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

FORM 10-K

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

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

For the fiscal year ended: December 31, 2018

For the transition period from _____ to _____

Commission File Number: 000-53078

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

Delaware
(State or other jurisdiction of incorporation or organization)

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

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

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

None

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

Common Stock, $0.001 par value per share

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

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 [X]

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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in

Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the Company is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ] (Do not check if a smaller reporting company)	Smaller reporting company	[X]

[X] 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 Company is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [ ] No [X]

Approximate aggregate market value of registrant’s common equity held by non-affiliates of the registrant at the close of business on June 30, 2018, was $6,005,238.

As of March 25, 2019, there were 27,938,243 shares of common stock, par value $0.001, outstanding.

Documents Incorporated by Reference

None.

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Cautionary Note on Forward-Looking Statements

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

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

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

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

PART I

Item 1. *Business*

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/DBX®. The NELL-1/DBX® combination product is an osteostimulative recombinant protein that provides target specific control over bone regeneration. The protein, as part of the UCB-1 technology platform has been licensed exclusively for worldwide applications to us through a technology transfer from the UCLA Technology Development Group on behalf of UC Regents ("UCLA TDG"). UCLA TDG and the Company received guidance from the FDA that NELL-1/DBX® will be classified as a combination product with a device lead.

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, which we refer to as the JOBS Act. We would cease to be an emerging growth company upon the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are $1.07 billion or more; (ii) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700.0 million as of the end of the second quarter of that fiscal year; or (iii) the date on which we have, during the previous three-year period, issued more than $1.07 billion in non-convertible debt securities. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. We have elected to take advantage of these reduced disclosure obligations, and may elect to take advantage of other reduced reporting obligations in the future.

The JOBS Act permits an emerging growth company like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to irrevocably "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

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

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

PRODUCTS

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

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

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

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

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

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

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

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

Hip & Knee Revisions. The use of bone substitutes in reconstruction surgery is generally limited to revision cases where the products are used to account for the significant bone loss that accompanies these cases. The treatment of osteoporotic patients also represents a substantial opportunity for NELL-1's use in hip and knee reconstruction.

Implant Coating. The use of NELL-1 as a direct coating on hip and knee implants could have a very significant impact on the market. A NELL-1 coating may prolong the life of primary implants and allow for differentiation in a commodity market.

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

UCLA's initial research was funded with approximately $18 million in resources from UCLA TDG and government grants. Since licensing the exclusive worldwide intellectual property rights from UCLA TDG, our continued development has been funded through various strategic investments. Our research and development expenses for the years ended December 31, 2018 and 2017 were $1,229,570 and $869,785 net of the fair value of stock options amortization and forfeitures by our consultants of $(1,125,080) and $(2,199,049), for a total expense of $104,490 and $(1,329,264), respectively. We anticipate that it will require an additional $11 million to complete protein synthesis, animal studies, and commence first in man studies. An estimated additional $62 million will be required to achieve product launch for spine interbody fusion.

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

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

RESEARCH & PUBLICATIONS

Our leading scientists have been published in notable scientific journals and publications in our field. There are more than 80 publications that serve to highlight the work and achievements of the researchers and the Company.

PROPOSED INITIAL CLINICAL APPLICATION

The NELL-1/DBX® Fusion Device will be indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease ("DDD") at one level from L4-S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level. The NELL-1/DBX® Fusion Device is to be implanted via an anterior open or an anterior laparoscopic approach in conjunction with a cleared intervertebral body fusion device. Patients receiving the device should have had at least six months of non-operative treatment prior to treatment with the device. A cervical indication is currently under consideration. This indication for use would fill a current clinical gap, created by potentially dangerous inflammatory responses caused by commercially available catalytic bone growth agents, the subject of a Public Health Notification from the FDA on July 1, 2008 about life threatening complications associated with a recombinant human protein in cervical spine fusion. We do not expect our product to see the same adverse events with NELL-1/DBX® as have been observed with other commercially available protein. We have performed a rat femoral onlay model to compare proinflammatory response of rhBMP-2 and NELL-1 within Helistate collagen sponges. While NELL-1 induced normal healing, rhBMP-2 induced significant amounts of swelling and histological evidence of intense inflammatory response.

DESCRIPTION OF THE DBX® PUTTY TO BE USED WITH NELL-1

The DBX® Demineralized Bone Putty provided in the convenience kit with NELL-1/DBX® is a Class III device with a pre-market approval (PMA). The common name is "Bone Void Filler Containing Human Demineralized Bone Matrix." The product is regulated under 21 C.F.R. §888.3045 Resorbable calcium salt bone void filler device, Product Codes MQV, GXP, and MBP. MTF is the manufacturer of the DBX® Putty. This product was cleared by the FDA under 510(k) number K053218 for spine indication in December 2006.

DBX® Putty is a matrix composed of processed human cortical bone. Demineralized bone granules are mixed with sodium hyaluronate to form the DBX® Putty. Every lot of final DBX® 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 Restated License Agreement between UCLA TDG and the Company we believe the NELL-1/DBX® Fusion Device will be regulated as a Class III medical device and will therefore require submission and approval of a pre-market approval, ("PMA"). The FDA response to the submission of our plan is: "We have determined that the product is a combination product that will be regulated under Device authorities, with CDRH (Center for Devices and Radiological Health) as the lead center."

OUR BUSINESS STRATEGY

Our business strategy is to develop our target specific platform technology to meet a current established market with improvement in patient outcomes and reduction in costs to the healthcare delivery system. Our focus continues to narrow from the research to the development stage to allow for the approval for use of our target specific protein exhibiting efficacy and safety by matching or exceeding current market approved products. Identifying the best future strategic partners to facilitate the development through pre Investigational Device Exemption ("IDE"), clinical, and ultimate commercialization is critical as we fund the pre-IDE work and continue achieving milestones. We believe that the licensing of the distribution of the NELL-1 product in the fields of use focused upon will generate sufficient funding to provide for the ongoing development of the Platform Technology across other surgical and therapeutic fields.

DEVELOPMENT OF THE COMPANY

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

On July 16, 2018, the Company closed a rights offering in which Hankey Capital purchased 3,539,654 shares of the Company's Common Stock and executed amendments (the "Amendments") to the convertible promissory notes (the "Existing Convertible Notes") payable to Hankey Capital dated October 24, 2014, May 4, 2015 and February 24, 2016. The Amendments reduced the conversion price of the Existing Convertible Notes from $15.80 per share to $1.00 per share and extended the maturity date of the February 24, 2016 convertible promissory note from February 24, 2019 to December 31, 2019. As a result of the share issuance and Amendments, Hankey Capital and Don Hankey, the Chairman of the Company's Board of Directors, acquired a majority of the voting common shares issued and outstanding and thus effective control of the Company.

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

UCLA TDG Exclusive License Agreement

Effective August 18, 2017, the Company entered into an Amended and Restated Exclusive License Agreement (the "Restated License Agreement") with UCLA TDG. The Restated License Agreement amends and restates the Exclusive License Agreement, effective March 15, 2006, between the Company and UCLA TDG, as amended by ten amendments. Under the terms of the Restated License Agreement, the UCLA TDG have continued to grant the Company exclusive rights to develop and commercialize NELL-1 (the "Licensed Product") for spinal fusion, trauma and osteoporosis 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 to pay certain royalties to UCLA TDG under the Restated License Agreement at the rate of 3.0% of net sales of licensed products. We must pay the royalties to UCLA TDG on a quarterly basis. Upon a first commercial sale, we also must pay between $50,000 and $250,000, depending on the calendar year which is after the first commercial sale. If we are required to pay any third party any royalties as a result of us making use of UCLA TDG patents, then we may reduce the royalty owed to UCLA TDG by 0.333% for every percentage point paid to a third party. If we grant sublicense rights to a third party to use the UCLA TDG patent, then we will pay to 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 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, 2017, such payment to equal the greater of:

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

We are obligated to diligently proceed with developing and commercializing licensed products under UCLA TDG patents set forth in the Restated 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 Restated License Agreement.

We must reimburse or pre-pay UCLA TDG for patent prosecution and maintenance costs incurred during the term of the Restated License Agreement. We have the right to bring infringement actions against third party infringers of the Restated 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 Restated License Agreement or any sublicense.

COMPETITION

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

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

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

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

CUSTOMERS

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

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

INTELLECTUAL PROPERTY

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

Additional patent applications are currently in preparation. The intellectual property is unique and 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 all 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 fifteen (15) UCLA TDG issued patents:

U.S. Patent No.	Summary	Date Issued
7052856	NELL-1 Enhanced Bone Mineralization	5/30/2006
7544486	NELL-1 Peptide Expression Systems	6/9/2009
7687462	Composition for promoting Cartilage	3/30/2010
7691607	Expression system of NELL-1 peptide	4/6/2010
7776361	NELL-1 Enhanced Bone Mineralization	8/17/2010
7807787	NELL-1 Peptide	10/5/2010
7833968	Pharmaceutical compositions for treating or preventing bone conditions	11/16/2010
7844066	NELL-1 Enhanced Bone Mineralization	2/8/2011
8044026	Composition for promoting cartilage	10/25/2011
8048646	NELL-1 peptide expression systems	11/1/2011
8053412	NELL-1 Peptides	11/8/2011
8207120	NELL-1 Enhanced Bone Mineralization	6/26/2012
9447155	Isoform NELL-1 peptide	9/20/2016
9511115	Pharmaceutical compositions for treating or preventing bone conditions	12/6/2016
9598480	Recombinant NEL-like (NELL) protein production	3/21/2017

GOVERNMENT REGULATION

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

In the U.S., drugs are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. Drug 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 United States Food and Drug Administration ("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 pharmaceutical agent may be marketed in the U.S. include:

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

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

Non-clinical Trials

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

Clinical Trials

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

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

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

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

Premarket Approval and FDA Approval Process

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

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

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

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

International Approval

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

Other Regulation

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

EMPLOYEES

As of the date hereof, we have three (3) full-time employees.

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

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

Risks Related to Our Business

Our ability to grow and compete in the future will be adversely affected if adequate capital is not available to us or not available on terms favorable to us.

The ability of our business to grow and compete depends on the availability of adequate capital. We currently have no cash flow. We cannot assure you that we will be able to obtain equity or debt financing on acceptable terms or at all to implement our growth strategy. As a result, we cannot assure you that adequate capital will be available to finance our current growth plans, take advantage of business opportunities or respond to competitive pressures, any of which could harm our business.

We rely on Hankey Capital for Funding

For the past several years, we have depended on our relationship with Hankey Capital for working capital to fund our operations, which has been raised in the form of both debt and equity capital. Hankey Capital, directly and indirectly, controls approximately 88% of our issued and outstanding shares of common stock (including collateral shares) and has been issued convertible notes payable with an aggregate principal balance of $9,000,000 at December 31, 2018. We drew down an additional $700,000 of working capital under a $2,000,000 secured credit facility during March 2019. No assurance can be given that any future financing from Hankey Capital will be available or, if available, that it will be on terms that are satisfactory to the Company. In the absence of financing from other sources, the inability to obtain additional financing from Hankey Capital will result in the scaling back or discontinuance of our product development programs or operations entirely.

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. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as and for the years ended December 31, 2018 and 2017 with respect to this uncertainty. The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, suppliers and employees.

We have incurred losses for the years ended December 31, 2018 and 2017 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, 2018 have incurred accumulated losses of approximately $63.6 million. We will continue to incur significant expenses for development activities for our lead product NELL-1/DBX®. Operating expenditures for the next twelve months are estimated at $10.3 million. Our auditors have included in their audit report for the year ended December 31, 2018 an explanatory paragraph regarding our ability to continue as a going concern. As reflected in the financial statements, we had a stockholders' deficit of $8,598,175 at December 31, 2018, incurred a net loss of $4,430,399, and used net cash in operating activities of $4,104,884 during the year ended December 31, 2018. These factors raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

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

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

The Company has the following debt outstanding with Hankey Capital, a related party:

Note Type	Issue Date	Maturity Date	Interest Rate	March 25, 2019
First Secured Convertible Note	10/24/14	12/31/19	9.25%	5,000,000
Second Secured Convertible Note	5/4/15	12/31/19	9.25%	2,000,000
Third Secured Convertible Note	5/4/15	12/31/19	9.25%	2,000,000
Credit Facility Line	3/19/19	12/31/19	9.25%	700,000
Total Notes payable				$ 9,700,000

Since all of the Notes and Credit Facility Line mature on December 31, 2019, the Company will be required to obtain an extension, refinance the Notes or obtain alternative funding to replace the Notes and Credit Facility. No assurance can be given that any of these alternatives will be available.

Incurring a substantial amount of debt may require us 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. Our 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.

The Convertible Notes are secured by 20,638,298 collateral shares of Common Stock issued by the Company in the name of Hankey Capital, in such amount so as to maintain a loan to value ratio equal to 50% (the "Collateral Shares"). The number of shares in the Collateral Shares shall be adjusted on a yearly basis. A Collateral Shares adjustment of 18,009,696 shares of Common Stock was issued during the year ended December 31, 2018. The principal amount of the loans are pre-payable in whole or in part at any time, without premium or penalty. Upon any voluntary partial prepayment of outstanding principal, Hankey Capital will return Collateral Shares to the Company in the amount necessary, if any, to maintain the loan to value ratio at no less than 50%. Upon a full payment of the outstanding principal, all Collateral Shares shall be returned return and cancelled. Hankey Capital will also return Collateral Shares under the same terms in case of partial or full conversion of the Convertible Notes. All of the Company's personal property further secure the Convertible Notes, including collateral assignments of all the Company's license agreements and the MTF Sygnal Option Agreement.

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

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

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

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

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

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

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

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

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

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

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

We anticipate that it will require an additional $11 million to complete protein synthesis, animal studies, and commence first in man studies. An estimated additional $62 million will be required to achieve product launch for spine interbody fusion. We anticipate we will need to raise substantial additional funds for the pivotal clinical trial prior to marketing our first product. Our long term capital requirements are expected to 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 drug formulations or products;
- costs for recruiting and retaining employees and consultants;
- costs for training physicians; and
- legal, accounting and other professional costs.

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.

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

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

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

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

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

Others may file patent applications or obtain patents on similar technologies or compounds 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 product, 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, current or prospective corporate collaborators, may unintentionally or willfully disclose our confidential information to competitors or use our proprietary technology for their own benefit. Furthermore, enforcing a claim alleging the infringement of our trade secrets would be expensive and difficult to prove, making the outcome uncertain. Our competitors may also independently develop similar knowledge, methods, and know-how or gain access to our proprietary information through some other means.

We may 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 three full-time employees. We also engaged 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 drug-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 drug substance and drug product, which may be difficult or uneconomical to procure or manufacture. We and our suppliers and vendors may not be able to (i) produce our drug substance or drug product 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.

Clinical trials are very expensive, time-consuming, and difficult to implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. We estimate that clinical trials of our product candidates would take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. Commencement and completion of clinical trials may be delayed by several factors, including:

- obtaining an IDE approval with the FDA to commence clinical trials;
- identification of, and acceptable arrangements with, one or more clinical sites;
- obtaining Institutional Review Board (“IRB”) approval to commence clinical trials;
- unforeseen safety issues;
- determination of dosing;
- lack of effectiveness during clinical trials;

- slower than expected rates of patient recruitment;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators to follow clinical protocols; and
- unwillingness of the FDA or IRBs to permit the clinical trials to be initiated.

In addition, we, IRBs or the FDA may suspend clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if IRBs or the FDA finds deficiencies in our submissions or the conduct of our trials.

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

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

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

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

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

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 files patent applications, or is issued patents, claiming technology also claimed by us, we may be required to participate in interference proceedings in the U.S. Patent and Trademark Office to determine priority of invention. We or our licensors 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 patents. 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 another's foreign patent or by persons opposing the validity of our foreign patents.

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

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

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

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 drugs in development, only a small percentage successfully completes the FDA regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our product candidates, could result in the failure of our business and a loss of all of your investment in our company.

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

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

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

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

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, recent events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals could prevent us from commercializing our product candidates.

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

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

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

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

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

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

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.

Privacy Provisions of HIPAA

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.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to us.

As is common in the medical device industry, we engage the services of consultants to assist in the development of our product candidates. Many of these consultants were previously employed at, or may have previously been or are currently providing consulting services to, other healthcare and life science companies, including our competitors or potential competitors. We may become subject to claims that we or our consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of our former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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 one research program. 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 incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and intend to maintain product liability insurance relating to our clinical trials, our coverage may not be sufficient to cover claims that may be made, and we may be unable to maintain such insurance. Any claims, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that may be approved for marketing. Additionally, it is expected that we will need to enter into various agreements where we indemnify third parties for certain claims relating to the testing of our product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

We use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Risks Related to Ownership of Our Common Stock

There is a limited public trading market for our Common Stock, and you may not be able to resell your Common Stock.

There is a limited public trading market for our securities. In the absence of an active trading market, an investor may be unable to liquidate its investment, which will result in the loss of your investment.

We have no plans to pay dividends.

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

The application of the SEC's "penny stock" rules to our Common Stock could limit trading activity in the market, and our stockholders may find it more difficult to sell their stock.

It is expected that our Common Stock will be trading at less than $5.00 per share and will therefore be subject to the SEC's penny stock rules. Penny stocks generally are equity securities with a price of less than $5.00. Penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The broker-dealer must also make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These requirements may have the effect of reducing the level of trading activity, if any, in the secondary market for a security that becomes subject to the penny stock rules. The additional burdens imposed upon broker-dealers by such requirements may discourage broker-dealers from effecting transactions in our securities, which could severely limit their market price and liquidity of our securities. These requirements may restrict the ability of broker-dealers to sell our Common Stock and may affect your ability to resell our Common Stock.

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

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, 2018, management identified a material weakness in internal controls over financial reporting as described in Item 9 A. Controls and Procedures.

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

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

The market price of our Common Stock may be volatile.

The market price of our Common Stock may be highly volatile. Some of the factors that may materially affect the market price of our Common Stock are beyond our control, such as changes in financial estimates by industry and securities analysts, conditions or trends in the industry in which we operate or sales of our Common Stock. These factors may materially adversely affect the market price of our Common Stock, regardless of our performance. In addition, public stock markets have experienced extreme price and trading volume volatility. This volatility has significantly affected the market prices of securities of many companies for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our Common Stock.

There may be potential conflicts of interest involving Don Hankey and Bret Hankey, as directors, and as affiliates of Hankey Capital, a creditor of the Company, with the Company's other stockholders

Don Hankey and Bret Hankey, two of our directors, are affiliated with Hankey Capital. Don Hankey, directly and indirectly, is our controlling stockholder. Don Hankey and Bret Hankey may be able to exert significant control over our business affairs. As a result of Hankey Capital's loans to the Company, Hankey Capital has a security interest in all our assets and has been issued 20,638,298 collateral shares securing the loans. Accordingly, Don Hankey and Bret Hankey may have actual or potential economic and/or legal interests that may diverge from our other stockholders' interests.

Our directors and executive officers can exert significant control over our business and affairs and have actual or potential interests that may depart from those of investors in the subsequent financings.

The interests of our directors and officers may differ from the interests of our other stockholders, including purchasers of our securities, in future financings. As a result, based on their board seats and offices, such persons will have significant influence over and control all corporate actions requiring stockholder approval, irrespective of how the Company's other stockholders, may vote, including the following actions:

- to elect or defeat the election of our directors;

- to amend or prevent amendment of our Amended and Restated Certificate of Incorporation or By-laws;
- to effect or prevent a merger, sale of assets or other corporate transaction; and
- to control the outcome of any other matter submitted to our stockholders for vote.

This concentration of ownership by itself may have the effect of impeding a merger, consolidation, takeover or other business consolidation, or discouraging a potential acquirer from making a tender offer for the Common Stock which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price.

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

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

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

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

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

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

IN ADDITION TO THE ABOVE RISKS, BUSINESSES ARE OFTEN SUBJECT TO RISKS NOT FORESEEN OR FULLY APPRECIATED BY OUR MANAGEMENT. IN REVIEWING THIS PROSPECTUS, POTENTIAL INVESTORS SHOULD KEEP IN MIND THAT THERE MAY BE OTHER POSSIBLE RISKS THAT COULD BE IMPORTANT.

Item 1B. Unresolved Staff Comments

None.

Item 2. ***Properties***

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

Item 3. ***Legal Proceedings***

In July 2018, AFH Holding & Advisory, LLC, Amir Heshmatpour, Steve Richards, and Bessie (Chia) Soo ("Plaintiffs") filed a verified shareholder derivative complaint (the "Complaint") in Massachusetts federal court against Bruce Stroever, John Booth, Stephen LaNeve, Bret Hankey, James Delshad (the "Initial Defendants"), and The Musculoskeletal Transplant Foundation, Inc. ("MTF"), and also named the Company as a nominal defendant. The Complaint alleged claims for violation of Section 14(c) of the Securities Exchange Act of 1934, breach of fiduciary duties, rescission of a reverse stock split, and in the alternative rescissory damages. The Complaint focuses on the financing transaction that the Company completed with Hankey Capital in July 2018. The Initial Defendants and the Company filed motions to dismiss on September 28, 2018. After changing counsel and obtaining several extensions of time, instead of responding to the motions to dismiss, Plaintiffs filed an Amended Complaint (the "Amended Complaint") on February 8, 2019 as a direct, instead of derivative complaint, and added two additional defendants, Don Hankey and Hankey Capital LLC (the "Added Defendants" and together with the Initial Defendants, MTF and the Company, the "Current Defendants"). The Amended Complaint asserts claims for violation of Section 14(c) of the Securities Exchange Act of 1934, breach of fiduciary duties, aiding and abetting breach of fiduciary duties, rescission of a reverse stock split, and in the alternative rescissory damages. On February 22, 2019, the Company and the Initial Defendants filed a Motion to Dismiss the Amended Complaint. The Initial Defendants have been sued for actions taken in their capacity as directors of the Company. As such, the Company has certain indemnification obligations to the Initial Defendants. The Company and the Initial Defendants intend to vigorously defend against the allegations in the Amended Complaint. Based on the very early stage of the litigation, it is not possible to estimate the amount or range of any possible loss arising from the expenditure of defense fees, a judgment or settlement of the matter.

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 trades over-the-counter and is quoted on the OTCQB of the OTC Markets under the symbol "BBLG." The table below sets forth the high and low bid prices for our common stock as reflected on the OTCQB. Quotations represent prices between dealers, do not include retail markups, markdowns or commissions, and do not necessarily represent prices at which actual transactions were affected. There is a limited public trading market for our securities.

Common Stock

	High	Low
Fiscal Year 2017		
First Quarter	$ 20.00	$ 11.10
Second Quarter	$ 39.77	$ 14.50
Third Quarter	$ 59.00	$ 10.10
Fourth Quarter	$ 52.50	$ 22.50
Fiscal Year 2018		
First Quarter	$ 30.00	$ 5.10
Second Quarter	$ 29.90	$ 10.00
Third Quarter	$ 100.00	$ 23.80
Fourth Quarter	$ 26.00	$ 26.00

Holders.

As of March 12, 2019, there are approximately 59 record holders of 26,448,881 shares of Common Stock. This number does not include the stockholders for whom shares are held in a "nominee" or "street" name.

Dividends.

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

Securities Authorized for Issuance under Equity Compensation Plans

2015 Equity Incentive Plan

The Company has 1,400,000 shares of Common Stock authorized and reserved for issuance under our 2015 Equity Incentive Plan for option awards. This reserve may be increased by the Board each year by up to the number of shares of stock equal to 5% of the number of shares of stock issued and outstanding on the immediately preceding December 31. Appropriate adjustments will be made in the number of authorized shares and other numerical limits in our 2015 Equity Incentive Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards granted under our 2015 Equity Incentive Plan which expire, are repurchased or are cancelled or forfeited will again become available for issuance under our 2015 Equity Incentive Plan. The shares available will not be reduced by awards settled in cash. Shares withheld to satisfy tax withholding obligations will not again become available for grant. The gross number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under our 2015 Equity Incentive Plan.

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

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

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	843,648	$ 16.43	556,352
Equity compensation plans not approved by security holders	-	-	-
Total	843,648	$ 16.43	556,35

Item 6. ***Selected Financial Data***

Not applicable.

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

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/DBX®. The NELL-1/DBX® combination product is an osteostimulative recombinant protein that provides target specific control over bone regeneration. The protein, as part of the UCB-1 technology platform has been licensed exclusively for worldwide applications to us through a technology transfer from the UCLA Technology Development Group on behalf of UC Regents ("UCLA TDG"). UCLA TDG and the Company received guidance from the FDA that NELL-1/DBX® will be classified as a combination product with a device lead.

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, which we refer to as the JOBS Act. We would cease to be an emerging growth company upon the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are $1.07 billion or more; (ii) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700.0 million as of the end of the second quarter of that fiscal year; or (iii) the date on which we have, during the previous three-year period, issued more than $1.07 billion in non-convertible debt securities. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. We have elected to take advantage of these reduced disclosure obligations, and may elect to take advantage of other reduced reporting obligations in the future.

The JOBS Act permits an emerging growth company like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to irrevocably "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

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

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

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, 2018	Year ended December 31, 2017	% Change
Operating expenses			
Research and development			
Trade	**104,490**	1,415,485	(92.62)%
Related party (includes Founders stock-based compensation of -0- and ($2,744,749) for the years ended December 31, 2018 and 2017, respectively)	**-**	(2,744,749)	(100.00)%
General and administrative	**2,686,399**	3,955,856	(32.09)%
Total operating expenses	**2,790,889**	2,626,592	6.26%
Loss from operations	**(2,790,889)**	(2,626,592)	6.26%
Loss on debt extinguishment	**(408,294)**	-	100.00%
Interest expense	**(1,229,487)**	(4,423,380)	(72.20)%
Total other income/expense	**(1,637,781)**	(4,423,380)	37.03%
Loss before provision for income taxes	**(4,428,670)**	(7,049,972)	(37.18)%
Provision for income taxes	**1,729**	1,600	8.06%
Net loss	**$ (4,430,399)**	$ (7,051,572)	(37.17)%

Research and Development

Our research and development related party expenses decreased from $(2,744,749) during the year ended December 31, 2017 to $-0- during the year ended December 31, 2018. The $2,744,749 decrease was due to the options forfeited with the termination of the Professional Services Agreements with each of the Founders in April 2017. Our trade research and development decrease between December 31, 2018 and 2017 was due to an adjustment to the fair value of options for services provided by our chief scientific advisor offset by costs related to the commencement of our large animal pivotal study. We will continue to incur significant expenses for development activities for NELL-1.

General and Administrative

Our general and administrative expenses decreased from $3,955,856 during the year ended December 31, 2017 to $2,686,399 during the year ended December 31, 2018. The $1,269,457 decrease was primarily due to a decrease in the required amortization of the fair value of management options.

Interest Expense

Our interest expense decreased from $4,423,380 for the year ended December 31, 2017 to $1,229,487 during the year ended December 31, 2018. The decrease in interest of $3,193,893 resulted from the conversion of $3,900,000 of notes and decreased amortization of debt discount costs due to the debt extinguishment.

Loss on debt extinguishment

In connection with the financing that closed on July 16, 2018, the Company and Hankey Capital executed amendments (the "Amendments") to the First, Second and Third convertible secured term notes (the "Existing Convertible Notes"). The Amendments change Hankey Capital's conversion price from $15.80 per share to $1.00 per share on a post reverse stock split basis on the Existing Convertible Notes and extends the maturity date of the Third Convertible Note from February 24, 2019 to December 31, 2019. The Amendments became effective on the closing of the rights offering, July 16, 2018. The Company determined that the change in the conversion prices of the Existing Convertible Notes and extension of the Third Convertible Note's maturity date resulted in debt extinguishments for accounting purposes since the change in fair value of the conversion options was more than 10% of the original value of the Existing Convertible Notes. The Company recorded a loss on extinguishment of debt totaling $408,294 for the remaining unamortized debt discount.

Liquidity and Capital Resources

Going Concern and Liquidity

The Company has no significant operating history and since inception to December 31, 2018 has incurred accumulated losses of approximately $63.6 million. The Company will continue to incur significant expenses for development activities for their lead product NELL-1/DBX®. Operating expenditures for the next twelve months are estimated at $10.3 million. The accompanying consolidated financial statements for the year ended December 31, 2018 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, the Company had a stockholders' deficit of $8,598,175 at December 31, 2018, and incurred a net loss of $4,430,399, and used net cash in operating activities of $4,104,884 during the year ended December 31, 2018. 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.

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

The Company closed $500,000 of equity financing in March 2018 and $600,000 of debt financing in May 2018. On July 16, 2018, the Company closed a Rights Offering ("Rights Offering") to existing shareholders and certain related parties and, on July 24, 2018, a private placement with Hankey Capital LLC ("Hankey Capital") in the aggregate amount of $3,869,979 and secured a credit facility with Hankey Capital for $2,000,000. In the Rights Offering the Company issued 330,325 shares to four shareholders, including 329,674 shares to certain related parties (the "Rights Shares") and issued 3,539,654 shares to Hankey Capital (the "Hankey Shares") pursuant to a Securities Purchase Agreement.

The proceeds from the sale of the Rights Shares and the Hankey Shares of $3,869,979 were used to repay the promissory note for $600,000 and the remaining proceeds have been and will be used for working capital, protein development, animal testing, regulatory and clinical expenses, as well as for other purposes not presently contemplated herein but which are related directly to growing the Company's current business, research and development activities.

Pursuant to our October 2016 and February 2017 Convertible Notes, which were subsequently converted into shares of common stock on December 31, 2017, the Company may only use the proceeds from the issuance of these Convertible Notes to focus on prioritizing operations on essential research and development activities. Also pursuant to the October 2016 Note Purchase Agreement, the Company's management has agreed to defer 20% of earned compensation and the Board of Directors has authorized a change in director compensation to defer 50% of the directors' cash compensation until at least $5,000,000 has been received in cumulative funding from non-current stockholders.

The Company has $9,000,000 in principal amount of Convertible Notes outstanding with Hankey Capital, a related party. The Convertible Notes mature on December 31, 2019 and bear interest at an annual rate of interest of the "prime rate" plus 4.0%, with a minimum rate of 8.5% per annum until maturity, with interest payable monthly in arrears. Prior to the Maturity Date, Hankey Capital has a right, in its sole discretion, to convert the Convertible Notes into shares of the Company's Common Stock, at a conversion rate equal to $1.00 per share.

Additionally we have a credit facility of $2,000,000 to be drawn down by the Company upon notice to Hankey Capital. The credit facility is evidenced by a convertible secured note convertible prior to the maturity date at $1.00 per share and due on December 31, 2019. Draws bear interest at an annual rate of interest at the "prime rate" plus 4.0%, with a minimum rate of 8.5% per annum until maturity, with interest payable monthly in arrears. At December 31, 2018, the Company had not drawn any funds under the facility. We drew down an additional $700,000 of working capital under the credit facility during March 2019.

Since all of the Notes and Credit Facility Line mature on December 31, 2019, the Company will be required to obtain an extension, refinance the Notes or obtain alternative funding to replace the Notes and Credit Facility. No assurance can be given that any of these alternatives will be available.

The Convertible Notes held by Hankey Capital are secured by 20,638,298 collateral shares of Common Stock issued by the Company in the name of Hankey Capital, in such amount so as to maintain a loan to value ratio equity to 50% (the "Collateral Shares"). The number of shares in the Collateral Shares shall be adjusted on a yearly basis. A Collateral Shares adjustment of 18,009,696 shares of Common Stock was issued during the year ended December 31, 2018. The principal amount of the loans are pre-payable in whole or in part at any time, without premium or penalty. The Collateral Shares are contractually restricted from transfer or sale. Upon any voluntary partial prepayment of outstanding principal, Hankey Capital will return Collateral Shares to the Company in the amount necessary, if any, to maintain the loan to value ratio at no less than 50%. Upon a full payment of the outstanding principal, all Collateral Shares shall be returned return and cancelled. Hankey Capital will also return Collateral Shares under the same terms in case of partial or full conversion of the Convertible Notes. All of the Company's personal property further secure the aggregate Convertible Notes, including collateral assignments of all the Company's license agreements and the MTF Sygnal Option Agreement.

For the past several years, we have depended on our relationship with Hankey Capital for working capital to fund our operations, which has been raised in the form of both debt and equity capital. Hankey Capital, directly and indirectly, controls approximately 87% of our issued and outstanding shares of common stock (including collateral shares) and has been issued convertible notes payable with an aggregate principal balance of $9,000,000 at December 31, 2018. We drew down an additional $700,000 of working capital under a $2,000,000 secured credit facility during March 2019. Representatives of Hankey Capital also currently serve as directors of the Company. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

As of December 31, 2018 and 2017, we had cash of $955,374 and $690,279, respectively.

Cash Flows

The following is a summary of our cash flows from operating, investing and financing activities for the years ended December 31, 2018 and 2017:

Operating activities

During the year ended December 31, 2018 and 2017, cash used in operating activities was $4,104,884 and $3,330,096 respectively. Cash expenditures for the year ended December 31, 2018 increased primarily due to the commencement of our large animal pivotal study. Management continues a 20% deferral of wages and the Board a 50% deferral of cash compensation.

Financing activities

During the year ended December 31, 2018, cash provided by financing activities of $4,369,979 resulted from the March 2018 equity purchase of common stock and the July 2018 Rights Offering and the private placement with Hankey Capital. During the year ended December 31, 2017, cash provided in financing activities of $3,400,000 resulted from the February and August 2017 convertible notes and the equity purchase of $700,000 of common stock.

Application of Critical Accounting Policies

We believe that our critical accounting policies are as follows:

- Research and Development Costs;
- Stock Based Compensation;
- Fair Value of Financial Instruments;
- Collateral Shares.

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

Research and Development Costs

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

Stock Based Compensation

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

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

Fair Value Measurements

We use fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures. We base our fair values on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Additionally, from time to time, we may be required to record certain assets at fair value on a non-recurring basis, such as certain impaired loans held for investment and securities held to maturity that are other-than-temporarily impaired. These non-recurring fair value adjustments typically involve write-downs of individual assets due to application of lower-of-cost or market accounting.

We have established and documented a process for determining fair value. We maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements. Whenever there is no readily available market data, management uses its best estimate and assumptions in determining fair value, but these estimates involve inherent uncertainties and the application of management's judgment. As a result, if other assumptions had been used, our recorded earnings or disclosures could have been materially different from those reflected in these financial statements. For detailed information on our use of fair value measurements and our related valuation methodologies, see Note 2 to the Consolidated Financial Statements of this report.

Collateral Shares

The Company accounts for the common shares issued as collateral for convertible promissory notes, whether upon original issuance or upon the required annual adjustment, as debt issuance costs in the form of a loan processing fee, which is determined by reference to the par value of the Company's common stock, with a corresponding charge to operations when such collateral shares are issued. The collateral shares are subject to significant contractual restrictions limiting their sale or transfer. As these common shares have been issued to and are held by the lender, and are contingently returnable to the Company under certain conditions, such shares are considered as issued and outstanding on the Company's balance sheet, but are not included in earnings per share calculations for all periods presented.

In the event of an uncured event of default, the Company will record a charge to operations to recognize that the collateral shares are no longer owned or controlled by the Company, and such prospective charge to operations would be based on the fair market value of the collateral shares at that time, and which would be classified as a cost of debt capital and recognized as a charge to operations.

Recently Issued Accounting Standards

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), Leases (Topic 842). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company has not yet evaluated the impact of the adoption of ASU 2016-02 on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued ASU No. 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception" ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered, and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common stockholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The guidance in ASU 2017-11 can be applied using a full or modified retrospective approach. The Company is currently evaluating the impact of the adoption of ASU 2017-11 on the Company's financial statement presentation or disclosures.

In September 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to nonemployee share-based payment accounting. This ASU simplifies the accounting and reporting for share-based payments issued to nonemployees by expanding the scope of ASC 718, Compensation - Stock Compensation, which currently only includes share-based compensation to employees, to also include share-based payments to nonemployees for goods and services. The standard is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than a company's adoption date of ASC 606. Management is currently in the process of evaluating the impact of the standard on its consolidated financial statements and disclosures.

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

Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the Company's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

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

Not applicable.

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

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

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

None.

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

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Financial Officer and Chief Executive Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (Exchange Act)) as of December 31, 2018. Based upon that evaluation, our Chief Financial Officer and Chief Executive Officer concluded that as of December 31, 2018, our disclosure controls and procedures were not effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the company's principal executive officers and effected by the company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

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

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

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

As of December 31, 2018, management assessed the effectiveness of our internal control over financial reporting and based on that assessment, we identified a material weakness in internal controls over financial reporting as of December 31, 2018 as further described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

During 2017, we did not maintain effective controls over the accounting for the occurrence, valuation, rights and obligations and presentation and disclosure of non-routine complex transactions. Specifically, we did not have effective controls surrounding the documentation, evaluation and review of the technical accounting considerations that were adequately designed to determine whether the transactions were accounted for appropriately. This control deficiency resulted in a misstatement of our prepaid expenses to related parties, shares to be issued, additional paid in capital, general and administrative expenses, other income (expense), and net loss. The misstatement was a result of certain non-cash transactions with consultants and the accounting for modifications to the terms of certain debt and warrant agreements, and resulted in the restatement of the Company's consolidated financial statements for the fiscal year 2016, each of the quarters of fiscal 2016 and the first three quarters of fiscal 2017. Additionally, this control deficiency could result in a misstatement of account balances or disclosures associated with non-routine complex transactions that would result in a material misstatement of the consolidated financial statements that would not be prevented or detected. Accordingly, our management has determined that this control deficiency constitutes a material weakness. Because of the material weakness, management concluded the Company did not maintain effective internal control over financial reporting as of December 31, 2018, based on criteria in Internal Control - Integrated Framework (1992) issued by the COSO.

Changes in Internal Control over Financial Reporting

During the fourth quarter, management implemented a third-party review of all non-routine transactions.

We believe that the controls that were implemented will improve the effectiveness of our internal control over financial reporting.

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

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

None.

Part III

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

The Company's directors are elected annually for a one year term or until their respective successors are duly elected and qualified or until their earlier resignation or removal. The following table sets forth certain information regarding the Company's directors and executive officers as of March 12, 2019:

Name	Age	Position
Stephen R. LaNeve	59	Chief Executive Officer and President and Director
Jeffrey Frelick	53	Chief Operating Officer
Deina H. Walsh	54	Chief Financial Officer
Don Hankey	75	Chairman of the Board of Directors
John Booth	64	Director
Bruce Stroever	68	Director
Bret Hankey	41	Director

Stephen R. LaNeve: Chief Executive Officer and President

Stephen R. La Neve has served as our Chief Executive Officer since August 17, 2015. He brings thirty-five years of health care experience, leadership and success. Prior to his current position, Steve held leadership roles in the device and diagnostic segments which include: CEO and president of Etex Corporation; president of Becton Dickinson's Pre-Analytical Systems business; president of Medtronic's $3.5b Spine and Biologics business; and president of Medtronic's then second largest country business unit, Medtronic Japan. He also served as senior vice president and executive vice president at Premier, one of the largest GPOs in the United States and ran the global Injection Systems business unit for Becton Dickinson. Additionally, Mr. LaNeve has held a number of commercial leadership roles at Becton Dickinson, Roche Diagnostics and E Merck Diagnostic Systems in sales, marketing, strategic planning and project management both in the US and outside the US. He serves on the board of directors for SkelRegen, LLC and Life Science Enterprise, and has served on the Board of Rapid Pathogen Screening, Inc. (RPS) up through its sale of the eye-care business. Mr. La Neve has consulted for private equity companies in the medical device area. Mr. LaNeve holds a B.S. in Health Planning and Administration from the Pennsylvania State University, an M.B.A. from West Chester University, and is a member of the Omicron Delta Epsilon honor society for academic excellence in economics.

Jeffrey Frelick: Chief Operating Officer

Jeffrey Frelick has served as our Chief Operating Officer since August 17, 2015. He was the COO of Life Science Enterprises, where he brings more than 25 years of med-tech experience. He spent the past 15 years on Wall Street as a sell-side analyst following the med-tech industry at investment banks such as Canaccord Genuity, ThinkEquity and Lazard. Prior to becoming an equity research analyst, Mr. Frelick worked at Boston Biomedical Consultants where he provided strategic planning assistance, market research data and due diligence for diagnostics companies. He previously held sales and sales management positions at Becton Dickinson's Primary Care Diagnostic Division after gaining technical experience as a laboratory technologist with Clinical Pathology Facility. Mr. Frelick received a B.S. in Biology from University of Pittsburgh and an M.B.A. from Suffolk University's Sawyer Business School.

Deina H. Walsh: Chief Financial Officer

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

Don Hankey: Chairman of the Board of Directors

Mr. Hankey holds his BA and post-graduate work from the University of Southern California. At age 27, Mr. Hankey became Vice President of a major investment banking firm, which would later become part of USB Paine Weber. Mr. Hankey acquired Midway Ford in 1972 and founded Hankey Investment Company in 1982. During the 1980s Mr. Hankey's organization grew its portfolio and established a foothold in the financial services industry. Mr. Hankey has incorporated technology into every aspect of the Hankey Group of companies improving efficiencies and outcomes. Mr. Hankey has been the manager of Hankey Capital, LLC, since its formation in 2002. Given Mr. Hankey's financial experience, the Company believes he is well qualified to serve as the Chairman of the Board of Directors.

Bruce Stroever: Director

Mr. Stroever has forty years of product development and general management experience in the medical device and orthobiologics fields. Mr. Stroever joined MTF in late 1988 as General Manager and and retired in mid-2018 from his position as the President and Chief Executive Officer of MTF. He served as MTF's President since his appointment in 1992 and as Chief Executive Officer since 1996. Under Mr. Stroever's leadership, MTF grew to be the largest tissue bank in the world providing over 500,000 grafts per year with revenues over $400 million. From 1971 to 1988, Mr. Stroever held several positions with Ethicon, Inc., a Johnson & Johnson, Inc. subsidiary. Mr. Stroever currently serves on the advisory board for the New Jersey Organ and Tissue Sharing Network. He was 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 has served as the Chairman of Bone's Board of Directors since 2012. Mr. Stroever received his B.E. in Mechanical/Chemical Engineering from Stevens Institute of Technology in 1972 and a Masters of Science in Bioengineering from Columbia University in 1977.

John Booth: Director

Mr. Booth has been CEO of Spineology Inc. since 2004 and has been a board member since its inception in 1998. Spineology is involved in the development and commercialization of minimally invasive spinal implants and access systems. Mr. Booth held various executive level positions at Phillips Plastics Corporation, most recently serving as CEO from June of 2001 to December 2002. Before serving as CEO of Phillips, he was CEO of Microvena Corporation, a cardiovascular device subsidiary of Phillips, from 1999 to 2001 and CEO of Phillips Origen Group Division from 1998 to 1999. Prior to Phillips, Mr. Booth was President and CEO of INCSTAR Corporation, a publicly held medical technology company involved in in-vitro diagnostics. He has held various positions in both financial and general management in the medical technology industry since 1981. Mr. Booth has also serve on the boards of directors of INCSTAR Corporation from 1994 to 1997, Microvena Corporation from 1998 to 2001, Phillips Plastics Corporation from 2000 to 2002, Imricor Medical Systems Inc. from 2007 to 2014, Data Sciences International from January 2017 to January 2018, and Spineology Inc. from 1998 to the present. Mr. Booth received a B.S. degree in accounting from Villanova University and an MBA from Seton Hall University.

Bret Hankey: Director

Mr. Hankey has served in various capacities within the Hankey Group and currently serves as the President of the Hankey Group and is a member of the board of directors on all major companies that comprise the Hankey Group. Headquartered in Los Angeles, California, the Hankey Group is comprised of seven operating companies specializing primarily in the automotive, finance, technology, real estate and insurance industries. Since 2007, Mr. Hankey has also served in various capacities with Westlake Financial Services, a member of the Hankey Group, and is currently the Vice Chairman and Executive Vice President of Westlake Financial. Westlake Financial is the largest privately held automotive finance company in the United States. Mr. Hankey graduated from the University of Southern California in 2000 with a B.S. in Business Administration and Finance.

Family Relationships

Don Hankey is the father of Bret Hankey.

Board of Directors and Corporate Governance

Our Board of Directors currently consists of five (5) members, consisting of Don Hankey, Bruce Stroever, John Booth, Bret Hankey, and Stephen R. LaNeve.

Board Committees

Our Board of Directors has appointed an audit committee, governance committee and compensation committee. The Board of Directors met or acted by written consent 11 times during 2018.

Audit Committee

The audit committee is responsible for overseeing: (i) our accounting and reporting practices and compliance with legal and regulatory requirements regarding such accounting and reporting practices; (ii) the quality and integrity of our financial statements; (iii) our internal control and compliance programs; (iv) our independent auditors' qualifications and independence and (v) the performance of our independent auditors and our internal audit function. In so doing, the audit committee maintains free and open means of communication between our directors, internal auditors and management. We are not required to have an Audit Committee consisting solely of independent directors or required to have an "audit committee financial expert" as we are neither listed on NASDAQ nor the New York Stock Exchange.

Our audit committee consists of John Booth, as Chairman. Jimmy Delshad was a member of the audit committee. He resigned effective August 1, 2018. The Audit committee met four times during 2018.

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.

Our compensation committee consists of John Booth, as Chairman. Jimmy Delshad was a member of the compensation committee. He resigned effective August 1, 2018. The compensation committee met once during 2018.

Nominating and Corporate Governance Committee

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

Our nominating and corporate governance committee consists of John Booth. Jimmy Delshad was a member of the compensation committee. He resigned effective August 1, 2018. The nominating and corporate governance committee met once during 2018.

Code of 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 Ethics is available at our website www.bonebiologics.com/investor-relations/corporate-governance/.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's 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 the Company with copies of all Section 16(a) forms they file.

To the Company's knowledge, based solely on a review of the copies of such reports furnished to the Company during the fiscal year ended December 31, 2018, all Section 16(a) filing requirements applicable to its officers, directors and greater than ten percent beneficial owners were complied with except that Don Hankey failed to file one report of one transaction.

Indemnification Agreements

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

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

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

Item 11. ***Executive Compensation***

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

Name and Principal Position	Year	Salary	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Deferred Compensation ($)[1]	All Other Compensation ($)	Total Compensation ($)
Stephen R. LaNeve, Chief Executive Officer, President, Director	2018	$400,000		$ -	$ -		$ 100,000		$ 500,000
	2017	$400,000		$ -	$ -		$ 100,000		$ 500,000
Jeffrey Frelick, Chief Operating Officer	2018	$240,000		$ -	$ -		$ 60,000		$ 300,000
	2017	$240,000		$ -	$ -		$ 60,000		$ 300,000
Deina Walsh, Chief Financial Officer	2018	$160,000		$ -	$ -		$ 40,000		$ 200,000
	2017	$160,000		$ -	$ -		$ 40,000		$ 200,000

(1) Pursuant to the October 2017 Note Purchase Agreement, the Company's management has agreed to defer 20% of earned compensation.

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

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

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

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

- **2015 Equity Incentive Plan:** The Company has 1,400,000 shares of Common Stock authorized and reserved for issuance under our 2015 Equity Incentive Plan for option awards. This reserve may be increased by the Board each year by up to the number of shares of stock equal to 5% of the number of shares of stock issued and outstanding on the immediately preceding December 31. Appropriate adjustments will be made in the number of authorized shares and other numerical limits in our 2015 Equity Incentive Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards granted under our 2015 Equity Incentive Plan which expire, are repurchased or are cancelled or forfeited will again become available for issuance under our 2015 Equity Incentive Plan. The shares available will not be reduced by awards settled in cash. Shares withheld to satisfy tax withholding obligations will not again become available for grant. The gross number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under our 2015 Equity Incentive Plan.

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

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

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

Stephen R. LaNeve, Chief Executive Officer:

Base Salary: Mr. LaNeve's base salary is $500,000.

Bonus: During each calendar year, Mr. LaNeve shall be eligible to earn an annual target bonus of seventy percent (70%) of his base salary as in-effect for the applicable calendar year, subject to the achievement of personal and corporate objectives or milestones to be established by the board of directors, or any compensation committee thereof, (after considering any input or recommendations from Mr. LaNeve) within sixty (60) days following the beginning of each calendar year during Mr. LaNeve's employment. In order to earn the annual bonus under this provision, the applicable objectives must be achieved and Mr. LaNeve 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 seventy percent (70%) of Mr. LaNeve's base salary.

There was no bonus accrual during the year ended December 31, 2018. During the year ended December 31, 2017, Mr. LaNeve received bonus of $280,000 consisting of a restricted stock grant.

Stock Options: Mr. LaNeve was granted an option to purchase 6% of the then outstanding shares of the Company's common stock, at an exercise price that equals to the fair market price on the date of the grant. These options will vest annually over three (3) years such that they are vested in full on the third year anniversary of the employment agreement date, provided, that any stock option that is unvested on the date of termination shall be forfeited on such date of termination, subject to certain exceptions.

Jeffrey Frelick, Chief Operating Officer:

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

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

There was no bonus accrual during the year ended December 31, 2018. During the year ended December 31, 2017, Mr. Frelick received bonus of $120,000 consisting of a restricted stock grant.

Stock Options: Mr. Frelick was granted an option to purchase 3% of the then outstanding shares of the Company's common stock, at an exercise price that equals to the fair market price on the date of the grant. These options will vest annually over three (3) years such that they are vested in full on the third year anniversary of the employment agreement date, provided, that any stock option that is unvested on the date of termination shall be forfeited on such date of termination, subject to certain exceptions.

Deina H. Walsh, Chief Financial Officer:

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

Bonus: During each calendar year beginning in 2017, Ms. Walsh shall be eligible to earn an annual target bonus of thirty-five percent (35%) of her base salary as in-effect for the applicable calendar year, subject to the achievement of personal and corporate objectives or milestones to be established by the board of directors, or any compensation committee thereof, (after considering any input or recommendations from Ms. Walsh) within sixty (60) days following the beginning of each calendar year during Ms. Walsh's employment. In order to earn the annual bonus under this provision, the applicable objectives must be achieved and Ms. Walsh must be employed by Company at the time the annual bonus is distributed by Company. The annual bonus, if any, shall be paid on or before March 15th of the calendar year following the year in which it is considered earned. The actual annual bonus paid may be more or less than thirty-five percent (35%) of Ms. Walsh's base salary.

There was no bonus accrual during the year ended December 31, 2018. During the year ended December 31, 2017, Ms. Walsh received bonus of $56,000 consisting of a restricted stock grant.

Stock Options: On November 4, 2014**,** Ms. Walsh was granted an option to purchase 0.75% or 23, 983 of the Company's fully diluted shares of common stock. The option was granted under Company's stock plan and related stock option documents. The Option was intended to be an "incentive stock option" (within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended) to the greatest extent permitted under the code. The option has an exercise price of $10.00 per share, equal to the price of the shares awarded under the Merger Agreement in connection with the Merger. As a condition of receipt of the option, Ms. Walsh was required to sign Company's standard form of stock option agreement and the option is subject to the terms and conditions of the plan, the option agreement and her employment agreement. The option vests over a three-year period from the effective date subject to Ms. Walsh's continued Service (as defined in the plan), with 33.33% of the shares subject to the option becoming vested and exercisable on the date that Ms. Walsh's employment agreement is executed, 33.33% of the shares subject to the option becoming vested and exercisable on the date that is twelve (12) months after the effective date, and 33.34% of the shares subject to the option vesting and becoming exercisable on the date that is twenty four (24) months after the effective date; provided, however, that all unvested shares subject to the option (and any additional equity awards hereafter issued by Company to Ms. Walsh pursuant to the plan) shall fully vest and be exercisable if Ms. Walsh's service ceases as a result of a "qualifying termination" occurring on or within twelve (12) months after a "change in control."

On December 1, 2015, Ms. Walsh is entitled to purchase 46,580 shares of Common Stock of the Company as of the date of the grant on the condition that i) the exercise price was the current market price on the date of the grant; and ii) 15,526 of the shares underlying the grant shall vest on the first anniversary of the execution of the Letter Agreement, 15,527 of the shares underlying the grant shall vest on the second anniversary of the execution of the Letter Agreement and 15,527 of the shares underlying the grant shall vest on the third anniversary of the Letter Agreement. Any portion of the stock option grant that is unvested on the date of her 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, which shall result in the immediate accelerated vesting of all options granted but unvested under the letter agreement as of (i) or (ii). such options shall be subject to the terms of the equity incentive plan and stock option agreements which shall be entered into at a later mutually agreed-upon date to prevent or mitigate dilution of her equity interests in the Company, in connection with each financing, she shall be provided an opportunity to invest in the Company such that her interest, at her option, remains un-diluted or partially diluted.

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

Potential Payments upon Termination of Change in Control

None.

Changes to Potential Payments upon Termination of Change in Control

None.

Consulting Agreements for Executives

None other than noted above.

Grants of Plan-Based Awards

None.

Executives Outstanding Equity Awards at Fiscal Year End

Name	Grant Date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares of units of stock that have not vested ($)	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested (#)	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested ($)
(a)		(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Stephen R. LaNeve, Chief Executive Officer, President, Director	May 27, 2017	53,829	-	-	$ 20.50	May 27, 2026	-	-	-	-
	December 28, 2015	208,120	-	-	$ 15.90	December 27, 2025	-	-	-	-
		-	-	-	-	-	-	-	17,656	$ 16,597
Jeffrey Frelick, Chief Operating Officer	May 27, 2017	26,915	-	-	$ 20.50	May 27, 2026	-	-	-	-
	December 28, 2015	104,060	-	-	$ 15.90	December 27, 2025	-	-	-	-
		-	-	-	-	-	-	-	7,739	$ 7,275
Deina Walsh, Chief Financial Officer	December 28, 2015	6,491	-	-	$ 15.90	December 27, 2025	-	-	-	-
	December 28, 2015	46,580	-	-	$ 15.90	December 27, 2025	-	-	-	-

December 28, 2015	17,492	-	-	$ 15.90	December 27, 2025	-	-	-	-
	-	-	-	-	-	-	-	3,954	$ 3,717

Director Compensation

The following table shows information regarding the compensation earned during the year ended December 31, 2018 by the members of our board of directors.

Name	Fees Earned or Paid in Cash[2]	Option Awards	Share Awards	Total
Bruce Stroever[1]	$ -	$ -	-	$ -
Don Hankey[1]	-	-	-	-
John Booth	17,500	50,000	-	67,500
Jimmy Delshad[3]	7,292	25,000	-	32,292
Bret Hankey[1]	-	-	-	-
Total	$ 24,792	$ 75,000	$ -	$ 99,792

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

(2) Pursuant to the October 2017 Note Purchase Agreement, the Board of Directors authorized a change in director compensation to defer 50% of the directors' cash compensation until at least $5,000,000 has been received in cumulative funding from non-current stockholders.

(3) Mr. Delshad resigned effective August 1, 2018.

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

Annual Cash Compensation

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

1. Annual Board Service Retainer:

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

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

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

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

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

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

Pursuant to the October 2017 Note Purchase Agreement, the Board of Directors has authorized a change in director compensation to defer 50% of the directors' cash compensation until at least $5,000,000 has been received in cumulative funding from non-current stockholders.

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 ("Common Stock") on the date of grant.

(a) Automatic Equity Grants.

(i) Initial Grant for New Directors. Without any further action of the Board, each person who, after the Effective Date, is elected or appointed for the first time to be a Non-Employee Director will automatically, upon the date of his or her initial election or appointment to be a Non-Employee Director, be granted a Nonstatutory Stock Option to purchase 50,000 shares of Common Stock (the "Initial Grant"), regardless of when such person is elected or appointed to the Board. Each Initial Grant will fully vest on the date of the annual meeting of the stockholders of the Company ("Annual Meeting") next following the Initial Grant.

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

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

The following table sets forth information with respect to the beneficial ownership of the Company's Common Stock as of March 25, 2019, by each person or group of affiliated persons known to the Company to beneficially own 5% or more of its Common Stock, each director, each named executive officer, and all of its directors and named executive officers as a group.

Name of Beneficial Owner or Identity of Group	Title of Class	Shares[1]	Percentage
5% or greater stockholders:			
The Musculoskeletal Transplant Foundation, Inc. 175 May Street Edison, NJ 08837	Common Stock	1,563,582(2)	5.9%
Hankey Capital, LLC 4751 Wilshire Blvd #110 Los Angeles, CA 90010	Common Stock	25,063,903(3)	88.0%
Executive Officers and Directors:			
Don R. Hankey 4751 Wilshire Blvd #110 Los Angeles, CA 90010	Common Stock	25,699,783(4)	90.2%
Stephen LaNeve, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	261,949(5)	1.0%
Jeffrey Frelick, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	130,975(6)	0.5%
Deina H. Walsh, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	70,563(7)	0.3%
Bruce Stroever 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803 (8)	Common Stock	-	-
John Booth, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	14,228(9)	0.1%
Bret Hankey, 2 Burlington Woods Drive, Ste 100, Burlington, MA 01803	Common Stock	28,034	0.1%
Total Officers and Directors as a Group (7 persons)	Common Stock	26,205,532(10)	90.5%

(1) Based on 27,938,243 issued and outstanding shares. The number of shares issued and outstanding that was used to calculate the percentage ownership of each listed person includes the shares underlying convertible debt, stock options and warrants that are exercisable 60 days from our report date.

(2) Consists of 1,479,243 shares, 79,339 shares underlying warrants exercisable within 60 days and 5,000 shares underlying stock options exercisable within 60 days.

(3) Consists of 3,867,870 shares, 20,638,298 collateral shares for which Hankey Capital has voting rights and 557,735 shares issuable upon exercise of warrants issued exercisable within 60 days. Collateral shares are contractually restricted from sale and will be returned and cancelled following payment of principal amounts on the loans with Hankey Capital. Excludes shares issuable upon draws under a credit facility provided by Hankey Capital.

(4) Mr. Hankey is the Manager of Hankey Capital. Mr. Hankey is the beneficial owner of 25,699,783 shares of the Company consisting of 3,867,870 shares owned by Hankey Capital, 20,638,298 collateral shares for which Hankey Capital has voting rights, 361,640 shares owned by the Don Hankey Trust (the "Trust") of which Mr. Hankey is the Trustee, 274,240 shares held by H&H Funding LLC of which Mr. Hankey is the sole manager and 557,735 shares issuable upon exercise of warrants issued to Hankey Capital. Hankey Capital is owned by Hankey Investment Company LP ("HIC") of which the Trust owns a 66.09% interest. The general partner of HIC is Knight Services Inc. of which the Trust is the sole owner. Collateral shares are contractually restricted from sale and will be returned and cancelled following payment of principal amounts on the loans with Hankey Capital.

(5) Includes 261,949 shares underlying stock options exercisable within 60 days.

(6) Includes 130,975 shares underlying stock options exercisable within 60 days.

(7) Includes 70,563 shares underlying stock options exercisable within 60 days.

(8) Mr. Stroever is the past President and Chief Executive Officer of the Musculoskeletel Transplant Foundation, Inc.

(9) Includes 12,145 shares underlying stock options exercisable within 60 days.

(10) Consisting of 4,533,867 shares, 20,638,298 collateral shares for which Hankey Capital has voting rights, 557,735 shares issuable upon exercise of warrants and 475,632 shares underlying stock options exercisable within 60 days. Collateral shares are contractually restricted from sale and will be returned and cancelled following payment of principal amounts on the loans with Hankey Capital.

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

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

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

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

Musculoskeletal Transplant Foundation (MTF)

On August 18, 2017, the Company entered into a share purchase agreement with MTF, pursuant to which MTF purchased from the Company an aggregate of 23,333 shares of common stock of the Company at a price per share equal to $30.00 for total proceeds of $700,000.

On May 23, 2018, pursuant to the August 2017 share purchase agreement with MTF, the Company issued 46,667 shares of common stock to equal the most favorable terms of the private placement offering.

Bruce Stroever, Director, is the past President and Chief Executive Officer of MTF.

Founders

The Company entered into a Letter Agreement dated September 24, 2015, with each of Dr. Chia Soo, Dr. Eric Kang Ting and Dr. Ben Wu (collectively, the "Founders"). The Founders were three of the original shareholders of the Company. Pursuant to the Letter Agreement, the Founders agrees to deliver to the Company all past work product and past data related to NELL-1 (the "Data") for use by the Company in its sole discretion, within the applicable licensing rights granted under the UCLA license and in exchange the Company agreed to the future issuance of an aggregate of 115,385 shares of the Company's common stock. The Shares are to be equally distributed between the Founders upon the earlier of (i) the third anniversary of the Agreement and (ii) the occurrence of a Liquidity Event (as defined in the Letter Agreement) and are currently reported as Shares to be Issued. During the year ended December 31, 2018, 115,385 shares were issued pursuant to the Letter Agreement.

Effective January 8, 2016, the Company entered into separate Professional Services Agreements with each of the Founders. Pursuant to each of the Agreements, each Founder agreed to provide certain services to the Company, including providing strategic advice and strategic introductions to the Company's management team as well as specific services set forth on an Exhibit to each Agreement. The Agreements are substantially identical. In consideration for the services to be rendered under the applicable Agreement, each Founder was granted a 10-year stock option (the "Options") to purchase 180,036 shares of the Company's common stock corresponding to 4% of the Company's outstanding common stock, on a fully diluted basis, at an exercise price of $15.90 (post reverse split) per share. Additionally, beginning January 1, 2017, the Company was to pay each Founder an annual consulting fee of $200,000 in cash or, at the option of the Company, in shares of its common stock valued as provided in the Agreement. On June 1, 2016, the Company agreed to issue to each Founder a 10-year stock option to purchase 3,310 shares of the Company's common stock at an exercise price of $20.50 (post reverse split) per share as an adjustment to amounts due under the Agreements. All options issued to the Founders under the Agreements immediately terminate if the Agreements are terminated for cause.

On December 13, 2016, the Company provided written notice to each of the Founders that it was terminating the Agreements for cause, indicating that absent cure of the material breach of the Agreements, termination of the Agreements was to be effective on January 12, 2017. Despite lengthy discussions with the Founders, and multiple extensions of the termination date to accommodate such discussions, the Company was unable to resolve the outstanding issues under the Agreements, and the Company provided notice that the Agreements were terminated, effective as of April 8, 2017. The Founders have disputed the right of the Company to terminate for cause.

Dr. Soo and Dr. Wu resigned as directors of the Company effective April 13, 2017, and Dr. Ting resigned as a member of the Company's Scientific Advisory Board on April 13, 2017. Each of the Advisors were involved in the founding of the Company. Our licensing agreement with UCLA is independent of the Founders' services and remains unchanged as a result of the Founders resignation.

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 currently consists of five (5) members: Don Hankey, Bruce Stroever, John Booth, Bret Hankey and Stephen R. LaNeve. 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 his background, employment and affiliations, including family relationships, our Board of Directors has determined that John Booth would qualify as "independent" as that term is defined by NASDAQ Listing Rule 5605(a) (2). Don Hankey would not qualify as "independent" under applicable NASDAQ Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he is the CEO and Chairman of the Hankey Group. Hankey Capital, LLC is part of the Hankey Group, and a significant shareholder of the Company and an entity to whom the Company continues to owe obligations to pursuant to notes outstanding to Hankey Capital, LLC. Bruce Stroever would not qualify as "independent" under applicable NASDAQ Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he was the Chief Executive Officer of MTF, a significant shareholder of the Company. Bret Hankey would not qualify as "independent" under applicable NASDAQ Listing Rules applicable to the Board of Directors generally or to separately designated board committees because he is the President of the Hankey Group and is a member of the board of directors on all major companies that comprise the Hankey Group. Hankey Capital, LLC is part of the Hankey Group, and a significant shareholder of the Company and an entity to whom the Company continues to owe obligations to pursuant to notes outstanding to Hankey Capital, LLC. In making such determinations, our Board of Directors considered the relationships that each of our nonemployee directors has with the Company and all other facts and circumstances deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

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

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

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

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

The following table sets forth the aggregate fees billed to us during the years ended December 31, 2018 and 2017.

Audit Fees

	2018	2017
Anton & Chia[(1)]	$ -	$ 41,612
Weinberg & Company, P.A.	$ 143,476	$ -

(1) Effective December 6, 2017, Anton & Chia, LLP ("Anton") was dismissed as the independent accountant of the Company.

Audit Related Fees

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

Tax Fees

Foster, Griffith and Allen, Inc.	$ 4,350	$ 4,632

Part IV

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

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

(1) Financial Statements:

(2) Financial Statement Schedules:

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

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

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of September 19, 2014, by and among AFH Acquisition X, Inc., Bone Biologics Acquisition Corp., and Bone Biologics, Inc. (incorporated herein by reference to Exhibit 2.1 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
2.2	Certificate of Merger as filed with the California Secretary of State effective September 19, 2014 (incorporated herein by reference to Exhibit 2.2 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
3.1(i)	Amended and Restated Articles of Incorporation, of Bone Biologics Corporation, as filed with the Delaware Secretary of State on July 28, 2014 (incorporated herein by reference to Exhibit 3.1(i) to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
3.1(ii)	Amended and Restated Bylaws of Bone Biologics Corporation (incorporated herein by reference to Exhibit 3.1(ii) to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.1	Bone Biologics Corporation September 2013 Warrant issued to AFH (incorporated herein by reference to Exhibit 4.1 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.2	Bone Biologics Corporation June 2013 Warrant issued to Orthofix (incorporated herein by reference to Exhibit 4.2 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.3	Bone Biologics Corporation April 2013 Warrant issued to MTF (incorporated herein by reference to Exhibit 4.3 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)

4.4	Amendment to Bone Biologics Corporation April 2013 Warrant issued to MTF, June 2013 Warrant issued to Orthofix and September 2013 Warrant issued to AFH (incorporated herein by reference to Exhibit 4.4 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.5	Bone Biologics Corporation March 2009 Warrant issued to MTF (incorporated herein by reference to Exhibit 4.6 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.6	Bone Biologics Corporation Warrant issued to Chia Soo (incorporated herein by reference to Exhibit 4.8 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.7	Bone Biologics Corporation Warrant issued to Aragen Bioscience, Inc. (incorporated herein by reference to Exhibit 4.9 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.8	Bone Biologics Corporation Warrant issued to Alquest, Inc. (incorporated herein by reference to Exhibit 4.10 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.9	Bone Biologics Corporation October 2013 Warrant issued to Orthofix (incorporated herein by reference to Exhibit 4.11 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.10	Bone Biologics Corporation July 2014 Warrant issued to AFH (incorporated herein by reference to Exhibit 4.14 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.11	Bone Biologics Corporation Warrant issued to Catherine Doll (incorporated herein by reference to Exhibit 4.15 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.12	Bone Biologics Corporation Warrant issued to Forefront Capital Markets, LLC (incorporated herein by reference to Exhibit 4.16 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.13	Bone Biologics Corporation September 2014 Warrant issued to MTF(incorporated herein by reference to Exhibit 4.17 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
4.14	Form of Registration Rights Agreement, by and between Bone Biologics Corporation, AFH, HIC and MTF (incorporated herein by reference to Exhibit 4.18 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
10.1	Director Offer Letter, dated July 1, 2014, by and between Bruce Stroever and Bone Biologics Corporation (incorporated herein by reference to Exhibit 10.4 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014) +
10.2	Director Offer Letter, dated August 22, 2014, by and between John Booth and Bone Biologics Corporation (incorporated herein by reference to Exhibit 10.5 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)+
10.3	Bone Biologics Corporation Convertible Secured Term Note issued to Hankey Capital, LLC on October 24, 2014 (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed October 30, 2014)
10.4	Bone Biologics Corporation Warrant issued to Hankey Capital, LLC on October 24, 2014 (incorporated herein by reference to Exhibit 10.2 to current report on Form 8-K, File No. 000-53078, filed October 30, 2014)

10.5	Registration Rights Agreement by and between Bone Biologics Corporation and Hankey Capital, LLC, dated October 24, 2014 (incorporated herein by reference to Exhibit 10.3 to current report on Form 8-K, File No. 000-53078, filed October 30, 2014)
10.6	Bone Biologics Corporation Convertible Secured Term Note issued to Hankey Capital, LLC on May 4, 2015 (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed May 6, 2015)
10.7	Bone Biologics Corporation Warrant issued to Hankey Capital, LLC on May 4, 2015 (incorporated herein by reference to Exhibit 10.2 to current report on Form 8-K, File No. 000-53078, filed May 6, 2015)
10.8	Chief Executive Officer Employment agreement, dated June 8, 2015 by and between Bone Biologics Corporation and Stephen R. LaNeve (incorporated herein by reference to Exhibit 10.1 to current report on Form 10-Q, File No. 000-53078, filed August 14, 2015)+
10.9	Chief Operating Officer Employment agreement, dated June 8, 2015, by and between Bone Biologics Corporation and Jeffrey Frelick (incorporated herein by reference to Exhibit 10.2 to current report on Form 10-Q, File No. 000-53078, filed August 14, 2015)+
10.10	Letter Agreement, dated October 2, 2015, by and between the Company and the Founders (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed October 08, 2015)
10.11	Chief Financial Officer full time Employment agreement, dated November 9, 2015, by and between Bone Biologics Corporation and Deina H. Walsh (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed November 13, 2015)+
10.12	Independent Contractor Agreement, dated November 13, 2015, by and between the Company and Consultant (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed November 16, 2015)
10.13	Bone Biologics Corporation Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.14	Amendment to Director Offer Letter by and between The Musculoskeletal Transplant Foundation and Bone Biologics Corporation and MTF Option Grant Package (incorporated herein by reference to Exhibit 10.2 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.15	Bone Biologics Corporation 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.16	Form of Stock Award Grant Notice and Stock Award Agreement for the Bone Biologics Corporation 2015 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.17	Form of Restricted Stock Unit Award (incorporated herein by reference to Exhibit 10.5 to current report on Form 8-K, File No. 000-53078, filed January 4, 2016)
10.18	AFH Letter of Intent dated May 6, 2014 (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed February 16, 2016)
10.19	Stock Purchase Agreement with Musculoskeletal Transplant Foundation, Inc. dated as of February 22, 2016 (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed February 26, 2016)
10.20	Stock Purchase Agreement with Orthofix, Inc. dated as of February 22, 2016 (incorporated herein by reference to Exhibit 10.2 to current report on Form 8-K, File No. 000-53078, filed February 26, 2016)

10.21	Option Agreement for the Distribution and Supply of Sygnal™ dated as of February 24, 2016 (incorporated herein by reference to Exhibit 10.3 to current report on Form 8-K, File No. 000-53078, filed February 26, 2016)
10.22	Bone Biologics Corporation Convertible Secured Term Note issued to Hankey Capital on February 24, 2016 (incorporated herein by reference to Exhibit 10.4 to current report on Form 8-K, File No. 000-53078, filed February 26, 2016)
10.23	Bone Biologics Corporation Warrant issued to Hankey Capital on February 24, 2016 (incorporated herein by reference to Exhibit 10.5 to current report on Form 8-K, File No. 000-53078, filed February 26, 2016)
10.24	Registration Rights Agreement between the Company and Hankey Capital dated as of February 24, 2016 (incorporated herein by reference to Exhibit 10.6 to current report on Form 8-K, File No. 000-53078, filed February 26, 2016)
10.25	Separation Agreement, dated as of February 29, 2016, effective March 14, 2016 between the Company and William Jay Treat (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed March 15, 2016)
10.26	Stock Purchase Agreement with Musculoskeletal Transplant Foundation, Inc. dated as of August 18, 2017 (incorporated herein by reference to Exhibit 10.2 to current report on Form 8-K, File No. 000-53078, filed August 23, 2017)
10.27	Amended and Restated Exclusive License Agreement, dated as of August 18, 2017, by and between the Company and The Regents of the University of California (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed August 23, 2017)
10.28	Subscription Agreement dated as of March 26, 2018 with Orthofix Holdings, Inc. (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed March 29, 2018)
10.29	Note Purchase Agreement with Hankey Capital, LLC dated as of May 14, 2018 (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed May 15, 2018)
10.30	Bone Biologics Corporation Note issued to Hankey Capital, LLC (incorporated herein by reference to Exhibit 10.2 to current report on Form 8-K, File No. 000-53078, filed May 15, 2018)
10.31	Securities Purchase Agreement with Hankey Capital, LLC dated as of June 11, 2018 (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed June 12, 2018)
10.32	Form of Convertible Secured Note (incorporated herein by reference to Exhibit 10.2 to current report on Form 8-K, File No. 000-53078, filed June 12, 2018)
10.33	Second Amendment to Convertible Secured Term Note (October 24, 2014 Note) with Hankey Capital, LLC dated as of June 11, 2018 (incorporated herein by reference to Exhibit 10.3 to current report on Form 8-K, File No. 000-53078, filed June 12, 2018)
10.34	Second Amendment to Convertible Secured Term Note (May 4, 2015 Note) with Hankey Capital, LLC dated as of June 11, 2018 (incorporated herein by reference to Exhibit 10.4 to current report on Form 8-K, File No. 000-53078, filed June 12, 2018)
10.35	First Amendment to Convertible Secured Term Note (February 24, 2016 Note) with Hankey Capital, LLC dated as of June 11, 2018 (incorporated herein by reference to Exhibit 10.5 to current report on Form 8-K, File No. 000-53078, filed June 12, 2018)

10.36	Amendment to Securities Purchase Agreement dated as of July 16, 2018 between the Company and Hankey Capital. (incorporated herein by reference to Exhibit 10.1 to current report on Form 8-K, File No. 000-53078, filed June 19, 2018)
10.37	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.17 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
14.1	Code of Ethics
21.1	Subsidiaries (incorporated herein by reference to Exhibit 21.1 to current report on Form 8-K, File No. 000-53078, filed September 25, 2014)
23.1	Consent of Weinberg & Company *
24.1	Power of Attorney (included on signature page of this Form 10-K)
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, 2018.*
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, 2018.*
32.1	Certification of the Company's Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of the Company's Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed Herewith

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

None.

SIGNATURES

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

March 29, 2019

BONE BIOLOGICS CORPORATION

By: */s/ Stephen R. LaNeve*
Name: Stephen R. LaNeve
Title: Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stephen R. LaNeve 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 Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Stephen R. LaNeve Stephen R. LaNeve	Chief Executive Officer (Principal Executive Officer)	March 29, 2019
/s/ Deina H. Walsh Deina H. Walsh	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2019
/s/ Bruce Stroever Bruce Stroever	Director	March 29, 2019
/s/ Bret Hankey Bret Hankey	Director	March 29, 2019
/s/ John Booth John Booth	Director	March 29, 2019
/s/ Don R. Hankey Don R. Hankey	Director	March 29, 2019

Bone Biologics Corporation

Contents

Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders 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, 2018 and 2017, the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the consolidated results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, during the year ended December 31, 2018 the Company incurred a net loss and utilized cash flows in operations, and at December 31, 2018 had a stockholders' deficit. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement, whether due to error 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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

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

WEINBERG & COMPANY, P.A.
Los Angeles, California
March 29, 2019

Bone Biologics Corporation
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets		
Cash	**$ 955,374**	$ 690,279
Prepaid expenses	**85,288**	105,234
Total current assets	**1,040,662**	795,513
Property and equipment, net	**50**	146
Total assets	**$ 1,040,712**	$ 795,659
Liabilities and Stockholders' Deficit		
Current liabilities		
Accounts payable and accrued expenses	**$ 197,220**	$ 720,128
Current portion of notes payable – related party	**9,000,000**	-
Deferred compensation	**441,667**	241,667
Total current liabilities	**9,638,887**	961,795
Notes payable – related party, net of debt discount of $0 and $770,313, respectively	**-**	8,229,687
Total liabilities	**9,638,887**	9,191,482
Commitments and Contingencies		
Stockholders' deficit		
Preferred Stock, $0.001 par value per share; 20,000,000 shares authorized; none issued or outstanding at December 31, 2018 and 2017	**-**	-
Common stock, $0.001 par value per share; 100,000,000 shares authorized; 26,448,881 and 4,328,080 shares issued and outstanding at December 31, 2018 and 2017, respectively	**26,449**	4,328
Additional paid-in capital	**54,990,797**	48,961,794
Common stock to be issued to related parties; -0- and 115,385 shares at December 31, 2018 and 2017, respectively	**-**	1,823,077
Accumulated deficit	**(63,615,421)**	(59,185,022)
Total stockholders' deficit	**(8,598,175)**	(8,395,823)
Total liabilities and stockholders' deficit	**$ 1,040,712**	$ 795,659

See accompanying notes to consolidated financial statements.

Bone Biologics Corporation
Consolidated Statements of Operations

	Year Ended December 31, 2018	Year Ended December 31, 2017
Revenues	**$ -**	**$ -**
Cost of revenues	**-**	-
Gross profit	**-**	-
Operating expenses		
Research and development		
Trade	**104,490**	1,415,485
Related party (includes Founders stock-based compensation of -0- and ($2,744,749) for the years ended December 31, 2018 and 2017, respectively)	**-**	(2,744,749)
General and administrative	**2,686,399**	3,955,856
Total operating expenses	**2,790,889**	2,626,592
Loss from operations	**(2,790,889)**	(2,626,592)
Other expenses		
Interest expense - related party	**(1,229,487)**	(4,423,380)
Loss on debt extinguishment - related party	**(408,294)**	-
Total other expenses	**(1,637,781)**	(4,423,380)
Loss before provision for income taxes	**(4,428,670)**	(7,049,972)
Provision for income taxes	**1,729**	1,600
Net loss	**$ (4,430,399)**	$ (7,051,572)
Weighted average shares outstanding - basic and diluted	**5,025,683**	3,893,280
Loss per share - basic and diluted	**$ (0.88)**	$ (1.81)

See accompanying notes to consolidated financial statements.

Bone Biologics Corporation
Consolidated Statement of Stockholders' Deficit

	Common Stock		Additional Paid-in	Common Stock to be	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Issued	Deficit	Deficit
Balance at December 31, 2016	3,882,861	3,883	41,942,792	1,823,077	(52,133,450)	(8,363,698)
Fair value of vested stock options issued to employees	-	-	1,615,022	-	-	1,615,022
Fair value of unvested stock options issued to consultants	-	-	545,700	-	-	545,700
Fair value of vested stock options issued to related parties	-	-	(2,744,749)	-	-	(2,744,749)
Beneficial conversion feature of notes recorded as debt discount	-	-	2,700,000	-	-	2,700,000
Issuance of common stock upon exercise of stock options	1,538	2	(2)	-	-	-
Shares issued to a related party for cash	23,333	23	699,977	-	-	700,000
Issuance of common stock upon conversion of related party debt and accrued interest	420,348	420	4,203,054	-	-	4,203,474
Net Loss	-	-	-	-	(7,051,572)	(7,051,572)
Balance at December 31, 2017	4,328,080	4,328	48,961,794	1,823,077	(59,185,022)	(8,395,823)
Fair value of vested stock options issued to employees	-	-	516,638	-	-	516,638
Fair value of unvested stock options issued to consultants	-	-	(1,125,080)	-	-	(1,125,080)
Shares issued for cash	25,000	25	492,475	-	-	492,500
Fair value of shares issued in settlement of bonus payable	23,146	23	455,977	-	-	456,000
Shares issued to related party upon net settlement of warrants	30,847	31	(31)	-	-	-
Shares issued to related party under anti-dilution provision	46,667	47	(47)	-	-	-
Shares issued to a related party for cash	3,539,654	3,540	3,536,114	-	-	3,539,654
Shares issued upon close of rights offering (including 329,674 shares to related parties)	330,325	330	329,995	-	-	330,325

Share adjustment for stock split rounding	81	-	-	-	-	-
Issuance pursuant founders agreement	115,385	115	1,822,962	(1,823,077)	-	-
Shares issued to related party for collateral pursuant to outstanding secured convertible note agreements	18,009,696	18,010	-	-	-	18,010
Net Loss	-	-	-	-	(4,430,399)	(4,430,399)
Balance at December 31, 2018	**26,448,881**	**$ 26,449**	**$54,990,797**	**$ -**	**$(63,615,421)**	**$ (8,598,175)**

See accompanying notes to consolidated financial statements.

Bone Biologics Corporation
Consolidated Statements of Cash Flows

	Year Ended December 31, 2018	Year Ended December 31, 2017
Cash flows from operating activities		
Net loss	**$ (4,430,399)**	$ (7,051,572)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**96**	96
Debt discount amortization	**340,735**	3,327,488
Debt issuance costs amortization	**21,283**	39,177
Stock-based compensation	**516,638**	1,615,022
Founders' Stock-based compensation	**-**	(2,744,749)
Options issued to consultants	**(1,125,080)**	545,700
Loss on debt extinguishment	**408,294**	-
Issuance costs of shares issued to related party for collateral pursuant to outstanding secured convertible note agreements	**18,010**	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	**12,447**	(24,711)
Accounts payable and accrued expenses	**(66,908)**	763,453
Deferred compensation	**200,000**	200,000
Net cash used in operating activities	**(4,104,884)**	(3,330,096)
Cash flows from financing activities		
Proceeds from issuance of common stock	**4,369,979**	700,000
Proceeds from issuance of note payable	**600,000**	2,700,000
Repayment of note payable	**(600,000)**	-
Net cash provided by financing activities	**4,369,979**	3,400,000
Net increase in cash	**265,095**	69,904
Cash, beginning of year	**690,279**	620,375
Cash, end of year	**$ 955,374**	$ 690,279
Supplemental information		
Interest paid - related party	**$ 821,958**	$ 516,375
Income taxes paid	**$ 1,729**	$ 1,600
Supplemental non-cash investing and finance activities:		
Beneficial conversion feature of notes payable	**$ -**	$ 2,700,000
Prepaid offering costs netted against proceeds from issuance of common stock	**$ 7,500**	$ -
Shares issued in settlement of bonus payable	**$ 456,000**	$ -

See accompanying notes to consolidated financial statements.

Bone Biologics Corporation
Notes to Consolidated Financial Statements

1. The Company

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

On July 16, 2018, the Company closed a rights offering in which Hankey Capital purchased 3,539,654 shares of the Company's Common Stock and executed amendments (the "Amendments") to the convertible promissory notes (the "Existing Convertible Notes") payable to Hankey Capital and dated October 24, 2014, May 4, 2015 and February 24, 2016. The Amendments reduced the conversion price of the Existing Convertible Notes from $15.80 per share to $1.00 per share and extended the maturity date of the February 24, 2016 convertible promissory note from February 24, 2019 to December 31, 2019. As a result of the share issuance and Amendments, Hankey Capital and Don Hankey, the Chairman of the Company's Board of Directors, acquired a majority of the voting common shares issued and outstanding and thus effective control of the Company.

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/DBX®. The NELL-1/DBX® combination product is an osteostimulative recombinant protein that provides target specific control over bone regeneration. The protein, as part of the UCB-1 technology platform, has been licensed exclusively for worldwide applications to us through a technology transfer from UCLA Technology Development Group on behalf of UC Regents ("UCLA TDG"). UCLA TDG and the Company received guidance from the FDA that NELL-1/DBX® will be classified as a combination product with a device lead.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, which we refer to as the JOBS Act. We would cease to be an emerging growth company upon the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are $1.07 billion or more; (ii) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700.0 million as of the end of the second quarter of that fiscal year; or (iii) the date on which we have, during the previous three-year period, issued more than $1.07 billion in non-convertible debt securities. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. We have elected to take advantage of these reduced disclosure obligations, and may elect to take advantage of other reduced reporting obligations in the future.

The JOBS Act permits an emerging growth company like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to irrevocably "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted.

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

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

Going Concern and Liquidity

The Company has no significant operating history and since inception to December 31, 2018 has incurred accumulated losses of approximately $63.6 million. The Company will continue to incur significant expenses for development activities for their lead product NELL-1/DBX®. Operating expenditures for the next twelve months are estimated at $10.3 million. The accompanying consolidated financial statements for the year ended December 31, 2018 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, the Company had a stockholders' deficit of $8,598,175 at December 31, 2018, and incurred a net loss of $4,430,399, and used net cash in operating activities of $4,104,884 during the year ended December 31, 2018. 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.

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

The Company closed $500,000 of equity financing in March 2018 and $600,000 of debt financing in May 2018. On July 16, 2018, the Company closed a Rights Offering ("Rights Offering") to existing shareholders and certain related parties and, on July 24, 2018, a private placement with Hankey Capital LLC ("Hankey Capital") in the aggregate amount of $3,869,979 and secured a credit facility with Hankey Capital for $2,000,000. In the Rights Offering the Company issued 330,325 shares to four shareholders, including 329,674 shares to certain related parties (the "Rights Shares") and issued 3,539,654 shares to Hankey Capital (the "Hankey Shares") pursuant to a Securities Purchase Agreement.

The proceeds from the sale of the Rights Shares and the Hankey Shares of $3,869,979 were used to repay the promissory note for $600,000 and the remaining proceeds have been and will be used for working capital, protein development, animal testing, regulatory and clinical expenses, as well as for other purposes not presently contemplated herein but which are related directly to growing the Company's current business, research and development activities.

Pursuant to our October 2016 and February 2017 Convertible Notes, which were subsequently converted into shares of common stock on December 31, 2017, the Company may only use the proceeds from the issuance of these Convertible Notes to focus on prioritizing operations on essential research and development activities. Also pursuant to the October 2016 Note Purchase Agreement, the Company's management has agreed to defer 20% of earned compensation and the Board of Directors has authorized a change in director compensation to defer 50% of the directors' cash compensation until at least $5,000,000 has been received in cumulative funding from non-current stockholders.

For the past several years, we have depended on our relationship with Hankey Capital for working capital to fund our operations, which has been raised in the form of both debt and equity capital. Hankey Capital, directly and indirectly, controls approximately 87% of our issued and outstanding shares of common stock (including collateral shares) and has been issued convertible notes payable with an aggregate principal balance of $9,000,000 at December 31, 2018. We drew down an additional $700,000 of working capital under a $2,000,000 secured credit facility during March 2019. Representatives of Hankey Capital also currently serve as directors of the Company. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

Reverse Stock Split

On June 11, 2018 and effective July 24, 2018, the directors of the Company approved a resolution to undertake a reverse split of the common stock of the Company on a basis of 1 new common share for 10 old common share. All references in these financial statements to number of common shares, price per share and weighted average number of shares outstanding prior to the 1 for 10 reverse split have been adjusted to reflect the stock split on a retroactive basis as of the earliest period presented, unless otherwise noted.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Reclassification

Certain amounts totaling $135,697 previously reflected in the prior-period financial statements as research and development expense have been reclassified to general and administrative expense to conform to the presentation in the current-period financial statements.

Use of Estimates

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

Fair Value of Financial Instruments

The Company's consolidated financial instruments are cash, accounts payable and notes payable. The recorded values of cash and accounts payable approximate their values based on their short-term nature. The fair value of convertible notes payable approximate their fair value since the current interest rates and terms on these obligations are the same as prevailing market rates.

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.

An "established trading market" for the Company's common stock does not exist. The fair value of the shares was determined based on the then most recent price per share at which we sold common stock to unrelated parties in a private placement during the periods then ended.

During the year ended December 31, 2017, the fair value of shares ranged between $19.70 to $20.05 (post reverse-split). During the period January 1, 2018 through June 30, 2018, the Company utilized $20.00 (post reverse split) per share as the fair value of its common stock for accounting purposes based on one common stock transaction with an investor during March 2018. Subsequently, based on the analysis as described below, management determined that the fair value of the Company's common stock for accounting purposes was $0.94 per share. The reduction in the fair value of the Company's common stock from $20.00 per share to $0.94 per share resulted in a reversal of certain stock-based compensation charges related to options held by a consultant recorded during the year and thus a credit balance in certain operating accounts for the year ended December 31, 2018.

In drawing its conclusions, management considered various relevant factors, including the work of an independent third party valuation firm engaged to provide a valuation analysis as of July 24, 2018, which indicated a valuation of $0.94 per common share. Management also took into account the recent cash transaction price for the Company's common stock pursuant to a July 2018 Rights Offering to all common stockholders, which resulted in the sale of common shares to an affiliate of the Company and parties related to such affiliate at a slightly higher price of $1.00 per share. The Company entered into a series of interrelated transactions with such affiliate at the same $1.00 price per share during the year ended December 31, 2018.

The July 24, 2018 valuation analysis employed the discounted future value method and utilized financial metrics observed in the marketplace. Management ultimately determined, and the valuation firm concurred, that the discounted future value method was the most appropriate valuation methodology under the circumstances.

The utilization of the discounted future value method involved the estimation of a business enterprise value ("BEV")/revenue multiple, the probability of approval of the Company's technology, the estimation of the Company's cost of equity and weighted average cost of capital, the estimation of a required rate of return appropriate for discounting projected revenues to calculate the present value of the business enterprise, and an appropriate discount period. This method involved projecting revenues through 2028 and applying an appropriate BEV/revenue multiple.

Research and Development Costs

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

Patents and Licenses

Effective August 18, 2017, the Company entered into an Amended and Restated Exclusive License Agreement (the "Restated License Agreement") with the UCLA Technology Development Group on behalf of UC Regents ("UCLA TDG"). The Restated License Agreement amends and restates the Exclusive License Agreement, effective March 15, 2006, between the Company and UCLA TDG, as amended by ten amendments. See Note 9 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.

Concentration of Credit Risk and Other Risks and Uncertainties

Cash balances are maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced any losses related to these balances. Federal insurance coverage is $250,000 per depositor at each financial institution. A substantial majority of the Company's cash balances exceed federally insured limits.

Stock Based Compensation

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

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

In light of the lack of an "established trading market", the fair value of the shares was determined based on factors discussed in "Fair Value of Financial Instruments" above. Pursuant to ASU No. 2016-09 – *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,* the Company accounts for forfeitures when they occur.

Stock options issued to non-employees and consultants are revalued each reporting period to determine the amount to be recorded in the statement of operations in the respective period. As stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting. Forfeitures of the unvested portion of stock option grants are recorded when the underlying event occurs, and are recorded as a reversal of the related expense. An increase in the Company's stock price during a reporting period will generally result in an increase in the fair value of unvested stock options and thus the related expense, and a decrease in the Company's stock price during a reporting period will generally result in a decrease in the fair value of unvested stock options and thus the related expense. Accordingly, depending on various factors, the recording of forfeitures and a decrease in the price of the Company's common stock during a reporting period can result in a credit balance in an operating account in the statement of operations.

Income Taxes

Income taxes are provided for the tax effects of transactions reported in the consolidated financial statements and consist of taxes currently due and deferred taxes resulting from timing differences in recording of transactions for tax purposes and financial reporting purposes.

The deferred tax assets and liabilities represent the future tax return consequences of those differences, which will either be taxable or deductible when the assets and liabilities are received or settled. Valuation allowances are established when necessary to reduce deferred tax assets to amounts expected to be realized.

The accounting provisions related to uncertain income tax positions require the Company to determine whether any tax position in all open years meets a more likely than not threshold of being sustained upon examination by the applicable taxing authority. The Company did not have any changes to its liability for uncertain tax positions as at December 31, 2018 and 2017.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. No such amounts are accrued as of December 31, 2018 and 2017.

The Company recognizes the financial statement effects of a tax position when it becomes more likely than not, based upon the technical merits, that the position will be sustained upon examination.

The Company recognizes interest and/or penalties related to uncertain tax positions. To the extent accrued interest and penalties do not ultimately become payable, amounts accrued will be reduced and reflected in the period that such determination is made. The interest and penalties are recognized as other expense and not tax expense. The Company currently has no interest and penalties related to uncertain tax positions.

Collateral Shares

The Company accounts for the common shares issued as collateral for convertible promissory notes, whether upon original issuance or upon the required annual adjustment, as debt issuance costs in the form of a loan processing fee, which is determined by reference to the par value of the Company's common stock, with a corresponding charge to operations when such collateral shares are issued. The collateral shares are subject to significant contractual restrictions limiting their sale or transfer. As these common shares have been issued to and are held by the lender, and are contingently returnable to the Company under certain conditions, such shares are considered as issued and outstanding on the Company's balance sheet, but are not included in earnings per share calculations for all periods presented.

In the event of an uncured event of default, the Company will record a charge to operations to recognize that the collateral shares are no longer owned or controlled by the Company, and such prospective charge to operations would be based on the fair market value of the collateral shares at that time, and which would be classified as a cost of debt capital and recognized as a charge to operations.

Loss per Common Share

The Company utilizes FASB ASC Topic No. 260, *Earnings per Share*. Basic loss per share is computed by dividing loss available to common shareholders by the weighted-average number of common shares outstanding. Shares issued for collateral for outstanding loans are excluded from weighted average shares outstanding. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. Diluted loss per common share reflects the potential dilution that could occur if convertible debentures, options and warrants were to be exercised or converted or otherwise resulted in the issuance of common stock that then shared in the earnings of the entity.

Since the effects of outstanding options, warrants, and the conversion of convertible debt are anti-dilutive for the years ended 2018 and 2017, shares of common stock underlying these instruments have been excluded from the computation of loss per common share.

The following sets forth the number of shares of common stock underlying outstanding options, warrants, and convertible debt as of December 31, 2018 and 2017:

	December 31,	
	2018	2017
Warrants	**845,096**	1,039,082
Stock options	**843,648**	839,722
Convertible promissory notes	**9,000,000**	959,620
	10,688,744	2,838,424

New Accounting Standards

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), Leases (Topic 842). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company has not yet evaluated the impact of the adoption of ASU 2016-02 on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued ASU No. 2017-11, "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception" ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered, and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common stockholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The guidance in ASU 2017-11 can be applied using a full or modified retrospective approach. The Company is currently evaluating the impact of the adoption of ASU 2017-11 on the Company's financial statement presentation or disclosures.

In September 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to nonemployee share-based payment accounting. This ASU simplifies the accounting and reporting for share-based payments issued to nonemployees by expanding the scope of ASC 718, Compensation - Stock Compensation, which currently only includes share-based compensation to employees, to also include share-based payments to nonemployees for goods and services. The standard is effective for public companies for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than a company's adoption date of ASC 606. Management is currently in the process of evaluating the impact of the standard on its consolidated financial statements and disclosures.

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

3. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	December 31, 2018	December 31, 2017
Accounts payable	**$ 125,203**	$ 216,903
Accrued bonus	**-**	456,000
Deferred Directors' fees	**72,017**	47,225
	$ 197,220	$ 720,128

4. Notes Payable - Related Parties

Note Type	Issue Date	Maturity Date	Interest Rate	**December 31, 2018**	December 31, 2017
(A) First Secured Convertible Note	10/24/14	12/31/19	9.25%	$ **5,000,000**	$ 5,000,000
(A) Second Secured Convertible Note	5/4/15	12/31/19	9.25%	**2,000,000**	2,000,000
(B) Third Secured Convertible Note	2/24/16	12/31/19	9.25%	**2,000,000**	2,000,000
				9,000,000	9,000,000
Less: Debt discount				**-**	(724,606)
Less: Debt issuance costs				**-**	(45,707)
Net Notes payable				**$ 9,000,000**	$ 8,229,687

First and Second Secured Convertible Notes and Warrants

(A) On October 24, 2014 and May 4, 2015, the Company issued two convertible promissory notes in the aggregate amount of $7,000,000 to Hankey Capital. Don Hankey, the CEO and Chairman of Hankey Group, is our non-independent Chairman of the Board and a significant shareholder. Bret Hankey, the president of Hankey Capital, is a non-independent board member. The Convertible Notes mature on December 31, 2019 and bear interest at an annual rate of interest of the "prime rate" plus 4.0%, with a minimum rate of 8.5% per annum until maturity, with interest payable monthly in arrears. Prior to the Maturity Date, Hankey Capital has a right, in its sole discretion, to convert the Convertible Notes into shares of the Company's Common Stock, at a conversion rate equal to $1.00 per share. The Company also issued warrants to Hankey Capital for an aggregate of 585,443 shares of Common Stock at an exercise price per share of $15.80 that expire five years from the dates of issuance. In connection with the Convertible Notes, the Company paid commitment fees in the amount of $210,000 (3.0% of the original principal amount of the loans) to Hankey Capital and other aggregate offering costs of $594,550. The aggregate value of the warrants and offering costs totaling $2,891,409 was considered to be a debt discount upon issuance of the notes.

Third Convertible Secured Term Note and Warrants

(B) On February 24, 2016, the Company issued a convertible promissory note in the amount of $2,000,000 to Hankey Capital. The Third Convertible Note matures on December 31, 2019 (the "Maturity Date") and bears interest at an annual rate of interest at the "prime rate" plus 4.0%, with a minimum rate of 8.5% per annum until maturity, with interest payable monthly in arrears. Prior to the Maturity Date, Hankey Capital has a right, in its sole discretion, to convert the Convertible Note into shares of the Company's common stock (the "Conversion Shares"), at a conversion rate equal to $1.00 per share and issued a warrant to Hankey Capital for 146,342 shares of Common Stock at an exercise price per share of $20.50. The Warrant will expire on February 23, 2021. In connection with the Convertible Note, the Company paid a commitment fee in the amount of $40,000 (2.0% of the original principal amount of the Loan) and other offering costs totaling $77,532. The aggregate value of the warrant, beneficial conversion feature and offering costs of $2,000,000 was considered a debt discount upon issuance of the note.

Converted Promissory Notes

On October 14, 2016, pursuant to Note Purchase Agreements, the Company issued to each of MTF (Bruce Stroever, our Chairman of the Board, is the President and Chief Executive Officer of MTF) and Hankey Capital convertible promissory notes in the aggregate amount of $1,200,000 (each a "Convertible Note"). The Convertible Note matures on December 31, 2017 (the "Maturity Date") and bears interest at an annual rate of interest of 8.5% per annum until maturity. Prior to the Maturity Date, each of MTF and Hankey Capital has a right, in its sole discretion, to convert their Convertible Note into shares of the Company's common stock (the "Conversion Shares"), at a conversion rate equal to $1.00 per share. In addition, if the Convertible Notes are not paid by the Maturity Date, they will be automatically converted in shares of Common Stock at a conversion price of $1.00 per share.

Per the terms of the Convertible Notes, these loans and unpaid accrued interest in the aggregate amount of $1,325,800 converted into 1,325,800 shares of common stock on December 31, 2017.

On February 10, 2017 and August 18, 2017 pursuant to three note purchase agreements, the Company issued MTF and Hankey Capital convertible promissory notes in the aggregate amount of $2,700,000 ("Convertible Notes"). The Convertible Notes mature on December 31, 2017 (the "Maturity Date") and bear interest at an annual rate of interest of 8.5% until maturity. Prior to the Maturity Date, each of MTF and Hankey Capital has a right, in its sole discretion, to convert their Convertible Note into shares of the Company's common stock (the "Conversion Shares"), at a conversion rate equal to $1.00 per share. Also, if the Convertible Notes are not paid by the Maturity Date, they will be automatically converted in shares of Common Stock at a conversion price of $1.00 per share. In the event of a financing resulting in gross proceeds of at least $5,000,000, the holders of the Convertible Notes will be required to convert their Convertible Notes into the same securities issued in such financing at the same price per share. The Convertible Notes are secured by all of the Company's assets. The Company has granted piggyback registration rights with respect to the Conversion Shares. As of February 10, 2017 and August 18, 2017, the conversion prices of the notes was less than the market price of shares of the Company's common stock. As such, the Company recognized an aggregate beneficial conversion feature of $2,700,000 which was considered to be a debt discount upon issuance of the notes and will be amortized as interest over the terms of the notes or in full upon the conversion of the notes.

Per the terms of the Convertible Notes, these loans and unpaid accrued interest in the aggregate amount of $2,877,673 converted into 2,877,673 shares of common stock on December 31, 2017.

Collateral

The aggregate Convertible Notes are secured by an aggregate of 19,148,936 collateral shares of Common Stock issued by the Company in the name of Hankey Capital, in such amount so as to maintain a loan to value ratio equal to 50% (the "Collateral"). The number of shares in the Collateral shall be adjusted on a yearly basis. A Collateral adjustment of 18,009,696 shares of Common Stock was issued during the year ended December 31, 2018. The principal amount of the loans are pre-payable in whole or in part at any time, without premium or penalty. Upon any voluntary partial prepayment of outstanding principal, Hankey Capital will return Collateral shares to the Company in the amount necessary, if any, to maintain the loan to value ratio at no less than 50%. Upon a full payment of the outstanding principal, all Collateral shares shall be returned return and cancelled. Hankey Capital will also return Collateral shares under the same terms in case of partial or full conversion of the Convertible Notes. All of the Company's personal property further secure the aggregate Convertible Notes, including collateral assignments of all the Company's license agreements and the MTF Sygnal Option Agreement.

Debt Amendments

On February 24, 2016, the First and Second Secured Convertible Notes were modified to extend the maturity date to December 31, 2019, fix the conversion price at $15.80 and the warrants were amended to extend their expiration date by two years. The Company determined that the extension of the convertible notes' maturity dates and the warrants' expiration dates resulted in a debt extinguishment for accounting purposes since the change in fair value of the warrants as a result of the extension of their expiration dates was more than 10% of the original value of the convertible notes. As such, the Company recorded the notes at their aggregate fair value of $7,000,000.

In connection with the financing that closed on July 16, 2018, as discussed in Note 6, the Company and Hankey Capital executed amendments (the "Amendments") to the First, Second and Third convertible secured term notes (the "Existing Convertible Notes"). The Amendments change Hankey Capital's conversion price from $15.80 per share to $1.00 per share on a post reverse stock split basis on the Existing Convertible Notes and extends the maturity date of the Third Convertible Note from February 24, 2019 to December 31, 2019. The Amendments became effective on the closing of the rights offering, July 16, 2018. The Company determined that the change in the conversion prices of the Existing Convertible Notes and extension of the Third Convertible Note's maturity date resulted in debt extinguishments for accounting purposes since the change in fair value of the conversion options was more than 10% of the original value of the Existing Convertible Notes. During the year ended December 31, 2018, the Company recorded a loss on extinguishment of debt totaling $408,294 for the remaining unamortized debt discount and debt issuance costs.

The total debt discount amortization related to our outstanding debt for the years ended December 31, 2018 and 2017, was $340,735 and $3,327,448, respectively. The unamortized debt discount at December 31, 2018 was $-0-. The unamortized debt discount at December 31, 2017 was $724,606. During 2018, $383,861 of debt discount was written off as a result of the debt extinguishment.

The total debt issuance amortization related to our outstanding debt for the years ended December 31, 2018 and 2017, was $21,283 and $39,177, respectively. The unamortized debt issuance costs at December 31, 2018 was $-0-. The unamortized debt issuance costs at December 31, 2017 was $45,707. During 2018, $24,433 of debt issuance costs were written off as a result of the debt extinguishment.

5. Credit Facility

On July 24, 2018, the Company and Hankey Capital entered into an agreement under which Hankey Capital will provide a credit facility of $2,000,000 to the Company to be drawn down by the Company upon notice to Hankey Capital. The credit facility is evidenced by a convertible secured note convertible prior to the maturity date at $1.00 per share and due on December 31, 2019. Draws bear interest at an annual rate of interest at the “prime rate” (as quoted in the “Money Rates” section of The Wall Street Journal) plus 4.0%, with a minimum rate of 8.5% per annum until maturity, with interest payable monthly in arrears. At December 31, 2018, the Company had not drawn any funds under the facility.

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, 2018 and December 31, 2017, the Company had an aggregate of 26,448,881 and 4,328,080 shares of common stock outstanding, respectively.

2018

In February 2018, 32,289 warrants were exercised on a cashless basis resulting in the issuance of 16,706 shares of common stock. In May 2018, 28,719 warrants were exercised on a cashless basis resulting in the issuance of 14,141 shares of common stock.

In February 2018, management was issued 23,146 shares of restricted common stock with a fair value of $456,000 in settlement of bonuses payable.

On March 26, 2018, the Company entered into a share purchase agreement pursuant to which an aggregate of 25,000 shares of common stock of the Company were issued at a price per share equal to $20.00 ($2.00 pre-split) for net proceeds of $492,500.

In May 2018, the Company closed a private placement offering and in accordance with the terms of the anti-dilution provision of the subscription agreement, which adjusts the shares to the most favored terms of the private placement, with Musculoskeletal Transplant Foundation (“MTF”), issued to MTF 46,667 shares of common stock.

In July 2018, the Company closed a Rights Offering, issued 330,325 shares to four shareholders (including an aggregate of 329,674 shares to two related parties), and issued 3,539,654 shares to Hankey Capital pursuant to a Securities Purchase Agreement for aggregate proceeds of $3,869,979. As part of the agreement, the lender also issued to the Company a $2,000,000 credit facility (see Note 4).

In September 2018, the Company issued 115,385 shares with a value of $1,823,077 previously reflected as common stock to be issued pursuant to the Founders' Letter Agreement dated October 2, 2015 (Note 8).

In December 2018, the Company issued an aggregate of 18,009,696 shares of common stock pursuant to collateral requirements of the three outstanding secured convertible note agreements (Note 4).

2017

On August 18, 2017, the Company sold to MTF an aggregate of 23,333 shares of common stock of the Company at a price per share equal to $3.00 for total proceeds of $700,000.

On August 18, 2017, 1,538 shares of common stock of the Company were issued from the exercise of options on a net exercise basis.

On December 31, 2017, 420,348 shares of common stock of the Company were issued upon conversion of $4,203,474 related parties' debt and accrued interest.

Common Stock Warrants

A summary of warrant activity for the years ended December 31, 2018 and 2017 are presented below:

Subject to Exercise	Number of Warrants	Weighted Average Exercise Price	Weighted Average Life (Years)
Outstanding as of December 31, 2016	1,039,082	$ 15.20	3.20
Granted – 2017	-	-	-
Forfeited/Expired – 2017	(12,658)	15,80	-
Exercised – 2017	-	-	-
Outstanding as of December 31, 2017	1,026,424	$ 15.17	2.23
Granted – 2018	-	-	-
Forfeited/Expired – 2018	(120,320)	-	-
Exercised – 2018	(61,008)	9.74	2.64
Outstanding as of December 31, 2018	845,096	$ 4.94	1.40

As of December 31, 2018, the Company had outstanding vested and unexercised Common Stock Warrants as follows:

Date Issued	Exercise Price	Number of Warrants	Expiration date
2009	$ 4.40	11,839	March 16, 2019
2010	$ 4.40	22,659	February 4, 2020
April 2013	$ 10.00	5,000	April 28, 2020
September 2013	$ 10.00	5,000	September 4, 2020
September 2013	$ 10.00	2,500	September 20, 2020
November 2013	$ 10.00	7,500	November 14, 2020
July 2014	$ 10.00	50,000	June 30, 2020
July 2014	$ 10.00	4,667	July 2, 2019
September 2014	$ 16.20	62,500	August 31, 2021
September 2014	$ 10.00	11,800	September 18, 2021
September 2014	$ 10.00	8,959	September 29, 2021
October 2014	$ 15.80	316,456	October 23, 2019
May 2015	$ 15.80	189,874	May 4, 2020
February 2016	$ 20.50	146,342	February 23, 2021

Total outstanding warrants at December 31, 2018	**845,096**

An aggregate of 61,008 common stock warrants were exercised on a non-cash basis resulting in the issuance of 30,847 common shares and 120,320 warrants expired during the year ended December 31, 2018. No common stock warrants were exercised and 12,658 warrants expired during the year ended December 31, 2017. The intrinsic value of the outstanding warrants on December 31, 2018 is $-0-.

7. Stock-based Compensation

2015 Equity Incentive Plan

The Company has 1,400,000 shares of Common Stock authorized and reserved for issuance under our 2015 Equity Incentive Plan for option awards. This reserve may be increased by the Board each year by up to the number of shares of stock equal to 5% of the number of shares of stock issued and outstanding on the immediately preceding December 31. Appropriate adjustments will be made in the number of authorized shares and other numerical limits in our 2015 Equity Incentive Plan and in outstanding awards to prevent dilution or enlargement of participants' rights in the event of a stock split or other change in our capital structure. Shares subject to awards granted under our 2015 Equity Incentive Plan which expire, are repurchased or are cancelled or forfeited will again become available for issuance under our 2015 Equity Incentive Plan. The shares available will not be reduced by awards settled in cash. Shares withheld to satisfy tax withholding obligations will not again become available for grant. The gross number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under our 2015 Equity Incentive Plan.

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

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

A summary of stock option activity for the years ended December 31, 2018 and 2017 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, 2016	1,265,617	$ 16.20	9.21	$ 4,373,120
Granted – 2017	8,034	20.50	10.00	-
Forfeited – 2017	(427,064)	16.00	8.54	-
Exercised – 2017	(6,855)	20.50	8.25	-
Outstanding as of December 31, 2017	839,732	$ 16.41	7.55	$ 4,373,120
Granted – 2018	5,222	19.70	10.00	-
Forfeited – 2018	(1,306)	-	-	-
Exercised – 2018	-	-	-	-
Outstanding as of December 31, 2018	**843,648**	**$ 16.43**	**6.56**	**$ -**

As of December 31, 2018, the Company had outstanding stock options as follows:

Date Issued	Exercise Price	Number of Options	Expiration date
September 2014	$ 15.90	58,307	December 27, 2025
November 2014	$ 15.90	17,492	December 27, 2025
August 2015	$ 15.90	312,180	December 27, 2025
September 2015	$ 15.90	20,000	December 27, 2025
November 2015	$ 15.90	122,464	December 27, 2025
December 2015	$ 15.90	80,275	December 27, 2025
January 2016	$ 15.90	127,581	January 9, 2026
March 2016	$ 20.50	5,400	February 24, 2021
May 2016	$ 20.50	80,744	May 26, 2026
September 2016	$ 20.50	9,933	May 31, 2026
January 2017	$ 20.50	5,356	January 1, 2027
January 2018	$ 19.70	3,916	January 1, 2028
Total outstanding options at December 31, 2018		**843,648**	

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value (*i.e.* , the difference between our closing stock price on the respective date and the exercise price, times the number of shares) that would have been received by the option holders had all option holders exercised their options. There were -0- and 6,855 options exercised during the years ended December 31, 2018 and 2017, respectively.

There were 5,222 options granted with a fair value of $100,000 during the year ended December 31, 2018. There were 8,034 options granted with a fair value of $150,000 during the year ended December 31, 2017. Vesting of options differs based on the terms of each option. The Company has valued the options at their date of grant utilizing the Black-Scholes option pricing model. As of the issuance of these consolidated financial statements, there was no active public market for the Company's shares. Accordingly, the fair value of the options was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. The risk-free interest rate used in the calculations is based on the implied yield available on U.S. Treasury issues with an equivalent term approximating the expected life of the options as calculated using the simplified method. The expected life of the options used was based on the contractual life of the option granted. Stock-based compensation is a non-cash expense because we settle these obligations by issuing shares of our common stock from our authorized shares instead of settling such obligations with cash payments.

During the years ended December 31, 2018 and 2017, the Company had stock-based compensation expense of $516,638 and $1,615,022, respectively, related to the vesting of stock options granted to the Company's employees, directors, and consultants included in our reported net loss. Stock compensation expense for stock options granted to consultants recognized in the statement of operations amounted to $(1,125,080) and $545,700 at December 31, 2018 and 2017, respectively. During the year ended December 31, 2018, 1,306 options forfeited upon the resignation of one of our directors. During the year ended December 31, 2017, there were 412,531 options cancelled in conjunction with the termination of the Founders Professional Services Agreement, 2,678 options were forfeited upon the resignation of one of our directors and 11,855 options expired per the terms of the options. Our policy is to account for forfeitures of the unvested portion of option grants when they occur; therefore, these forfeitures are recorded as a reversal to expense, which can result in a credit balance in the statement of operations. Forfeiture reversals for the years ended December 31, 2018 and 2017 were $13,400 and $2,744,749, respectively.

The Company utilized the Black-Scholes option-pricing model. The assumptions used for the years ended December 31, 2018 and 2017 are as follows:

	December 31, 2018	December 31, 2017
Risk free interest rate	2.302%-2.984%	1.99%-2.306%
Expected life (in years)	6.24-7.75	5.5-9.0
Expected Volatility	169.33%-175.89%	135.94%-153.79%
Expected dividend yield	0%	0%

A summary of the changes in the Company's non-vested options during the year ended December 31, 2018, is as follows:

	Number of Non-vested Options	Weighted Average Fair Value at Grant Date
Non-vested at December 31, 2017	265,304	$ 15.01
Granted in 2018	5,222	$ 19.15
Forfeited – 2018	(1,306)	$ 19.15
Vested in 2018	(151,759)	$ 14.10
Non-vested at December 31, 2018	117,464	$ 16.33
Exercisable at December 31, 2018	726,184	$ 14.33
Outstanding at December 31, 2018	**843,648**	$ 14.61

As of December 31, 2018, total unrecognized compensation cost related to unvested stock options was $22,006. The cost is expected to be recognized over a weighted average period of 1 year.

8. Income Taxes

The provision for income taxes consists of the following:

Year Ended	**December 31, 2018**	December 31, 2017
Current:		
Federal	**$ -**	$ -
State	**1,729**	1,600
Total current	**1,729**	1,600
Deferred:		
Federal	**-**	-
State	**-**	-
Total deferred	**-**	-
Provision for income taxes	**$ 1,729**	$ 1,600

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

	December 31, 2018	December 31, 2017
Deferred tax assets		
Net operating losses	$ 7,410,000	$ 6,618,000
Accrued expenses	688,000	651,000
R&D credits	534,000	456,000
Stock compensation	8,245,000	8,194,000
Total	16,877,000	15,919,000
Less: Valuation allowance	(16,877,000)	(15,919,000)
	$ -	$ -

The Company's federal and state net operating loss carryforwards at December 31, 2018 and 2017 were approximately $28,286,000 and $25,096,000, respectively, and will begin to expire in 2019 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 $16,877,000 at December 31, 2018. The net change in the valuation allowance for the year ended December 31, 2018 was $958,000.

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, 2018 and 2017 is as follows:

	December 31, 2018	December 31, 2017
Statutory federal income tax rate	**21.0%**	34.0%
State taxes, net of federal tax benefit	**3.0%**	3.8%
Nondeductible permanent items	**(0.4)%**	(0.2)%
Deferred tax rate change	**(6.2)%**	(5.7)%
Research and development credit	**1.8%**	0.8%
Change in valuation allowance	**(19.2)%**	(32.7)%
Income tax provision	**0.0%**	0.0%

The Company's effective tax rate is 0% for income tax for the years ended December 31, 2018 and 2017. 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 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.

9. Related Party Transactions

Hankey Capital LLC (Hankey Capital)

Hankey Capital holds certain convertible notes of the Company as discussed in Note 4. Don Hankey, the CEO and Chairman of Hankey Group, is our non-independent Chairman of the Board and a significant shareholder. Bret Hankey, the president of Hankey Capital, is a non-independent board member. The Hankey Group is an affiliate of Hankey Capital.

Founders

The Company entered into a Letter Agreement dated September 24, 2015, with each of Dr. Chia Soo, Dr. Eric Kang Ting and Dr. Ben Wu (collectively, the "Founders"). The Founders were three of the original shareholders of the Company. Pursuant to the Letter Agreement, the Founders agreed to deliver to the Company all past work product and past data related to NELL-1 (the "Data") for use by the Company in its sole discretion, within the applicable licensing rights granted under the UCLA license and in exchange the Company agreed to the future issuance of an aggregate of 115,385 shares of the Company's common stock. The Shares are to be equally distributed between the Founders upon the earlier of (i) the third anniversary of the Agreement and (ii) the occurrence of a Liquidity Event (as defined in the Letter Agreement) and are currently reported as Shares to be Issued. During the year ended December 31, 2018, 115,385 shares were issued pursuant to the Letter Agreement.

Effective January 8, 2016, the Company entered into separate Professional Services Agreements with each of the Founders. Pursuant to each of the Agreements, each Founder agreed to provide certain services to the Company, including providing strategic advice and strategic introductions to the Company's management team as well as specific services set forth on an Exhibit to each Agreement. The Agreements are substantially identical. In consideration for the services to be rendered under the applicable Agreement, each Founder was granted a 10-year stock option (the "Options") to purchase 180,036 shares of the Company's common stock corresponding to 4% of the Company's outstanding common stock, on a fully diluted basis, at an exercise price of $15.90 (post reverse split) per share. Additionally, beginning January 1, 2017, the Company was to pay each Founder an annual consulting fee of $200,000 in cash or, at the option of the Company, in shares of its common stock valued as provided in the Agreement. On June 1, 2016, the Company agreed to issue to each Founder a 10-year stock option to purchase 3,310 shares of the Company's common stock at an exercise price of $20.50 (post reverse split) per share as an adjustment to amounts due under the Agreements. All options issued to the Founders under the Agreements immediately terminate if the Agreements are terminated for cause.

On December 13, 2016, the Company provided written notice to each of the Founders that it was terminating the Agreements for cause, indicating that absent cure of the material breach of the Agreements, termination of the Agreements was to be effective on January 12, 2017. Despite lengthy discussions with the Founders, and multiple extensions of the termination date to accommodate such discussions, the Company was unable to resolve the outstanding issues under the Agreements, and the Company provided notice that the Agreements were terminated, effective as of April 8, 2017. The Founders have disputed the right of the Company to terminate for cause.

10. Commitments and Contingencies

UCLA TDG Exclusive License Agreement

Effective August 18, 2017, the Company entered into an Amended and Restated Exclusive License Agreement (the "Restated License Agreement") with the UCLA Technology Development Group on behalf of UC Regents ("UCLA TDG"). The Restated License Agreement amends and restates the Exclusive License Agreement, effective March 15, 2006, between the Company and UCLA TDG, as amended by ten amendments. Under the terms of the Restated License Agreement, the Regents have continued to grant the Company exclusive rights to develop and commercialize NELL-1 (the "Licensed Product") for spinal fusion applications. The Licensed Product is a recombinant human protein growth factor that is essential for normal bone development.

Following the completion of several key milestones, Bone Biologics has expanded its Field of Use definition beyond spine fusion within the NELL-1 license agreement with UCLA TDG. Consistent with that expansion, Bone Biologics has entered into an exclusive license agreement with UCLA TDG for the worldwide application of the NELL-1 protein for both osteoporosis and trauma through a technology transfer.

We have agreed to pay an annual maintenance fee to UCLA TDG of $10,000 as well as to pay certain royalties to UCLA TDG under the Restated License Agreement at the rate of 3.0% of net sales of licensed products. We must pay the royalties to UCLA TDG on a quarterly basis. Upon a first commercial sale, we also must pay between $50,000 and $250,000, depending on the calendar year that is after the first commercial sale. If we are required to pay any third party any royalties as a result of us making use of UCLA TDG patents, then we may reduce the royalty owed to UCLA TDG by 0.333% for every percentage point paid to a third party. If we grant sublicense rights to a third party to use the UCLA TDG patent, then we will pay to 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 to pay UCLA TDG a cash milestone payment within thirty (30) days of a Liquidity Event (including a Change of Control Transaction and a payment election by UCLA TDG exercisable after December 22, 2016, such payment to equal the greater of:

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

As of December 31, 2018, none of the above milestones has been met.

We are obligated to diligently proceed with developing and commercializing licensed products under UCLA patents set forth in the Restated 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 Restated License Agreement.

We must reimburse or pre-pay UCLA TDG for patent prosecution and maintenance costs incurred during the term of the Restated License Agreement. We have the right to bring infringement actions against third party infringers of the Restated 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 Restated License Agreement or any sublicense.

Payments to UCLA TDG under the Restated License Agreement for the years ended December 31, 2018 and 2017 were $70,627 and $130,278, 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.

In July 2018, AFH Holding & Advisory, LLC, Amir Heshmatpour, Steve Richards, and Bessie (Chia) Soo ("Plaintiffs") filed a verified shareholder derivative complaint (the "Complaint") in Massachusetts federal court against Bruce Stroever, John Booth, Stephen LaNeve, Bret Hankey, James Delshad (the "Initial Defendants"), and The Musculoskeletal Transplant Foundation, Inc. ("MTF"), and also named the Company as a nominal defendant. The Complaint alleged claims for violation of Section 14(c) of the Securities Exchange Act of 1934, breach of fiduciary duties, rescission of a reverse stock split, and in the alternative rescissory damages. The Complaint focuses on the financing transaction that the Company completed with Hankey Capital in July 2018. The Initial Defendants and the Company filed motions to dismiss on September 28, 2018. After changing counsel and obtaining several extensions of time, instead of responding to the motions to dismiss, Plaintiffs filed an Amended Complaint (the "Amended Complaint") on February 8, 2019 as a direct, instead of derivative complaint, and added two additional defendants, Don Hankey and Hankey Capital LLC (the "Added Defendants" and together with the Initial Defendants, MTF and the Company, the "Current Defendants"). The Amended Complaint asserts claims for violation of Section 14(c) of the Securities Exchange Act of 1934, breach of fiduciary duties, aiding and abetting breach of fiduciary duties, rescission of a reverse stock split, and in the alternative rescissory damages. On February 22, 2019, the Company and the Initial Defendants filed a Motion to Dismiss the Amended Complaint. The Initial Defendants have been sued for actions taken in their capacity as directors of the Company. As such, the Company has certain indemnification obligations to the Initial Defendants. The Company and the Initial Defendants intend to vigorously defend against the allegations in the Amended Complaint. Based on the very early stage of the litigation, it is not possible to estimate the amount or range of any possible loss arising from the expenditure of defense fees, a judgment or settlement of the matter.

11. Subsequent Events

On March 19, 2019, the Company drew $700,000 of working capital under a $2,000,000 secured credit facility secured by 1,489,362 collateral shares of Common Stock issued by the Company in the name of Hankey Capital (see Note 4). The credit facility is evidenced by a convertible secured note convertible prior to the maturity date at $1.00 per share and due on December 31, 2019. Draws bear interest at an annual rate of interest at the "prime rate" (as quoted in the "Money Rates" section of The Wall Street Journal) plus 4.0%, with a minimum rate of 8.5% per annum until maturity, with interest payable monthly in arrears.