factors described elsewhere in this Form 10-K, or in other filings by us with the Securities and Exchange Commission, could adversely affect our consolidated financial position, results of operations or cash flows. Other factors not presently known to us or that we presently believe are not material could also affect our business operations and financial results.

Risks Relating to Our Financial Position and Capital Needs

Our limited operating history makes it difficult to evaluate our current business and future prospects.

We have a limited operating history, and there is a risk that we will be unable to continue as a going concern. We have minimal assets and no significant financial resources. Our limited operating history makes it difficult to evaluate our current business model and future prospects. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development. Potential investors should carefully consider the risks and uncertainties that a new company with no operating history will face. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, which may or may not be sound;
- maintain our anticipated management and advisory team; and
- raise sufficient funds in the capital markets to effectuate our business plan.

If we cannot execute any one of the foregoing or similar matters relating to our business, the business may fail, in which case you would lose the entire amount of your investment in us.

Our long-term capital requirements are subject to numerous risks.

We anticipate that it will require approximately $15 million to complete first in man studies and an estimated additional $27 million to achieve FDA approval for a spine interbody fusion indication. These amounts are estimates based on data currently available to us, and are subject to many factors, including the risk factors discussed herein. We anticipate we will need to raise substantial additional funds for the pivotal clinical trial prior to marketing our first product. The above estimates and our long-term capital requirements will depend on many factors, including, among others:

- the number of potential formulations, products and technologies in development;
- continued progress and cost of our research and development programs;
- progress with pre-clinical studies and clinical trials;
- time and costs involved in obtaining regulatory (including FDA) clearance;
- costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- costs of developing sales, marketing and distribution channels and our ability to sell our formulations or products;
- costs involved in establishing manufacturing capabilities for commercial quantities of our products;
- competing technological and market developments;
- market acceptance of our device formulations or products;

- costs for recruiting and retaining employees and consultants;
- costs for training physicians;
- legal, accounting and other professional costs; and
- the effect of the novel coronavirus will have on our product development, clinical trials, and availability, cost, and type of financing.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding. We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. If adequate funds are not available, we may be required to significantly reduce or refocus our development and commercialization efforts with regard to our delivery technologies and our proposed formulations and products.

Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring operating losses raise substantial doubt about our ability to continue as a going concern. During the year ended December 31, 2022, we incurred a net loss of $1,484,620, and used net cash in operating activities of $3,566,913. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as and for the year ended December 31, 2022, with respect to this uncertainty. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

We have incurred losses since inception and we expect our operating expenses to increase in the foreseeable future, which may make it more difficult for us to achieve and maintain profitability.

We have no significant operating history and since inception to December 31, 2022 have incurred accumulated losses of approximately $72 million. We will continue to incur significant expenses for development activities for our lead product NELL-1/DBM.

On October 13, 2022, we completed a public offering generating net proceeds to us of $4,429,860.

We will continue to attempt to raise additional capital through debt and/or equity financing to provide additional working capital and fund future operations. However, there is no assurance that such financing will be consummated or obtained in sufficient amounts necessary to meet our needs. If cash resources are insufficient to satisfy our on-going cash requirements, we will be required to scale back or discontinue its product development programs, or obtain funds if available (although there can be no certainties) through strategic alliances that may require us to relinquish rights to our technology, or substantially reduce or discontinue our operations entirely. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to us. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing. As a result, we can provide no assurance as to whether or if we will ever be profitability. If we are not able to achieve and maintain profitability, the value of our company and our common stock could decline significantly.

We face a number of risks associated with the incurrence of substantial debt which could adversely affect our financial condition.

If we incur a substantial amount of debt, we may be required to use a significant portion of any cash flow to pay principal and interest on the debt, which will reduce the amount available to fund working capital, capital expenditures, and other general purposes. Any indebtedness may negatively impact our ability to operate our business and limit our ability to borrow additional funds by increasing our borrowing costs, and impact the terms, conditions, and restrictions contained in possible future debt agreements, including the addition of more restrictive covenants; impact our flexibility in planning for and reacting to changes in our business as covenants and restrictions contained in possible future debt arrangements may require that we meet certain financial tests and place restrictions on the incurrence of additional indebtedness and place us at a disadvantage compared to similar companies in our industry that have less debt.

Risks Related to the Development and Regulatory Approval of our Product Candidates

Our product candidates are at an early stage of development and may not be successfully developed or commercialized.

Our products are in the early stage of development and will require substantial further capital expenditures, development, testing, and regulatory clearances prior to commercialization. The development and regulatory approval process takes several years, and it is not likely that our products, technologies or processes, even if successfully developed and approved by the FDA, would be commercially available for five or more years. Of the large number of devices in development, only a small percentage successfully completes the FDA regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our product candidates, could result in the failure of our business and a loss of all of your investment in our company.

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

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

The FDA or another regulatory agency can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

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

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. Any delay in obtaining, or inability to obtain, applicable regulatory approvals could prevent us from commercializing our product candidates.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates that we advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

We have not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product or, if such product candidate is approved for marketing, future adverse events could cause us to withdraw such product from the market.

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

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

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

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

Suspensions or delays in the completion of clinical testing could result in increased costs to us and delay or prevent our ability to complete development of that product or generate product revenues.

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

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

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

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications for which there may be a greater likelihood of success.

Because we have limited financial and managerial resources, we are focused on our lead product for spine fusion. As a result, we may forego or delay pursuit of opportunities with other product candidates or, for other indications for which there may be a greater likelihood of success or may prove to have greater commercial potential. Notwithstanding our investment to date and anticipated future expenditures, we may never successfully develop, any marketed treatments using these products. Research programs to identify new product candidates or pursue alternative indications for current product candidates require substantial technical, financial and administrative support.

We may find it difficult to enroll patients in our clinical trials which could delay or prevent the start of clinical trials for our product candidate.

Identifying and qualifying patients to participate in clinical trials of our product candidate is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidate, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. If we experience delays in our clinical trials, the timeline for obtaining regulatory approval of our product candidate will most likely be delayed.

Many factors may affect our ability to identify, enroll and maintain qualified patients, including the following:

- eligibility criteria of our ongoing and planned clinical trials with specific characteristics appropriate for inclusion in our clinical trials;
- design of the clinical trial;
- size and nature of the patient population;
- patients' perceptions as to risks and benefits of the product candidate under study and the participation in a clinical trial generally in relation to other available therapies;
- the availability and efficacy of competing therapies and clinical trials;
- pendency of other trials underway in the same patient population;
- willingness of physicians to participate in our planned clinical trials;
- severity of the disease under investigation;
- proximity of patients to clinical sites;
- patients who do not complete the trials for personal reasons; and
- issues with Contract Research Organizations ("CROs") and/or with other vendors that handle our clinical trials.

We may not be able to initiate or continue to support clinical trials of our product candidates, for one or more applications, or any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidate may increase and the completion of our trials may be delayed or our trials could become too expensive to complete.

If we experience delays in the completion of, or termination of, any clinical trials of our product candidate, the commercial prospects of our product candidate could be harmed, and our ability to generate product revenue from any of our product candidate could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

The results of preclinical studies are not necessarily predictive of future results. Our product candidates that may advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of a device. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials.

Despite the results reported in earlier preclinical studies for our lead product candidate, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidate for a particular indication, in any particular jurisdiction. Efficacy data from prospectively designed trials may differ significantly from those obtained from retrospective subgroup analyses. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for our product candidate may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market our current product candidate or any future product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

Risks associated with operating in foreign countries could materially adversely affect our product development.

We may conduct future studies in countries outside of the U.S. Consequently, we may be subject to risks related to operating in foreign countries. Risks associated with conducting operations in foreign countries include:

- differing regulatory requirements for device approvals and regulation of approved devices in foreign countries; more stringent privacy requirements for data to be supplied to our operations in the U.S., *e.g.*, General Data Protection Regulation in the European Union;

- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign taxes, including withholding of payroll taxes;

- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;

- foreign currency fluctuations, which could result in increased operating expenses or reduced revenues, and other obligations incident to doing business or operating in another country;

- workforce uncertainty in countries where labor unrest is more common than in the U.S.;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geopolitical actions, including war and terrorism.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidate from being marketed abroad.

In addition to regulations in the U.S., to market and sell our product candidate in the European Union, United Kingdom, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. We may not be able to obtain approvals from regulatory authorities outside the U.S. on a timely basis, if at all. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the U.S. require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country.

We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product in any market. If we are unable to obtain approval of any of our current product candidate or any future product candidates we may pursue by regulatory authorities in the European Union, United Kingdom, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished, our business prospects could decline and this could materially adversely affect our business, results of operations and financial condition.

Even if our lead product candidate received regulatory approval, it may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for our lead product candidate, that approval would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by us and/or our Contract Development Manufacturing Organizations ("CDMOs") and CROs for any post-approval clinical trials that we may conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of our product candidate, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on such product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

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

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our product and generate revenues.

Advertising and promotion of any product candidates that obtains approval in the U.S. is heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of Health and Human Services, state attorneys general, members of Congress and the public. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. is heavily scrutinized by comparable foreign regulatory authorities. Violations, including actual or alleged promotion of our product for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, as well as prosecution under the federal False Claims Act. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business.

The results of our clinical trials may not support our product candidate claims and the results of preclinical studies and completed clinical trials are not necessarily predictive of future results.

To date, long-term safety and efficacy have not yet been demonstrated in clinical trials for any of our diagnostic product candidates. Favorable results in early studies or trials, if any, may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, it cannot be certain that the results will support our product candidate claims. Success in preclinical testing and pilot clinical trials does not ensure that later pilot or pivotal clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing. In particular, the limited results we have obtained for our tests may not predict results from studies in larger numbers of subjects drawn from more diverse populations over a longer period of time. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. Any such failure could cause us to abandon a product candidate and might delay development of other product candidates. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay us in obtaining FDA approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate.

Risks Related to Our Dependence on Third Parties

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

As of the date of this filing, we have two full-time employees. We also have engaged and plan to continue to engage regulatory consultants to advise us on our dealings with the FDA and other foreign regulatory authorities and have been and will be required to retain additional consultants and employees. Our future performance will depend in part on our ability to successfully integrate newly hired officers into our management team and our ability to develop an effective working relationship among senior management.

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

Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives. There is intense competition for qualified personnel in the biomedical-development field, and we may not be able to attract and retain the qualified personnel we need to develop our business.

We rely on independent organizations, advisors and consultants to perform certain services for us, including handling substantially all aspects of regulatory approval, clinical management, manufacturing, marketing, and sales. We expect that this will continue to be the case. Such services may not always be available to us on a timely basis.

We rely on third parties to supply our raw materials, and if certain manufacturing-related services do not timely supply these products and services, it may delay or impair our ability to develop, manufacture and market our products.

We rely on suppliers for raw materials and other third parties for certain manufacturing-related services to produce material that meets appropriate content, quality and stability standards and to use in clinical trials of our products. To succeed, clinical trials require adequate supplies of such materials, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our products to appropriate standards for use in clinical studies, (ii) perform under any definitive manufacturing, supply or service agreements or (iii) remain in business for a sufficient time to successfully produce and market our product candidates. If we do not maintain important manufacturing and service relationships, we may fail to find a replacement supplier or required vendor or develop our own manufacturing capabilities which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we do find replacement providers, we may not be able to enter into agreements with suppliers on favorable terms and conditions, or there could be a substantial delay before a new third party could be qualified and registered with the FDA and foreign regulatory authorities as a provider.

We depend on third parties, including researchers, who are not under our control.

We depend upon independent investigators and scientific collaborators, such as universities and medical institutions or private physician scientists, to conduct our preclinical and clinical trials under agreements. These collaborators are not our employees, and they cannot control the amount or timing of resources that they devote to their programs or the timing of their procurement of clinical-trial data or their compliance with applicable regulatory guidelines. Should any of these scientific inventors/advisors become disabled or die unexpectedly, or should they fail to comply with applicable regulatory guidelines, we may be forced to scale back or terminate development of that program. They may not assign as great a priority to our programs or pursue them as diligently as we would if it were undertaking those programs itself. Failing to devote sufficient time and resources to our development programs, or substandard performance and failure to comply with regulatory guidelines, could result in delay of any FDA applications and our commercialization of the product candidate involved.

These collaborators may also have relationships with other commercial entities, some of which may compete with us. Our collaborators assisting our competitors at our expense could harm our competitive position. We have been and continue to be highly dependent on our strategic partner, MTF, for technical support.

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

Our operations, and those of our directors, advisors, contractors, consultants, CROs, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics and other natural and man-made disaster or business interruptions including the current war between Russia and Ukraine. Our phones, electronic devices and computer systems and those of our directors, advisors, contractors, consultants, CROs, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man-made disasters. Operating as a virtual company, our employees conduct business outside of our headquarters and leased or owned facilities. These locations may be subject to additional security and other risk factors due to the limited control of our employees. If such an event as described above were to occur in the future, it may cause interruptions in our operations, delay research and development programs, clinical trials, regulatory activities, manufacturing and quality assurance activities, sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

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

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

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. 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 be in compliance with such 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 and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

Risks Related to our Intellectual Property

We rely on patents and patent applications and various regulatory exclusivities to protect some of our product candidates, and our ability to compete may be limited or eliminated if we are not able to protect our products.

The patent positions of medical device companies are uncertain and involve complex legal and factual questions. We may incur significant expenses in protecting our intellectual property and defending or assessing claims with respect to intellectual property owned by others. Any patent or other infringement litigation by or against us could cause us to incur significant expenses and divert the attention of our management.

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

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

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

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

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

We cannot guarantee that our technologies will not conflict with the rights of others. In some foreign jurisdictions, we could become involved in opposition proceedings, either by opposing the validity of others' foreign patents or by persons opposing the validity of our foreign patents.

We may also face frivolous litigation or lawsuits from various competitors or from litigious securities attorneys. The cost of any litigation or other proceeding relating to these areas, even if deemed frivolous or resolved in our favor, could be substantial and could distract management from its business. Uncertainties resulting from initiation and continuation of any litigation could have a material adverse effect on our ability to continue our operations.

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

If our products, methods, processes, and other technologies are found to infringe the rights of other parties, we could be required to pay damages, or may be required to cease using the technology or to license rights from the prevailing party. Any prevailing party may be unwilling to offer us a license on commercially acceptable terms.

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

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

- we or our licensors might not have been the first to make the inventions covered by our issued patents, or pending or future patent applications;
- we or our licensors might not have been the first to file patent applications for the inventions;
- others may independently develop duplicative, similar or alternative technologies;
- it is possible that our patent applications will not result in an issued patent or patents, or that the scope of protection granted by any patents arising from our patent applications will be significantly narrower than expected;
- any patents under which we hold ultimate rights may not provide us with a basis for commercially-viable products, may not provide us with any competitive advantages or may be challenged by third parties as not infringed, invalid, or unenforceable under United States or foreign laws;
- any patent issued to us in the future or under which we hold rights may not be valid or enforceable; or
- we may develop additional technologies that are not patentable and which may not be adequately protected through trade secrets; for example, if a competitor independently develops duplicative, similar, or alternative technologies.

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

We have entered and may be required to enter into intellectual property license agreements that are important to our business, including our license agreements with UCLA TDG. These license agreements have imposed various diligence, milestone payment, royalty and other obligations on us. For example, we may enter into exclusive license agreements with various third parties (for example, universities and research institutions), we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and may need to satisfy specified milestones and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we may be subject to termination of the license agreements in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreements will be impaired.

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

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

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

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

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

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products or product candidates, or manufacture or use of our products or product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates or products. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way to get around the patent and may need to halt commercialization of the relevant product candidate(s) or product(s). In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical, medical device and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, and then we will have to defend an infringement action or challenge the validity of the patent in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, fail to develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent applications may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed US patent applications on inventions similar to ours that claims priority to any applications filed prior to the priority dates of our applications, we may have to participate in an interference proceeding declared or a derivation proceed instituted by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and thus the third party's patent or patent application may be entitled to priority over our applications in such jurisdictions.

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

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

As is common in the medical device, biotechnology and pharmaceutical industries, we employ, and may employ in the future, individuals who were previously employed at other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our products from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property will be sufficient to prevent third parties from designing around the patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products.

Our approach involves filing patent applications covering new methods of use and/or new formulations of previously known, studied and/or marketed devices. Although the protection afforded by patents issued from our patent applications may be significant, when looking at our patents' ability to block competition, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents claiming the composition of matter previously unknown. If a competitor were able to successfully design around any method of use and formulation patents we may have in the future, our business and competitive advantage could be significantly affected.

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

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

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

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated, rendered unenforceable or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products or product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

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

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

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

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

We may incur substantial costs enforcing our patents, defending against third-party patents, invalidating third-party patents or licensing third-party intellectual property, as a result of litigation or other proceedings relating to patent and other intellectual property rights.

We may be unaware of or unfamiliar with prior art and/or interpretations of prior art that could potentially impact the validity or scope of our patents, pending patent applications, or patent applications that we will file. We may have elected, or elect now or in the future, not to maintain or pursue intellectual property rights that, at some point in time, may be considered relevant to or enforceable against a competitor.

We take efforts and enter into agreements with employees, consultants, collaborators, and advisors to confirm ownership and chain of title in intellectual property rights. However, an inventorship or ownership dispute could arise that may permit one or more third parties to practice or enforce our intellectual property rights, including possible efforts to enforce rights against us.

We may not have rights under some patents or patent applications that may cover technologies that we use in our research, product candidates and particular uses thereof that we seek to develop and commercialize, as well as synthesis of our product candidates. Third parties may own or control these patents and patent applications in the United States and elsewhere. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. We or our collaborators therefore may choose to seek, or be required to seek, a license from the third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product or product candidate, or forced to cease some aspect of our business operations, as a result of patent infringement claims, which could harm our business.

There has been substantial litigation and other legal proceedings regarding patent and other intellectual property rights in the pharmaceutical, medical device and biotechnology industries. Although we are not currently a party to any patent litigation or any other adversarial proceeding, including any interference or derivation proceeding declared or instituted before the United States Patent and Trademark Office, regarding intellectual property rights with respect to our products, product candidates and technology, it is possible that we may become so in the future. We are not currently aware of any actual or potential third-party infringement claim involving our product candidates. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. The outcome of patent litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of the adverse party, especially in pharmaceutical, medical device and biotechnology related patent cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If a patent or other proceeding is resolved against us, we may be enjoined from researching, developing, manufacturing or commercializing our products or product candidates without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

If we are unable to protect our intellectual property rights, our competitors may develop and market products with similar features that may reduce demand for our potential products.

The following factors are important to our success:

- receiving patent protection for our product candidates;
- preventing others from infringing our intellectual property rights; and
- maintaining our patent rights and trade secrets.

We will be able to protect our intellectual property rights in patents and trade secrets from unauthorized use by third parties only to the extent that such intellectual property rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

Because issues of patentability involve complex legal and factual questions, the issuance, scope and enforceability of patents cannot be predicted with certainty. Patents may be challenged, invalidated, found unenforceable, or circumvented. United States patents and patent applications may be subject to interference and derivation proceedings, United States patents may also be subject to post grant proceedings, including re-examination, derivation, *Inter Partes* Review and Post Grant Review, in the United States Patent and Trademark Office and foreign patents may be subject to opposition or comparable proceedings in corresponding foreign patent offices, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, post grant and opposition proceedings may be costly. Thus, any patents that we own or license from others may not provide any protection against competitors. Furthermore, an adverse decision in an interference or derivation proceeding can result in a third-party receiving the patent rights sought by us, which in turn could affect our ability to market a potential product to which that patent filing was directed. Our pending patent applications, those that we may file in the future, or those that we may license from third parties may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, compulsory licenses may be required in cases where the patent owner has failed to "work" the invention in that country, or the third-party has patented improvements. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of our patents. Moreover, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which makes it difficult to stop infringement.

In addition, our ability to enforce our patent rights depends on our ability to detect infringement. It is difficult to detect infringers who do not advertise or otherwise promote the compositions that are used in their products. Any litigation to enforce or defend our patent rights, even if we prevail, could be costly and time-consuming and would divert the attention of management and key personnel from business operations.

We will also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We will seek to protect this information by entering into confidentiality agreements with parties that have access to it, such as strategic partners, collaborators, employees, contractors and consultants. Any of these parties may breach these agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were disclosed to, or independently developed by, a competitor, our business, financial condition and results of operations could be materially adversely affected.

Risks Relating to Commercializing of our Lead Product Candidate and Future Product Candidates

Our commercial success depends upon attaining significant market acceptance of our lead product candidate and future product candidates, if approved, among physicians, patients, healthcare payors and treatment centers.

Even if we obtain regulatory approval for our lead product candidate or any future product candidates, the products may not gain market acceptance among physicians, healthcare payors, patients or the medical community, including treatment centers. Market acceptance of any product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians, major treatment centers and patients of the product candidates as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including our use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;

- the timing of market introduction of our product as well as competitive products;
- the development of manufacturing and distribution processes for commercial scale manufacturing for our current product candidate and any future product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

If our current product and any future product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors or surgery centers, we will not be able to generate significant revenues, which would compromise our ability to become profitable.

Even if we are able to commercialize our lead product candidate or any future product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the U.S. and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such product and related treatments will be available from third-party payors, including government health administration authorities, private health insurers and other organizations.

Third-party payors determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that biomedical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefit and value in specific patient populations before covering our product for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if coverage is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved devices, and coverage may be more limited than the purposes for which the device is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any device will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new devices, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the device and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost devices and may be incorporated into existing payments for other services. Net prices for devices may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of devices from countries where they may be sold at lower prices than in the U.S. No uniform policy for coverage and reimbursement exists in the U.S., and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved product that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize our product and overall financial condition.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The business and financial condition of biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the cost of healthcare. The U.S. Congress has enacted legislation to reform the healthcare system. While we anticipate that this legislation may, over time, increase the number of patients who have insurance coverage for our products, it also imposes cost containment measures that may adversely affect the amount of reimbursement for our products. The measures include increasing the minimum rebates for products covered by Medicaid programs. In addition, such legislation contains a number of provisions designed to generate the revenues necessary to fund coverage expansion, including new fees or taxes on certain health related industries, including medical device manufacturers. Some states are also considering legislation that would control the prices of drugs. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on coverage. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations. This would result in managed care organizations influencing decisions in a corresponding constraint on prices and reimbursement. We are unable to predict what additional legislation or regulation relating to the health care industry or third-party coverage and reimbursement may be enacted or what effect such legislation or regulation would have on our business. Pendency or approval of future proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidate, if we obtain regulatory approval;
- our ability to receive or set a price that we believe is fair for our product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidate, if approved.

Risks Related to Our Business Operations

We operate in a highly competitive environment.

The medical device industry is characterized by rapidly evolving technology and intense competition. Our competitors include major multi-national orthopedic and med-tech companies developing both generic and proprietary therapies to treat serious diseases. Many of these companies are well-established and possess technical, human, research and development, financial and sales and marketing resources significantly greater than ours. In addition, many of our potential competitors have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies potential research and development and commercialization advantages in the therapeutic areas we are currently pursuing.

Academic research centers, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those being developed by us. In addition, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals, and begin commercial sales of their products before us.

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

We are presently dependent largely upon the experience, abilities and continued services of Jeffrey Frelick, our President and Chief Executive Officer. The loss of services of Mr. Frelick could have a material adverse effect on our business, financial condition or results of operation.

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

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

- receipt of regulatory approval of marketing claims for the uses that we are developing;
- establishment and demonstration of the advantages, safety and efficacy of our formulations, products and technologies;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- our ability to attract corporate partners, including medical device, biotechnology and pharmaceutical companies, to assist in commercializing our proposed products; and
- our ability to market our products.

Physicians, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our proposed formulations or products. If we are unable to obtain regulatory approval, commercialize and market our proposed formulations or products when planned, we may not achieve any market acceptance or generate revenue.

Competitors could develop and/or gain FDA approval of our products for a different indication.

We cannot provide any assurances that any other company won't obtain FDA approval for similar products that might adversely affect our ability to develop and market these products in the U.S. We are aware that other companies have intellectual property protection and have conducted clinical trials. Many of these companies may have more resources than us. We cannot provide any assurances that our products will be FDA-approved prior to our competitors.

The FDA does not regulate the practice of medicine and, as a result, cannot direct physicians to select certain products for their patients. Consequently, we might be limited in our ability to prevent off-label use of a competitor's product to treat the diseases we intend to commercialize, even if we have issued method of use patents for that indication. If we are not able to obtain and enforce our patents, a competitor could develop and commercialize similar products for the same indications that we are pursuing. We cannot provide any assurances that a competitor will not obtain FDA approval for a product that contains the same active ingredients as our products.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We will face competition from numerous medical device, pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current product candidate. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Competition could result in reduced sales and pricing pressure on our current product candidate, if approved, which in turn would reduce our ability to generate meaningful revenues and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidate could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidate. The biotechnology industry is intensely competitive and involves a high degree of risk. We compete with other companies that have far greater experience and financial, research and technical resources than us. Potential competitors in the U.S. and worldwide are numerous and include medical device, pharmaceutical and biotechnology companies, educational institutions and research foundations, many of which have substantially greater capital resources, marketing experience, research and development staffs and facilities than ours. Some of our competitors may develop and commercialize products that compete directly with those incorporating our technology or may introduce products to market earlier than our product or on a more cost-effective basis. Our competitors compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our technology. We may face competition with respect to product efficacy and safety, ease of use and adaptability to various modes of administration, acceptance by physicians, the timing and scope of regulatory approvals, availability of resources, reimbursement coverage, price and patent position, including the potentially dominant patent positions of others. An inability to successfully complete our product development or commercializing our product candidate could result in our having limited prospects for establishing market share or generating revenue.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Mergers and acquisitions in the medical device, pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or potentially advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our current product candidate. Our competitors may also develop devices that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidate obsolete or non-competitive before we can recover the expenses of development and commercialization.

Our business may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel coronavirus (COVID-19) has evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

As a result of the continuing spread of the coronavirus, our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, and study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or non-performance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently utilize third parties to, among other things, manufacture raw materials. If either any third-party parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and research and development operations.

As a result of the shelter-in-place order and other mandated local travel restrictions, individuals conducting research and development or manufacturing activities may not be able to access their laboratory or manufacturing space which may result in our core activities being significantly limited or curtailed, possibly for an extended period of time.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

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

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

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

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

As of the date of this filing, we had two full-time employees. We will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidate. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources may increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

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

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

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our current product candidate or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product. If we cannot successfully defend ourselves against claims that our product candidate or product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Prior to engaging in future clinical trials, we intend to obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we may be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise and such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on devices that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2022, we had federal net operating loss, or NOLs, carryforwards of approximately $35,757,000. Our NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax laws, and will begin to expire, if not utilized, beginning in 2027. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Act, federal NOLs incurred in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act, or whether any further regulatory changes may be adopted in the future that could minimize its applicability. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and certain corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in the ownership of its equity over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited.

Risks Related to Healthcare Compliance Regulations

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. If we or they are unable to comply with these provisions, we may become subject to civil and criminal investigations and proceedings that could have a material adverse effect on our business, financial condition and prospects.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with healthcare providers, healthcare entities, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, develop and will market, sell and distribute our product. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the federal False Claims Act that can be enforced through civil whistleblower or qui tam actions, and civil monetary penalty laws, prohibit individuals or entities from knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment or approval that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") which imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information;

- the federal physician sunshine requirements under the ACA which requires certain manufacturers of , devices, biologics and medical supplies, with certain exceptions, to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing information; and certain state and local laws which require the registration of pharmaceutical sales representatives; and

- state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

The application of privacy provisions of HIPAA is uncertain.

The application of privacy provisions of HIPAA is uncertain. HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates "covered entities" (healthcare providers, insurers and clearinghouses) and indirectly regulates "business associates" with respect to the privacy of patients' medical information. All entities that receive and process protected health information are required to adopt certain procedures to safeguard the security of that information. It is uncertain whether we would be deemed to be a covered entity under HIPAA, and it is unlikely that we, based on our current business model, would be a business associate. Nevertheless, we may be contractually required to physically safeguard the integrity and security of any patient information that we receive, store, create or transmit. If we fail to adhere to our contractual commitments, then certain of our contract counterparties may be subject to civil monetary penalties and this could adversely affect our ability to market our product. If we are deemed to be a vendor, under the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, then we will be obligated to adopt various security measures. We may also be subject to state and foreign privacy laws under which breaches could lead to substantial fines and liability.

Risks Related to Owning our Common Stock

If we are unable to establish appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, subject us to regulatory scrutiny and sanction, cause investors to lose confidence in our reported financial information and have a negative effect on the market price for shares of our Common Stock and Public Warrants.

Effective internal controls are necessary for us to provide reliable financial reports and to effectively prevent fraud. We maintain a system of internal control over financial reporting, which is defined as a process designed by, or under the supervision of, our principal executive officer and principal financial officer, or persons performing similar functions, and effected by our 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 of December 31, 2022, management assessed the effectiveness of our internal controls over financial reporting, and based on that evaluation, they concluded that our internal controls and procedures were effective.

As a public company, we have significant additional requirements for enhanced financial reporting and internal controls. We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, which requires annual management assessments of the effectiveness of our internal controls over financial reporting. The process of designing and implementing effective internal controls is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a system of internal controls that is adequate to satisfy our reporting obligations as a public company.

We cannot assure you that we will, in the future, identify areas requiring improvement in our internal control over financial reporting. We cannot assure you that the measures we will take to remediate any areas in need of improvement will be successful or that we will implement and maintain adequate controls over our financial processes and reporting in the future as we continue our growth. If we are unable to establish appropriate internal financial reporting controls and procedures, it could cause us to fail to meet our reporting obligations, result in the restatement of our financial statements, harm our operating results, subject us to regulatory scrutiny and sanction, cause investors to lose confidence in our reported financial information and have a negative effect on the market price for shares of our Common Stock.

There may be potential conflicts of interest involving Don Hankey, as a director and as an affiliate of Hankey Capital, with our other stockholders.

Don Hankey, Chairman of our Board of Directors, is affiliated with Hankey Capital. Don Hankey, directly and indirectly, owns approximately 43.8% of our outstanding shares of common stock. Don Hankey may be able to exert significant control over our business affairs. Accordingly, Don Hankey may have actual or potential economic and/or legal interests that may diverge from our other stockholders' interests.

We may issue more shares in a future financing or pursuant to existing agreements which will result in substantial dilution.

Our Amended and Restated Certificate of Incorporation authorizes the issuance of a maximum of 100,000,000 shares of Common Stock and a maximum of 20,000,000 shares of Preferred Stock. Any future merger or acquisition effected by us would result in the issuance of additional securities without stockholder approval and the substantial dilution in the percentage of our Common Stock held by our then existing stockholders. Moreover, the Common Stock issued in any such merger or acquisition transaction may be valued on an arbitrary or non-arm's-length basis by our management, resulting in an additional reduction in the percentage of Common Stock held by our then existing stockholders. Additionally, we expect to seek additional financing in order to provide working capital to the operating business. Our Board of Directors has the power to issue any or all of such authorized but unissued shares without stockholder approval. To the extent that additional shares of Common Stock or Preferred Stock are issued in connection with and following a business combination or otherwise, dilution to the interests of our stockholders will occur and the rights of the holders of Common Stock might be materially and adversely affected.

Our Board of Directors is authorized to issue Preferred Stock without obtaining shareholder approval.

Our Amended and Restated Certificate of Incorporation authorizes the issuance of up to 20,000,000 shares of Preferred Stock with designations, rights and preferences determined from time to time by the Board of Directors. Accordingly, our Board of Directors is empowered, without stockholder approval, to issue Preferred Stock with dividend, liquidation, conversion, voting, or other rights which could adversely affect the voting power or other rights of the holders of the Common Stock. In the event of issuance, the Preferred Stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of the Company. Although we have no present intention to issue any shares of Preferred Stock, there can be no assurance that we will not do so in the future.

Provisions of our warrants could discourage an acquisition of us by a third party.

In addition to the discussion of the provisions of our certificate of incorporation and our bylaws, certain provisions of our warrants could make it more difficult or expensive for a third party to acquire us. The warrants prohibit us from engaging in certain transactions constituting "fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the warrants. These and other provisions of the warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

The price of our common stock and public warrants may fluctuate substantially.

You should consider an investment in our common stock and public warrants to be risky. Some factors that may cause the market price of our common stock and public warrants to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section are:

- failure to meet the Nasdaq listing requirements;
- sale of our common stock by our stockholders, executives, and directors and our stockholders whose shares are being registered in this offering;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;

- network outages or security breaches;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidate or any future clinical trials we may conduct;
- changes in the development status of our product candidate;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned preclinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidate;
- unanticipated safety concerns related to the use of our product candidate;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

A sale or perceived sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

All of our executive officers and directors and certain of our stockholders and warrant holders have agreed not to sell shares of our common stock for a period of 180 days from October 13, 2022 subject to extension under specified circumstances. Common stock subject to these lock-up agreements will become eligible for sale in the public market upon expiration of these lock-up agreements, subject to limitations imposed by Rule 144 under the Securities Act of 1933, as amended. If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. Moreover, the perceived risk of this potential dilution could cause stockholders to attempt to sell their shares and investors to short our common stock. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns (including the current downturn related to the current COVID-19 pandemic), volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflationary pressures and interest rate changes, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. More recently, the closures of Silicon Valley Bank and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation (FDIC) created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at Silicon Valley Bank and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our business plans and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to conduct our business plans on schedule and on budget.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

Don Hankey directly or indirectly beneficially owns approximately 43.8% of our outstanding shares of common stock. As a result, Don Hankey would have the ability to control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, Don Hankey would have the ability to control the management and affairs of our Company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including increased marketing, hiring new personnel, commercializing our product, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, medical device, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws, and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 20,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our Board of Directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;

- place limitations on the removal of directors;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant additional legal, accounting and other expenses. The obligations of being a public company in the U.S. require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

There can be no assurance that the results and events contemplated by forward-looking statements will, in fact, transpire.

There are statements in this Registration Statement that are not historical facts. These "forward-looking statements" can be identified by the use of terminology such as "believe," "hope," "may," "anticipate," "should," "intend," "plan," "will," "expect," "estimate," "project," "positioned," "strategy" and similar expressions. You should be aware that these forward-looking statements are subject to risks and uncertainties that are beyond our control. Actual results could differ significantly from these forward-looking statements. In light of these risks and uncertainties, there can be no assurance that the results and events contemplated by the forward-looking statements contained in this Registration Statement will in fact transpire. You are cautioned to not place undue reliance on these forward-looking statements, which speak only as of their dates. We do not undertake any obligation to update or revise any forward-looking statements.

The Company received a written notice from Nasdaq that it has failed to comply with certain listing requirements of the Nasdaq Stock Market, which could result in the Company's being delisted from the Nasdaq Stock Market.

On November 17, 2022, the Company received a notification from Nasdaq related to its failure to maintain a minimum bid price of $1 per share. Based upon the closing bid price for the last 30 consecutive business days, the Company no longer meets this requirement. However, the Nasdaq Listing Rules also provide the Company a compliance period of 180 calendar days in which to regain compliance. Accordingly, if at any time from the date of this notice until May 16, 2023, the closing bid price the Company's common stock is at least $1 for a minimum of ten consecutive business days, Nasdaq will provide the Company with written confirmation of compliance and the matter will be closed. If the Company does not regain compliance with the minimum bid price requirement by May 16, 2023, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company would be required to meet all other initial listing standards, except for the minimum bid price requirement. In addition, the Company would be required to notify Nasdaq of its intent to cure the deficiency during the second compliance period. If the Company does not regain compliance with the minimum bid price requirement by the end of the compliance period (or the second compliance period, if applicable), the Company's common stock will become subject to delisting. If the Company is delisted from Nasdaq, its common stock may be eligible for trading on an over-the-counter market. If the Company is not able to obtain a listing on another stock exchange or quotation service for the Company's common stock, it may be extremely difficult or impossible for stockholders to sell their shares. The Company intends to monitor the closing bid price of the Company's common stock and may be required to seek approval from its stockholders to effect a reverse stock split of the issued and outstanding shares of the Company's common stock. However, there can be no assurance that the reverse stock split would be approved by the Company's stockholders. Further, there can be no assurance that the market price per new share of the Company's common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of the Company's common stock outstanding before the reverse stock split. Even if the reverse stock split is approved by the Company's stockholders, there can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing rules.

If the Company is delisted from Nasdaq, its common stock may be eligible for trading on an over-the-counter market. If the Company is not able to obtain a listing on another stock exchange or quotation service for its common stock, it may be extremely difficult or impossible for stockholders to sell their shares of common stock. Moreover, if the Company is delisted from Nasdaq, but obtains a substitute listing for its common stock, it will likely be on a market with less liquidity, and therefore experience potentially more price volatility than experienced on Nasdaq. Stockholders may not be able to sell their shares of common stock on any such substitute market in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if the Company's common stock is delisted from Nasdaq, the value and liquidity of the Company's common stock, warrants and pre-funded warrants would likely be significantly adversely affected. A delisting of the Company's common stock from Nasdaq could also adversely affect the Company's ability to obtain financing for its operations and/or result in a loss of confidence by investors, employees and/or business partners.

If the Company implements a reverse stock split, liquidity of its common stock may be adversely effected.

The Company may be required to seek approval from its stockholders to effect a reverse stock split of the issued and outstanding shares of its common stock in order to regain compliance with the Nasdaq minimum bid price requirement. However, there can be no assurance that the reverse stock split would be approved by the Company's stockholders. Further, there can be no assurance that the market price per new share of the Company's common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of the Company's common stock outstanding before the reverse stock split. The liquidity of the shares of the Company's common stock may be affected adversely by any reverse stock split given the reduced number of shares of the Company's common stock that will be outstanding following the reverse stock split, especially if the market price of the Company's common stock does not increase as a result of the reverse stock split.

Following any reverse stock split, the resulting market price of the Company's common stock may not attract new investors and may not satisfy the investing requirements of those investors. Although the Company believes that a higher market price of the Company's comm011 stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of the Company's common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of the Company's common stock may not necessarily improve.

Item 1B. Unresolved Staff Comments

None.

Item 2. ***Properties***

We lease our primary office which is located at 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803 on a month to month lease.

Item 3. ***Legal Proceedings***

In July 2019, Dr. Bessie (Chia) Soo and Dr. Kang (Eric) Ting ("Plaintiffs") filed a complaint (the "Complaint") in federal court in Massachusetts against the Company, Bruce Stroever ("Stroever"), John Booth ("Booth"), Stephen LaNeve ("LaNeve", and together with Stroever and Booth, the "Individual Defendants"), and MTF Biologics (f/k/a The Musculoskeletal Transplant Foundation, Inc.) ("MTF"). The Complaint alleges claims for breach of contract against the Company and tortious interference with contract against the Individual Defendants and MTF arising from the termination of the Professional Service Agreements, dated as of January 8, 2016, between the Company and each of the Plaintiffs. The Individual Defendants have been sued for actions taken by them in connection with their service to the Company as directors and/or officers of the Company. As such, the Company has certain indemnification obligations to the Individual Defendants. The Company and the Individual Defendants intend to vigorously defend against the allegations in the Complaint. Although the Complaint was filed several years ago, due to the Covid-19 Pandemic and long delays in the court ruling on various motions to dismiss, in terms of case progression the case is still in its early stages with the claims in the case not being set until April 2022 and preliminary discovery starting since then. Based on the early stage of the litigation, it is not possible to estimate the amount or range of any possible loss arising from the expenditure of defence fees, a judgment or settlement of the matter.

In the normal course of our business, we may periodically become subjected to various lawsuits. However, there are currently no legal actions pending against us or, to our knowledge, are any such proceedings contemplated.

Item 4. ***Mine Safety Disclosures***

Not applicable.

PART II

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

Market

Effective October 13, 2021, our common stock and warrants began to trade on The Nasdaq Capital Market under the symbols "BBLG" and "BBLGW," respectively. Prior to October 13, 2021, our common stock traded on the OTCQB. Quotations represent prices between dealers, do not include retail markups, markdowns or commissions, and do not necessarily represent prices at which actual transactions were affected. There is a limited public trading market for our securities.

All share and per share amounts and information presented herein have been retroactively adjusted for all periods presented to reflect the 1-for-2.5 reverse stock split effected October 12, 2021.

Common Stock		
	High	Low
Fiscal Year 2022		
First Quarter	$ 5.39	$ 1.48
Second Quarter	$ 3.04	$ 1.19
Third Quarter	$ 1.73	$ 1.05
Fourth Quarter	$ 1.09	$ 0.19
Fiscal Year 2021		
First Quarter	$ 10.00	$ 10.00
Second Quarter	$ 10.00	$ 10.00
Third Quarter	$ 10.00	$ 7.50
Fourth Quarter	$ 18.75	$ 6.25

Holders

As of March 28, 2023, we had 31 stockholders of record holding 16,702,912 shares of our common stock outstanding, including 14,060,792 shares of common stock held by an indeterminate number of beneficial owners of securities whose shares are held in the names of various depository accounts, brokerage firms and clearing agencies.

Dividends

To date, we have paid no cash dividends on our Common Stock. For the foreseeable future, earnings generated from our operations will be retained for use in our business and not to pay dividends.

Repurchases of Equity Securities

None

Recent Sales of Unregistered Securities

None

Securities Authorized for Issuance under Equity Compensation Plans

2015 Equity Incentive Plan

We have 1,077,529 shares of Common Stock authorized and reserved for issuance under our 2015 Equity Incentive Plan for option awards. This reserve may be increased by the Board each year by up to the number of shares of stock equal to 5% of the number of shares of stock issued and outstanding on the immediately preceding December 31. Appropriate adjustments will be made in the number of authorized shares and other numerical limits in our 2015 Equity Incentive Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards granted under our 2015 Equity Incentive Plan which expire, are repurchased or are cancelled or forfeited will again become available for issuance under our 2015 Equity Incentive Plan. The shares available will not be reduced by awards settled in cash. Shares withheld to satisfy tax withholding obligations will not again become available for grant. The gross number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under our 2015 Equity Incentive Plan.

Awards may be granted under our 2015 Equity Incentive Plan to our employees, including officers, director or consultants, and our present or future affiliated entities. While we may grant incentive stock options only to employees, we may grant non-statutory stock options, stock appreciation rights, restricted stock purchase rights or bonuses, restricted stock units, performance shares, performance units and cash-based awards or other stock based awards to any eligible participant.

The 2015 Equity Incentive Plan is administered by our compensation committee. Subject to the provisions of our 2015 Equity Incentive Plan, the compensation committee determines, in its discretion, the persons to whom, and the times at which, awards are granted, as well as the size, terms and conditions of each award. All awards are evidenced by a written agreement between us and the holder of the award. The compensation committee has the authority to construe and interpret the terms of our 2015 Equity Incentive Plan and awards granted under our 2015 Equity Incentive Plan.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	452,829	$ 16.84	624,700
Equity compensation plans not approved by security holders	-	-	-
Total	452,829	$ 16.84	624,700

Item 6. ***[Reserved]***

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

We are a medical device company that is currently focused on bone regeneration in spinal fusion using the recombinant human protein, known as NELL-1/DBM. The NELL-1/DBM combination product is an osteopromotive recombinant protein that provides target specific control over bone regeneration. The protein, as part of the UCB-1 technology platform has been licensed exclusively for worldwide applications to us through a technology transfer from UCLA TDG. UCLA TDG and the Company received guidance from the FDA that NELL-1/DBM will be classified as a combination product with a device lead.

We were founded by University of California professors in collaboration with an Osaka University professor and a University of Southern California surgeon in 2004 as a privately-held company with proprietary, patented technology that has been validated in sheep and non-human primate models to facilitate bone growth. Our platform technology has application in delivering improved outcomes in the surgical specialties of spinal, orthopedic, general orthopedic, plastic reconstruction, neurosurgery, interventional radiology, and sports medicine. Lead product development and clinical studies are targeted on spinal fusion surgery, one of the larger segments in the orthopedic market.

We are a development stage entity. The production and marketing of our products and ongoing research and development activities will be subject to extensive regulation by numerous governmental authorities in the United States. Prior to marketing in the United States, any combination product developed by us must undergo rigorous preclinical (animal) and clinical (human) testing and an extensive regulatory approval process implemented by the FDA under the Food, Drug and Cosmetic Act. There can be no assurance that we will not encounter problems in clinical trials that will cause us or the FDA to delay or suspend the clinical trials.

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

Nasdaq Notification of Failure to Satisfy a Continued Listing Rule or Standard

On November 17, 2022, we received a notification from Nasdaq related to our failure to maintain a minimum bid price of $1 per share. Based upon the closing bid price for the last 30 consecutive business days, we no longer meet this requirement. However, the Nasdaq Listing Rules also provide us a compliance period of 180 calendar days in which to regain compliance. Accordingly, if at any time from the date of this notice until May 16, 2023, the closing bid price our common stock is at least $1 for a minimum often consecutive business days, Nasdaq will provide us with written confirmation of compliance and the matter will be closed. If we do not regain compliance with the minimum bid price requirement by May 16, 2023, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet all other initial listing standards, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period. If we do not regain compliance with the minimum bid price requirement by the end of the compliance period (or the second compliance period, if applicable), our common stock will become subject to delisting. If we are delisted from Nasdaq, our common stock may be eligible for trading on an over-the-counter market. If we are not able to obtain a listing on another stock exchange or quotation service for our common stock, it may be extremely difficult or impossible for stockholders to sell their shares. We intend to monitor the closing bid price of our common stock and may be required to seek approval from our stockholders to effect a reverse stock split of the issued and outstanding shares of our common stock. However, there can be no assurance that the reverse stock split would be approved by our stockholders. Further, there can be no assurance that the market price per new share of our common stock after the reverse stock split will remain unchanged or increase in proportion to the reduction in the number of old shares of our common stock outstanding before the reverse stock split. Even if the reverse stock split is approved by our stockholders, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing rules.

Results of Operations

Since our inception, we devoted substantially all of our efforts and funding to the development of the NELL-1 protein and raising capital. We have not yet generated revenues from our planned operations.

	Year ended December 31, 2022	Year ended December 31, 2021	% Change
Operating expenses			
Research and development	**$ 1,579,298**	$ 82,044	1824.94%
General and administrative	**2,085,875**	1,021,032	104.29%
Total operating expenses	**3,665,173**	1,103,076	232.27%
Loss from operations	**(3,665,173)**	(1,103,076)	232.27%
Interest expense	**-**	(805,109)	(100.00)%
Finance cost related to public offering	**(731,714)**	-	-%
Change in fair value of warrant liability	**2,912,267**	-	-%
Gain on forgiveness of deferred compensation	**-**	297,500	(100.00)%
Net loss	**$ (1,484,620)**	$ (1,610,685)	(7.83)%

Research and Development

Our research and development increased from $82,044 during the year ended December 31, 2021 to $1,579,298 during the year ended December 31, 2022. We continue to implement research activities after curtailing our operations during 2021. We will continue to incur significant expenses for development activities for NELL-1 in the future.

General and Administrative

Our general and administrative expenses increased from $1,021,032 during the year ended December 31, 2021 to $2,085,875 during the year ended December 31, 2022. The $1,064,843 increase was due to resuming operations in 2022. Significant expenses incurred during 2022 were Directors and Officers insurance, directors' compensation, the revised CFO employment agreement for full-time services and the services of an investor relations firm. We incurred stock based compensation expense for our directors and management team totaling $266,633.

Interest Expense

Our interest expense decreased from $805,109 for the year ended December 31, 2021 to $-0- during the year ended December 31, 2022. All the outstanding convertible notes were converted in October 2021.

Finance cost related to public offering

Finance cost related to public offering of $731,714 represents the excess of the fair value of the derivative warrant instruments issued on our October 2022 over the net proceeds from the offering.

Change in fair value of warrant liability

In October 2022, we completed a public equity offering (see Financial Statements Note 5), which included the issuance of 13,001,445 warrants. The warrants provide for a Black Scholes value calculation in the event of certain transactions ("Fundamental Transactions," as defined), which includes a floor on volatility utilized in the value calculation at 100% or greater. We have determined that this provision introduces leverage to the holders of the warrants that could result in a value that would be greater than the settlement amount of a fixed-for-fixed option on the Company's own equity shares. Accordingly, pursuant to ASC 815, we have classified the fair value of the warrants as a liability to be re-measured at the end of every reporting period with the change in value reported in the statement of operations.

The change in fair value of warrant liability represents the re-measurement of the outstanding warrants at December 31, 2022.

Liquidity and Capital Resources

Going Concern and Liquidity

We have no significant operating history and since inception to December 31, 2022 have incurred accumulated losses of approximately $72 million. The Company will continue to incur significant expenses for development activities for their lead product NELL-1/DBM. Operating expenditures for the next twelve months are estimated at $8.8 million. The accompanying consolidated financial statements for the year ended December 31, 2022 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, the Company incurred a net loss of $1,484,620, and used net cash in operating activities of $3,566,913 during the year ended December 31, 2022. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. In addition the Company's independent registered public accounting firm, in their report on the Company's December 31, 2022, audited financial statements, raised substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

On October 13, 2022, we completed a public offering generating net proceeds to us of $4,429,860.

We will continue to attempt to raise additional debt and/or equity financing to fund future operations and to provide additional working capital. However, there is no assurance that such financing will be consummated or obtained in sufficient amounts necessary to meet our needs. If cash resources are insufficient to satisfy our on-going cash requirements, we will be required to scale back or discontinue its product development programs, or obtain funds if available (although there can be no certainties) through strategic alliances that may require us to relinquish rights to our technology, substantially reduce or discontinue its operations entirely. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to us. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

As of December 31, 2022 and 2021, we had cash of $7,538,312 and $6,675,365, respectively.

We anticipate that it will require approximately $15 million to complete first in man studies, and an estimated additional $27 million to achieve FDA approval for a spine interbody fusion indication.

Cash Flows

The following is a summary of our cash flows from operating, investing and financing activities for the years ended December 31, 2022 and 2021:

Operating activities

During the year ended December 31, 2022 and 2021, cash used in operating activities was $3,566,913 and $1,228,586 respectively. Cash expenditures for the year ended December 31, 2022 increased primarily due to implementing research activities after curtailing our operations during 2021, directors' compensation, the revised CFO employment agreement for full-time services and investor relation services.

Financing activities

During the year ended December 31, 2022, cash provided by financing activities of $4,429,860 resulted from the net proceeds of our October 2022 public offering of common stock units. During the year ended December 31, 2021, cash provided by financing activities of $7,903,951 resulted primarily from draws on our second and third credit facilities with Hankey Capital and the October 2021 Primary Offering which provided proceeds from sale of common stock units in public offering, net of offering costs of $6,858,843.

Critical Accounting Policies and Estimates

Use of Estimates and Assumptions.

The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Significant estimates include the assumptions used in the valuation of stock options and warrants and income tax valuation allowances. Actual results could differ from those estimates.

Research and Development Costs

Research and development costs include, but are not limited to, payroll and other personnel expenses, consultants, expenses incurred under agreements with contract research and manufacturing organizations and animal clinical investigative sites and the cost to manufacture clinical trial materials. Costs related to research, design and development of products are charged to research and development expense as incurred.

Stock Based Compensation

ASC 718, *Compensation – Stock Compensation*, prescribes accounting and reporting standards for all share-based payment transactions in which employee services are acquired. Transactions include incurring liabilities, or issuing or offering to issue shares, options, and other equity instruments such as employee stock ownership plans and stock appreciation rights. Share-based payments to employees, including grants of employee stock options, are recognized as compensation expense in the consolidated financial statements based on their fair values. That expense is recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period).

We account for stock-based compensation issued to non-employees and consultants in accordance with the provisions of ASC 505-50, *Equity – based Payments to Non-Employees*. Measurement of share-based payment transactions with non-employees is based on the fair value of whichever is more reliably measurable: (a) the goods or services received; or (b) the equity instruments issued. The fair value of the share-based payment transaction is determined at the earlier of performance commitment date or performance completion date.

Recently Issued Accounting Standards

See discussion in Note 2 to the consolidated financial statements.

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 effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Item 7A. ***Quantitative and Qualitative Disclosures about Market Risk***

Not applicable.

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

The financial statements and supplementary data required by Regulation S-X are included in Item 15. "Exhibits, Financial Statements Schedules" contained in Part IV, Item 15 of this Annual Report.

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

None.

Item 9A. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Financial Officer and Chief Executive Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (Exchange Act)) as of December 31, 2022. Based upon that evaluation, our Chief Financial Officer and Chief Executive Officer concluded that as of December 31, 2022, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the company's principal executive officers and effected by the company's 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 GAAP and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

As of December 31, 2022, management assessed the effectiveness of our internal control over financial reporting and based on that evaluation assessment, concluded that our internal control over financial reporting were effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

Item 9B. ***Other Information***

None.

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

Not applicable.

Part III

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

Our directors are elected annually for a one year term or until their respective successors are duly elected and qualified or until their earlier resignation or removal. The following table sets forth certain information regarding our directors and executive officers as of March 28, 2023:

Name	Age	Position
Jeffrey Frelick	57	Chief Executive Officer and President
Deina H. Walsh	58	Chief Financial Officer
Don Hankey	79	Chairman of the Board of Directors
Bruce Stroever	73	Director
Erick Lucera	55	Director
Siddhesh Angle	39	Director

Jeffrey Frelick: Chief Executive Officer and President

Jeffrey Frelick serves as the President and Chief Executive Officer of Bone Biologics, bringing more than 25 years of leadership, operational, and investment experience in the life science industry. He joined Bone Biologics in 2015 as our Chief Operating Officer and assumed his current role in June 2019. Prior to Bone Biologics, Mr. Frelick spent 15 years on Wall Street as a sell-side analyst following the med-tech industry at investment banks Canaccord Genuity, ThinkEquity and Lazard. He also previously worked at Boston Biomedical Consultants where he provided strategic planning assistance, market research data and due diligence for diagnostic companies. He began his career at Becton Dickinson in sales and sales management positions after gaining technical experience as a laboratory technologist with Clinical Pathology Facility. Mr. Frelick received a B.S. in Biology from University of Pittsburgh and an M.B.A. from Suffolk University's Sawyer Business School.

Deina H. Walsh: Chief Financial Officer

Deina Walsh has served as our Chief Financial Officer since November 2014. She is a certified public accountant and owner/founder of DHW CPA, PLLC a Public Companies Accounting Oversight Board (PCAOB) registered firm since 2014. Prior to forming her firm, Ms. Walsh has 13 years at a public accounting firm where as a partner she was actively responsible for leading firm audit engagements of publicly held entities in accordance with PCAOB standards and compliance with SEC regulations, including internal control requirements under section 404 of the Sarbanes-Oxley Act. Ms. Walsh had a global client base including entities throughout the United States, Canada and China. These entities encompass a diverse range of industries including manufacturing, wholesale, life sciences, pharmaceuticals, and technology. Her experience includes work with start-up companies and well-established operating entities. She has assisted many entities seeking debt and equity capital. Areas of specialty include mergers, acquisitions, reverse mergers, consolidations, complex equity structures, foreign currency translations and revenue recognition complexities. Ms. Walsh has an Associates of Science Degree in Business Administration from Monroe Community College and a Bachelor of Science Degree in Accounting from the State University of New York at Brockport.

Don Hankey: Chairman of the Board of Directors

Mr. Hankey has served as Chairman of the Board of Directors since 2018. Mr. Hankey holds his BA and post-graduate work from the University of Southern California. At age 27, Mr. Hankey became Vice President of a major investment banking firm, which would later become part of USB Paine Weber. Mr. Hankey acquired Midway Ford in 1972 and founded Hankey Investment Company. During the 1980s, Mr. Hankey's organization grew its portfolio and established a foothold in the financial services industry. Mr. Hankey has incorporated technology into every aspect of the Hankey Group of companies improving efficiencies and outcomes. Mr. Hankey has been the manager of Hankey Capital, LLC, since its formation in 2002. Given Mr. Hankey's financial experience, we believe he is well qualified to serve as the Chairman of the Board of Directors.

Bruce Stroever: Director

Mr. Stroever has served on Biologics board of directors since 2012, bringing forty years of product development and general management experience in the medical device and orthobiologics fields. Mr. Stroever most recently served as President and Chief Executive Officer at MTF until he retired in 2020 after 32 years of service. Under Mr. Stroever's leadership, MTF grew to be the largest tissue bank in the world. From 1971 to 1988, Mr. Stroever held several positions with Ethicon, Inc., a Johnson & Johnson, Inc. subsidiary. Mr. Stroever served on the advisory board for the New Jersey Organ and Tissue Sharing Network. He was also elected to the Board of Governors of the American Association of Tissue Banks for a three-year term in 1999 and subsequently in 2012. He was a founding member of the Tissue Policy Group subsidiary of the AATB and served as its Chairman for two terms. Mr. Stroever received his B.E. in Mechanical/Chemical Engineering from Stevens Institute of Technology in 1972 and a Masters of Science in Bioengineering from Columbia University in 1977. Given Mr. Stroever's educational background, his senior management experience in our industry and the continuity he brings to the Board of Directors, .we believe that Mr. Stroever is well qualified to serve as a member of the Board of Directors.

Erick Lucera: Director

Mr. Lucera's appointment to the Board became effective upon completion of the October 2021 Primary Offering. From 2020 to the present, Mr. Lucera served as Chief Financial Officer of AVEO Oncology, a public biotech company. From 2016 to 2020, Mr. Lucera served as Chief Financial Officer, Treasurer and Secretary of VALERITAS, a publicly held medical device company. From 2017 to the present, Mr. Lucera has served as a member of the Board of Directors and Audit Chairman of Beyond Air, a publicly held medical device company. From 2015 to 2016, Mr. Lucera served as Chief Financial Officer, Treasurer and Secretary of VIVENTIA Bio, a privately held biotech company. From 2012 to 2015, Mr. Lucera served as Vice President, Corporate Development of Aratana Therepeutics, a publicly held biotech company. In 2012, Mr. Lucera served as Vice President, Corporate Development of Sunshine Heart, a publicly held medical device manufacturer. From 2008 to 2011, Mr. Lucera served as Vice President, Healthcare Analyst at Eaton Vance. From 2004 to 2008, he served as Portfolio Manager, Triathlon Life Sciences Fund. From 1995 to 2004, he served as Senior Vice President and Principal of Independence Investments, as head of healthcare research team. From 1990 to 1993, Mr. Lucera served as Staff Accountant at Price Waterhouse. Given Mr. Lucera's extensive experience in strategic planning and finance, we believe that Mr. Lucera is well qualified to serve as a member of the Board of Directors.

Siddhesh (Sid) R. Angle: Director

Dr. Angle's appointment to the Board became effective upon completion of October 2021 Offering. From 2018 to the present, Dr. Angle is Co-Founder, President and Chief Executive Officer of Regenosine, an early stage start-up for osteoarthritic disease. From 2021 to present, Dr. Angle also serves on the Executive Team of Vetosine, an animal health affiliate of Regenosine. From 2020 to 2021, Dr. Angle was Associate Director, Innovation Commercialization at NYU Langone. From 2017 to 2020, Dr. Angle was Program Manager, Innovation Commercialization at NYU Langone. From 2013 to 2017, Dr. Angle worked in various R&D capacities at Zimmer Biomet, culminating as R&D manager of global orthobiologics. From 2011 to 2013, Dr. Angle served as Research Scientist at Carnegie Mellon University. Given Mr. Angle's extensive background in research and development, we believe that Mr. Angle is well qualified to serve as a member of the Board of Directors.

Director Terms; Qualifications

Members of our board of directors serve until the next annual meeting of stockholders, or until their successors have been duly elected.

When considering whether directors and nominees have the experience, qualifications, attributes and skills to enable the board of directors to satisfy its oversight responsibilities effectively in light of our business and structure, the board of directors focuses primarily on the industry and transactional experience, and other background, in addition to any unique skills or attributes associated with a director.

Family Relationships

None.

Board of Directors and Corporate Governance

Our Board of Directors consists of four (4) members, consisting of Don Hankey, Bruce Stroever, Erick Lucera, and Sid Angle.

Board Committees

Our Board of Directors has appointed an audit committee, governance committee and compensation committee. The Board of Directors met or acted by written consent three times during 2022.

Audit Committee

The audit committee is responsible for overseeing: (i) our accounting and reporting practices and compliance with legal and regulatory requirements regarding such accounting and reporting practices; (ii) the quality and integrity of our financial statements; (iii) our internal control and compliance programs; (iv) our independent auditors' qualifications and independence and (v) the performance of our independent auditors and our internal audit function. In so doing, the audit committee maintains free and open means of communication between our directors, internal auditors and management.

The Audit Committee consists of Bruce Stroever, Erick Lucera, and Sid Angle, with Mr. Lucera acting as Chairman and the Audit Committee financial expert. The Audit Committee met or acted by written consent once during 2022.

Compensation Committee

The compensation committee is responsible for reviewing and approving the compensation of our executive officers and directors and our performance plans and other compensation plans. The compensation committee makes recommendations to our Board of Directors in connection with such compensation and performance plans.

The Compensation Committee consists of Bruce Stroever, Erick Lucera, and Sid Angle, with Mr. Stroever acting as Chairman. The Compensation Committee met or acted by written consent once during 2022.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee is responsible for (i) identifying, screening and reviewing individuals qualified to serve as directors (consistent with criteria approved by our Board of Directors) and recommending to our Board candidates for nomination for election at the annual meeting of shareholders or to fill board vacancies or newly created directorships; (ii) developing and recommending to our Board of Directors and overseeing the implementation of our corporate governance guidelines (if any); (iii) overseeing evaluations of our Board of Directors and (iv) recommending to our Board of Directors candidates for appointment to board committees.

The Nominating and Corporate Governance Committee consists of Bruce Stroever, Erick Lucera, and Sid Angle, with Dr. Angle acting as Chairman. The Nominating and Corporate Governance Committee met or acted by written consent once during 2022.

The following Board Diversity Matrix presents our Board Diversity statistics, in accordance with Nasdaq Rule 5606, as self-disclosed by the directors. While the Board satisfies minimum objectives of Nasdaq Rule 5605(f)(2), the Board will continue to consider the diversity of the Board in its selection of director nominees.

BOARD DIVERSITY MATRIX (as of March 28, 2023)

Total Number of Directors	4		
	Female	**Male**	**Did Not Disclose Gender**
Part I: Gender Identity			
Directors	-	3	1
Part II: Demographic Background			
Asian	-	1	-
White	-	2	-
Did Not Disclose Demographic Background	1		

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of the Company's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of Common Stock and other equity securities of the Company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us during the fiscal year ended December 31, 2022, all Section 16(a) filing requirements applicable to its officers, directors and greater than ten percent beneficial owners were complied with except Bruce Stroever, Erick Lucera and Sid Angle each failed to file a reports of one transaction.

Indemnification Agreements

Our Board has approved a form of indemnification agreement for our directors and executive officers ("Indemnification Agreement"). Following Board approval, we entered into Indemnification Agreements with each of our current directors and executive officers.

The Indemnification Agreement provides for indemnification against expenses, judgments, fines and penalties actually and reasonably incurred by an indemnitee in connection with threatened, pending or completed actions, suits or other proceedings, subject to certain limitations. The Indemnification Agreement also provides for the advancement of expenses in connection with a proceeding prior to a final, non-appealable judgment or other adjudication, provided that the indemnitee provides an undertaking to repay to us any amounts advanced if the indemnitee is ultimately found not to be entitled to indemnification by us. The Indemnification Agreement sets forth procedures for making and responding to a request for indemnification or advancement of expenses, as well as dispute resolution procedures that will apply to any dispute between us and an indemnitee arising under the Indemnification Agreement.

The foregoing description is qualified in its entirety by reference to the form of Indemnification Agreement filed as Exhibit 10.17 to the Current Report on Form 8-K filed on September 25, 2014.

Item 11. ***Executive Compensation***

The table below summarizes the compensation earned for services rendered to us in all capacities, for the fiscal years indicated, by its named executive officers:

Name and Principal Position	Year	Salary	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Deferred Compensation ($)[1]	All Other Compensation ($)	Total Compensation ($)
Jeffrey Frelick,..... Chief Executive Officer and President	2022	$300,000	$37,750	$ 7,965	$ -		$ -		$ 345,715
	2021	$240,000		$ -	$ -		$ 45,000		$ 290,000
Deina Walsh, ... Chief Financial Officer[2]	2022	$200,000	$18,875	$ 3,983	$ -		$ -	$ -	$ 222,858
	2021	$ -		$ -	$ -		$ -	$ 21,100	$ 21,100

(1) Pursuant to the October 2016 Note Purchase Agreement, management agreed to defer 20% of earned compensation. This stipulation was met with the closing of the October 2021 Primary Offering.

(2) From June 28, 2019 through January 2, 2022, Ms. Deina Walsh, our Chief Financial Officer, was employed through an independent contractor agreement. On December 17, 2021, Bone Biologics Corporation entered into a revised employment agreement with Ms. Walsh to become full time. The employment agreement was effective January 3, 2022.

Our 2015 Equity Incentive Plan was approved by majority shareholder consent on December 30, 2015 and all options outstanding as of the effective date were cancelled and re-issued under the new plan at current plan terms.

- **Base Salary:** The Company's base salaries are designed as a means to provide a fixed level of compensation in order to attract and retain talent. The base salaries of our named executive officers depend on their job responsibilities, the market rate of compensation paid by companies in our industry for similar positions, our financial position and the strength of our business.

- **Performance-Based Cash Awards:** As part of the Company's executive compensation program, the board intends to establish an annual performance-based cash award program for our executive officers and other key employees based upon individual performance and the Company's performance. The award program will also be designed to reinforce the Company's goals and then current strategic initiatives. The annual performance-based cash awards will be based on the achievement of Company and individual performance metrics established at the beginning of each fiscal year by the compensation committee and our Board of Directors. Following the end of each fiscal year, the compensation committee will be responsible for determining the bonus amount payable to the executive officer based on the achievement of the Company's performance and the individual performance metrics established for such executive.

- **Long-Term Equity Awards:** Our Board of Directors believes that equity ownership by our executive officers and key employees encourages them to create long-term value and aligns their interest with those of our stockholders. We grant annual equity awards to our executive officers under our 2015 Equity Incentive Plan. Our Board of Directors adopted and approved the following 2015 Equity Incentive Plan and intends to submit it for approval by our stockholders.

- **2015 Equity Incentive Plan:** We have 1,077,529 shares of Common Stock authorized and reserved for issuance under our 2015 Equity Incentive Plan for option awards. This reserve may be increased by the Board each year by up to the number of shares of stock equal to 5% of the number of shares of stock issued and outstanding on the immediately preceding December 31. Appropriate adjustments will be made in the number of authorized shares and other numerical limits in our 2015 Equity Incentive Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards granted under our 2015 Equity Incentive Plan which expire, are repurchased or are cancelled or forfeited will again become available for issuance under our 2015 Equity Incentive Plan. The shares available will not be reduced by awards settled in cash. Shares withheld to satisfy tax withholding obligations will not again become available for grant. The gross number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under our 2015 Equity Incentive Plan.

- Awards may be granted under our 2015 Equity Incentive Plan to our employees, including officers, director or consultants, and our present or future affiliated entities. While we may grant incentive stock options only to employees, we may grant non-statutory stock options, stock appreciation rights, restricted stock purchase rights or bonuses, restricted stock units, performance shares, performance units and cash-based awards or other stock based awards to any eligible participant.

- The 2015 Equity Incentive Plan will be administered by our compensation committee. Subject to the provisions of our 2015 Equity Incentive Plan, the compensation committee determines, in its discretion, the persons to whom, and the times at which, awards are granted, as well as the size, terms and conditions of each award. All awards are evidenced by a written agreement between us and the holder of the award. The compensation committee has the authority to construe and interpret the terms of our 2015 Equity Incentive Plan and awards granted under our 2015 Equity Incentive Plan.

Our Board of Directors approved the following compensation for our named executive officers:

Jeffrey Frelick, Chief Executive Officer and President:

Base Salary: Mr. Frelick's base salary is $300,000.

Bonus: During each calendar year, Mr. Frelick shall be eligible to earn an annual target bonus of fifty percent (50%) of his base salary as in-effect for the applicable calendar year, subject to the achievement of personal and corporate objectives or milestones to be established by the board of directors, or any compensation committee thereof, (after considering any input or recommendations from Mr. Frelick) within sixty (60) days following the beginning of each calendar year during Mr. Frelick's employment. In order to earn the annual bonus under this provision, the applicable objectives must be achieved and Mr. Frelick must be employed by Company at the time the annual bonus is distributed by Company. The annual bonus, if any, shall be paid on or before March 15th of the calendar year following the year in which it is considered earned. The actual annual bonus paid may be more or less than fifty percent (50%) of Mr. Frelick's base salary.

For the year ended December 31, 2022, Mr. Frelick's bonus accrual was $37,750 cash and 37,750 stock options. There was no bonus accrual during the year ended December 31, 2021.

Stock Options: On January 1, 2022, Mr. Frelick received a stock option grant whereby he is entitled to 50,000 shares of Common Stock of the Company as of the date of the grant on the condition that i) the exercise price will be the current market price on the date of the grant; and ii) the options will be issued with a two-year maturity. Any portion of this stock option grant that is not exercised on the date of termination shall be forfeited on such date of termination except: (i) in the case of Termination by the Company Without Cause; and (ii) upon a Change in Control (as defined in the Equity Incentive Plan) of the Company. To allow Mr. Frelick to prevent or mitigate dilution of his equity interests in the Company, in connection with each financing, Mr. Frelick will be provided an opportunity to invest in the Company such that his interest, at his option, remains undiluted or partially diluted.

Deina H. Walsh, Chief Financial Officer:

Ms. Walsh was retained through an independent contractor agreement through December 31, 2021. On December 17, 2021, Bone Biologics Corporation entered into a revised Employment Agreement with Deina H. Walsh. The Employment Agreement was effective January 3, 2022.

Base Salary: Ms. Walsh's base salary is $200,000.

Bonus: During each calendar year, Ms. Walsh shall be eligible to earn an annual target bonus of twenty-five percent (25%) of her base salary as in-effect for the applicable calendar year, subject to the achievement of personal and corporate objectives or milestones to be established by the board of directors, or any compensation committee thereof, (after considering any input or recommendations from Ms. Walsh) within sixty (60) days following the beginning of each calendar year during Ms. Walsh's employment. In order to earn the annual bonus under this provision, the applicable objectives must be achieved and Ms. Walsh must be employed by Company at the time the annual bonus is distributed by Company. The annual bonus, if any, shall be paid on or before March 15th of the calendar year following the year in which it is considered earned. The actual annual bonus paid may be more or less than twenty-five percent (25%) of Ms. Walsh's base salary.

For the year ended December 31, 2022, Ms. Walsh's bonus accrual was $18,875 cash and 18,875 stock options.

Stock Options: On January 3, 2022, Ms. Walsh received a stock option grant whereby she is entitled to 25,000 shares of Common Stock of the Company as of the date of the grant on the condition that i) the exercise price will be the current market price on the date of the grant; and ii) the options will be issued with a two-year maturity. Any portion of this stock option grant that is not exercised on the date of termination shall be forfeited on such date of termination except: (i) in the case of Termination by the Company Without Cause; and (ii) upon a Change in Control (as defined in the Equity Incentive Plan) of the Company. To allow Ms. Walsh to prevent or mitigate dilution of her equity interests in the Company, in connection with each financing, Ms. Walsh shall be provided an opportunity to invest in the Company such that her interest, at her option, remains undiluted or partially diluted.

Our compensation committee believes the agreements and other incentives granted to these named executive officers align our named executive officers' interests with those of our stockholders. Our compensation committee and board of directors continues to evaluate our executive compensation program with a view toward motivating our named executive officers to meet our strategic operational and financial goals in the best interests of our stockholders.

Potential Payments upon Termination of Change in Control

None.

Changes to Potential Payments upon Termination of Change in Control

None.

Consulting Agreements for Executives

None other than noted above.

Grants of Plan-Based Awards

None.

Executives Outstanding Equity Awards at Fiscal Year End

Name	Grant Date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested ($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
(a)		(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Jeffrey Frelick,... Chief Operating Officer	January 1, 2022	50,000	-	-	$ 3.72	January 1, 2024	-	-	-	-
	May 27, 2016	10,765	-	-	$ 51.25	May 27, 2026	-	-	-	-
	December 28, 2015	41,624	-	-	$ 39.75	December 27, 2025	-	-	-	-
Deina Walsh, Chief Financial Officer....	January 3, 2022	25,000	-	-	$ 3.72	January 3, 2024	-	-	-	-

Director Compensation

The following table shows information regarding the compensation earned during the year ended December 31, 2022 by the members of our board of directors.

Name	Fees Earned or Paid in Cash	Option Awards	Share Awards	Total
Bruce Stroever	$ 30,000	$ 56,678	-	$ 86,678
Don Hankey[(1)]	-	-	-	-
Erick Lucera	30,000	56,678	-	86,678
Sid Angle	30,000	56,678	-	86,678
Stephen R. La Neve[(1)(2)]	-	-	-	-
Total	$ 90,000	$ 170,034	$ -	$ 260,034

(1) Non-independent director. No compensation paid per our Non-Employee Director Compensation Policy.

(2) Resigned effective December 18, 2022.

The Board adopted a Non-Employee Director Compensation Policy (the "Director Compensation Policy") as following:

Annual Cash Compensation

Each Non-Employee Director will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts will be payable in equal quarterly installments, in arrears following the end of each quarter in which the service occurred, pro-rated for any partial months of service. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:

    a. All Non-Employee Directors other than the Board Chair: $25,000

    b. Non-Employee Director who is the Board Chair: $35,000

2. Annual Committee Chair Service Retainer (in addition to Annual Board Service Retainer):

    a. Chairman of the Audit Committee: $5,000

    b. Chairman of the Compensation Committee: $5,000

    c. Chairman of the Corporate Governance Committee: $5,000

Equity Compensation

Equity awards will be granted under our 2015 Equity Incentive Plan or any successor equity incentive plan (the "Plan"). All stock options granted under this Director Compensation Policy will be Nonstatutory Stock Options (as defined in the Plan), with a term of ten years from the date of grant and an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company ("Common Stock") on the date of grant.

(a) Automatic Equity Grants.

(i) Initial Grant for New Directors. Without any further action of the Board, each person who, after the Effective Date, is elected or appointed for the first time to be a Non-Employee Director will automatically, upon the date of his or her initial election or appointment to be a Non-Employee Director, be granted a Nonstatutory Stock Option to purchase 20,000 shares of Common Stock (the "Initial Grant"), regardless of when such person is elected or appointed to the Board. Each Initial Grant will fully vest on the date of the annual meeting of the stockholders of the Company ("Annual Meeting") next following the Initial Grant.

(ii) Annual Grant. Without any further action of the Board, at the close of business on the date of each Annual Meeting following the Effective Date, each person who is then a Non-Employee Director will automatically be granted a Nonstatutory Stock Option to purchase a number of shares of Common Stock having an Option Value (calculated on the date of grant) of $50,000 (the "Annual Grant"). Each Annual Grant will vest in a series of four (4) successive equal quarterly installments over the one-year period measured from the date of grant.

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

The following table sets forth certain information regarding beneficial ownership of our common stock as of March 28, 2023 by (i) each person (or group of affiliated persons) who is known by us to own more than five percent (5%) of the outstanding shares of our common stock, (ii) each director and executive officer, and (iii) all of our directors, executive officers and director nominees as a group. As of March 28, 2023, there were 16,702,912 shares of our common stock issued and outstanding.

Beneficial ownership is determined in accordance with SEC rules and generally includes voting or investment power with respect to securities. For purposes of this table, a person or group of persons is deemed to have "beneficial ownership" of any shares of common stock that such person currently owns or has the right to acquire within 60 days of March 28, 2023. With respect to options and warrants, this would include options and warrants that are currently exercisable within 60 days. With respect to convertible securities, this would include securities that are currently convertible within 60 days.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Bone Biologics Corporation, 2 Burlington Woods Drive, Suite 100, Burlington, MA 01803.

Name of Beneficial Owner or Identity of Group	Title of Class	Shares[1]	Percentage
5% or greater stockholders:			
Knight Insurance Company, Ltd. 4751 Wilshire Blvd #110 Los Angeles, CA 90010	Common Stock	2,469,281[2]	14.6%
Sabby Management LLC 115 Hidden Hills Dr. Spicewood, TX 78669	Common Stock	1,237,205	7.4%
Ionic Ventures, LLC 3053 Fillmore St. Suite 256 San Francisco, CA 94123	Common Stock	788,747[10]	4.9%
Executive Officers and Directors:			
Don R. Hankey 4751 Wilshire Blvd #110 Los Angeles, CA 90010	Common Stock	7,144,395[3]	41.7%
Jeffrey Frelick, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	143,237[4]	0.9%
Deina H. Walsh, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	43,875[5]	0.3%
Bruce Stroever, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	39,305[6]	0.2%
Erick Lucera, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	59,305[7]	0.4%
Sid Angle, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	59,305[8]	0.4%
Total Officers and Directors as a Group (6 persons).	Common Stock	7,445,546[9]	42.7%

(1) Based on 16,702,912 issued and outstanding shares. The number of shares issued and outstanding that was used to calculate the percentage ownership of each listed person includes the shares underlying convertible debt, stock options and warrants that are exercisable 60 days from our report date.

(2) Knight Insurance Company, Ltd. is the beneficial owner of 2,312,918 shares and 156,363 shares issuable upon exercise of warrants consisting of 1,466,603 shares and 99,148 shares issuable upon exercise of warrants held by Knight Insurance Company, Ltd., 285,438 shares and 19,297 shares issuable upon exercise of warrants held by Knightbrook Insurance Company which is a wholly owned subsidiary of Knight Insurance Company, Ltd. and 560,877 shares and 37,918 shares issuable upon exercise of warrants held by Knight Specialty Insurance Company a wholly owned subsidiary of Knight Insurance Company, Ltd.

(3) Mr. Hankey is the beneficial owner of 6,702,016 shares and 442,379 shares issuable upon exercise of warrants of the Company consisting of 4,279,721 shares and 280,764 shares issuable upon exercise of warrants owned by the Don Hankey Trust (the "Trust") of which Mr. Hankey is the Trustee, 31,696 shares held by H&H Funding LLC of which Mr. Hankey is the sole manager, 77,681 shares and 5,252 shares issuable upon exercise of warrants held by Knight Services, Inc. which is 100% owned by the Trust, and Knight Insurance Company, Ltd. the beneficial owner of 2,312,918 shares and 156,363 shares issuable upon exercise of warrants consisting of 1,466,603 shares and 99,148 shares issuable upon exercise of warrants held by Knight Insurance Company, Ltd., 285,438 shares and 19,297 shares issuable upon exercise of warrants held by Knightbrook Insurance Company which is a wholly owned subsidiary of Knight Insurance Company, Ltd. and 560,877 shares and 37,918 shares issuable upon exercise of warrants held by Knight Specialty Insurance Company a wholly owned subsidiary of Knight Insurance Company, Ltd.

(4) Includes 140,140 shares underlying stock options exercisable within 60 days.

(5) Includes 43,875 shares underlying stock options exercisable within 60 days.

(6) Includes 39,305 shares underlying stock options exercisable within 60 days.

(7) Includes 59,305 shares underlying stock options exercisable within 60 days.

(8) Includes 59,305 shares underlying stock options exercisable within 60 days.

(9) Consists of 6,705,113 shares, 442,379 shares issuable upon exercise of warrants and 298,054 shares underlying stock options exercisable within 60 days.

(10) Does not include an additional 1,717,652 shares issuable upon exercise of stock warrants which due to the blocker, the holder is prohibited from exercising if as a result of such exercise, the holder and its affiliates would beneficially own more than 4.99% of the then outstanding shares of the Company.

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

Except as disclosed below, none of the following persons has any direct or indirect material interest in any transaction to which we are a party since our incorporation or in any proposed transaction to which we are proposed to be a party:

- Any of our directors or officers;
- Any proposed nominee for election as our director;
- Any person who beneficially owns, directly or indirectly, shares carrying more than 5% of the voting rights attached to our Common Stock; or
- Any relative or spouse of any of the foregoing persons, or any relative of such spouse, who has the same house as such person or who is a director or officer of any parent or subsidiary of our Company.

Hankey Capital LLC - please refer to **Liquidity and Capital Resources** section of the MD&A

Review, Approval or Ratification of Transactions with Related Persons

Due to the small size of our Company, we do not at this time have a formal written policy regarding the review of related party transactions, and rely on our full Board of Directors to review, approve or ratify such transactions and identify and prevent conflicts of interest. Our Board of Directors reviews any such transaction in light of the particular affiliation and interest of any involved director, officer or other employee or stockholder and, if applicable, any such person's affiliates or immediate family members. Management aims to present transactions to our Board of Directors for approval before they are entered into or, if that is not possible, for ratification after the transaction has occurred. If our Board of Directors finds that a conflict of interest exists, then it will determine the appropriate action or remedial action, if any. Our Board of Directors approves or ratifies a transaction if it determines that the transaction is consistent with our best interests and the best interest of our stockholders.

Director Independence

Our Board of Directors consists of four (4) members: Don Hankey, Bruce Stroever, Erick Lucera and Sid Angle. Our Board of Directors undertook a review of the composition of our Board of Directors and the independence of each director. Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our Board of Directors has determined that Bruce Stroever, Erick Lucera, and Sid Angle qualify as "independent" as that term is defined by Nasdaq Listing Rule 5605(a) (2). Don Hankey would not qualify as "independent" under applicable Nasdaq Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he is the CEO and Chairman of the Hankey Group. Hankey Capital, LLC is part of the Hankey Group, and a significant shareholder of the Company. In making such determinations, our Board of Directors considered the relationships that each of our nonemployee directors has with the Company and all other facts and circumstances deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Subject to some exceptions, Nasdaq Listing Rule 5605(a)(2) provides that a director will only qualify as an "independent director" if, in the opinion of our Board of Directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, and that a director cannot be an "independent director" if (a) the director is, or in the past three years has been, an employee of ours; (b) a member of the director's immediate family is, or in the past three years has been, an executive officer of ours; (c) the director or a member of the director's immediate family has received more than $120,000 per year in direct compensation from us within the preceding three years, other than for service as a director or benefits under a tax-qualified retirement plan or non-discretionary compensation (or, for a family member, as a non-executive employee); (d) the director or a member of the director's immediate family is a current partner of our independent public accounting firm, or has worked for such firm in any capacity on our audit at any time during the past three years; (e) the director or a member of the director's immediate family is, or in the past three years has been, employed as an executive officer of a company where one of our executive officers serves on the compensation committee; or (f) the director or a member of the director's immediate family is an executive officer, partner or controlling shareholder of a company that makes payments to, or receives payments from, us in an amount which, in any twelve-month period during our past three fiscal years, exceeds the greater of 5% of the recipient's consolidated gross revenues for that year or $200,000 (except for payments arising solely from investments in our securities or payments under non-discretionary charitable contribution matching programs). Additionally, in order to be considered an independent member of an audit committee under Rule 10A-3 of the Exchange Act, a member of an audit committee may not, other than in his or her capacity as a member of the audit committee, the Board of Directors, or any other committee of the Board of Directors, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the applicable company or any of its subsidiaries or otherwise be an affiliated person of the applicable company or any of its subsidiaries.

Item 14. ***Accounting Fees and Services***

Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

The audit committee pre-approves all audit and permissible non-audit services provided by our independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. The audit committee has adopted policies and procedures for the pre-approval of services provided by our independent registered public accounting firm. The policies and procedures provide that management and our independent registered public accounting firm jointly submit to the audit committee a schedule of audit and non-audit services for approval as part of the annual plan for each year. In addition, the policies and procedures provide that the audit committee may also pre-approve particular services not in the annual plan on a case-by-case basis. For each proposed service, management must provide a detailed description of the service and the projected fees and costs (or a range of such fees and costs) for the service. The policies and procedures require management and our independent registered public accounting firm to provide quarterly updates to the audit committee regarding services rendered to date and services yet to be performed.

The following table sets forth the aggregate fees billed to us during the years ended December 31, 2022 and 2021.

Audit Fees

	2022	2021
Weinberg & Company, P.A.	$ 76,194	$ 37,565

Audit Related Fees

There were no fees billed to us by Weinberg & Company, P.A. for assurance and related services that are reasonably related to the performance of the audit related fees.

Tax Fees

	2022	2021
Foster, Griffith and Allen, Inc.	$ 6,650	$ -

Part IV

Item 15. ***Exhibits, Financial Statement Schedules***

(a) The following documents are filed as part of this report:

(1) Financial Statements:

(2) Financial Statement Schedules:

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

(3) Exhibits. The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 19, 2014, by and among AFH Acquisition X, Inc., Bone Biologics Acquisition Corp., and Bone Biologics, Inc. (incorporated herein by reference to Exhibit 2.1 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
2.2	Certificate of Merger as filed with the California Secretary of State effective September 19, 2014 (incorporated herein by reference to Exhibit 2.2 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
3.1	Amended and Restated Articles of Incorporation, of Bone Biologics Corporation, as filed with the Delaware Secretary of State on July 28, 2014 (incorporated herein by reference to Exhibit 3.1(i) to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
3.2	Certificate of Amendment as filed with the Delaware Secretary of State on October 18, 2021 (incorporated herein by reference to Exhibit 3.1 to current report on Form 8-K, File No. 000-53078, filed October 15, 2021)
3.3	Amended and Restated Bylaws of Bone Biologics Corporation (incorporated herein by reference to Exhibit 3.1 to current report on Form 8-K, File No. 000-53078, filed March 8, 2022)
4.1	Warrant Agent Agreement including Form of Warrant between the Company and Equiniti (incorporated by reference to Exhibit 10.42 to current report on Form S-1, File No. 000-53078, filed October 15, 2021)
4.2	Warrant Agent Agreement including Form of Series A Warrant, Form of Series B Warrant and Form of Series C Warrant between the Company and Equiniti (incorporated by reference to Exhibit 4.2 to current report on Form S-1, File No. 001-40899, filed September 23, 2022)
10.1	Director Offer Letter, dated July 1, 2014, by and between Bruce Stroever and Bone Biologics Corporation (incorporated herein by reference to Exhibit 10.4 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)

Exhibit No.	Description
10.2	Chief Operating Officer Employment agreement, dated June 8, 2015, by and between Bone Biologics Corporation and Jeffrey Frelick (incorporated herein by reference to Exhibit 10.2 to current report on Form 10-Q, File No. 000-53078, filed August 14, 2015)
10.3	Letter Agreement, dated October 2, 2015, by and between the Company and the Founders (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed October 08, 2015)
10.4	Bone Biologics Corporation Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.5	Bone Biologics Corporation 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.6	Form of Stock Award Grant Notice and Stock Award Agreement for the Bone Biologics Corporation 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.7	Form of Restricted Stock Unit Award (incorporated herein by reference to Exhibit 10.5 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.8	Option Agreement for the Distribution and Supply of Sygnal™ dated as of February 24, 2016 (incorporated herein by reference to Exhibit 10.3 to current report on Form 8-K, File No. 000-53078, filed February 26, 2016)
10.9	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.17 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
10.10	Amended and Restated Exclusive License Agreement, dated as of March 21, 2019, by and between the Company and The Regents of the University of California (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed April 16, 2019)
10.11	First Amendment to the Amended License Agreement dated August 13, 2020 between the Company and the Regents of the University of California (incorporated herein by reference to Exhibit 10.40 to current report on Form S-1/A, File No. 000-53078, filed October 7, 2021)
10.12	Employment Agreement dated December 17, 2021 between the Company and Deina Walsh (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed December 22, 2021)
10.13	Supply and Development Support Agreement dated March 3, 2022 between the Company and Musculoskeletal Transplant Foundation, Inc. (incorporated herein by reference to Exhibit 10.30 to current report on Form 10-K, File No. 000-53078, filed March 15, 2022)
10.14	Third Amendment to the Amended License Agreement dated June 8, 2022 between the Company and the Regents of the University of California (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 001-40899, filed June 9, 2022)
21.1	List of Subsidiaries (incorporated herein by reference to Exhibit 21.1 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
23.1	Consent of Weinberg & Company*
31.1	Certification of the Company's Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Report on Form 10-K for the year ended December 31, 2022.*
31.2	Certification of the Company's Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant's Report on Form 10-K for the year ended December 31, 2022.*

Exhibit No.	Description
32.1	Certification of the Company's Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of the Company's Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
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*
104	Cover Page formatted in Inline XBRL and contained in Exhibit 101

* Filed Herewith

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

None.

SIGNATURES

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

March 30, 2023

BONE BIOLOGICS CORPORATION

By: */s/ Jeffrey Frelick*
Name: Jeffrey Frelick
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Frelick and Deina H. Walsh, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jeffrey Frelick Jeffrey Frelick	Chief Executive Officer (Principal Executive Officer)	March 30, 2023
/s/ Deina H. Walsh Deina H. Walsh	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2023
/s/ Don R. Hankey Don R. Hankey	Director	March 30, 2023
/s/ Bruce Stroever Bruce Stroever	Director	March 30, 2023
/s/ Erick Lucera Erick Lucera	Director	March 30, 2023
/s/ Siddhesh Angle Siddhesh Angle	Director	March 30, 2023

Bone Biologics Corporation

Contents

Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of Bone Biologics Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Bone Biologics Corporation (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022 and 2021, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, during the year ended December 31, 2022 the Company incurred a net loss and utilized cash flows in operations, and has had recurring losses since inception. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement, 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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates 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 consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Warrant liability

As described in Note 3 to the financial statements, during the year ended December 31, 2022, the Company issued warrants that required management to assess whether the warrants required liability classification. The Company determined that the warrants were required to be accounted for as liabilities and recorded at fair value when issued and subsequently remeasured to fair value upon settlement or at the end of each reporting period. The Company's warrant liability balance was $1.7 million at December 31, 2022. The Company determines the fair value of the warrant liabilities utilizing the Black-Scholes pricing model.

We identified auditing the determination and valuation of the warrant liabilities as a critical audit matter due to the significant judgements used by the Company in determining whether the warrants required liability classification and the significant judgements used in determining the fair value of the warrant liabilities. This required a high degree of auditor judgment and increased auditor effort in auditing the determination and valuation of the warrant liabilities.

The primary procedures we performed to address this critical audit matter included:

- We inspected and reviewed the warrant agreements to evaluate the Company's determination of whether liability accounting was required.
- We tested the reasonableness of the assumptions used by the Company in the Black-Scholes model, including exercise price, expected term, expected volatility, and risk-free interest rate.
- We developed an independent expectation of the warrant liability using a Black-Scholes model and compared our independent expectation to the Company's estimate.

We have served as the Company's auditor since 2017.

/s/Weinberg & Company, P.A.
Los Angeles, California
March 30, 2023

Bone Biologics Corporation
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash	**$ 7,538,312**	$ 6,675,365
Prepaid expenses	**956,925**	-
Total assets	**$ 8,495,237**	$ 6,675,365
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable and accrued expenses	**$ 888,461**	$ 99,909
Warrant liability	**1,659,468**	-
Total current liabilities	**2,547,929**	99,909
Total liabilities	**2,547,929**	99,909
Commitments and Contingencies		
Stockholders' Equity		
Preferred Stock, $0.001 par value per share; 20,000,000 shares authorized; none issued or outstanding at December 31, 2022 and 2021	**-**	-
Common stock, $0.001 par value per share; 100,000,000 shares authorized; 15,301,986 and 10,350,574 shares issued and outstanding at December 31, 2022 and 2021, respectively	**15,300**	10,350
Additional paid-in capital	**77,892,235**	77,040,713
Accumulated deficit	**(71,960,227)**	(70,475,607)
Total stockholders' equity	**5,947,308**	6,575,456
Total liabilities and stockholders' equity	**$ 8,495,237**	$ 6,675,365

See accompanying notes to consolidated financial statements.

Bone Biologics Corporation
Consolidated Statements of Operations

	Year Ended December 31, 2022	Year Ended December 31, 2021
Revenues	**$ -**	**$ -**
Cost of revenues	**-**	-
Gross profit	**-**	-
Operating expenses		
Research and development	**1,579,298**	82,044
General and administrative	**2,085,875**	1,021,032
Total operating expenses	**3,665,173**	1,103,076
Loss from operations	**(3,665,173)**	(1,103,076)
Other income (expenses)		
Finance cost related to public offering	**(731,714)**	-
Change in fair value of warrant liability	**2,912,267**	-
Interest expense - related party	**-**	(805,109)
Gain on forgiveness of deferred compensation	**-**	297,500
Total other income (expenses)	**2,180,553**	(507,609)
Net loss	**$ (1,484,620)**	$ (1,610,685)
Weighted average shares outstanding - basic and diluted	**11,423,074**	4,541,861
Loss per share - basic and diluted	**$ (0.13)**	$ (0.35)

See accompanying notes to consolidated financial statements.

Bone Biologics Corporation
Consolidated Statement of Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2020	12,273,036	$ 12,273	$55,160,339	$(68,864,922)	$ (13,692,310)
Fair value of vested stock options issued to employees and Directors	-	-	207,035	-	207,035
Proceeds from sale of common stock units in public offering, net of offering costs $1,073,311	1,510,455	1,510	6,857,333	-	6,858,843
Shares issued upon debt and accrued interest conversion	5,928,774	5,929	14,816,006	-	14,821,935
Cancellation of collateral shares upon debt conversion	(9,361,702)	(9,362)	-	-	(9,362)
Share adjustment for stock split rounding	11	-	-	-	-
Net Loss	-	-	-	(1,610,685)	(1,610,685)
Balance at December 31, 2021	**10,350,574**	**10,350**	**77,040,713**	**(70,475,607)**	**6,575,456**
Fair value of vested stock options issued to employees and directors	-	-	266,633	-	266,633
Proceeds from sale of common stock units in public offering, net of offering costs $686,822	3,777,778	3,777	4,426,083	-	4,429,860
Fair value of warrant liability recognized upon issuance of warrants	-	-	(4,429,860)	-	(4,429,860)
Exercise of warrants	1,173,629	1,173	(1,173)	-	-
Extinguishment of warrant liability upon exercise of warrants	-	-	589,839	-	589,839
Share adjustment for October 2021 stock split rounding	5	-	-	-	-
Net Loss	-	-	-	(1,484,620)	(1,484,620)
Balance at December 31, 2022	**15,301,986**	**$ 15,300**	**$77,892,235**	**$(71,960,227)**	**$ 5,947,308**

See accompanying notes to consolidated financial statements.

Bone Biologics Corporation
Consolidated Statements of Cash Flows

	Year Ended December 31, 2022	Year Ended December 31, 2021
Cash flows from operating activities		
Net loss	**$ (1,484,620)**	$ (1,610,685)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	**266,633**	207,035
Finance cost related to public offering	**731,714**	-
Change in fair value of warrant liability	**(2,912,267)**	-
Interest payable – related party	**-**	793,051
Gain on forgiveness of deferred compensation	**-**	(297,500)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	**(956,925)**	-
Accounts payable and accrued expenses	**788,552**	(365,487)
Deferred compensation	**-**	45,000
Net cash used in operating activities	**(3,566,913)**	(1,228,586)
Cash flows from financing activities		
Cash overdraft	**-**	(10,609)
Proceeds from sale of common stock units in public offering, net of offering costs	**4,429,860**	6,858,843
Proceeds from credit facilities – related party	**-**	1,055,717
Net cash provided by financing activities	**4,429,860**	7,903,951
Net increase in cash	**862,947**	6,675,365
Cash, beginning of year	**6,675,365**	-
Cash, end of year	**$ 7,538,312**	$ 6,675,365
Supplemental information		
Interest paid - related party	**$ -**	$ 12,059
Income taxes paid	**$ -**	$ -
Non-cash financing activities		
Issuance of shares upon cashless exercise of warrants	**$**	$ -
Common shares issued upon conversion of Related Party Notes Payable and credit facilities	**$ -**	$ 14,821,935

See accompanying notes to consolidated financial statements.

Bone Biologics Corporation
Notes to Consolidated Financial Statements

1. The Company

Bone Biologics Corporation (the "Company") was incorporated under the laws of the State of Delaware on October 18, 2007 as AFH Acquisition X, Inc. Pursuant to a Merger Agreement, dated September 19, 2014, by and among the Company, its wholly-owned subsidiary, Bone Biologics Acquisition Corp., ("Merger Sub"), and Bone Biologics, Inc., Merger Sub merged with and into Bone Biologics Inc., with Bone Biologics Inc. remaining as the surviving corporation. On September 22, 2014, the Company changed its name to "Bone Biologics Corporation" and Bone Biologics, Inc. became a wholly owned subsidiary of the Company. Bone Biologics, Inc. was incorporated in California on September 9, 2004.

We are a medical device company that is currently focused on bone regeneration in spinal fusion using the recombinant human protein known as NELL-1. NELL-1 in combination with DBM, demineralized bone matrix, is an osteopromotive recombinant protein that provides target specific control over bone regeneration. The NELL-1 technology platform, has been licensed exclusively for worldwide applications to us through a technology transfer from the UCLA Technology Development Group on behalf of UC Regents ("UCLA TDG"). UCLA TDG and the Company received guidance from the FDA that NELL-1/DBM will be classified as a device/drug combination product with a pre-market approval filing ("PMA").

The production and marketing of the Company's products and its ongoing research and development activities will be subject to extensive regulation by numerous governmental authorities in the United States. Prior to marketing in the United States, any combination product developed by the Company must undergo rigorous preclinical (animal) and clinical (human) testing and an extensive regulatory approval process implemented by the FDA under the Food, Drug and Cosmetic Act. There can be no assurance that the Company will not encounter problems in clinical trials that will cause the Company or the FDA to delay or suspend clinical trials.

The Company's success will depend in part on its ability to obtain patents and product license rights, maintain trade secrets, and operate without infringing on the proprietary rights of others, both in the United States and other countries. There can be no assurance that patents issued to or licensed by the Company will not be challenged, invalidated, or circumvented, or that the rights granted thereunder will provide proprietary protection or competitive advantages to the Company.

On October 12, 2021, an amendment to our certificate of incorporation for a reverse split of the Company's outstanding common stock at a ratio of 1 for 2.5 became effective. On June 24, 2021, our board of directors authorized the amendment which became effective upon distribution to the stockholders of the Company and in conjunction with the Company's Common Stock being listed on the Nasdaq Capital Market. Our common stock became listed on the Nasdaq Capital Market on October 13, 2021. All share and per share amounts have been retro-actively restated as if the reverse split occurred at the beginning of the earliest period presented.

Going Concern and Liquidity

The Company has no significant operating history and since inception to December 31, 2022 has incurred accumulated losses of approximately $72 million. The Company will continue to incur significant expenses for development activities for their lead product NELL-1/DBM. Operating expenditures for the next twelve months are estimated at $8.8 million. The accompanying consolidated financial statements for the year ended December 31, 2022 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, the Company incurred a net loss of $1,484,620, and used net cash in operating activities of $3,566,913 during the year ended December 31, 2022. These factors raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

On October 12, 2022, the Company completed a public equity offering, generating gross proceeds to the Company of $5,100,000, and net proceeds, after underwriters discounts and expenses, of approximately $4,454,000 (see Note 5).

The Company will continue to attempt to raise additional debt and/or equity financing to fund future operations and to provide additional working capital. However, there is no assurance that such financing will be consummated or obtained in sufficient amounts necessary to meet the Company's needs. If cash resources are insufficient to satisfy the Company's on-going cash requirements, the Company will be required to scale back or discontinue its product development programs, or obtain funds if available (although there can be no certainties) through strategic alliances that may require the Company to relinquish rights to its technology, substantially reduce or discontinue its operations entirely. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements and related notes include activities of the Company and have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Significant estimates include the assumptions used in the accrual for potential liabilities, the valuation of debt and equity instruments, the valuation of stock options and warrants issued for services, and deferred tax valuation allowances. Actual results could differ from those estimates.

Impact of the Novel Coronavirus (COVID-19) on the Company's Business Operations

The global outbreak of the novel coronavirus (COVID-19) has led to severe disruptions in general economic activities worldwide, as businesses and governments have taken broad actions to mitigate this public health crisis. In light of the uncertain and continually evolving situation relating to the spread of COVID-19, this pandemic could pose a risk to the Company. The extent to which the coronavirus may impact the Company's business operations will depend on future developments, which are highly uncertain and cannot be predicted at this time. The Company intends to continue to monitor the situation and may adjust its current business plans as more information and guidance become available.

The coronavirus pandemic presents a challenge to medical facilities worldwide. As the Company's clinical trials are conducted on an outpatient basis, it is not currently possible to predict the full impact of this developing health crisis on such clinical trials, which could include delays in and increased costs of such clinical trials. Current indications from the clinical research organizations conducting the clinical trials for the Company are that such clinical trials are being delayed or extended for several months as a result of the coronavirus pandemic.

There is also significant uncertainty as to the effect that the coronavirus may have on the amount and type of financing available to the Company in the future.

Inflation

Macroeconomic factors such as inflation, rising interest rates, governmental responses there to and possible recession caused thereby also add significant uncertainty to our operations and possible effects to the amount and type of financing available to the Company in the future.

Cash

Cash primarily consists of bank demand deposits maintained by a major financial institution. The Company's policy is to maintain its cash balances with financial institutions with high credit ratings and in accounts insured by the Federal Deposit Insurance Corporation (the "FDIC") and/or by the Securities Investor Protection Corporation (the "SIPC"). The Company may periodically have cash balances in financial institutions in excess of the FDIC and SIPC insurance limits of $250,000 and $500,000, respectively. The Company has not experienced any losses to date resulting from this policy.

Fair Value of Financial Instruments

Accounting standards require certain assets and liabilities be reported at fair value in the financial statements and provide a framework for establishing that fair value. The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 assumptions: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities including liabilities resulting from embedded derivatives associated with certain warrants to purchase common stock.

There were no financial instruments measured on a recurring basis outstanding as of December 31, 2022. The fair value of financial instruments measured on a recurring basis was as follows as of December 31, 2022:

	As of December 31, 2022			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Liabilities:				
Warrant liability	$ 1,659,468	—	—	$ 1,659,468
Total liabilities at fair value	$ 1,659,468	—	—	$ 1,659,468

As of December 31, 2021, there was no warrant liability. The following table provides a roll-forward of the warrant liability measured at fair value on a recurring basis using unobservable level 3 inputs for the years ended December 31, 2022 as follows:

	2022
Warrant liability	
Balance as of beginning of period – December 31, 2021	$ -
Fair value of warrant liability recognized upon issuance of warrants	5,161,574
Extinguishment of warrant liability upon exercise of warrants	(589,839)
Change in fair value	(2,912,267)
Balance as of end of period – December 31, 2022	$ 1,659,468

The Company's financial instruments are cash, accounts payable and the warrant liability. The recorded values of cash, and accounts payable approximate their values based on their short-term nature.

Prepaid Expenses

At December 31, 2022, prepaid expenses consist of prepaid insurance and prepaid services. Prepaid expenses are amounts paid to secure the use of assets or the receipt of services at a future date or continuously over one or more future periods. When the prepaid expenses are eventually consumed, they are charged to expense. The Company had $956,925 and $-0- in prepaid expenses December 31, 2022 and 2021, respectively.

Research and Development Costs

Research and development costs include, but are not limited to, payroll and other personnel expenses, consultants, expenses incurred under agreements with contract research and manufacturing organizations and animal clinical investigative sites and the cost to manufacture clinical trial materials. Costs related to research, design and development of products are charged to research and development expense as incurred.

Patents and Licenses

Effective April 9, 2019, we entered into an Amended and Restated Exclusive License Agreement dated as of March 21, 2019 and amended through three sets of amendments (as so amended the "Amended License Agreement") with the UCLA TDG. The Amended License Agreement amends and restates the Amended and Restated Exclusive License Agreement, dated as of June 19, 2017 (the "2017 Agreement"). The 2017 Agreement amended and restated the Exclusive License Agreement, effective March 15, 2006, between the Company and UCLA TDG, as amended by ten amendments. See Note 7 for commitments related to the Exclusive License Agreement. Patent expenses include costs to acquire the license of NELL-1, which was de minimis, and costs to file patent applications related to NELL-1.

The Company expenses the costs incurred to file patent applications, all costs related to abandoned patent applications and maintenance costs, and these costs are included in general and administrative expenses. Costs associated with licenses acquired to be able to use products from third parties prior to receipt of regulatory approval to market the related products are also expensed. The Company's licensed technologies may have alternative future uses in that they are enabling (or platform) technologies that can be the basis for multiple products that would each target a specific indication. Costs of acquisition of licenses are expensed.

Stock Based Compensation

ASC 718, *Compensation – Stock Compensation*, prescribes accounting and reporting standards for all share-based payment transactions to employees and non-employes. Transactions include incurring liabilities, or issuing or offering to issue shares, options, and other equity instruments such as employee stock ownership plans and stock appreciation rights. Share-based payments to employees, including grants of employee stock options, are recognized as compensation expense in the consolidated financial statements based on their fair values. That expense is recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period). Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services.

Income Taxes

The Company uses an asset and liability approach for accounting and reporting for income taxes that allows recognition and measurement of deferred tax assets based upon the likelihood of realization of tax benefits in future years. Under the asset and liability approach, deferred taxes are provided for the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A valuation allowance is provided for deferred tax assets if it is more likely than not these items will either expire before the Company is able to realize their benefits, or that future deductibility is uncertain. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. No such amounts are accrued as of December 31, 2022 and 2021.

Loss per Common Share

Basic loss per share is computed by dividing the loss available to common shareholders by the weighted-average number of common shares outstanding during the period. All collateral shares were returned and cancelled on October 13, 2021 when the outstanding debt was converted. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. Diluted loss per common share reflects the potential dilution that could occur if convertible debentures, options and warrants were to be exercised or converted or otherwise resulted in the issuance of common stock that then shared in the earnings of the entity.

Since the effects of outstanding options, warrants, and the conversion of convertible debt are anti-dilutive for the years ended December 31, 2022 and 2021, shares of common stock underlying these instruments have been excluded from the computation of loss per common share.

The following sets forth the number of shares of common stock underlying outstanding options, warrants, and convertible debt as of December 31, 2022 and 2021:

	December 31,	
	2022	2021
Warrants	**13,844,354**	1,827,650
Stock options	**452,829**	241,128
	14,297,183	2,068,778

New Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06 ("ASU 2020-06") "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)." ASU 2020-06 reduces the number of accounting models for convertible debt instruments by eliminating the cash conversion and beneficial conversion models. The diluted net income per share calculation for convertible instruments will require the Company to use the if-converted method. For contracts in an entity's own equity, the type of contracts primarily affected by this update are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement conditions of the derivative scope exception. This update simplifies the related settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective January 1, 2024, for the Company and the provisions of this update can be adopted using either the modified retrospective method or a fully retrospective method. Early adoption is permitted, but no earlier than January 1, 2021, including interim periods within that year. Effective January 1, 2021, the Company early adopted ASU 2020-06 and that adoption did not have an impact on our financial statements and related disclosures.

Other recent accounting pronouncements issued by the FASB, its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future financial statements.

3. Warrant Liability

In October 2022, the Company completed a public equity offering (see Note 5), which included the issuance of 13,001,445 warrants. The warrants provide for a Black Scholes value calculation in the event of certain transactions ("Fundamental Transactions," as defined), which includes a floor on volatility utilized in the value calculation at 100% or greater. The Company has determined that this provision introduces leverage to the holders of the warrants that could result in a value that would be greater than the settlement amount of a fixed-for-fixed option on the Company's own equity shares. Accordingly, pursuant to ASC 815, the Company has classified the fair value of the warrants as a liability to be re-measured at the end of every reporting period with the change in value reported in the statement of operations.

The warrant liability was valued at the following dates using a Black-Scholes model with the following assumptions:

	December 31, 2022	**October 12, 2022 (date issued)**
Warrant liability:		
Risk-free interest rate	4.26%	4.12%
Expected volatility	112.58%	112.73%
Expected life (in years)	4.78	5.0
Expected dividend yield	-	-
Fair Value:		
Warrant liability	$ 1,659,468	$ 5,161,574

The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. Expected volatility was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. The expected term of the warrants granted are determined based on the duration of time the warrants are expected to be outstanding. The dividend yield on the Company's warrants is assumed to be zero as the Company has not historically paid dividends.

4. Income Taxes

The provision for income taxes consists of the following:

Year Ended	**December 31, 2022**	December 31, 2021
Current:		
Federal	**$ -**	$ -
State	**-**	-
Total current	**-**	-
Deferred:		
Federal	**-**	-
State	**-**	-
Total deferred	**-**	-
Provision for income taxes	**$ -**	$ -

The components of deferred tax assets and liabilities consist of the following:

	December 31, 2022	December 31, 2021
Deferred tax assets		
Net operating losses	**$ 10,971,000**	$ 9,189,000
Accrued expenses	**692,000**	693,000
R&D credits	**938,000**	624,000
Stock compensation	**7,751,000**	8,287,000
Total	**20,352,000**	18,793,000
Less: Valuation allowance	**(20,352,000)**	(18,793,000)
	$ -	$ -

The Company's federal and state net operating loss carryforwards at December 31, 2022 and 2021 were approximately $35,757,000 and $32,673,000, respectively, and will begin to expire in 2027 if not utilized.

The Company reviews its deferred tax assets for realization based upon historical taxable income, prudent and feasible tax planning strategies, the expected timing of the reversals of existing temporary differences and expected future taxable income. The Company has concluded that it is more likely than not that the deferred tax assets will not be realized. Accordingly, the Company has recorded a valuation allowance against the net deferred tax assets in the amount of $20,352,000 at December 31, 2022. The net change in the valuation allowance for the year ended December 31, 2022 was $1,559,000.

The effective tax rate differs from the statutory tax rate principally due to the change in valuation allowance, nondeductible permanent differences, credits, and state income taxes.

A reconciliation of the federal income tax rate to the Company's effective tax rate for the years ended December 31, 2022 and 2021 is as follows:

	December 31, 2022	December 31, 2021
Statutory federal income tax rate	**21.0%**	21.0%
State taxes, net of federal tax benefit	**24.9%**	6.2%
Nondeductible permanent items	**(4.4)%**	(0.1)%
Deferred tax rate change	**-%**	-%
Research and development credit	**21.1%**	0.3%
Change in valuation allowance	**(62.6)%**	(27.4)%
Income tax provision	**0.0%**	0.0%

The Company's effective tax rate is 0% for income tax for the years ended December 31, 2022 and 2021. Based on the weight of available evidence, including cumulative losses since inception and expected future losses, the Company has determined that it is more likely than not that the deferred tax asset amount will not be realized and therefore a valuation allowance has been provided on net deferred tax assets.

The Company files tax returns for U.S. Federal, State of Massachusetts, and State of California. The Company is not currently subject to any income tax examinations. Since the Company's inception, the Company had incurred losses from operations, which generally allows all tax years to remain open.

5. Stockholders' Deficit

Preferred Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue a total of 20,000,000 shares of preferred stock. No shares have been issued.

Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue a total of 100,000,000 shares of common stock. As of December 31, 2022 and 2021, the Company had an aggregate of 15,301,986 and 10,350,574 shares of common stock outstanding, respectively.

2022

On October 12, 2022, the Company completed a public offering of 3,777,778 units (the "2022 Units") at a price of $1.35 per unit, generating gross proceeds to the Company of $5,100,000, and net proceeds, after underwriters discounts and expenses, of approximately $4,454,000. Each unit consists of: (i) one share of common stock, par value $0.001 per share; (ii) one Series A warrant to purchase one share of common stock at an exercise price equal to $1.62 per share (120% of the per 2022 Unit offering price), exercisable until the fifth anniversary of the issuance date; (iii) one Series B warrant to purchase one share of common stock at an exercise price equal to $1.35 per share (100% of the per 2022 Unit offering price), exercisable until the fifth anniversary of the issuance date; and (iv) one Series C warrant to purchase one share of common stock at an exercise price equal to $2.16 per share (160% of the per 2022 Unit offering price), exercisable until the fifth anniversary of the issuance date.

The underwriter also received 188,888 warrants as part of the offering at an exercise price of $1.62 per common share representing 5% of the raise.

In October 2022, 1,173,629 Series C warrants were exchanged for 1,173,629 shares of common stock.

2021

On October 15, 2021, the Company completed a public offering (the "October 2021 Primary Offering") of 1,510,455 units (the "2021 Units"). Each Unit consists of one share of common stock of the Company, par value $0.001 per share (the "Common Stock"), and one warrant (a "Warrant") to purchase one share of Common Stock for $6.30 per share. The Units were sold at a price of $5.25 per Unit, generating net proceeds to the Company of $6,858,843. The Company granted to WallachBeth Capital LLC, the underwriter in the Offering, a 45-day option to purchase up to 226,568 additional shares of Common Stock and/or 226,568 Warrants to cover over-allotments, if any. The underwriter has exercised its option with respect to the Warrants. WallachBeth also received 90,627 warrants as part of the October 2021 Primary Offering at an exercise price of $6.30 per common share representing 6% of the raise.

During October 2021, Hankey Capital converted all the outstanding convertible notes in accordance with the original term of the note agreements ($12,767,894 in principal amount and $2,054,041 of accrued interest) into 5,928,774 shares of our common stock and 9,361,702 collateral shares were cancelled.

6. Common Stock Warrants

A summary of warrant activity for the years ended December 31, 2022 and 2021 are presented below:

Subject to Exercise	Number of Warrants	Weighted Average Exercise Price	Weighted Average Life (Years)
Outstanding as of December 31, 2020	91,841	$ 14.88	0.34
Granted – 2021	1,827,650	6.30	5.00
Forfeited/Expired – 2021	(91,841)	-	-
Exercised – 2021	-	-	-
Outstanding as of December 31, 2021	1,827,650	$ 6.30	4.79
Granted – 2022	13,190,333	1.63	5.00
Forfeited/Expired – 2022	-	-	-
Exercised – 2022	(1,173,629)	-	4.78
Outstanding as of December 31, 2022	**13,844,354**	**$ 1.78**	**4.65**

As of December 31, 2022, the Company had outstanding vested and unexercised Common Stock Warrants as follows:

Date Issued	Exercise Price	Number of Warrants	Expiration date
October 2021	$ 6.30	1,827,650	October 13, 2026
October 2022	$ 1.62	4,522,703	October 12, 2027
October 2022	$ 1.35	4,333,815	October 12, 2027
October 2022	$ 0.00	3,160,186	October 12, 2027
Total outstanding warrants at December 31, 2022		**13,844,354**	

Based on a fair market value of $0.21 per share on December 31, 2022, there 3,160,186 exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, the intrinsic value attributed to exercisable but unexercised common stock warrants at December 31, 2022 was $663,639.

7. Stock-based Compensation

2015 Equity Incentive Plan

The Company has 1,077,529 shares of Common Stock authorized and reserved for issuance under our 2015 Equity Incentive Plan for option awards. This reserve may be increased by the Board each year by up to the number of shares of stock equal to 5% of the number of shares of stock issued and outstanding on the immediately preceding December 31. Appropriate adjustments will be made in the number of authorized shares and other numerical limits in our 2015 Equity Incentive Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards granted under our 2015 Equity Incentive Plan which expire, are repurchased or are cancelled or forfeited will again become available for issuance under our 2015 Equity Incentive Plan. The shares available will not be reduced by awards settled in cash. Shares withheld to satisfy tax withholding obligations will not again become available for grant. The gross number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under our 2015 Equity Incentive Plan.

Awards may be granted under our 2015 Equity Incentive Plan to our employees, including officers, director or consultants, and our present or future affiliated entities. While we may grant incentive stock options only to employees, we may grant non-statutory stock options, stock appreciation rights, restricted stock purchase rights or bonuses, restricted stock units, performance shares, performance units and cash-based awards or other stock based awards to any eligible participant.

The 2015 Equity Incentive Plan is administered by our compensation committee. Subject to the provisions of our 2015 Equity Incentive Plan, the compensation committee determines, in its discretion, the persons to whom, and the times at which, awards are granted, as well as the size, terms and conditions of each award. All awards are evidenced by a written agreement between us and the holder of the award. The compensation committee has the authority to construe and interpret the terms of our 2015 Equity Incentive Plan and awards granted under our 2015 Equity Incentive Plan.

A summary of stock option activity for the years ended December 31, 2022 and 2021 are presented below:

Subject to Exercise	Number of Options	Weighted Average Exercise Price	Weighted Average Life (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	226,418	$ 37.00	4.65	$ -
Granted – 2021	48,847	4.24	10.00	-
Forfeited/Expired – 2021	(34,137)	40.48	-	-
Exercised – 2021	-	-	-	-
Outstanding as of December 31, 2021	241,128	$ 32.76	5.43	$ -
Granted – 2022	211,701	2.60	7.17	-
Forfeited/Expired – 2022	-	-	-	-
Exercised – 2022	-	-	-	-
Outstanding as of December 31, 2022	**452,829**	**$ 16.84**	**5.60**	**$ -**
Options vested and exercisable at December 31, 2022	**397,560**	**$ 18.97**	**5.04**	**$ -**

As of December 31, 2022, the Company had outstanding stock options as follows:

Date Issued	Exercise Price	Number of Options	Expiration date
August 2015	$ 39.75	41,624	December 27, 2025
September 2015	$ 39.75	8,000	December 27, 2025
November 2015	$ 39.75	48,986	December 27, 2025
December 2015	$ 39.75	2,228	December 27, 2025
January 2016	$ 39.75	51,032	January 9, 2026
May 2016	$ 51.25	10,766	May 26, 2026
September 2016	$ 51.25	3,973	May 31, 2026
January 2017	$ 51.25	2,142	January 1, 2027
January 2018	$ 49.25	1,566	January 1, 2028
January 2019	$ 2.35	21,964	January 1, 2029
October 2021	$ 5.25	48,847	October 26, 2031
January 2022	$ 3.52	26,166	January 1, 2032
January 2022	$ 3.72	50,000	January 1, 2024
January 2022	$ 3.72	25,000	January 3, 2024
August 2022	$ 1.61	110,535	August 23, 2032
Total outstanding options at December 31, 2022		**452,829**	

Based on a fair value of $0.21 per share on December 31, 2022, there was no intrinsic value attributed to exercisable but unexercised stock options at December 31, 2022.

There were 211,701 options granted during the year ended December 31, 2022 with a fair value of $321,592. Vesting of options differs based on the terms of each option. During the year ended December 31, 2022 and 2021, the Company had stock-based compensation expense of $266,633 and $207,035, respectively, related to the vesting of stock options granted to the Company's employees and directors included in our reported net loss. Our policy is to account for forfeitures of the unvested portion of option grants when they occur; therefore, these forfeitures are recorded as a reversal to expense, which can result in a credit balance in the statement of operations.

The Company utilized the Black-Scholes option-pricing model. The assumptions used for the years ended December 31, 2022 and 2021 are as follows:

	December 31, 2022	December 31, 2021
Risk free interest rate	0.39% - 3.157%	1.21%
Expected life (in years)	1.00 - 5.87	2 - 10
Expected Volatility	96.24% - 112.54%	113.93%
Expected dividend yield	0%	0%

At December 31, 2022, management determined that the Company has limited trading history by which to determine the volatility of its own common stock price. Accordingly, the fair value of the options was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. The risk-free interest rate used in the calculations is based on the implied yield available on U.S. Treasury issues with an equivalent term approximating the expected life of the options as calculated using the simplified method. The expected life of the options used was based on the contractual life of the option granted. Stock-based compensation is a non-cash expense because we settle these obligations by issuing shares of our common stock from our authorized shares instead of settling such obligations with cash payments.

As of December 31, 2022, total unrecognized compensation cost related to unvested stock options was $54,959. The cost is expected to be recognized over a weighted average period of 0.37 years.

8. Commitments and Contingencies

UCLA TDG Exclusive License Agreement

Effective April 9, 2019, we entered into an Amended and Restated Exclusive License Agreement dated as of March 21, 2019 and amended through three sets of amendments (as so amended the "Amended License Agreement") with the UCLA TDG. The Amended License Agreement amends and restates the Amended and Restated Exclusive License Agreement, dated as of June 19, 2017 (the "2017 Agreement"). The 2017 Agreement amended and restated the Exclusive License Agreement, effective March 15, 2006, between the Company and UCLA TDG, as amended by ten amendments. Under the terms of the Amended License Agreement, the Regents have continued to grant us exclusive rights to develop and commercialize NELL-1 (the "Licensed Product") for spinal fusion by local administration, osteoporosis and trauma applications. The Licensed Product is a recombinant human protein growth factor that is essential for normal bone development.

We have agreed to pay an annual maintenance fee to UCLA TDG of $10,000 as well as pay certain royalties to UCLA TDG under the Amended License Agreement at the rate of 3.0% of net sales of licensed products or licensed methods. We must pay the royalties to UCLA TDG on a quarterly basis. Upon a first commercial sale, we also must pay a minimum annual royalty between $50,000 and $250,000, depending on the calendar year which is after the first commercial sale. If we are required to pay any third party any royalties as a result of us making use of UCLA TDG patents, then we may reduce the royalty owed to UCLA TDG by 0.333% for every percentage point paid to a third party. If we grant sublicense rights to a third party to use the UCLA TDG patent, then we will pay UCLA TDG 10% to 20% of the sublicensing income we receive from such sublicense.

We are obligated to make the following milestone payments to UCLA TDG for each Licensed Product or Licensed Method:

- $100,000 upon enrollment of the first subject in a Feasibility Study;
- $250,000 upon enrollment of the first subject in a Pivotal Study:
- $500,000 upon Pre-Market Approval of a Licensed Product or Licensed Method; and
- $1,000,000 upon the First Commercial Sale of a Licensed Product or Licensed Method.

We are also obligated pay to UCLA TDG a fee (the "Diligence Fee") of $8,000,000 upon the sale of any Licensed Product (the "Triggering Sale Date") in accordance with the payment schedule below:

- Due upon cumulative Net Sales equaling $50,000,000 following the Triggering Sale Date - $2,000,000;
- Due upon cumulative Net Sales equaling $100,000,000 following the Triggering Sale Date - $2,000,000; and
- Due upon cumulative Net Sales equaling $200,000,000 following the Triggering Sale Date - $4,000,000.

Our obligation to pay the Diligence Fee will survive termination or expiration of the agreement and we are prohibited from assigning, selling, or otherwise transferring any of its assets related to any Licensed Product unless our Diligence Fee obligation is assigned, sold, or transferred along with such assets, or unless we pay UCLA TDG the Diligence Fee within ten (10) days of such assignment, sale or other transfer of such rights to any Licensed Product.

We are also obligated to pay UCLA TDG a cash milestone payment within thirty (30) days of a Liquidity Event (including a Change of Control Transaction and a payment election by UCLA TDG exercisable after December 22, 2016) such payment to equal the greater of:

- $500,000; or
- 2% of all proceeds in connection with a Change of Control Transaction.

As of December 31, 2022, none of the above milestones has been met.

We are obligated to diligently proceed with developing and commercializing licensed products under UCLA TDG patents set forth in the Amended License Agreement. UCLA TDG has the right to either terminate the license or reduce the license to a non-exclusive license if we do not meet certain diligence milestone deadlines set forth in the Amended License Agreement.

We must reimburse or pre-pay UCLA TDG for patent prosecution and maintenance costs incurred during the term of the Amended License Agreement. We have the right to bring infringement actions against third party infringers of the Amended License Agreement, UCLA TDG may join voluntarily, at its own expense, or, at our expense, be joined involuntarily to the action. We are required to indemnify UCLA TDG against any third party claims arising out of our exercise of the rights under the Amended License Agreement or any sublicense.

Payments to UCLA TDG under the Amended License Agreement for the years ended December 31, 2022 and 2021 were $25,623 and $45,500, respectively.

Development Contracts

During the year ended December 31, 2022, the Company entered into two contracts with one vendor for development activities of NELL-1. At December 31, 2022, there was $295,990 of prepaid expenses and $755,359 in accounts payable for this vendor. Amounts remaining for services contained within the contracts was $5,625,731 at December 31, 2022.

Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations or cash flows.

In July 2019, Dr. Bessie (Chia) Soo and Dr. Kang (Eric) Ting ("Plaintiffs") filed a complaint (the "Complaint") in federal court in Massachusetts against the Company, Bruce Stroever ("Stroever"), John Booth ("Booth"), Stephen LaNeve ("LaNeve", and together with Stroever and Booth, the "Individual Defendants"), and MTF Biologics (f/k/a The Musculoskeletal Transplant Foundation, Inc.) ("MTF"). The Complaint alleges claims for breach of contract against the Company and tortious interference with contract against the Individual Defendants and MTF arising from the termination of the Professional Service Agreements, dated as of January 8, 2016, between the Company and each of the Plaintiffs. The Individual Defendants have been sued for actions taken by them in connection with their service to the Company as directors and/or officers of the Company. As such, the Company has certain indemnification obligations to the Individual Defendants. The Company and the Individual Defendants intend to vigorously defend against the allegations in the Complaint. Although the Complaint was filed several years ago, due to the Covid-19 Pandemic and long delays in the court ruling on various motions to dismiss, in terms of case progression the case is still in its early stages with the claims in the case not being set until April 2022 and preliminary discovery starting since then. Based on the early stage of the litigation, it is not possible to estimate the amount or range of any possible loss arising from the expenditure of defense fees, a judgment or settlement of the matter.

NASDAQ Notice

On November 17, 2022, the Company received a written notice from the NASDAQ Stock Market LLC ("Nasdaq") that the Company has not been in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for a period of 30 consecutive business days. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum closing bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. The Notice has no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is provided a compliance period of 180 calendar days from the date of the Notice, or until May 16, 2023, to regain compliance with the minimum closing bid price requirement. If the Company does not regain compliance during the compliance period ending May 16, 2023, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify for the second compliance period, the Company must (i) meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum closing bid price requirement and (ii) notify Nasdaq of its intent to cure the deficiency. The Company can achieve compliance with the minimum closing bid price requirement if, during either compliance period, the minimum closing bid price per share of the Company's common stock is at least $1.00 for a minimum of 10 consecutive business days. The Company anticipates that its shares of common stock will continue to be listed and traded on the Nasdaq Capital Market during the compliance period(s).

The Company plans to carefully assess potential actions to regain compliance. However, the Company may be unable to regain compliance with the minimum closing bid price requirement during the compliance period(s), in which case the Company anticipates Nasdaq would provide a notice to the Company that its shares of common stock are subject to delisting, and the Company's common shares would thereupon be delisted.

9. Subsequent Events

On January 25, 2023, the Company's CEO, Mr. Frelick, received a stock option grant for 2022 bonus achievements whereby he is entitled to 37,750 shares of Common Stock of the Company as of the date of the grant. Also on January 25, 2023, the Company's CFO, Ms. Walsh, received a stock option grant for 2022 bonus achievements whereby she is entitled to 18,750 shares of Common Stock of the Company as of the date of the grant.

The grants were made on the condition that i) the exercise price will be the current market price on the date of the grant; and ii) the options will be issued with a two-year maturity. Any portion of this stock option grant that is not exercised on the date of termination shall be forfeited on such date of termination except: (i) in the case of Termination by the Company Without Cause; and (ii) upon a Change in Control (as defined in the Equity Incentive Plan) of the Company. To allow Mr. Frelick or Ms. Walsh to prevent or mitigate dilution of their equity interests in the Company, in connection with each financing, Mr. Frelick or Ms. Walsh shall be provided an opportunity to invest in the Company such that their interest, at their option, remains undiluted or partially diluted.

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Stockholder and Corporate Information

Stock Exchange Listing
Nasdaq: BBLG; BBLGW

2023 Annual Meeting
The 2023 annual meeting of stockholders will be held on Tuesday, September 12, 2023, at 11:00 a.m. Eastern Time at our corporate headquarters. Stockholders will be able vote shares at the meeting and may vote prior to the meeting by visiting: www.proxyvote.com

Transfer Agent and Registrar
For services such as change of address, replacement of lost certificates and changes in registered ownership, or for inquiries about your account, contact:
Equiniti Trust
Mail:
EQ Shareowner Services
PO Box 64874, St Paul, MN 55164-0874
Overnight Mail:
EQ Shareowner Services
1110 Centre Pointe Curve, Suite 101, Mendota Heights, MN 55120-4100
Shareowner Services:
U.S. - (800) 401-1957
Canada or U.S. Virgin Islands - (800) 468-9716
Other Locations – See website telephone number.
https://www.shareowneronline.com/

Investor Relations
Investors, stockbrokers, security analysts and others seeking information about us should contact:
LHA Investor Relations
Kim Golodetz
(212) 838-3777
kgolodetz@lhai.com
Additional information about Bone Biologics is available at:
www.bonebiologics.com

Independent Registered Public Accounting Firm
Weinberg & Company, P.A.
Los Angeles, California

Corporate Counsel
Harter Secrest & Emery LLP
Rochester, New York

Executive Officers and Senior Management

Jeffrey Frelick

President and Chief Executive Officer

Deina H. Walsh

Chief Financial Officer

Board of Directors

Don R. Hankey

Chairman of our Board
CEO/Chairman, Hankey Group

Bruce Stroever [1, 2*, 3]

Former CEO, Musculoskeletal Transplant Foundation

Erick Lucera [1*, 2, 3]

Executive Vice President and Chief Financial Officer Editas Medicine, Inc.

Siddhesh Angle [1, 2, 3*]

President and CEO Regenosine

1 Audit Committee

2 Compensation Committee

3 Nominating and Corporate Governance Committee

* Committee Chair

Copies of our Annual Report on Form 10-K and proxy statement filed with the Securities and Exchange Commission and other information pertinent to our investors, including contact information for investor relations inquiries, are available free of charge on the Investors section of our website, www.bonebiologics.com

Bone Biologics Corporations
2 Burlington Woods Drive, Ste 100
Burlington, MA 01803

P: 781-552-4452
www.bonebiologics.com/investor-relation