# 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**

**For the fiscal year ended: December 31, 2025**

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

**For the transition period from _____ to _____**

**Commission File Number: 001-40899**

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

| **Delaware** | **42-1743430** |
|---|---|
| (State or other jurisdiction of incorporation or formation) | (I.R.S. employer identification number) |

**2 Burlington Woods Drive, Ste 100, Burlington, MA 01803**
(Address of principal executive offices) (Zip Code)

**(781) 552-4452**
(Registrant's telephone number, including area code)

**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 Capital Market** |
| Warrants to Purchase Common stock, $0.001 par value per share | **BBLGW** | **The Nasdaq Capital Market** |

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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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. ☐

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 ☒

The approximate aggregate market value of the registrant's common equity held by non-affiliates of the registrant at the close of business on June 30, 2025, was $7,232,186.

As of February 23, 2026, there were 1,795,260 shares of common stock, par value $0.001, outstanding.

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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 "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "project," "seek," "should," "will," "would," 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 U.S. Food and Drug Administration 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," "Bone Biologics," "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*

| | |
|---|---|
| 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 | U.S. Food and Drug Administration |
| HIPAA | Health Insurance Portability and Accountability Act of 1996 |
| 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 |
| PMA | Pre-market approval |
| rhBMP-2 | Recombinant Bone Morphogenic Protein |
| rhNELL-1 | Recombinant NELL-1 |
| 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 U.S. Food and Drug Administration ("FDA") that NELL-1/DBM will be classified as a device/drug combination product that will require an FDA-approved pre-market approval ("PMA") application before it can be commercialized in the United States.

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 platform technology. Our platform technology has been validated in sheep and non-human primate models to facilitate bone growth. We believe 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 clinical-stage entity. The production and marketing of our products and ongoing research and development activities are 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 Federal 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 clinical trials.

Our success will depend in part on our ability to obtain and retain 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.

During 2024, we announced the treatment of the first subjects in the multicenter, prospective, randomized pilot clinical study of our NB1 bone graft device. NB1 is NELL-1 protein combined with demineralized bone matrix (DBM) to provide rapid, specific and guided control over bone regeneration.

The pilot clinical study will evaluate the safety and effectiveness, fusion success, pain, function improvement and adverse events of NB1 in up to 30 adult subjects who undergo transforaminal lumbar interbody fusion (TLIF) to treat degenerative disc disease (DDD). To be enrolled in the study, subjects must have DDD at one level from L2-S1 and may also have up to Grade 1 spondylolisthesis or Grade 1 retrolisthesis at the involved level. The study is being conducted in Australia. The study design was previously reviewed and agreed upon by the FDA's Division of Orthopedic Devices in a Pre-submission to support progression to a pivotal clinical trial in the United States.

#### Product Candidates

We have developed a stand-alone platform technology through significant laboratory and small and large animal research over more than 10 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 that 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 which grants us exclusive rights to develop and commercialize NELL-1 for spinal fusion by local administration, osteoporosis and trauma applications. A major challenge associated with orthopedic surgery is effective bone regeneration, including challenges related to rapid, uncontrolled bone growth that can cause unsound structure; less dense bone formation; unwanted bone formation, and cysts, swelling; and intense inflammatory response to current bone regeneration compounds. We believe NELL-1 will address these unmet clinical challenges for effective bone regeneration, especially in hard healers.

We are currently focused on bone regeneration in lumbar spinal fusion using NELL-1 in combination with DBM, a demineralized bone matrix from MTF Biologics ("MTF"). The combination NELL-1/DBM medical device is an osteopromotive recombinant protein that provides target specific control over bone regeneration. We have successfully surpassed four critical milestones:

- Demonstrated a successful small laboratory scale pilot run for the manufacturing of the recombinant NELL-1 protein in Chinese hamster ovary cells;
- Validated protein dosing and effectiveness in established large animal (sheep) model pilot studies;
- Completed pivotal animal study; and
- Initiated a first-in-man pilot clinical study in Australia.

Our lead product candidate 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, NB1, 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. Use of NB1 will not require changes to the orthobiologic preparation or implantation protocol.

The NELL-1/DBM Fusion Device, NB1, 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 for application in a variety of procedures including:

*Spine Implants*. The global bone graft substitute market presents a $3 billion opportunity per Fortune Business Insights. While use of the patient's own bone, also referred to as autograft, to enhance fusion of vertebral segments is currently the optimal procedure for this type of treatment, complications associated with 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 will perform as well as other growth factors, addressing this $8 billion global market opportunity per Fortune Business Insights.

*Osteoporosis*. The global osteoporosis market presents an $11.2 billion opportunity per Evercore analyst reports. Finding 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, we have continued development with funding through capital raises. Our research and development expenses for the years ended December 31, 2025 and 2024 were $1,060,191 and $2,130,385, respectively.

NELL-1's powerful specific bone forming properties are derived from the ability of NELL-1 to only target cells that exhibit an activated "master switch" to develop into bone. 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 regeneration.

We have completed two preclinical sheep studies that demonstrated our recombinant NELL-1 ("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. Our pivotal sheep study evaluated the effect of rhNELL-1 combined with DBM on lumbar interbody arthrodesis in an adult ovine model and demonstrated a 37.5% increased frequency of fusion at 26 weeks compared with the control.

We began subject enrollment in 2024 in our first-in-man pilot clinical study to evaluate the safety and effectiveness of NB1 in adult subjects with spinal degenerative disc disease at one level from L2-S1, who may also have up to Grade 1 spondylolisthesis or Grade 1 retrolisthesis at the involved level, and are undergoing transforaminal lumbar interbody fusion. The multi-center, prospective, randomized study is being conducted in Australia and will enroll up to 30 subjects. The primary end-point is fusion success at 12 months and change from baseline in the Oswestry Disability Index pain score. We anticipate completing the trial 12 months after enrolling the 30$^{th}$ patient. We intend to use the pilot clinical trial data from the Australia study to enable a future, larger U.S. pivotal clinical study, prior to submission of a PMA to the FDA.

**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 that 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, NB1, will be indicated for spinal fusion procedures in skeletally mature patients with spinal degenerative disk disease ("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 that are 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. NELL-1 induced normal healing, while 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 medical 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. DBM Putty is manufactured by MTF and was cleared by the FDA for use in spine indications 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, NB1, will be regulated as a Class III medical device and will therefore require submission and approval of a PMA.

**Our Business Strategy**

Our business plan is to develop our target-specific growth factor for bone regeneration, based on preclinical and clinical data demonstrating increases in the quantity and quality of bone, and a strong safety profile. Our initial focus on lumbar spinal fusion entails advancing our target-specific growth factor through clinical studies to achieve FDA approval with comparable effectiveness and safety to the gold standard for spine fusion (autografts). 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. 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 June 10, 2025, we implemented a reverse split of the outstanding common stock of the Company at a ratio of 1-for-6.

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.

***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 a 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 Amended License 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 (i) $500,000; or (ii) 2% of all proceeds in connection with a Change of Control Transaction.

During 2024, the first subjects were treated in the multicenter, prospective, randomized pilot clinical study of the Company's NB1 bone graft device, triggering the payment of the initial $100,000 Feasibility Study milestone.

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, 2025 and 2024 were $25,701 and $129,867, respectively.

**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, Globus Medical, 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.

**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 five (5) UCLA TDG issued patents:

| U.S. Patent No. | Summary | Date Issued | Expiration Date |
|---|---|---|---|
| 7833968 | Pharmaceutical compositions for treating or preventing bone conditions | 11/16/2010 | 5/20/2026 |
| 9447155 | Isoform NELL-1 peptide | 9/20/2016 | 11/7/2033 |
| 9974828 | Isoform NELL-1 peptide | 5/22/2018 | 3/24/2030 |
| 11000570 | Isoform NELL-1 peptide | 5/11/2021 | 6/13/2030 |
| 12186367 | Isoform NELL-1 peptide | 1/7/2025 | 6/9/2030 |

These patents will expire between 2026 through 2033. We may be entitled to obtain a patent term extension or extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. Although such extensions may be available, the life of a patent and the protection it affords is by definition limited.

We intend to expand our portfolio through composition of matter, methods of use and methods of production patent applications, as the opportunity arises through the development of our platform technology. We submitted a patent application with the United States Patent and Trademark Office (“USPTO”) in 2025 regarding proprietary compositions of rhNELL-1 polypeptide for treating bone conditions. 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 the USPTO will approve our patent application or the 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. 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.

**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, effectiveness and quality by governmental authorities in the U.S. and other countries. We anticipate 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, effectiveness, 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 drug-device combination product 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 one or more Investigational Device Exemptions ("IDEs") which must become effective before human clinical trials can commence;
- Clinical trials to characterize the effectiveness and safety of the product in the intended patient population;
- The submission of a Pre Market Approval ("PMA") to the FDA; and
- FDA approval of the PMA prior to any commercial sale or shipment of the product.

Several FDA agencies may be involved in the review for a combination product. These include the Center for Devices and Radiological Health, CDRH, the Center for Drug Evaluation and Research, CDER, and the Center for Biological Evaluation and Research, CBER. In addition to obtaining FDA approval for each product, each manufacturing establishment must be registered with, pass a pre-approval inspection 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 Tests***

Non-clinical testing includes laboratory evaluation of chemistry, manufacturing and controls, CMC, as well as tissue culture and animal studies to assess the safety and potential effectiveness of the product. Non-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding good laboratory practices. We have relied and intend to continue to rely on third-party Contract Research Organizations, CROs, to perform GLP non-clinical tests. Non-clinical results can be unpredictable or difficult to interpret. The results of non-clinical testing are submitted to the FDA or Therapeutic Goods Administration (the "TGA") who approve the commencement of clinical trials in the US and Australia, respectively. Unless the FDA or TGA objects, clinical studies may begin.

***Clinical Trials***

Our first-in-man pilot clinical study, with the first subject enrolled in 2024, will evaluate the safety and effectiveness of NB1 in adult subjects with 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. The study has been approved to commence in Australia by the TGA and Ethics Committee(s). The multi-center, prospective, randomized trial will consist of up to 30 subjects in Australia, with the primary effectiveness end-points of fusion success and change from baseline in the Oswestry Disability Index pain score. The trial is managed by an independent Clinical Research Organization that is based in Australia. We anticipate submitting an IDE approximately 12 months after enrolling the $30^{th}$ subject.

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. (which may also include Australia subjects) pivotal IDE clinical study, prior to submission of a PMA to the FDA.

Device clinical trials involve the administration of the investigational product to subjects under the supervision of a qualified investigator/surgeon. 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 effectiveness criteria to be evaluated. In Australia, the effectiveness, quality, safety and timely availability of medical devices is governed by the TGA, through the Therapeutic Goods Act 1989. The approval process for commencing pilot studies in Australia resides with the TGA and the Human Research Ethics Committee. In the United States, the approval process for commencing pilot studies resides with the FDA and Institutional Review Boards prior to its conduct. Further, each clinical study must be conducted under the auspices of an independent safety data monitoring committee ("DMC"). The DMC will consider, among other things, ethical factors and the safety of human subjects.

Both components of the combination device, the drug product and the device that 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 a limited subject population in order to:

- assess the feasibility of the clinical study design;
- assess the potential effectiveness of the product in a non-statistically significant manner;
- identify the lowest dose that is likely to be safe and effective for the indication; and
- identify possible adverse events and safety risks.

When there is evidence that the product may be safe and effective in pilot evaluations, pivotal trials are undertaken within a larger population that can confer statistical assessment 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 subject nor the investigator knows what treatment is being administered. The Company, the DMC, the institutional review board ("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 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 the product's chemistry, manufacturing and controls.

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 labeling and associated Risk Evaluation and Mitigation Strategies, 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 surveillance studies to monitor certain aspects of company's product if it believes that the PMA did not sufficiently address. 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.

***Post-Approval Regulation***

Medical device products manufactured or distributed pursuant to FDA approval are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are also continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with data.

The FDA may impose a number of post-approval requirements as a condition of approval of marketing authorization. For example, the FDA may require post-marketing testing and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, medical device manufacturers and other entities involved in the design, manufacture and distribution of approved products are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMPs requirements. Changes to the manufacturing process are strictly regulated and may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMPs 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. Once approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions. Other potential consequences include, but are not limited to:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the US market. Devices may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In addition, products, if deemed adulterated, can lead to serious consequences as set forth above as well as civil and criminal penalties.

Manufacturing, sales, promotion and other activities of medical devices following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments and governmental agencies.

***Healthcare Law and Regulation***

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of devices that are granted FDA marketing approval. If we obtain FDA approval for our product candidates, arrangements with providers, consultants, third-party payors, and customers will be subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching physicians and patient privacy laws and regulations and other healthcare laws and regulations. Restrictions under applicable federal and state healthcare laws include and are not limited to the U.S. federal Anti-Kickback Statute; the federal civil and criminal false claims laws, including the civil U.S. False Claims Act, and civil monetary penalties laws; the federal false statements statute; the anti-inducement law; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations; the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the U.S. Patient Protection and Affordable Care Act, as amended by the U.S. Health Care and Education Reconciliation Act, collectively, the Affordable Care Act; federal government price reporting laws; and analogous laws and regulations in other national jurisdictions and states, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

***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 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 full-time employees, Jeffery Frelick and Deina Walsh. See “Management” below for biographies of Mr. Frelick and Ms. Walsh. 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.

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. Losing key personnel or failing to recruit necessary additional personnel would impede our ability to attain our development objectives.

**Corporate Information**

Our principal executive offices are located at 2 Burlington Woods Drive, Suite 100, Burlington, MA 01803 and our telephone number is (781) 552-4452. Our website address is www.bonebiologics.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report.

**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 (the "SEC"), 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.

**Risk Factor Summary**

The following is a summary of the principal risks that could materially adversely affect our business operations, industry and financial results.

- Risks Related to Our Financial Position and Capital Needs
    - We have a limited operating history.
    - Our long-term capital requirements are subject to numerous risks.
    - Our recurring operating losses have raised substantial doubt regarding our ability to continue as a going concern.
    - We have incurred losses since inception and we expect our operating expenses to increase in the foreseeable future.
    - We face a number of risks associated with the incurrence of substantial debt which could adversely affect our financial condition.

- 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.
    - FDA regulation is costly and time consuming, which may delay or prevent us from commercializing our product candidates.
    - Any product candidate we advance into clinical trials may cause unacceptable adverse events.
    - Suspensions or delays in the commencement and 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.
    - We have limited resources to pursue product candidates and indications.
    - We may find it difficult to enroll subjects in our clinical trials.
    - Any success in preclinical studies and early clinical trials does not predict the success of later trials; our product candidates may not have favorable results or receive regulatory approval.
    - Risks associated with operating in foreign countries could negatively affect our product development.
    - We may be unable to obtain regulatory approval in non-U.S. jurisdictions.
    - Even if our lead product candidate received regulatory approval, it may still face future development and regulatory difficulties.
    - 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.

- 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.
    - We rely on third parties to supply raw materials for our product candidates and to conduct our preclinical and clinical trials.
    - We depend on third parties, including researchers, who are not under our control.
    - Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our costs and expenses.
    - Our employees may engage in misconduct or other improper activities, which could cause significant liability for us and harm our reputation.

- Risks Related to our Intellectual Property
    - Our ability to compete may be limited or eliminated if we are not able to protect our products.
    - The terms of our patents may not be sufficient to effectively protect our product candidates and business.
    - 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.
    - We may not be able to obtain patent protection to protect our product candidates and technology.
    - We must comply with our obligations under license agreements or risk losing rights that are important to our business.
    - 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, and force us to pay damages.
    - We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.
    - 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.
    - 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 may incur substantial costs in legal proceedings or other actions relating to intellectual property rights.
- 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.

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

    - Our commercial success and ability to generate revenue 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.
    - Our product candidates, if approved, may not be covered or adequately reimbursed by third-party payors.
    - Healthcare legislative measures aimed at reducing healthcare costs may negatively impact our business.

- Risks Related to Our Business Operations

    - We operate in a highly competitive environment.
    - Our future success depends on the performance and continued service of our officers and directors.
    - Competitors could develop and/or gain FDA approval of our products for a different indication.
    - We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
    - The impact of public health crises is difficult to predict and could materially and adversely affect our business and results of operations.
    - Significant disruptions of information technology systems, computer system failures or breaches of information security could adversely affect our business.
    - We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.
    - Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.
    - Our ability to use net operating losses to offset future taxable income may be subject to limitations.

- Risks Related to Healthcare Compliance Regulations

    - If we or they are unable to comply with healthcare laws and regulations, 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.
    - The application of privacy provisions of HIPAA is uncertain.

- Risks Related to Owning our Common Stock

    - The price of our common stock may fluctuate substantially.
    - 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 may be unable to comply with the continued listing standards of the Nasdaq Stock Market LLC (“Nasdaq”).
    - We do not intend to pay cash dividends on our shares of common stock.
    - Our President and Chief Executive Officer and Chief Financial Officer have contractual rights to participate in future financings.
    - If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares.

- General Risk Factors

    - If we are unable to establish appropriate internal financial reporting controls and procedures, it could 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.
    - We may be at risk of securities class action litigation.
    - Market and economic conditions may negatively impact our business, financial condition and share price.
    - 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.
    - Our governing documents and Delaware law have anti-takeover effects that could discourage, delay or prevent a change in control.
    - Provisions of our warrants could discourage an acquisition of us by a third party.
    - 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.

**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 company with a limited operating history will face. In particular, potential investors should consider that there is a significant risk that we will not be able to, among other things:

- implement or execute our current business plan, which may or may not be sound;
- maintain our anticipated management and advisory team;
- raise sufficient funds in the capital markets to effectuate our business plan; and
- utilize the funds that we do have and/or raise in the future to efficiently execute our business strategy.

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 we will need to raise substantial additional funds to achieve FDA approval, if possible, for a spine interbody fusion indication, including costs related to a pivotal clinical trial prior to marketing our first product. 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.

In addition, due to the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of expenses, or when or if we will generate revenue and ultimately be able to achieve or maintain profitability. 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, 2025, we incurred a net loss of $3.1 million and used net cash in operating activities of $2.7 million. Our available cash is expected to fund our operations into the fourth quarter of 2026. In addition, our independent registered public accounting firm, in its audit report to the financial statements as of and for the year ended December 31, 2025, expressed substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment. In order to have sufficient cash and cash equivalents to fund our operations in the future, we will need to raise additional equity or debt capital and cannot provide any assurance that we will be successful in doing so. 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, 2025 have incurred accumulated losses of approximately $88.1 million. We will continue to incur significant expenses for development activities for our lead product candidate NELL-1/DBM.

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 our 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 profitable. 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., including our pilot clinical study which is being conducted in Australia;
- 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 subjects to participate in a clinical trial;
- retaining subjects 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 clinical trials in non-U.S. countries, such as our first-in-man pilot clinical trial being conducted 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 candidate 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 subjects in our clinical trials which could delay or prevent the start of clinical trials for our product candidate.***

Identifying and qualifying subjects 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 subjects 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 subjects, 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;
- subjects' 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 effectiveness 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 subjects to clinical sites;
- subjects 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 subjects 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 effectiveness 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 effectiveness and safety to result in regulatory approval to market our product candidate for a particular indication, in any particular jurisdiction. Effectiveness 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 are conducting our pilot clinical study in Australia and may conduct future studies in countries outside of the U.S. Consequently, we are currently and may be subject in the future 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 effectiveness 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 independent investigators and scientific collaborators 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 we were undertaking those programs ourselves. 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.

***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. 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 have filed a patent application with the USPTO regarding proprietary compositions of rhNELL-1 polypeptide for treating bone conditions. There can be no assurance that the USPTO will approve our patent application. If our patent application is not approved by the USPTO, we may not be able to protect our product candidates.

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.

***The terms of our patents may not be sufficient to effectively protect our product candidates and business.***

In most countries in which we file patent applications, including the U.S., the term of an issued patent is twenty years from the earliest claimed filing date of a non-provisional patent application in the applicable country. With respect to any issued patents in the U.S., we may be entitled to obtain a patent term extension or extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. Although such extensions may be available, the life of a patent and the protection it affords is by definition limited. Even if patents covering our product candidates are obtained, we may be open to competition from other companies as well as generic products once the patent life has expired for a product. Our six currently issued patents are expected to expire on dates ranging approximately from 2026 through 2033, excluding any potential patent term extension or adjustment. Upon the expiration of our issued patents, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our technologies, platforms and product candidates. Moreover, we are a clinical stage entity in the process of completing our pilot clinical study. Because of the extensive time required for development, testing and regulatory review of a potential product, we are many years away from being able to commercialize our product candidates and it is possible that any related patents to our product candidates may expire before they can be commercialized or that such patents will remain in force for only a short period following commercialization, thereby reducing any significant protection or advantage of the patents.

***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.

***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 USPTO, 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 agreement with UCLA TDG. These license agreements may impose various diligence, milestone payment, royalty and other obligations on us, such as those imposed by the license agreement with UCLA TDG. For example, we may enter into exclusive license agreements with various third parties (for example, universities and research institutions) and 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, stop us from commercializing or increase the costs of commercializing our product candidates, and force us to pay damages.***

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 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 USPTO, 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 USPTO 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 and ability to generate revenue 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.***

Our future financial performance will depend upon the introduction and customer acceptance of our products. 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:

- receipt of regulatory approval of marketing claims for the uses that we are developing;
- the effectiveness 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;
- relative convenience and ease of administration;
- 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 government and third-party payors, 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
- the effectiveness of our sales and marketing efforts and those of our collaborators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our proposed formulations or products. If our current product and any future product candidates are approved but fail to achieve market acceptance, 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, and Deina Walsh, our Chief Financial Officer. The loss of services of Mr. Frelick or Ms. Walsh could have a material adverse effect on our business, financial condition or results of operations. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

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

Another company may obtain FDA approval for similar products that might adversely affect our ability to develop and market our product candidates 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 product candidates 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 our product candidates to address, 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 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 or future product candidates. 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 or future product candidates, 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 candidates could allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates. 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 candidates 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 effectiveness 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 candidates 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 or future product candidates. 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 candidates obsolete or non-competitive before we can recover the expenses of development and commercialization.

***The impact of public health crises is difficult to predict and could materially and adversely affect our business and results of operations.***

Any adverse widespread public health developments in locations where we conduct business, as well as any governmental restrictive measures implemented to control such outbreaks and consumer responses to such outbreaks, could have a material adverse impact on our business and results of operations. For instance, our clinical trials may be affected by a public health crisis. 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 the public health crisis efforts, or other reasons related to the public health crisis. During a public health crisis, 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 our operations are adversely impacted by a public health crisis, 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.

Additionally, infections and deaths related to a public health crisis 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. We cannot predict 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. Furthermore, we currently utilize third parties to, among other things, manufacture raw materials. Third-parties in the supply chain for materials used in the production of our product candidates may be adversely impacted by restrictions resulting from public health crises which could limit our ability to manufacture our product candidates for our clinical trials and research and development operations. These impacts could be significant and long term. Further, any actions taken to mitigate any health crises could lead to an economic recession. For example, the COVID-19 pandemic and the efforts to control it caused significantly increased economic uncertainty, global inflationary pressure, supply chain disruptions, volatility in the capital markets, significant economic deterioration, and an increasingly competitive labor market.

The ultimate impact of a public health crisis on our business operations will depend on, among other things, the severity and length of the health crisis, the duration, effectiveness and extent of the mitigation measures and actions designed to contain the outbreak, the emergence, contagiousness and threat of new and different strains of the disease, the availability and effectiveness of vaccines and effective treatments, public acceptance of vaccines and treatments for the disease, if any, as well as the resulting economic conditions and how quickly and to what extent normal economic and operating conditions resume, all of which are highly uncertain. Such extraordinary events and their aftermaths can cause investor fear and panic, which could further materially and adversely affect our operations, the economies in which we operate, and the financial markets generally in ways that cannot necessarily be predicted and 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 a public health crisis could materially and adversely affect our business and the value of our common stock.

***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 our first-in-man pilot clinical study in Australia, we obtained 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. 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, 2025, we had federal net operating loss, or NOLs, carryforwards of approximately $46,140,000. 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 2037. 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 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**

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

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

- our ability to meet the Nasdaq listing requirements;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financing to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- the timing and success of our clinical trials and introduction of products to the market;
- 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;
- safety concerns related to the use of our product candidate;
- 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;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- analyst research reports, recommendations and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigation;
- 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 stock 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.

***Future sales and issuances of our common stock or equity-linked securities 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. 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, and may cause you to lose the value of your investment.

***There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq, a failure of which could result in a delisting of our common stock and certain warrants.***

Nasdaq requires that the trading price of listed stock remain above $1.00 in order for the stock to remain listed. If a listed stock trades below $1.00 for more than 30 consecutive trading days, then it is subject to delisting from the Nasdaq. In addition, to maintain a listing on Nasdaq, we must satisfy minimum financial and other continued listing standards, including those regarding minimum stockholders' equity, minimum publicly available shares, director independence and independent committee requirements and other corporate governance requirements. We recently regained compliance with Nasdaq's listing standards, and Nasdaq will continue to monitor our compliance with its requirements. Nasdaq also recently proposed a rule that, if approved, would require companies to maintain a minimum market value of listed securities ("MVLS") of at least $5 million. If we are unable to satisfy these standards, or if Nasdaq's proposed rule is approved and we fail to maintain a MVLS of at least $5 million for 30 consecutive trading days, we could be subject to delisting, which would have a negative effect on the price of our common stock, impair your ability to sell or purchase our common stock or warrants when you wish to do so, and potentially cause you to lose the value of your investment in us. In the event of a delisting, we would expect to take actions to restore our compliance with the listing standards, but we can provide no assurance that any action we take to restore our compliance would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the minimum bid price requirement, or prevent future noncompliance with the listing requirements.

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 of common stock. Moreover, if we are delisted from Nasdaq, but obtain a substitute listing for our 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 our common stock is delisted from Nasdaq, the value and liquidity of our common stock would likely be significantly adversely affected. A delisting of our common stock from Nasdaq could also adversely affect our ability to obtain financing for our operations and/or result in a loss of confidence by investors, employees and/or business partners.

***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, if any, 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.

***The right of our President and Chief Executive Officer and Chief Financial Officer to participate in future financings of ours could impair our ability to raise capital.***

Jeffrey Frelick, our President and Chief Executive Officer, and Deina Walsh, our Chief Financial Officer, hold contractual preemptive rights which allow them to participate, at their option, in all future financings up to an amount necessary to maintain their percentage interest in our common stock. The existence of such preemptive rights, or the exercise of such rights, may deter potential investors from providing us needed financing, or may deter investment banks from working with us. This may have a material adverse effect on our ability to raise capital which, in turn, could have a material adverse effect on our business prospects.

***If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares.***

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

**General Risk Factors**

***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.***

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, 2025, 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 not, 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.

***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.

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

Concerns over public health crises, energy costs, terrorism and geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit and financial markets and financial conditions, inflationary pressures and interest rate changes, 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. 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. 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 these conditions or 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 relies 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.

***Our Amended and Restated Certificate of Incorporation ("Certificate of Incorporation") and our Amended and Restated Bylaws ("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 Certificate of Incorporation, 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 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.

***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.

***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 Securities Exchange Act of 1934, as amended (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, the Jumpstart Our Business Startups 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. These reporting requirements, rules, and regulations will make some activities more time-consuming and costly and may make it more difficult and more expensive for us to maintain 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.

**Item 1B.** ***Unresolved Staff Comments***

None.

**Item 1C.** ***Cybersecurity***

**Risk Management and Strategy**

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We monitor cybersecurity threats, including any potential unauthorized occurrence on or conducted through information systems that we use through third party providers that may result in adverse effects on the confidentiality, integrity, or availability of any information residing therein.

We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

We have not encountered cybersecurity challenges that have, or are reasonably likely to, materially impair our operations or financial standing.

**Governance**

One of the key functions of our Board of Directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our Board of Directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our Board of Directors administers its cybersecurity risk oversight function directly as a whole.

Our Chief Executive Officer and Chief Financial Officer are primarily responsible to assess and manage our material risks from cybersecurity threats.

Our Chief Financial Officer oversees our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. Under such policies and processes, our Chief Financial Officer is responsible for reporting to our Board of Directors regarding any cybersecurity incidents.

**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 the normal course of our business, we may periodically become subject to various lawsuits. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**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**

Our common stock, par value $0.001 per share, and certain warrants to purchase shares of common stock trade on the Nasdaq Capital Market under the symbols "BBLG" and "BBLGW," respectively.

**Holders**

As of February 23, 2026, there were 22 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Dividends**

We have never declared or paid cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination to pay dividends on the common stock will be at the discretion of our Board of Directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our Board of Directors deems relevant.

**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. 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 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 that will require an FDA-approved PMA before it can be commercialized in the United States.

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 platform technology. Our platform technology has been validated in sheep and non-human primate models to facilitate bone growth. We believe 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 clinical-stage entity. The production and marketing of our products and ongoing research and development activities are 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 Federal 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 clinical trials.

Our success will depend in part on our ability to obtain and retain 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.

During 2024, we announced the treatment of the first subjects in the multicenter, prospective, randomized pilot clinical study of our NB1 bone graft device. NB1 is NELL-1 protein combined with demineralized bone matrix (DBM) to provide rapid, specific and guided control over bone regeneration.

The pilot clinical study will evaluate the safety and effectiveness, fusion success, pain, function improvement and adverse events of NB1 in up to 30 adult subjects who undergo transforaminal lumbar interbody fusion (TLIF) to treat degenerative disc disease (DDD). To be enrolled in the study, subjects must have DDD at one level from L2-S1 and may also have up to Grade 1 spondylolisthesis or Grade 1 retrolisthesis at the involved level. The study is being conducted in Australia. The study design was previously reviewed and agreed upon by the FDA's Division of Orthopedic Devices in a Pre-submission to support progression to a pivotal clinical trial in the United States.

***Reverse Stock Split***

On June 5, 2025, we filed a Certificate of Amendment to our Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a 1-for-6 reverse stock split of our outstanding common stock. The reverse stock split became effective on June 10, 2025. The conversion or exercise prices of our issued and outstanding stock options and warrants were adjusted accordingly in connection with the reverse stock split. All historical share and per share amounts reflected throughout this Annual Report have been adjusted to reflect the reverse stock split.

***June 2025 Public Offering***

On June 27, 2025, we issued investors 793,750 shares of common stock and pre-funded warrants to purchase 456,250 shares of common stock for $4.00 per share (the shares of common stock had a public offering price of $4.00 per share. The pre-funded warrants had a public offering price of $3.999 per share, and the Company also received at closing the pre-funded warrants exercise price of $0.001 per share). In addition, we issued investors Series D warrants to purchase 1,250,000 shares of its common stock (exercise price of $4.00 per share), expiring on June 30, 2030, and Series E warrants to purchase 1,250,000 shares of common stock (exercise price of $4.00 per share), expiring on November 30, 2027. The net proceeds received from the sale of common stock, pre-funded warrants and warrants, net of cash costs of $647,208, were $4,352,792.

On June 27, 2025, 266,250 shares of common stock were issued upon the exercise of 266,250 pre-funded warrants. On June 30, 2025, another 80,000 shares of common stock were issued upon the exercise of 80,000 pre-funded warrants.

On July 1, 2025, 95,000 shares of common stock were issued upon the exercise of 95,000 pre-funded warrants and on July 2, 2025, 15,000 shares of common stock were issued upon the exercise of 15,000 pre-funded warrants.

In addition, warrants to purchase 75,000 shares of common stock were issued to the placement agent. The placement agent warrants have an exercise price of $5.00 per share and were exercisable immediately upon issuance for a term of five years.

***ATM Offering***

In September 2024, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"). Under the ATM Agreement, the Company may, from time to time, in its sole discretion, issue and sell through Wainwright up to $1,143,121 of shares of its common stock. In December 2024, the Company filed a prospectus supplement and increased the aggregate offering that can be sold under the ATM Agreement by $535,000 (the "ATM Facility").

Pursuant to the ATM Agreement, the Company may sell the shares by any method permitted that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act. The Company will pay Wainwright a commission of 3.0% of the gross sales price per share sold under the ATM Agreement.

During the year ended December 31, 2025, the Company sold 52,843 shares of common stock through the ATM Facility for net proceeds of $347,549, after deducting $13,029 in offering costs.

**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, 2025 | Year ended December 31, 2024 | % Change |
|---|---|---|---|
| Operating expenses | | | |
| Research and development | $ 1,060,191 | $ 2,130,385 | (50.23)% |
| General and administrative | 2,174,751 | 2,088,776 | 4.12% |
| Total operating expenses | 3,234,942 | 4,219,161 | (23.33)% |
| Loss from operations | (3,234,942) | (4,219,161) | (23.33)% |
| Change in fair value of warrant liability | 3,967 | 51,081 | (92.23)% |

| | | | |
|---|---|---|---|
| Interest Income | 121,984 | 55,660 | 119.16% |
| Net loss | $ (3,108,991) | $ (4,112,420) | (24.40)% |

*Research and Development*

Research and development expenses decreased from $2,130,385 during the year ended December 31, 2024 to $1,060,191 during the year ended December 31, 2025, a decrease of $1,070,194. This reduction resulted from lower protein needs during our pilot clinical study. We expect ongoing significant investment in NELL-1 development as we prepare for our pivotal clinical study.

*General and Administrative*

Our general and administrative expenses increased by $85,975, from $2,088,776 during the year ended December 31, 2024, to $2,174,751 during the year ended December 31, 2025. The increase is primarily due to the appointment of an independent director in late 2024, replacing a non-independent director. Independent directors receive compensation for their Board duties.

*Change in fair value of warrant liability*

In October 2022, we completed a public equity offering, which included the issuance of 9,029 warrants to purchase shares of common stock that expire in October 2027. 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 Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("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, 2025.

**Liquidity and Capital Resources**

***Going Concern and Liquidity***

We have no significant operating history and since inception to December 31, 2025 have incurred accumulated losses of approximately $88.1 million. We will continue to incur significant expenses for development activities for our lead product NELL-1/DBM. Operating expenditures for the next twelve months are estimated at $4.9 million. The accompanying consolidated financial statements for the year ended December 31, 2025 have been prepared assuming we will continue as a going concern. As reflected in the financial statements, we incurred a net loss of $3.1 million, and used net cash in operating activities of $2.7 million during the year ended December 31, 2025. These factors raise substantial doubt about our ability to continue as a going concern within a reasonable period of time, which is considered to be one year after the date that the financial statements are issued. In addition, our independent registered public accounting firm, in their report on the Company's audited financial statements for the year ended December 31, 2025, expressed substantial doubt about our 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 June 27, 2025, we completed a public offering of common stock, pre-funded warrants and warrants for net proceeds of $4,352,792. See “June 2025 Public Offering” above for additional information.

During the year ended December 31, 2025, we sold 52,843 shares of common stock through the ATM Facility for net proceeds of $347,549, after deducting $13,029 in offering costs.

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 our 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 of December 31, 2025 and 2024, we had cash of $5,334,322 and $3,325,131, respectively.

We expect our available cash to fund our operations into the fourth quarter of 2026.

**Cash Flows**

The following is a summary of our cash flows from operating, investing and financing activities for the years ended December 31, 2025 and 2024:

*Operating activities*

During the year ended December 31, 2025 and 2024, cash used in operating activities was $2,691,150 and $4,124,935 respectively. Cash expenditures for the year ended December 31, 2025 decreased primarily due to our reduced research and development activities.

*Financing activities*

During the year ended December 31, 2025, cash provided by financing activities of $4,700,341 resulted from the net proceeds of our June 2025 public offering of common stock units and proceeds from the ATM Facility. During the year ended December 31, 2024, cash provided by financing activities of $4,423,497 resulted from the net proceeds of our March 2024 public offering of common stock units, warrant inducement offering in August 2024 and proceeds from the ATM Facility.

**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.

**Critical Accounting Policies and Use of Estimates**

***Use of Estimates and Assumptions.***

The preparation of the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("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 related to research, design and development of products are charged to research and development expense as incurred. 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.

***Stock Based Compensation***

ASC 718, Compensation – Stock Compensation, prescribes accounting and reporting standards for all share-based payment transactions to employees and non-employees. 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.

**Recently Issued Accounting Standards**

See discussion in Note 2 to the consolidated financial statements for the year ended December 31, 2025.

**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 and 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 Exchange Act) as of December 31, 2025. Based upon that evaluation, our Chief Financial Officer and Chief Executive Officer concluded that as of December 31, 2025, 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 Exchange Act 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 GAAP 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, 2025, management assessed the effectiveness of our internal control over financial reporting. In making this assessment, management used the criteria set forth in the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control - Integrated Framework (2013)*. Based on the assessment using those criteria, management concluded that as of December 31, 2025, 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, 2025 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 SEC that permit the Company to provide only management's report in this Annual Report.

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

During the three months ended December 31, 2025, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

On February 23, 2026, the Board of Directors determined that its 2026 Annual Meeting of Stockholders (the "2026 Annual Meeting") will be held on August 11, 2026. The 2026 Annual Meeting date, the record date for the 2026 Annual Meeting and detailed information regarding the proposals to be presented at the 2026 Annual Meeting will be set forth in our Definitive Proxy Statement on Schedule 14A to be filed with the SEC. Since the 2026 Annual Meeting will take place more than 60 days after the anniversary of our last annual meeting of stockholders, the due dates for the submission of any qualified stockholder proposal or qualified stockholder nomination under applicable SEC rules and our Bylaws, as amended, listed in our Definitive Proxy Statement on Schedule 14A for our last annual meeting of stockholders, filed with the SEC on April 23, 2025, are no longer applicable. Such nominations or proposals are now due to be received by the Company no later than 90 calendar days prior to the 2026 Annual Meeting, or May 13, 2026, and must comply with all of the applicable requirements set forth in the rules. Stockholder proposals and director nominations should be mailed to the following address: Bone Biologics Corporation, Attention: Corporate Secretary, 2 Burlington Woods Drive, Suite 100, Burlington, MA 01803

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

Not applicable.

## Part III

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

**MANAGEMENT**

The following table sets forth certain information regarding our directors and executive officers as of February 23, 2026:

| Name | Age | Position |
|---|---|---|
| Jeffrey Frelick | 60 | Chief Executive Officer and President |
| Deina H. Walsh | 61 | Chief Financial Officer |
| Bruce Stroever | 76 | Chairman of the Board of Directors |
| Siddhesh Angle | 42 | Director |
| Robert Gagnon | 51 | Director |
| Phil Meikle | 62 | Director |

**Jeffrey Frelick: Chief Executive Officer and President**

Jeffrey Frelick serves as our President and Chief Executive Officer, bringing more than 35 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 was the owner/founder of DHW CPA, PLLC, a public accounting firm. Prior to forming her firm, Ms. Walsh spent 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.

**Bruce Stroever: Chairman of the Board of Directors**

Mr. Stroever has served on the 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 2018 after 30 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 serves on the Board of Donate Life New York State, a non-profit based in Albany, New York. Mr. Stroever received his B.E. in Mechanical/Chemical Engineering from Stevens Institute of Technology in 1972 and a M.S. 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.

**Siddhesh (Sid) R. Angle: Director**

Dr. Angle's appointment to the Board of Directors 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 2025, Dr. Angle also served 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. Dr. Angle holds a PhD from University of Illinois in Bioengineering. 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.

**Robert Gagnon: Director**

Mr. Gagnon became a Board of Directors member on January 8, 2024. He is currently the Chief Financial Officer at Opus Genetics, a role he started in August 2025. Prior to that, he served as CFO for Remix Therapeutics from March 2023 to August 2025, as an Operating Partner at Gurnet Point Capital, a healthcare venture capital and private equity fund, from October 2022 to June 2023, Verastem, Inc. from August 2018 to October 2022, Harvard Bioscience, Inc. from November 2013 to August 2018, and Clean Harbors, Inc. between 2012 and 2013. His professional experience also includes senior roles at Biogen Idec, Deloitte & Touche, and PricewaterhouseCoopers. Mr. Gagnon earned his M.B.A. from MIT Sloan and a B.A. in accounting from Bentley College. He currently sits on the boards of both Verastem, Harvard Bioscience and Purple Biotech Ltd. With his comprehensive expertise in financial management, accounting, and leadership, we believe Mr. Gagnon is well qualified to serve as a member of the Board of Directors.

**Phil Meikle: Director**

Mr. Meikle is a seasoned healthcare executive with over 32 years of orthopedic and spine industry experience. He founded Biosystems of New England, Inc. in 1992 and has served as CEO and President since. He has broad experience representing diverse and innovative orthopedic industry companies in developing and distributing innovative products. He sold his company to Stryker in 2019 and has served as a Stryker consultant for the past five years.

**Family Relationships**

There are no family relationships between any of our directors or executive officers.

## CORPORATE GOVERNANCE

Our Board of Directors consists of four members: Bruce Stroever, Sid Angle, Robert Gagnon and Phil Meikle.

### Director Independence

The listing standards of Nasdaq require that a majority of our Board of Directors be independent. No director will qualify as independent unless the Board of Directors affirmatively determines that the director has no relationship with us that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Based upon the Nasdaq listing standards and applicable SEC rules and regulations, our Board of Directors has determined that each of Bruce Stroever, Sid Angle, Robert Gagnon and Phil Meikle are independent.

### Board of Directors Leadership Structure and Role in Risk Oversight

The Board of Directors believe it is important to select the Company's Chairman and Chief Executive Officer in the manner it considers in the best interests of the Company at any given time. The Board of Directors has elected a Chairman of the Board who is different from the Company's Chief Executive Officer.

The Board of Directors currently is comprised of individuals who are independent from the management of the Company. The Board of Directors and its committees meet regularly throughout the year to assure that the independent directors are well briefed and informed with regard to the Company's affairs. Independent directors have unfettered access to any employee within the Company and are encouraged to call upon whatever employee he deems fit to secure the information each director feels is important to their understanding of our Company. In this fashion, we seek to maintain well informed, independent directors who are prepared to make informed decisions regarding our business affairs.

Management is responsible for the day-to-day management of risks the Company faces, while the Board of Directors as a whole plays an important role in overseeing the identification, assessment and mitigation of such risks. The Board of Directors reviews information regarding the Company's finances and operations, as well as the risks associated with each. For example, the oversight of financial risk management lies primarily with the Board of Directors' Audit Committee, which is empowered to appoint and oversee our independent auditors, monitor the integrity of our financial reporting processes and systems of internal controls and provide an avenue of communication among our independent auditors, management and the Board of Directors. The Company's Compensation Committee is responsible for overseeing the management of risks relating to the Company's compensation plans and arrangements. In fulfilling its risk oversight responsibility, the Board, as a whole and acting through any established committees, regularly consults with management to evaluate and, when appropriate, modify our risk management strategies.

### Board of Directors Committees

Our Board of Directors has appointed a standing audit committee, nominating and corporate governance committee, and compensation committee. Each committee acts pursuant to a written charter adopted by our Board of Directors. The current charters for each board committee are available on our website, www.bonebiologics.com under the heading, "Investors" and the subheading, "Corporate Governance."

*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. In so doing, the Audit Committee maintains free and open means of communication between our directors and management. The Board of Directors has determined that each member of the Audit Committee, consisting of Bruce Stroever, Robert E. Gagnon (Chair), and Sid Angle, meets the independence and financial literacy requirements applicable to audit committee members under the Nasdaq listing standards and SEC rules. The Board of Directors has further determined that Mr. Gagnon qualifies as an "audit committee financial expert" in accordance with the applicable rules and regulations of the SEC. Our Audit Committee was established in accordance with Section 3(a)(58)(A) of the Exchange Act.

*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 Board of Directors has determined that each member of the Compensation Committee, consisting of Bruce Stroever (Chair), Robert E. Gagnon, and Sid Angle, meets the independence requirements applicable to compensation committee members under the Nasdaq listing standards.

*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 of Directors candidates for nomination for election at the annual meeting of stockholders or to fill Board of Directors 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 of Directors committees. The Board of Directors has determined that each member of the Nominating and Corporate Governance Committee, consisting of Bruce Stroever, Robert E. Gagnon, and Sid Angle (Chair), meets the independence requirements applicable to nominating committee members under the Nasdaq listing standards.

**Indemnification Agreements**

Our Board of Directors has approved and we have entered into an indemnification agreement with each of our directors and executive officers ("Indemnification Agreement"). 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.

**Code of Conduct and Ethics**

The Company adopted a formal code of ethics within the meaning of Item 406 of Regulation S-K promulgated under the Securities Act that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and that that establishes, among other things, procedures for handling actual or apparent conflicts of interest. Our Code of Conduct and Ethics is available at our website www.bonebiologics.com/investor-relation.

**Insider Trading Policy**

We have adopted an insider trading policy designed to promote compliance with insider trading laws, rules and regulations, and any listing standards applicable to the Company. Insiders, who include our directors, executive officers, and certain employees who we may designate from time to time (the "Designated Individuals"), may buy and sell our stock within an open "window period," which begins on the first trading day after the release of the Company's quarterly or annual financial results for that particular quarter and ends on the 14$^{th}$ day prior to the close of the next fiscal quarter. Designated Individuals are prohibited from purchasing or selling our stock if they are in possession of material non-public information, even if it is within the open "window period." We reserve the right to impose event-specific black-out periods if we deem certain employees or groups to be in possession of non-public information regarding potentially significant matters, regardless of if it is an open "window period" and we may do so with little or no notice. Employees subject to an event-specific black-out period will be notified by our Chief Financial Officer.

**Anti-Hedging Policy**

Our insider trading policy prohibits directors, officers and employees from engaging in transactions that hedge or offset any decrease in the market value of equity securities granted as compensation.

**Delinquent Section 16(a) Reports**

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, 2025, all Section 16(a) filing requirements applicable to its officers, directors and greater than ten percent beneficial owners were complied with except with respect to Jeffrey Frelick and Deina Walsh who each filed one late Form 4 disclosing one transaction.

**Item 11. *Executive Compensation***

**Summary Compensation Table**

As a smaller reporting company under the Exchange Act, we are providing the following executive compensation information in accordance with the scaled disclosure requirements of Regulation S-K.

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

| Name and Principal Position | Year | Salary ($) | Option Awards ($)[1] | Non-Equity Incentive Plan Compensation ($)[2] | Total Compensation ($) |
|---|---|---|---|---|---|
| Jeffrey Frelick, | 2025 | $ 300,000 | $ 26,269 | $ 100,000 | $ 426,269 |
| Chief Executive Officer and President | 2024 | $ 300,000 | $ 30,788 | $ 54,109 | $ 384,897 |
| Deina Walsh, | 2025 | $ 200,000 | $ 13,136 | $ 50,000 | $ 263,136 |
| Chief Financial Officer | 2024 | $ 200,000 | $ 15,394 | $ 27,054 | $ 242,448 |

(1) Represents the grant date fair value of the option award, calculated in accordance with FASB ASC 718, "Compensation – Stock Compensation," or ASC 718. The assumptions used in calculating the grant date fair value of the option awards for 2025 are set forth in Note 8 of the financial statements included with this Form 10-K.

(2) The amounts shown in this column reflect performance-based cash awards earned during the applicable fiscal year under our executive compensation program.

**Annual Performance-Based Awards**

The Company has an annual performance-based cash award program for our executive officers, which is designed to reinforce the Company's goals and strategic initiatives, and reward our executive officers for meeting objective performance goals for a fiscal year. The annual performance-based awards are determined by 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. For each of the fiscal years ended December 31, 2025 and 2024, annual bonuses were based on achievement of Company goals related to clinical development objectives, business development goals, capital raising and certain investor goals. The target award opportunity under the annual performance-based award program for each of the fiscal years ended December 31, 2025 and 2024 as a percentage of base salary was 50% for Mr. Frelick and 25% for Ms. Walsh.

Following the Compensation Committee's review of the achievement of corporate and individual performance for the fiscal year ended December 31, 2025, the Compensation Committee awarded Mr. Frelick $100,000 in cash and options to purchase 16,668 shares of common stock and Ms. Walsh $50,000 in cash and options to purchase 8,335 shares of common stock, respectively. For fiscal year ended December 31, 2024, the Compensation Committee awarded Mr. Frelick $54,109 in cash and options to purchase 9,019 shares of common stock and Ms. Walsh $27,054 in cash and options to purchase 4,510 shares of common stock, respectively.

**Employment Agreements with Consultants and Named Executive Officers**

*Jeffrey Frelick – Chief Executive Officer and President*

On March 12, 2024, the Company entered into an amended and restated letter agreement, effective as of January 1, 2024 (the "Frelick Agreement"), with Jeffrey Frelick, to serve as the Company's Chief Executive Officer with an annual salary of $300,000. The Frelick Agreement automatically renews for successive one-year periods on January 1st of each calendar year, unless either party provides notice of non-renewal to the other no later than July 9th during any term. Under the terms of the amended and restated agreement, Mr. Frelick is eligible to receive a transaction bonus of 1% to 2% of the transaction value depending on the size of the transaction in the event the Company is acquired. The Frelick agreement contains standard restrictive covenants, including non-competition and non-solicitation, and terms and conditions customarily found in similar agreements.

Pursuant to the Frelick Agreement, he is eligible to earn an annual target bonus of 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 the Compensation Committee (after considering any input or recommendations from Mr. Frelick) within 60 days of 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 50% of Mr. Frelick's base salary. In the event of Mr. Frelick's termination without cause, Mr. Frelick is entitled to receive any unpaid salary and expenses, a payment equal to 12 months of his base salary, a pro-rated annual bonus at the Board of Directors' discretion, and a continuation of benefits for 12 months. 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 Walsh – Chief Financial Officer*

On December 17, 2021, the Company entered into an employment agreement with Ms. Walsh, effective January 3, 2022, to serve as the Company's full-time Chief Financial Officer with an annual salary of $200,000. Ms. Walsh's employment agreement has an indeterminate term and is at will.

Pursuant to Ms. Walsh's employment agreement she is eligible to earn an annual target bonus of 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 60 days of 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 25% of Ms. Walsh's base salary. In the event of Ms. Walsh's termination without cause, Ms. Walsh is entitled to receive any unpaid salary and expenses, a payment equal to 4 months of her base salary, a pro-rated annual bonus at the Board of Directors' discretion, and a continuation of benefits for 4 months. 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.

On March 12, 2024, the Company entered into an amendment (the "Amendment") to the letter agreement between the Company and Ms. Walsh, dated December 17, 2021. The Amendment became effective as of March 11, 2024. Under the terms of the Amendment, Ms. Walsh is eligible to receive a transaction bonus of 0.5% to 1% of the transaction value depending on the size of the transaction in the event the Company is acquired.

**Stock Options**

On January 8, 2026, Mr. Frelick received a stock option grant whereby he is entitled to purchase 16,668 shares of common stock at an exercise price of $1.55. The stock options vested immediately and expire on January 8, 2036. In the event Mr. Frelick is terminated prior to January 8, 2036, any unexercised portion of this stock option grant will be forfeited unless such termination is without Cause, as defined in the 2015 Equity Incentive Plan, in which case the vested and unexercised options will not be forfeited until the earlier of three months from such termination or January 8, 2036.

On January 8, 2026, Ms. Walsh received a stock option grant whereby she is entitled to purchase 8,335 shares of common stock at an exercise price of $1.55. The stock options vested immediately and expire on January 8, 2036. In the event Ms. Walsh is terminated prior to January 8, 2036, any unexercised portion of this stock option grant will be forfeited unless such termination is without Cause, as defined in the 2015 Equity Incentive Plan, in which case the vested and unexercised options will not be forfeited until the earlier of three months from such termination or January 8, 2036.

On January 15, 2025, Mr. Frelick received a stock option grant whereby he is entitled to purchase 9,019 shares of common stock at an exercise price of $5.82. The stock options vested immediately and expire on January 15, 2027. In the event Mr. Frelick is terminated prior to January 15, 2027, any unexercised portion of this stock option grant will be forfeited unless such termination is without Cause, as defined in the 2015 Equity Incentive Plan, in which case the vested and unexercised options will not be forfeited until the earlier of three months from such termination or January 15, 2027.

On January 15, 2025, Ms. Walsh received a stock option grant whereby she is entitled to purchase 4,510 shares of common stock at an exercise price of $5.82. The stock options vested immediately and expire on January 15, 2027. In the event Ms. Walsh is terminated prior to January 15, 2027, any unexercised portion of this stock option grant will be forfeited unless such termination is without Cause, as defined in the 2015 Equity Incentive Plan, in which case the vested and unexercised options will not be forfeited until the earlier of three months from such termination or January 15, 2027.

Our Compensation Committee believes the compensation under the employment agreements and other incentives granted to our named executive officers align our named executive officers' interests with those of our stockholders. Our Compensation Committee and Board of Directors continue 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.

**Outstanding Equity Awards at Fiscal Year End**

| Name | Number of securities underlying unexercised options (#) exercisable | Option exercise price ($) | Option expiration date |
|---|---|---|---|
| (a) | (b) | (e) | (f) |
| Jeffrey Frelick, Chief Executive Officer and President | 9,019 | $ 5.82 | January 15, 2027 |
| | 4,167 | $ 21.66 | January 17, 2026 |
| | 8 | $ 73,800.00 | May 26, 2026 |
| Deina Walsh, Chief Financial Officer | 4,510 | $ 5.82 | January 17, 2026 |
| | 2,084 | $ 21.66 | January 17, 2026 |

**Director Compensation**

As a smaller reporting company under the Exchange Act, we are providing the following director compensation information in accordance with the scaled disclosure requirements of Regulation S-K.

The following table shows information regarding the compensation earned during the year ended December 31, 2025 by the members of our Board of Directors.

| Name | Fees Earned or Paid in Cash | Option Awards[(1)] | Total |
|---|---|---|---|
| Bruce Stroever | $ 40,000 | $ 64,089 | $ 104,089 |
| Sid Angle | 30,000 | 64,089 | 94,089 |
| Robert Gagnon | 30,000 | 64,089 | 94,089 |
| Phil Meikle | 25,000 | 64,089 | 89,089 |

(1) The amounts in this column reflect the aggregate grant date fair value of stock options under FASB ASC Topic 718, which was determined using a Black-Scholes option-pricing model with the assumptions that will be disclosed in our consolidated financial statements for the fiscal year 2025. The following table provides information regarding equity awards held by each independent non-employee director as of December 31, 2025:

| Name | Stock Options Outstanding (#) |
|---|---|
| Bruce Stroever | 17,425 |
| Sid Angle | 17,438 |
| Robert Gagnon | 16,939 |
| Phil Meikle | 15,183 |

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

**Annual Cash Compensation**

Each member of the Board of Directors who (i) is an independent director under applicable Nasdaq Listing Rules, except that the amount of compensation as referred to in the Nasdaq Rule 5605 shall not exceed $10,000 per year and/or (ii) does not beneficially own, or is not a director or executive officer of an entity which beneficially owns, 5% or more of the Company's common stock (each such member an, "Independent Director") will receive compensation set forth below for service on the Board of Directors. 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 Independent Directors other than the Board of Directors Chair: $25,000
    b. Independent Director who is the Board of Directors Chair: $35,000

2. Annual Committee Chair Service Retainer (in addition to Annual Board of Directors 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 the Company's 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 on the date of grant.

(a) Automatic Equity Grants.

(i) **Initial Grant for New Directors.** Without any further action of the Board of Directors, each person who, after the Effective Date, is elected or appointed for the first time to be an Independent Director will automatically, upon the date of his or her initial election or appointment to be an Independent Director, be granted a Nonstatutory Stock Option to purchase 2 shares of common stock (the "Initial Grant"), regardless of when such person is elected or appointed to the Board of Directors. 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 of Directors, at the close of business on the date of each Annual Meeting following the Effective Date, each person who is then an Independent Director will automatically be granted to 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 successive equal quarterly installments over the one-year period measure from the date of grant.

(iii) **Pro-rated Annual Grant**. If a person is elected or appointed to the Board of Directors at a time other than at the annual stockholder meeting, then on the date of such election or appointment, the person will be automatically, and without further action by the Board of Directors, granted an Annual Grant covering a pro-rated number of shares of common stock pursuant to the Director Compensation Policy.

**Policies and Practices Related to the Grant of Certain Equity Awards**

We have adopted a policy governing the grant of equity awards in order to create a framework for the consistent process for the granting of equity awards and to ensure the integrity and efficiency of our equity award process. Equity awards, including stock options, are granted in accordance with a predetermined schedule. Initial grants of equity awards, including stock options, to newly appointed Independent Directors are granted as of the date of the Independent Director's appointment to the Board of Directors. Annual grants of equity awards, including stock options, to Independent Directors are made at the close of business on the date of each annual meeting of stockholders. Equity awards, including stock options, to executive officers are granted on the third Wednesday in the month of January, or as soon as reasonably practicable thereafter.

Our Compensation Committee does not purposely accelerate or delay the public release of material information in order to allow the award recipient to benefit from a more favorable stock price. Management advises the Compensation Committee and the Board of Directors whenever it is aware that material non-public information is planned to be released to the public in close proximity to the grant date of any equity award, including stock options.

During the fiscal ended December 31, 2025, we did not grant any equity awards, including stock options, to our named executive officers in the period beginning four business days before and ending one business day after the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a current report on Form 8-K that disclosed material non-public information.

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

**Equity Compensation Plan Information**

The following table summarizes the number of shares subject to currently outstanding equity awards, their weighted-average exercise price, and the number of shares available for future grants under our equity compensation plans as of December 31, 2025:

| 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 | 87,777 | $ 53.62 | 5,017,138 |
| Equity compensation plans not approved by security holders | - | - | - |
| Total | 87,777 | $ 53.62 | 5,017,138 |

**Security Ownership of Management and Certain Beneficial Owners**

The following table sets forth information, as of February 23, 2026, regarding the beneficial ownership of our common stock by:

- each person known by us to be a beneficial owner of more than five percent of our outstanding common stock;
- each of our directors and director nominee;
- each of our named executive officers; and
- all directors and executive officers as a group.

The amounts and percentage of common stock beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, a person is deemed to be a "beneficial owner" of a security if that person has or shares "voting power," which includes the power to vote or to direct the voting of such security, or "investment power," which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which that person has a right to acquire beneficial ownership within 60 days. Under these rules, more than one person may be deemed a beneficial owner of the same securities and a person may be deemed a beneficial owner of

securities as to which he has no economic interest. Except as indicated by footnote, the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them.

| Name of Beneficial Owner or Identity of Group | Shares[1] | Percentage |
|---|---|---|
| **5% or greater stockholders:** | | |
| Intracoastal Capital LLC[2] | 199,251 | 9.9% |
| **Executive Officers and Directors[3]:** | | |
| Jeffrey Frelick | 26,055 [4] | 1.4% |
| Sid Angle | 14,817 [5] | * |
| Bruce Stroever | 14,804 [6] | * |
| Deina H. Walsh | 13,158 [7] | * |
| Robert E. Gagnon | 14,318 [8] | * |
| Phil Meikle | 12,562 [9] | * |
| **Total Officers and Directors as a Group (6 persons)** | 95,714 [10] | 5.1% |

* Represents beneficial ownership of less than 1% of our outstanding common stock.

(1) Based on 1,795,260 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 within 60 days from our report date.

(2) This information is based on a Schedule 13G/A filed with the SEC on November 7, 2025 by Intracoastal Capital LLC ("Intracoastal"), Daniel B. Asher and Mitchell P. Kopin, which reports shared voting and dispositive power of 199,251 shares of common stock issuable upon exercise of a warrant held by Intracoastal (the "Warrant"), based on 1,795,260 shares of common stock outstanding as of August 14, 2025, plus 199,251 shares of common stock issuable upon the exercise of the Warrant. Due to certain beneficial ownership blockers, the foregoing excludes (i) 50,749 shares of common stock issuable upon exercise of the Warrant, (ii) 250,000 shares of common stock issuable upon exercise of a second warrant held by Intracoastal, (iii) 5 shares of common stock issuable upon exercise of a third warrant held by Intracoastal, (iv) 6,185 shares of common stock issuable upon exercise of a fourth warrant held by Intracoastal, (v) 32,552 shares of common stock issuable upon exercise of a fifth warrant held by Intracoastal, and (vi) 32,552 shares of common stock issuable upon exercise of a sixth warrant held by Intracoastal. Without such blocker provisions, each of the reporting persons may have been deemed to have beneficial ownership of 571,294 shares of common stock. The principal business office of Mr. Kopin and Intracoastal is 245 Palm Trail, Delray Beach, Florida 33483. The principal business office of Mr. Asher is 1011 Lake Street, Suite 311, Oak Park, Illinois 60301.

(3) Except as indicated by footnote, the address for our executive officers and directors is 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803.

(4) Includes 25,695 shares underlying stock options exercisable within 60 days.

(5) Includes 14,817 shares underlying stock options exercisable within 60 days.

(6) Includes 14,804 shares underlying stock options exercisable within 60 days.

(7) Includes 12,845 shares underlying stock options exercisable within 60 days.

(8) Includes 14,318 shares underlying stock options exercisable within 60 days.

(9) Includes 12,562 shares underlying stock options exercisable within 60 days.

(10) Consists of 673 shares and 95,041 shares underlying stock options exercisable within 60 days.

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

Since January 1, 2024, 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.

**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 members: Bruce Stroever, Sid Angle, Robert Gagnon and Phil Meikle. 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 all directors qualify as "independent" as that term is defined by Nasdaq Listing Rule 5605(a)(2) and pursuant to applicable provisions of the Exchange Act, based upon the Nasdaq listing standards and applicable SEC rules and regulations. In making such determinations, our Board of Directors considered the relationships that each of our 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 director.

**Item 14.** ***Principal Accountant 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 tables set forth the aggregate fees billed to us by Weinberg & Company, P.A. during the years ended December 31, 2025 and 2024.

| | 2025 | 2024 |
|---|---|---|
| Audit Fees | $ 111,155 | $ 89,108 |
| Audit Related Fees | 36,000 | 89,620 |
| Tax fees | - | - |
| All other fees | - | - |
| Total | $ 147,155 | $ 178,728 |

***Audit Fees***

Audit fees during the years ended December 31, 2025 and 2024 were for professional services rendered for the audit of our annual consolidated financial statements, for the reviews of our quarterly financial statements, and for services that are normally provided in connection with statutory and regulatory filings or engagements.

***Audit Related Fees***

Audit-related fees consist of fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under “Audit Fees.”

***Tax Fees***

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

***All Other Fees***

There were no fees billed to us by Weinberg & Company, P.A. for services not set forth above.

## Part IV

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

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

(1) Financial Statements:


| | |
|---|---|
| Report of Independent Registered Public Accounting Firm (PCAOB ID: 572) | F-2 |
| Consolidated Balance Sheets | F-3 |
| Consolidated Statements of Operations | F-4 |
| Consolidated Statements of Stockholders' Deficit | F-5 |
| Consolidated Statements of Cash Flows | F-6 |
| Notes to Consolidated Financial Statements | F-7 |


(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 Number | Exhibit Title | Incorporated by reference (unless otherwise indicated) | | | |
|---|---|---|---|---|---|
| | | Form | File | Exhibit | Filing date |
| 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. | 8-K | 000-53078 | 2.1 | September 25, 2014 |
| 2.2 | Certificate of Merger as filed with the California Secretary of State effective September 19, 2014 | 8-K | 000-53078 | 2.2 | September 25, 2014 |
| 3.1 | Amended and Restated Certificate of Incorporation of Bone Biologics Corporation | 8-K | 000-53078 | 3.1(i) | September 25, 2014 |
| 3.2 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of Bone Biologics Corporation | 8-K | 000-53078 | 3.1 | October 15, 2021 |
| 3.3 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of Bone Biologics Corporation | 8-K | 001-40899 | 3.1 | June 6, 2023 |
| 3.4 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of Bone Biologics Corporation | 8-K | 001-40899 | 3.1 | December 18, 2023 |
| 3.5 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation, filed June 5, 2025 | 8-K | 001-40899 | 3.1 | June 6, 2025 |
| 3.6 | Amended and Restated Bylaws of Bone Biologics Corporation | 8-K | 001-40899 | 3.1 | March 8, 2022 |
| 3.7 | Amendment No. 1 to the Amended and Restated Bylaws of Bone Biologics Corporation | 8-K | 001-40899 | 3.1 | October 24, 2023 |

| | | | | | |
|---|---|---|---|---|---|
| 4.1 | Warrant Agent Agreement between the Company and Equiniti Trust Company dated as of October 13, 2021 | 8-K | 000-53078 | 4.1 | October 15, 2021 |
| 4.2 | Form of Warrant (October 2021) | S-1 | 333-276771 | 4.2 | January 30, 2024 |
| 4.3 | Form of Representative's Warrant (October 2021) | 8-K | 000-53078 | 1.1 | October 15, 2021 |
| 4.4 | Warrant Agent Agreement between the Company and Equiniti Trust Company dated as of October 7, 2022 | 8-K | 001-40899 | 4.1 | October 11, 2022 |

| | | | | | |
|---|---|---|---|---|---|
| 4.5 | Form of Series A Warrant (October 2022) | S-1 | 333-276771 | 4.5 | January 30, 2024 |
| 4.6 | Form of Series B Warrant (October 2022) | S-1 | 333-276771 | 4.6 | January 30, 2024 |
| 4.7 | Form of Series C Warrant (October 2022) | S-1 | 333-276771 | 4.7 | January 30, 2024 |
| 4.8 | Form of Representative's Warrant (October 2022) | 8-K | 001-40899 | 1.1 | October 11, 2022 |
| 4.9 | Form of Warrant (November 2023) | S-3 | 333-276412 | 4.1 | January 5, 2024 |
| 4.10 | Form of Placement Agent Warrant (November 2023) | 8-K | 001-40899 | 4.2 | November 20, 2023 |
| 4.11 | Form of Warrant dated March 6, 2024 | 8-K | 001-40899 | 4.1 | March 6, 2024 |
| 4.12 | Form of Placement Agent Warrant dated March 6, 2024 | 8-K | 001-40899 | 4.3 | March 6, 2024 |
| 4.13 | Form of New Warrant dated August 2, 2024 | 8-K | 001-40899 | 4.1 | August 2, 2024 |
| 4.14 | Form of Placement Agent Warrant dated August 2, 2024 | 8-K | 001-40899 | 4.2 | August 2, 2024 |
| 4.15 | Form of Series D Warrant dated June 30, 2025 | 8-K | 001-40899 | 4.1 | June 30, 2025 |
| 4.16 | Form of Series E Warrant dated June 30, 2025 | 8-K | 001-40899 | 4.2 | June 30, 2025 |
| 4.17 | Form of Placement Agent Warrant dated June 30, 2025 | 8-K | 001-40899 | 4.4 | June 30, 2025 |
| 4.18* | Description of Securities | - | - | - | - |
| 10.1+ | Director Offer Letter, dated July 1, 2014, by and between Bruce Stroever and Bone Biologics Corporation | 8-K | 000-53078 | 10.4 | September 25, 2014 |
| 10.2+ | Form of Indemnification Agreement | S-1 | 333-276771 | 10.2 | January 30, 2024 |
| 10.3+ | Amended and Restated Employment Agreement, dated January 1, 2024, by and between Bone Biologics Corporation and Jeffrey Frelick | 10-Q | 001-40899 | 10.2 | May 14, 2024 |
| 10.4+ | Employment Agreement dated December 17, 2021 between the Company and Deina Walsh | 8-K | 001-40899 | 10.1 | December 22, 2021 |
| 10.5+ | Amendment No. 1 to Employment Agreement dated December 17, 2021 between the Company and Deina Walsh | 10-Q | 001-40899 | 10.3 | May 14, 2024 |

| | | | | | |
|---|---|---|---|---|---|
| 10.6+ | Bone Biologics Corporation Non-Employee Director Compensation Policy | 8-K | 000-53078 | 10.1 | January 4, 2016 |
| 10.7+ | Bone Biologics Corporation 2015 Equity Incentive Plan | 8-K | 000-53078 | 10.3 | January 4, 2016 |
| 10.8+ | First Amendment to the Bone Biologics Corporation 2015 Equity Incentive Plan | Schedule 14A | 001-40899 | Appendix B | August 3, 2023 |
| 10.9+ | Second Amendment to the Bone Biologics Corporation 2015 Equity Incentive Plan | 8-K | 001-40899 | 10.1 | May 30, 2025 |
| 10.10+ | Form of Stock Option Grant Notice and Option Agreement for the Bone Biologics Corporation 2015 Equity Incentive Plan | 8-K | 000-53078 | 10.4 | January 4, 2016 |
| 10.11+ | Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement | 8-K | 000-53078 | 10.5 | January 4, 2016 |
| 10.12 | 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 | 8-K | 000-53078 | 10.1 | April 16, 2019 |

| | | | | | |
|---|---|---|---|---|---|
| 10.13 | First Amendment to the Amended License Agreement dated August 13, 2020 between the Company and the Regents of the University of California | S-1/A | 333-257484 | 10.40 | October 7, 2021 |
| 10.14 | Third Amendment to the Amended License Agreement dated June 8, 2022 between the Company and the Regents of the University of California | 8-K | 001-40899 | 10.1 | June 9, 2022 |
| 10.15 | Supply and Development Support Agreement dated March 3, 2022 between the Company and Musculoskeletal Transplant Foundation, Inc. | 10-K | 001-40899 | 10.30 | March 15, 2022 |
| 10.16 | At The Market Offering Agreement, dated September 27, 2024, by and between Bone Biologics Corporation and H.C. Wainwright & Co., LLC | 8-K | 001-40899 | 1.1 | September 27, 2024 |
| 10.17 | Form of Securities Purchase Agreement dated June 27, 2025 | 8-K | 001-40899 | 10.1 | June 30, 2025 |
| 19.1 | Bone Biologics Corporation Insider Trading Policy | 10-K | 001-40899 | 19.1 | February 26, 2025 |
| 21.1* | List of Subsidiaries | — | — | — | — |
| 23.1* | Consent of Independent Registered Public Accounting Firm, Weinberg & Company, P.A. | — | — | — | — |
| 24* | Power of Attorney (included in signature page hereto) | — | — | — | — |
| 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, 2025. | — | — | — | — |
| 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, 2025. | — | — | — | — |
| 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. | — | — | — | — |
| 97 | Policy for the Recovery of Erroneously Awarded Compensation | 10-K | 001-40899 | 97 | February 21, 2024 |
| 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.
** Furnished herewith.
+ Management contract or compensatory arrangement.
± Certain information has been omitted from this exhibit in reliance upon Item 601(a)(5) of Regulation S-K and will be furnished to the Securities and Exchange Commission upon request.

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

None.

**SIGNATURES**

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

March 2, 2026

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*<br>Jeffrey Frelick | Chief Executive Officer (Principal Executive Officer) | March 2, 2026 |
| */s/ Deina H. Walsh*<br>Deina H. Walsh | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | March 2, 2026 |
| */s/ Bruce Stroever*<br>Bruce Stroever | Director | March 2, 2026 |
| */s/ Robert Gagnon*<br>Robert Gagnon | Director | March 2, 2026 |
| */s/ Siddhesh Angle*<br>Siddhesh Angle | Director | March 2, 2026 |
| */s/ Phillip Meikle*<br>Phillip Meikle | Director | March 2, 2026 |

**Bone Biologics Corporation**

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## 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, 2025 and 2024, the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

**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, 2024, the Company incurred a net loss of $3.1 million and used cash in operating activities of $2.7 million. 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 the Company's 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 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 a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

*Accounting for June 2025 Public Offering and Equity Classification of Warrants*

As described in Note 6 to the consolidated financial statements, in June 2025 the Company entered into a Securities Purchase Agreement and completed a public offering of common stock, pre-funded warrants, and warrants, resulting in net proceeds of approximately $4.4 million. The Company evaluated the terms of the pre-funded warrants and warrants under ASC 815, including the scope exception in ASC 815-40, and concluded the instruments qualified for equity classification.

We identified the evaluation of the warrant terms and the related accounting classification as a critical audit matter because auditing management's analysis involved especially challenging auditor judgment in assessing multiple tranches of warrants with differing

exercise prices and features, and in applying the complex guidance in ASC 815-40 to determine whether the instruments met the criteria for equity classification rather than liability treatment.

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

● We obtained and read the Securities Purchase Agreement and all related warrant agreements and evaluated the key contractual terms, including exercise prices, expiration dates and settlement provisions.
● We evaluated management's accounting analysis and assessed the appropriateness of the equity classification conclusion by reference to the criteria in ASC 815-40.
● We recalculated the allocation of proceeds and evaluated the related financial statement disclosures.

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

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 2, 2026

**Bone Biologics Corporation**
**Consolidated Balance Sheets**

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| **Assets** | | |
| **Current Assets** | | |
| Cash | **$ 5,334,322** | $ 3,325,131 |
| Advances on research and development contract services | **208,972** | 258,059 |
| Prepaid insurance | **232,946** | 268,179 |
| Interest Receivable | **9,895** | - |
| Prepaid expenses | **10,000** | 10,000 |
| Total current assets | **$ 5,796,135** | $ 3,861,369 |
| Total assets | **$ 5,796,135** | $ 3,861,369 |
| **Liabilities and Stockholders' Equity** | | |
| **Current Liabilities** | | |
| Accounts payable and accrued expenses | **$ 417,884** | $ 373,042 |
| Warrant liability | **703** | 4,670 |
| Total current liabilities | **418,587** | 377,712 |
| Total liabilities | **418,587** | 377,712 |
| **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, 2025 and 2024 | **-** | - |
| Common stock, $0.001 par value per share; 100,000,000 shares authorized; 1,795,260 and 492,417 shares issued and outstanding at December 31, 2025 and 2024, respectively[(1)] | **1,795** | 492 |
| Additional paid-in capital[(1)] | **93,506,122** | 88,504,543 |
| Accumulated deficit | **(88,130,369)** | (85,021,378) |
| Total stockholders' equity | **5,377,548** | 3,483,657 |
| Total liabilities and stockholders' equity | **$ 5,796,135** | $ 3,861,369 |

(1) Adjusted to reflect the reverse stock split as described in Note 1.

*See accompanying notes to consolidated financial statements.*

**Bone Biologics Corporation**
**Consolidated Statements of Operations**

| | Year Ended December 31, 2025 | Year Ended December 31, 2024 |
|---|---|---|
| **Revenues** | **$ -** | **$ -** |
| **Operating expenses** | | |
| Research and development | **1,060,191** | 2,130,385 |
| General and administrative | **2,174,751** | 2,088,776 |
| **Total operating expenses** | **3,234,942** | 4,219,161 |
| **Loss from operations** | **(3,234,942)** | (4,219,161) |
| Other income | | |
| Change in fair value of warrant liability | **3,967** | 51,081 |
| Interest income | **121,984** | 55,660 |
| **Total other income** | **125,951** | 106,741 |
| **Net loss** | **(3,108,991)** | (4,112,420) |
| Deemed dividend on warrant inducements | **-** | (3,212,504) |
| **Net loss attributable to common stockholders** | **$ (3,108,991)** | $ (7,324,924) |
| **Weighted average shares of common outstanding – basic and diluted[(1)]** | **1,174,869** | 252,960 |
| **Loss per share – attributable to common stockholders, basic and diluted[(1)]** | **$ (2.65)** | $ (28.96) |

(1) Adjusted to reflect the reverse stock split as described in Note 1.

*See accompanying notes to consolidated financial statements.*

**Bone Biologics Corporation**
**Consolidated Statement of Stockholders' Equity[(1)]**

| | *Common Stock* | | Additional Paid-in | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Equity |
| Balance at December 31, 2023 | 89,127 | $ 89 | $ 83,815,230 | $(80,908,958) | $ 2,906,361 |
| Fair value of vested stock options | - | - | 188,819 | - | 188,819 |
| Options issued to settle accrued bonus | - | - | 77,400 | - | 77,400 |
| Proceeds from sale of common stock, warrants, and pre-funded warrants in public offering, net of offering costs of $495,227 | 19,833 | 20 | 1,504,093 | - | 1,504,113 |
| Exercise of pre-funded warrants | 110,376 | 110 | 552 | - | 662 |
| Issuance of common shares from warrant inducement, net of costs of $287,233 | 130,208 | 130 | 1,806,390 | - | 1,806,520 |
| Incremental value of warrant inducement | - | - | 3,212,504 | - | 3,212,504 |
| Deemed dividend on warrant inducement | - | - | (3,212,504) | - | (3,212,504) |
| Issuance of common shares from ATM, net of costs of $205,256 | 142,873 | 143 | 1,112,059 | - | 1,112,202 |
| Net Loss | - | - | - | (4,112,420) | (4,112,420) |
| Balance at December 31, 2024 | 492,417 | 492 | 88,504,543 | (85,021,378) | 3,483,657 |
| Fair value of vested stock options | - | - | 256,358 | - | 256,358 |
| Options issued to settle accrued bonus | - | - | 46,183 | - | 46,183 |
| Issuance of common shares from ATM, net of costs of $13,029 | 52,843 | 53 | 347,496 | - | 347,549 |
| Proceeds from sale of common stock, warrants, and pre-funded warrants in public offering, net of offering costs of $647,208 | 793,750 | 794 | 4,351,998 | - | 4,352,792 |
| Exercise of pre-funded warrants | 456,250 | 456 | (456) | - | - |
| Net Loss | - | - | - | (3,108,991) | (3,108,991) |
| **Balance at December 31, 2025** | **1,795,260** | **$ 1,795** | **$ 93,506,122** | **$(88,130,369)** | **$ 5,377,548** |

(1) Adjusted to reflect the reverse stock split as described in Note 1.

*See accompanying notes to consolidated financial statements.*

**Bone Biologics Corporation**
**Consolidated Statements of Cash Flows**

| | Year Ended December 31, 2025 | Year Ended December 31, 2024 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Net loss | **$ (3,108,991)** | $ (4,112,420) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | **256,358** | 188,819 |
| Change in fair value of warrant liability | **(3,967)** | (51,081) |
| Changes in operating assets and liabilities: | | |
| Advances on research and development contract services | **49,087** | 70,785 |
| Prepaid insurance | **35,233** | 104,171 |
| Interest receivable | **(9,895)** | |
| Accounts payable and accrued expenses | **91,025** | 89,780 |
| Accrued legal settlement | **-** | (414,989) |
| Net cash used in operating activities | **(2,691,150)** | (4,124,935) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common shares from ATM, net of costs | **347,549** | 1,112,202 |
| Proceeds from sale of common stock, warrants, and pre-funded warrants in public offering, net of offering costs | **4,352,792** | 1,504,113 |
| Proceeds from issuance of common shares from warrant inducement, net of costs | **-** | 1,806,520 |
| Exercise of pre-funded warrants | **-** | 662 |
| Net cash provided by financing activities | **4,700,341** | 4,423,497 |
| **Net increase in cash** | **2,009,191** | 298,562 |
| **Cash, beginning of year** | **3,325,131** | 3,026,569 |
| **Cash, end of year** | **$ 5,334,322** | $ 3,325,131 |
| | | |
| **Supplemental information** | | |
| Income taxes paid | **$ -** | $ - |
| **Noncash investing and financing activities** | | |
| Options issued to settle accrued bonus | **$ 46,183** | $ 77,400 |
| Deemed dividend – warrant inducement | **$ -** | $ 3,212,504 |

*See accompanying notes to consolidated financial statements.*

**Bone Biologics Corporation**
**Notes to Consolidated Financial Statements**

## 1. The Company, General Organization, and Going Concern and Liquidity

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.

The Company is 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 the Company 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 U.S. Food and Drug Administration ("FDA") that NELL-1/DBM will be classified as a device/drug combination product that will require an FDA-approved pre-market approval ("PMA") application before it can be commercialized in the United States of America.

The production and marketing of the Company's products and its ongoing research and development activities are 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 Federal 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, rendered unenforceable, or circumvented, or that the rights granted thereunder will provide proprietary protection or competitive advantages to the Company.

### *Going Concern and Liquidity*

The Company has no significant operating history and since inception to December 31, 2025, has incurred accumulated losses of approximately $88.1 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 $4.9 million. The accompanying consolidated financial statements for the year ended December 31, 2025 have been prepared assuming the Company will continue as a going concern. As reflected in the accompanying financial statements, the Company incurred a net loss of $3.1 million and used net cash in operating activities of $2.7 million during the year ended December 31, 2025. 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.

At December 31, 2025, the Company had cash of $5.3 million. Available cash is expected to fund the Company's operations into the fourth quarter of 2026.

On June 27, 2025, the Company issued investors 793,750 shares of its common stock and pre-funded warrants to purchase 456,250 shares of common stock for $4.00 per share. In addition, warrants exercisable into 2,500,000 shares of common stock were also issued (see Note 7). The net proceeds received from the sale of common stock and pre-funded warrants, net of cash costs of $647,208, were $4,352,792.

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 the Company's operations, in the case of debt financing, or cause substantial dilution for its stockholders, in the case of equity financing.

***Reverse stock split***

On June 5, 2025, the Company filed an amendment to its amended and restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware to effect a 1-for-6 reverse stock split of its outstanding common stock and warrants. The amendment was authorized by the Company's stockholders on May 30, 2025, and was effective on June 10, 2025.

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.

**2. Summary of Significant Accounting Policies**

***Principles of Consolidation***

The accompanying consolidated financial statements of the Company have been prepared in accordance with United States accompanying generally accepted accounting principles ("GAAP") and include the financial statements of Bone Biologics Corporation and its wholly-owned subsidiary, Bone Biologics Inc. Intercompany balances and transactions have been eliminated in consolidation.

***Segment Information***

The Company operates and reports in one segment, which focuses on bone regeneration in spinal fusion using the recombinant human protein known as NELL-1. The Company's operating segment is reported in a manner consistent with the internal reporting provided to the Chief Operating Decision Maker (the "CODM"), which is the Company's Chief Executive Officer and President (the "CEO").

The CODM uses consolidated net income (loss) as the sole measure of segment profit or loss. Significant segment expenses include research and development, salaries, insurance, and stock-based compensation. Operating expenses include all remaining costs necessary to operate our business, which primarily include external professional services and other administrative expenses (see Note 9).

***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 accounting for potential liabilities, the valuation of the warrant liability, the valuation of debt and equity instruments, the valuation of stock options and warrants issued for services, and the realizability of the Company's deferred tax assets. Actual results could differ from those estimates.

***Inflation***

Macroeconomic factors such as inflation, rising interest rates, governmental responses there to and possible recession caused thereby also add significant uncertainty to the Company's 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 holds $5.2 million in a flexible CD account at Bank of America. This CD has no set maturity date, and funds can be withdrawn any time without penalty.

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.

The fair value of financial instruments measured on a recurring basis was as follows as of December 31, 2025:

| | As of December 31, 2025 | | | |
|---|---|---|---|---|
| **Description** | **Total** | **Level 1** | **Level 2** | **Level 3** |
| Liabilities: | | | | |
| Warrant liability | $ 703 | — | — | $ 703 |
| Total liabilities at fair value | $ 703 | — | — | $ 703 |

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, 2025 as follows:

| | **2025** |
|---|---|
| **Warrant liability** | |
| Balance as of beginning of period – December 31, 2024 | $ 4,670 |
| Change in fair value | (3,967) |
| Balance as of end of period – December 31, 2025 | $ 703 |

The Company believes the carrying amount of certain financial instruments, including cash and accounts payable approximate their values based on their short-term nature and are excluded from the fair value tables above.

***Prepaid Insurance***

Prepaid insurance represents the premiums paid for directors and officers insurance coverage and for general liability insurance coverage in excess of the amortization of the total policy premium charged to operations at each balance sheet date. Such amount is determined by amortizing the total policy premium charged on a straight-line basis over the respective policy period. As the policy premiums incurred are generally amortizable over the ensuing twelve-month period, they are recorded as a current asset in the Company's consolidated balance sheet at each reporting date and appropriately amortized to the Company's consolidated statement of operations for each reporting period. The Company had $232,946 and $268,179 in prepaid insurance at December 31, 2025 and 2024, 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. Research and development costs are generally charged to operations ratably over the life of the underlying contracts, unless the achievement of milestones, the completion of contracted work, the termination of an agreement, or other information indicates that a different expensing schedule is more appropriate. However, payments for research and development costs that are contractually defined as non-refundable are charged to operations as incurred.

Advances on research and development contract services

Payments made pursuant to contracts are initially recorded as advances on research and development contract services in the Company's consolidated balance sheet and are then charged to research and development costs in the Company's consolidated statement of operations as those contract services are performed. Expenses incurred under contracts in excess of amounts advanced are recorded as research and development contract liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations. The Company reviews the status of its various clinical trial and research and development contracts on a quarterly basis. The Company had $208,972 and $258,059 in advances on research and development contract services at December 31, 2025 and 2024, respectively.

***Patents and Licenses***

Effective April 9, 2019, the Company entered into an Amended and Restated Exclusive License Agreement as so amended, the "Amended License Agreement") with the UCLA Technology Development Group on behalf of UC Regents ("UCLA TDG"). See Note 10 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***

Accounting Standards Codification ("ASC") 718, *Compensation – Stock Compensation*, prescribes accounting and reporting standards for all share-based payment transactions to employees and non-employees. 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 were accrued as of December 31, 2025 and 2024.

***Foreign Currency Translation***

The consolidated financial statements are presented in the United States dollar, which is the functional and reporting currency of the Company.

The Company periodically incurs a cost or expense in a foreign jurisdiction denominated in a local currency. The Company purchases the required foreign currency to pay such cost or expense on an as-needed basis. Such cost or expense is converted into United States dollars for financial statement purposes based on the foreign currency conversion rate in effect on the transaction date. The Company purchases the requisite foreign currency to pay such cost or expense on an as-needed basis. For the years ended December 31, 2025 and 2024, any gain or loss resulting from the purchase of the foreign currency has been de minimis.

During the years ended December 31, 2025 and 2024, the Company incurred various costs and expenses denominated in the Australian dollar (AUD), which were converted into United States dollars at the average rate of 0.6451 and 0.6598 AUD per United States dollar, respectively. During the year ended December 31, 2025 the Company incurred various costs and expenses denominated in the Singapore dollar (SGD), which were converted into United States dollars at the average rate of 0.7656 SGD per United States dollar. No SGD transactions occurred during the year ended December 31, 2024. As of December 31, 2025 and 2024, the Company did not hold any currencies other than the United States dollar in its bank accounts, and was not a party to any foreign currency forward or exchange contracts.

***Warrants***

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"), and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all of the criteria for equity classification, the warrants are required to be liability classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each balance sheet date thereafter. Changes in the estimated fair value of the warrants that are liability classified are recognized as a non-cash gain or loss in the statement of operations at each balance sheet date.

***Net Loss per Common Share***

Basic loss per share is computed by dividing the loss available to common stockholders by the weighted-average number of common shares outstanding during the period. 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 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, 2025 and 2024, 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 and warrants as of December 31, 2025 and 2024:

| | **December 31, 2025** | December 31, 2024 |
|---|---|---|
| Warrants | 2,884,037 | 309,037 |
| Stock options | 87,777 | 32,434 |
| | 2,971,814 | 341,471 |

***New Accounting Standards***

In November 2024, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2024-03 "Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses." This ASU requires public business entities to disclose, for interim and annual reporting periods, additional information about certain income statement expense categories. The requirements are effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027. Entities are permitted to apply either the prospective or retrospective transition methods. The Company is in the process of evaluating this ASU to determine its impact on the Company's disclosures.

In November 2024, the FASB issued ASU 2024-04 "Debt with Conversion and Other Options (Subtopic 470-20)". This ASU clarifies the requirements related to accounting for the settlement of a debt instrument as an induced conversion. An induced conversion is when a company induces debt holders to convert their debt into equity shares under changed terms and involved additional consideration. The amendments in this ASU are effective for all entities for annual reporting periods beginning January 1, 2026, and interim reporting periods within those annual reporting periods. The adoption of this ASU has not had a material effect on the Company's financial position, results of operations or cash flows.

In December 2023, the FASB issued ASU 2023-09, Income Taxes: Improvements to Income Tax Disclosures, which requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The standard was effective for public companies for fiscal years beginning after December 15, 2024. The Company adopted the ASU on January 1, 2025 on a prospective basis. This standard did not affect the Company's financial position, operating results, or cash flows (see Note 5).

The Company's management has evaluated all other recently issued, but not yet effective, accounting standards and guidance that have been issued or proposed by the FASB or other standards-setting bodies through the filing date of these financial statements and does not believe the future adoption of any such pronouncements will have a material effect on the Company's financial position and results of operations.

**3. Research and Development**

The Company has 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, including the completion of two preclinical sheep studies that demonstrated our recombinant NELL-1 ("rhNELL-1") growth factor effectively promotes bone formation in a phylogenetically advanced spine model.

During 2024, the Company announced the treatment of the first subjects in the multicenter, prospective, randomized pilot clinical study of our NB1 bone graft device. NB1 is NELL-1 protein combined with demineralized bone matrix (DBM) to provide rapid, specific and guided control over bone regeneration.

The pilot clinical study will evaluate the safety and effectiveness, fusion success, pain, function improvement and adverse events of NB1 in up to 30 adult subjects who undergo transforaminal lumbar interbody fusion to treat degenerative disc disease. To be enrolled in the study, subjects must have DDD at one level from L2-S1 and may also have up to Grade 1 spondylolisthesis or Grade 1 retrolisthesis at the involved level. The study is being conducted in Australia. The study design was previously reviewed and agreed upon by the FDA's Division of Orthopedic Devices in a Pre-submission to support progression to a pivotal clinical trial in the United States.

The Company has entered into various agreements with Contract Manufacturing Organizations ("CMOs"), Contract Research Organizations ("CROs") and other third parties related to our pilot clinical study. For the years ending December 31, 2025 and 2024, research and development expenses were principally attributable to clinical trials conducted for the Company's lead product candidate. Management does not believe it is dependent on any single service provider. At December 31, 2025, the estimated remaining commitment under these agreements is approximately $251,999.

Research and development costs are summarized below based on the respective geographical regions where such costs are incurred.

| | Years Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| United States | $ 653,215 | $ 1,478,785 |
| Australia | 329,330 | 651,600 |
| Singapore | 77,646 | - |
| Total | $ 1,060,191 | $ 2,130,385 |

**4. Warrant Liability**

In October 2022, the Company completed a public equity offering, which included the issuance of 9,029 warrants to purchase shares of common stock that expire in October 2027. The warrants provide for a Black Scholes value calculation, as defined, in the event of certain fundamental transactions, which includes a floor on volatility utilized in the Black Scholes 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, 2025** | December 31, 2024 |
|---|---|---|
| Warrant liability: | | |
| Risk-free interest rate | 3.47% | 4,28% |
| Expected volatility | 155.04% | 146.75% |
| Expected life (in years) | 1.78 | 2.78 |
| Expected dividend yield | - | - |
| | | |
| Fair Value: | | |
| Warrant liability | $ 703 | $ 4,670 |

The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. The Company determines expected volatility based upon the historical volatility of the Company's common stock. The Company does not believe that the future volatility of its common stock over an option's expected term is likely to differ significantly from the past. 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.

**5. Income Taxes**

No federal or state tax provisions have been provided for the years ended December 31, 2025 and 2024 due to the losses incurred during such periods. The provision for income taxes consists of the following:

| Year Ended | **December 31, 2025** | December 31, 2024 |
|---|---|---|
| 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, 2025 | December 31, 2024 |
|---|---|---|
| Deferred tax assets | | |
| Net operating loss carryforwards | $ 14,145,000 | $ 10,771,000 |
| Accrued expenses | 1,809,000 | 2,125,000 |
| Research and development credit carryforwards | 938,000 | 938,000 |
| Stock-based compensation | 7,919,000 | 7,848,000 |
| Deferred tax assets before valuation allowance | 24,811,000 | 21,682,000 |
| Less: Valuation allowance | (24,811,000) | (21,682,000) |
| Net deferred income tax assets | - | - |
| Deferred tax liabilities | - | - |
| Net deferred tax assets (liabilities) | $ - | $ - |

The Company's federal and state net operating loss carryforwards at December 31, 2025 and 2024 were approximately $46,140,000 and $34,585,000, respectively, and will begin to expire in 2037 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 $24,811,000 at December 31, 2025. The net change in the valuation allowance for the year ended December 31, 2025 was $3,129,000.

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, 2025 and 2024 is as follows:

| | December 31, 2025 | | December 31, 2024 | |
|---|---|---|---|---|
| Statutory federal income tax rate | $ (652,888) | 21.0% | $ (863,608) | 21.0% |
| State taxes, net of federal tax benefit | (885,062) | 28.5% | (978,736) | 23.8% |
| Nondeductible permanent items | - | -% | - | -% |
| Deferred tax rate change | - | -% | - | -% |
| Research and development credit | - | -% | - | -% |
| Change in valuation allowance | 1,537,950 | (49.5)% | 1,842,344 | (44.8)% |
| Income tax provision | $ - | 0.0% | $ - | 0.0% |

The Company's effective tax rate is 0% for income tax for the years ended December 31, 2025 and 2024. 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.

**6. 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, 2025 and 2024, the Company had an aggregate of 1,795,260 and 492,417 shares of common stock outstanding, respectively.

***2025 transactions***

June 2025 Public Offering

On June 27, 2025, the Company entered into a Securities Purchase Agreement and issued investors 793,750 shares of its common stock and pre-funded warrants to purchase 456,250 shares of common stock for $4.00 per share (the shares of common stock had a public offering price of $4.00 per share. The pre-funded warrants had a public offering price of $3.999 per share, and the Company also received at closing the pre-funded warrants exercise price of $0.001 per share). In addition, the Company issued investors Series D warrants to purchase 1,250,000 shares of its common stock (exercise price of $4.00 per share), expiring on June 30, 2030, and Series E warrants to purchase 1,250,000 shares of common stock (exercise price of $4.00 per share), expiring on November 30, 2027. The pre-funded warrants and the Series D and Series E warrants were classified as equity. The net proceeds received from the sale of common stock, pre-funded warrants and warrants, net of cash costs of $647,208, were $4,352,792.

During June and July 2025, 456,250 shares of common stock were issued upon the exercise of the 456,250 pre-funded warrants.

In addition, warrants to purchase 75,000 shares of common stock were issued to the placement agent. The placement agent warrants have an exercise price of $5.00 per share and were exercisable immediately upon issuance for a term of five years.

At the Market (ATM) Offering Program

In September 2024, the Company entered into an At The Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"). Under the ATM Agreement, the Company may, from time to time, in its sole discretion, issue and sell through Wainwright up to $1,143,121 of shares of its common stock. In December 2024, the Company filed a prospectus supplement and increased the aggregate offering that can be sold under the ATM Agreement by $535,000 (the "ATM Facility").

Pursuant to the ATM Agreement, the Company may sell the shares by any method permitted that is deemed an "at the market" offering as defined in Rule 415 under the Securities Act. The Company will pay Wainwright a commission of 3.0% of the gross sales price per share sold under the ATM Agreement.

During the year ended December 31, 2024, the Company sold 142,874 shares of common stock through the ATM facility for net proceeds of $1,112,202, after deducting $205,256 in offering costs.

During the year ended December 31, 2025, the Company sold 52,843 shares of common stock through the ATM Facility for net proceeds of $347,549, after deducting $13,029 in offering costs.

***2024 transactions***

March 2024 Offering

On March 6, 2024, the Company sold 19,833 shares of common stock together with warrants to purchase 19,833 shares of common stock (exercise price of $14.58 per share), expiring on March 6, 2029, at a combined public offering price of $15.36. In addition, the Company sold pre-funded warrants to purchase 110,375 shares of common stock together with warrants to purchase 110,375 shares of common stock, for a combined price of $15.354. The net proceeds received from the sale of common stock, pre-funded warrants and warrants, net of cash costs of $495,227, were $1,504,113.

The 130,208 warrants have an exercise price of $14.58 per share, and were exercisable immediately for a term of five years. The 110,375 pre-funded warrants have an exercise price of $0.001 per share and were exercisable immediately until fully exercised.

During the three months ended March 31, 2024, 60,542 pre-funded warrants were exercised and 60,542 shares of common stock were issued. During the nine months ended September 30, 2024, the balance of 49,833 pre-funded warrants were exercised and 49,833 shares of common stock were issued.

In addition, warrants to purchase 7,812 shares of common stock were issued to the placement agent, in connection with the March 2024 offering. The placement agent warrants have an exercise price of $19.20 per share and were exercisable immediately upon issuance for a term of five years.

August 2024 Warrant Inducement

On August 2, 2024, existing warrants to purchase 130,210 shares of common stock issued in March 2024, were exercised for cash at the exercise price of $14.58 per share, for gross proceeds of $1,898,440. As an inducement for the warrant holders to exercise the existing warrants for cash, new warrants to purchase 260,420 shares of common stock (the “Inducement Warrants”) were issued to the warrant holders for gross proceeds of $195,313. The proceeds received from the exercise of the 130,210 existing warrants, and the issuance of the Inducement Warrants, net of cash costs of $287,233, were $1,806,520. As a result of the inducement and subsequent exercise, the Company determined the incremental fair value provided to the holders was $3,212,504, which was recorded as a non-cash deemed dividend.

The Inducement Warrants have an exercise price of $12.00 per share and were immediately exercisable upon issuance. 130,210 of the Inducement Warrants expire on February 2, 2026, and 130,210 of the Inducement Warrants expire on August 2, 2029.

In addition, warrants to purchase 7,814 shares of common stock were issued to the placement agent, in connection with the August 2024 warrant inducement. The placement agent warrants have an exercise price of $3.35 per share and were exercisable immediately upon issuance and for a term of five years.

Due to certain beneficial ownership limitations set forth in the March 2024 warrants, the Company issued the number of shares that would not cause a holder to exceed such beneficial ownership limitation and agreed to hold such balance of shares of common stock in abeyance until notice was received that the shares of common stock could be issued in compliance with such beneficial ownership limitations. As of September 23, 2024, all abeyance shares were released and issued.

**7. Common Stock Warrants**

A summary of warrant activity for the years ended December 31, 2025 and 2024 are presented below:

| Subject to Exercise | Number of Warrants | Weighted Average Exercise Price | Weighted Average Life (Years) |
|---|---|---|---|
| **Outstanding as of December 31, 2023** | 32,995 | $ 767.16 | 4.95 |
| **Granted – 2024** | 516,626 | 10.32 | 4.12 |
| **Forfeited/Expired – 2024** | - | - | - |
| **Exercised – 2024** | (240,584) | 7.80 | 4.43 |
| **Outstanding as of December 31, 2024** | 309,037 | $ 92.94 | 3.04 |
| **Granted – 2025** | 3,031,250 | 3.47 | 3.28 |
| **Forfeited/Expired – 2025** | - | - | - |
| **Exercised – 2025** | (456,250) | 0.001 | - |
| **Outstanding as of December 31, 2025** | **2,884,037** | **$ 13.59** | **2.63** |

As of December 31, 2025, the Company had outstanding vested and unexercised Common Stock Warrants as follows:

| Date Issued | Exercise Price | Number of Warrants | Expiration date |
|---|---|---|---|
| October 2021 | $ 9,072.00 | 1,279 | October 13, 2026 |
| October 2022 | $ 2,332.80 | 3,010 | October 12, 2027 |
| October 2022 | $ 1,944.00 | 3,142 | October 12, 2027 |
| October 2022 | $ 0.00 | 399 | October 12, 2027 |
| November 2023 | $ 24.96 | 23,732 | November 16, 2028 |
| November 2023 | $ 38.40 | 1,427 | May 21, 2029 |
| March 2024 | $ 19.20 | 7,814 | March 6, 2029 |
| August 2024 | $ 12.00 | 130,210 | February 2, 2026 |
| August 2024 | $ 12.00 | 130,210 | August 2, 2029 |
| August 2024 | $ 20.10 | 7,814 | August 2, 2029 |
| June 2025 | $ 4.00 | 1,250,000 | October 17, 2027 |
| June 2025 | $ 4.00 | 1,250,000 | June 30, 2030 |
| June 2025 | $ 5.00 | 75,000 | June 30, 2030 |
| Total outstanding warrants at December 31, 2025 | | **2,884,037** | |

Based on a fair market value of $1.45 per share on December 31, 2025, there were 399 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, 2025 was $579.

**8. Stock-based Compensation**

***2015 Equity Incentive Plan***

The Company has 5,104,915 shares of common stock authorized and reserved for issuance under its 2015 Equity Incentive Plan for option awards. This reserve may be increased by the Board of Directors 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. In May 2025, the Company's stockholders approved an amendment to the 2015 Equity Incentive Plan that, among other items, increased the number of shares available under the 2015 Equity Incentive Plan by 5,000,000 shares. Appropriate adjustments were made in the number of authorized shares and other numerical limits in the Company's 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 the Company's capital structure. Shares subject to awards granted under the 2015 Equity Incentive Plan which expire, are repurchased or are cancelled or forfeited will again become available for issuance under the 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 the 2015 Equity Incentive Plan.

Awards may be granted under the 2015 Equity Incentive Plan to the Company's employees, including officers, director or consultants, and its present or future affiliated entities. While the Company may grant incentive stock options only to employees, it 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 the Company's compensation committee. Subject to the provisions of the 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 the Company and the holder of the award. The compensation committee has the authority to construe and interpret the terms of the 2015 Equity Incentive Plan and awards granted under the 2015 Equity Incentive Plan.

A summary of stock option activity for the years ended December 31, 2025 and 2024 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, 2023** | 5,739 | $ 1,420.20 | 8.62 | $ - |
| **Granted – 2024** | 27,641 | 13.80 | 8.19 | - |
| **Forfeited/Expired – 2024** | (946) | 325.44 | 7.46 | - |
| **Exercised – 2024** | - | - | - | - |
| **Outstanding as of December 31, 2024** | 32,434 | $ 42.14 | 7.25 | $ - |
| **Granted – 2025** | 55,461 | 5.41 | 8.05 | - |
| **Forfeited/Expired – 2025** | (118) | 37,364.44 | - | - |
| **Exercised – 2025** | - | - | - | - |
| **Outstanding as of December 31, 2025** | **87,777** | **$ 53.62** | **6.97** | **$ -** |
| **Options vested and exercisable at December 31, 2025** | **66,811** | **$ 68.78** | **6.20** | **$ -** |

As of December 31, 2025, the Company had outstanding stock options as follows:

| Date Issued | Exercise Price | Number of Options | Expiration date |
|---|---|---|---|
| January 2016 | $ 57,240.00 | 39 | January 9, 2026 |
| May 2016 | $ 73,800.00 | 8 | May 26, 2026 |
| June 2016 | $ 57,240.00 | 3 | May 31, 2026 |
| January 2017 | $ 73,800.00 | 2 | January 1, 2027 |
| January 2018 | $ 70,920.00 | 2 | January 1, 2028 |
| January 2019 | $ 3,384.00 | 15 | January 1, 2029 |
| October 2021 | $ 7,560.00 | 35 | October 26, 2031 |
| January 2022 | $ 5,068.80 | 21 | January 1, 2032 |
| August 2022 | $ 2,323.58 | 78 | August 23, 2032 |
| September 2023 | $ 30.72 | 4,468 | September 12, 2033 |
| January 2024 | $ 28.08 | 1,337 | January 8, 2034 |
| January 2024 | $ 21.66 | 6,251 | January 17, 2026 |
| September 2024 | $ 10.38 | 15,357 | September 17, 2034 |
| October 2024 | $ 11.28 | 4,700 | October 16, 2034 |
| January 2025 | $ 5.82 | 13,529 | January 15, 2027 |
| June 2025 | $ 5.28 | 41,932 | June 5, 2035 |
| Total outstanding options at December 31, 2025 | | **87,777** | |

Based on a fair value of $1.45 per share on December 31, 2025, there was no intrinsic value attributed to exercisable but unexercised stock options at December 31, 2025.

There were 41,932 options granted during the year ended December 31, 2025 with a fair value of $200,000 and options exercisable into 118 shares of common stock expired. Vesting of options differs based on the terms of each option. During the year ended December 31, 2025 and 2024, the Company had stock-based compensation expense of $256,358 and $188,819, respectively, related to the vesting of stock options granted to the Company's employees and directors included in the Company's reported net loss. In addition, during the year ended December 31, 2025 and 2024, options exercisable into 13,529 and 6,251, shares of common stock respectively, were issued to employees in settlement of previously accrued bonuses of $46,183 and $77,400, respectively.

The Company's 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, 2025 and 2024 are as follows:

| | **December 31, 2025** | December 31, 2024 |
|---|---|---|
| Risk free interest rate | 3.99% | 3.88% |
| Expected Volatility | 139.92% | 148.86% |
| Expected life (in years) | 5.31 | 6.21 |
| Expected dividend yield | 0% | 0% |

The expected volatility is a measure of the amount by which the Company stock price is expected to fluctuate during the expected term of options granted. The Company determines the expected volatility based upon the historical volatility of our common stock since listing on The Nasdaq Capital Market. The Company does not believe that the future volatility of its common stock over an option's expected term is likely to differ significantly from the past. 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 the Company settles these obligations by issuing shares of its common stock from its authorized shares instead of settling such obligations with cash payments.

As of December 31, 2025, total unrecognized compensation cost related to unvested stock options was $77,431. The cost is expected to be recognized over a weighted average period of 0.25 years.

**9. Segment information**

The CODM has been identified as the CEO. The Company's CODM evaluates performance and makes operating decisions about allocating resources based on financial data presented on a consolidated basis. Because the CODM evaluates financial performance on a consolidated basis, the Company has determined that it has a single operating segment composed of the consolidated financial results of Bone Biologics Corporation.

Significant segment expenses include research and development, salaries, insurance, and stock-based compensation. Operating expenses include all remaining costs necessary to operate our business, which primarily include external professional services and other administrative expenses. The following table presents the significant segment expenses and other segment items regularly reviewed by our CODM:

| | Year ended December 31, | |
|---|---|---|
| | 2025 | 2024 |
| **Revenue** | $ - | $ - |
| **Less:** | | |
| Research and development | 1,060,191 | 2,130,385 |
| Salaries | 650,000 | 581,163 |
| Insurance | 285,339 | 391,697 |
| Stock-based compensation | 256,358 | 188,819 |
| Operating expenses | 983,054 | 927,097 |
| Other income | (125,951) | (106,741) |
| **Net loss** | $ (3,108,991) | $ (4,112,420) |

**10. Commitments and Contingencies**

***UCLA TDG Exclusive License Agreement***

Effective April 9, 2019, the Company entered into 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 the Company 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.

The Company has 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. The Company must pay the royalties to UCLA TDG on a quarterly basis. Upon a first commercial sale, the Company 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 the Company is required to pay a third party any royalties as a result of it making use of UCLA TDG patents, then it may reduce the royalty owed to UCLA TDG by 0.333% for every percentage point paid to a third party. If the Company grants sublicense rights to a third party to use the UCLA TDG patent, then it will pay UCLA TDG 10% to 20% of the sublicensing income it receives from such sublicense.

The Company is 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.

The Company is 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.

The Company's obligation to pay the Diligence Fee will survive termination or expiration of the Amended License and it is prohibited from assigning, selling, or otherwise transferring any of its assets related to any Licensed Product unless its Diligence Fee obligation is assigned, sold, or transferred along with such assets, or unless it pays UCLA TDG the Diligence Fee within ten (10) days of such assignment, sale or other transfer of such rights to any Licensed Product.

The Company is 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 (i) $500,000; or (ii) 2% of all proceeds in connection with a Change of Control Transaction.

During the year ended December 31, 2024, the first subjects were treated in the multicenter, prospective, randomized pilot clinical study of the Company's NB1 bone graft device, triggering the payment of the initial $100,000 Feasibility Study milestone.

The Company is 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 it does not meet certain diligence milestone deadlines set forth in the Amended License Agreement.

The Company must reimburse or pre-pay UCLA TDG for patent prosecution and maintenance costs incurred during the term of the Amended License Agreement. The Company has 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 the Company's expense, be joined involuntarily to the action. The Company is required to indemnify UCLA TDG against any third-party claims arising out of its 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, 2025 and 2024 were $25,701 and $129,867, respectively.

***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.

**11. Subsequent Events**

On January 8, 2026, the Company granted options to purchase 16,668 and 8,335 shares of common stock of the Company to Mr. Frelick, the Company's Chief Executive Officer, and Ms. Walsh, the Company's Chief Financial Officer, respectively. The grants were related to 2025 bonus achievements for Mr. Frelick and Ms. Walsh.

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 ten-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.

**Exhibit 4.18**

# DESCRIPTION OF SECURITIES

The following is a brief description of (i) the common stock, par value $0.001 per share (the "common stock") and (ii) warrants to purchase common stock (the "warrants"), of Bone Biologics Corporation (the "Company," "we," "our," and "us"), which are the only securities of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended. This description is not complete, and we qualify it by referring to our amended and restated articles of incorporation, as amended (the "Articles of Incorporation"), our amended and restated bylaws, as amended (the "Bylaws"), the terms of the Warrant Agent Agreement between the Company and Equiniti, dated October 15, 2021 and the form of Warrant thereunder for our outstanding warrants registered under Section 12, which is filed as an exhibit to our Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

## Authorized Capital Stock

Our authorized capital stock consists of 100,000,000 shares of common stock and 20,000,000 shares of preferred stock, each with a par value of $0.001 per share.

## Common Stock

### Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. All other actions by stockholders will be approved by the majority of the votes cast affirmatively or negatively (excluding abstentions and broker non-votes) except as otherwise required by law.

### Dividend Rights

Holders of common stock are entitled to receive proportionately any dividends that may be declared by our Board of Directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue.

### Liquidation Rights

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the preferential rights of any outstanding preferred stock.

### Absence of Other Rights

Holders of our common stock have no preemptive, subscription, redemption, or conversion rights. The rights, preferences, and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue.

## Preferred Stock

Under our Articles of Incorporation, our Board of Directors has the authority, without further action by stockholders, to designate one or more series of preferred stock and to fix the voting powers, designations, preferences, limitations, restrictions, and relative rights granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference, and sinking fund terms, any or all of which may be preferential to or greater than the rights of the common stock.

The authority possessed by our Board of Directors to issue preferred stock could potentially be used to discourage attempts by third parties to obtain control of our company through a merger, tender offer, proxy contest, or otherwise by making such attempts more difficult or more costly. Our Board of Directors may issue preferred stock with voting rights, conversion rights, and other rights that, if exercised, could adversely affect the voting power of the holders of common stock.

**Anti-Takeover Effects of Our Articles of Incorporation and Bylaws**

Certain provisions of our Articles of Incorporation and Bylaws contain provisions that could have the effect of delaying or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids.

Our Articles of Incorporation and Bylaws include provisions that:

- authorize our Board of Directors to issue, without further action by the stockholders, up to 20,000,000 shares of preferred stock in one or more series designated by the Board of Directors;
- specify that meetings of our stockholders can be called only by our Board of Directors, or any officer instructed by the director to call the meeting; and
- provide that vacancies on our Board of Directors may be filled only by the vote of a majority of the remaining directors even though less than a quorum.

Our Bylaws also provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the day on which a public announcement of the date of such meeting is first made by us. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

**Delaware Anti-Takeover Statute**

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation such as Bone Biologics Corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not for determining the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers of the corporation and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 662/3% of the outstanding voting stock which is not owned by the interested stockholder.

In this context, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our Board of Directors does not approve in advance. We also anticipate that Section 203 may discourage business combinations or other attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

**Warrants**

As of December 31, 2025, there were 1,279 warrants outstanding, which are listed on the Nasdaq Capital Market under the symbol "BBLGW," to purchase an aggregate of 1,279 shares of common stock that were issued by the Company in connection with an underwritten public offering in October 2021 (the "2021 Warrants").

*2021 Warrants*

Each 2021 Warrant entitles the holder to purchase one share of our common stock. The 2021 Warrants are exercisable at an exercise price of $9,072 per share and will expire on October 13, 2026. The 2021 Warrants may also be exercised on a cashless basis in the event that no effective registration statement or prospectus is available at the time of exercise. The exercise price and number of shares of common stock issuable upon exercise of the 2021 Warrants is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting the common stock and the exercise price.

The 2021 Warrants will not be exercisable or exchangeable by any holder to the extent (and only to the extent) that such holder or any of its affiliates would beneficially own in excess of 4.99% of our outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from a holder to the Company, such holder may increase the amount of ownership of outstanding shares after exercising such holder's 2021 Warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the 2021 Warrants. No fractional shares of common stock will be issued in connection with the exercise of the 2021 Warrants. In lieu of fractional shares, the Company will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

If, at any time a 2021 Warrant is outstanding, the Company consummates any fundamental transaction, as described in the 2021 Warrants and generally including any consolidation or merger into another corporation, or the sale of all or substantially all of the Company's assets, or other transaction in which our common stock is converted into or exchanged for other securities or other consideration, each holder of a 2021 Warrant will have the right to receive, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, at the option of such holder, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock for which the 2021 Warrant is exercisable immediately prior to such fundamental transaction.

The terms of the 2021 Warrants are governed by a Warrant Agent Agreement, dated as of October 13, 2021, between the Company and Equiniti, as the warrant agent.

**Exhibit 21.1**

**List of Subsidiaries**

The following is a list of all of the subsidiaries of Bone Biologics Corp., a Delaware corporation:

- Bone Biologics, Inc. incorporated in the state of California

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-257484), Form S-1MEF (No. 333-260209), Form S-1 (No. 333-267588), Form S-1MEF (No. 333-267768), Form S-1MEF (No. 333-267770), Form S-1 (No. 333-276771), Form S-1 (No. 333-288252), Form S-3 (No. 333-276412), Form S-3 (No. 333-281494), Form S-3 (No. 333-288290), Form S-8 (No. 333-212890), Form S-8 (No. 333-274545), and Form S-8 (No. 333-290552) of our report dated March 2, 2026, relating to the financial statements of Bone Biologics Corporation as of and for the years ended December 31, 2025 and 2024 (which report includes an explanatory paragraph relating to substantial doubt about the Bone Biologic Corporation's ability to continue as a going concern) which appear in Bone Biologics Corporation's Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Weinberg and Company, P.A.

Los Angeles, California
March 2, 2026

**Exhibit 31.1**

**Certification of Principal Executive Officer**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
**and Securities and Exchange Commission Release 34-46427**

I, Jeffrey Frelick, certify that:

1. I have reviewed this annual report on Form 10-K of Bone Biologics Corporation.

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

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

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

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

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

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

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

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

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

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

Date: March 2, 2026

*/s/ Jeffrey Frelick*
Jeffrey Frelick
Principal Executive Officer

**Exhibit 31.2**

**Certification of Principal Financial Officer**
**Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**
**and Securities and Exchange Commission Release 34-46427**

I, Deina H. Walsh, certify that:

1. I have reviewed this annual report on Form 10-K of Bone Biologics Corporation.

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

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

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

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

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

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

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

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

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

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

Date: March 2, 2026

*/s/ Deina H. Walsh*
Deina H. Walsh
Principal Financial Officer

**Exhibit 32.1**

**Certification of Principal Executive Officer**
**Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to**
**Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Report of Bone Biologics Corporation (the "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey Frelick, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: March 2, 2026

*/s/ Jeffrey Frelick*
Jeffrey Frelick
Principal Executive Officer

**Exhibit 32.2**

**Certification of Principal Financial Officer**
**Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to**
**Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Report of Bone Biologics Corporation (the "Company") on Form 10-K for the period ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Deina H. Walsh, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Date: March 2, 2026

*/s/ Deina H. Walsh*
Deina H. Walsh
Principal Financial Officer