

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2023

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

For the transition period from _____ to _____

Commission File No. **001-40899**

Bone Biologics Corporation

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or formation)

42-1743430

(I.R.S. employer
identification number)

2 Burlington Woods Drive, Ste 100, Burlington, MA 01803

(Address of principal executive offices and Zip Code)

(781) 552-4452

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value per share	BBLG	The Nasdaq Stock Market LLC
Warrants to Purchase Common stock, \$0.001 par value per share	BBLGW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the issuer was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

☒ Yes ☐ No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

As of May 1, 2023, there were 16,702,912 shares of the issuer's common stock, \$0.001 par value, outstanding.

Bone Biologics Corporation
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NOTE ON FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this “Form 10-Q”) 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. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. For a more detailed listing of some of the risks and uncertainties facing the Company, please see our Current Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the Securities and Exchange Commission (“SEC”) on March 30, 2023.

All statements other than historical facts contained in this 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, inflation, rising interest rates, governmental responses there to and possible recession caused thereby, 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, 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, its wholly owned subsidiary as defined under the heading “Management’s Discussion and Analysis” in this Form 10-Q.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

Bone Biologics Corporation

Condensed Consolidated Balance Sheets

	<u>March 31, 2023</u> (unaudited)	<u>December 31, 2022</u>
Assets		
Current Assets		
Cash	\$ 6,188,319	\$ 7,538,312
Prepaid expenses	<u>595,434</u>	<u>956,925</u>
Total assets	<u>\$ 6,783,753</u>	<u>\$ 8,495,237</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable and accrued expenses	\$ 2,279,194	\$ 888,461
Warrant liability	<u>1,732,160</u>	<u>1,659,468</u>
Total current liabilities	<u>4,011,354</u>	<u>2,547,929</u>
Total liabilities	<u>4,011,354</u>	<u>2,547,929</u>
Commitments and Contingencies		
Stockholders' Equity		
Preferred Stock, \$0.001 par value per share; 20,000,000 shares authorized; none issued or outstanding at March 31, 2023 and December 31, 2022	-	-
Common stock, \$0.001 par value per share; 100,000,000 shares authorized; 16,702,912 and 15,301,986 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	16,701	15,300
Additional paid-in capital	78,425,824	77,892,235
Accumulated deficit	<u>(75,670,126)</u>	<u>(71,960,227)</u>
Total stockholders' equity	<u>2,772,399</u>	<u>5,947,308</u>
Total liabilities and stockholders' equity	<u>\$ 6,783,753</u>	<u>\$ 8,495,237</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Condensed Consolidated Statements of Operations

	Three Months Ended March 31, 2023 (unaudited)	Three Months Ended March 31, 2022 (unaudited)
Revenues	\$ -	\$ -
Cost of revenues	-	-
Gross profit	-	-
Operating expenses		
Research and development	2,590,645	36,400
General and administrative	556,892	653,099
Total operating expenses	3,147,537	689,499
Loss from operations	(3,147,537)	(689,499)
Other income (expenses)		
Change in fair value of warrant liability	(562,918)	-
Interest income	556	-
Net loss	\$ (3,709,899)	\$ (689,499)
Weighted average shares outstanding - basic and diluted	16,115,577	10,350,579
Loss per share - basic and diluted	\$ (0.23)	\$ (0.07)

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Consolidated Statement of Stockholders' Equity
For the Three Months ended March 31, 2023
(unaudited)

	<u>Common Stock</u>		Additional	Accumulated	Total
	<u>Shares</u>	<u>Amount</u>	Paid-in <u>Capital</u>	<u>Equity</u>	Stockholders' <u>Equity</u>
Balance at December 31, 2022	15,301,986	\$ 15,300	\$ 77,892,235	\$(71,960,227)	\$ 5,947,308
Fair value of vested stock options issued to employees and directors	-	-	44,764	-	44,764
Exercise of warrants	1,400,926	1,401	(1,401)	-	-
Extinguishment of warrant liability upon exercise of warrants	-	-	490,226	-	490,226
Net Loss	-	-	-	(3,709,899)	(3,709,899)
Balance at March 31, 2023	<u>16,702,912</u>	<u>\$ 16,701</u>	<u>\$ 78,425,824</u>	<u>\$(75,670,126)</u>	<u>\$ 2,772,399</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

**Consolidated Statement of Stockholders' Equity
For the Three Months ended March 31, 2022
(unaudited)**

	<i>Common Stock</i>		Additional	Accumulated	Total
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in Capital</u>	<u>Equity</u>	<u>Stockholders' Equity</u>
Balance at December 31, 2021	10,350,574	\$ 10,350	\$ 77,040,713	\$(70,475,607)	\$ 6,575,456
Fair value of vested stock options issued to employees and directors	-	-	152,844	-	152,844
Share adjustment for October 2021 stock split rounding	5	-	-	-	-
Net Loss	-	-	-	(689,499)	(689,499)
Balance at March 31, 2022	<u>10,350,579</u>	<u>\$ 10,350</u>	<u>\$ 77,193,557</u>	<u>\$(71,165,106)</u>	<u>\$ 6,038,801</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Condensed Consolidated Statements of Cash Flows

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
	(unaudited)	(unaudited)
Cash flows from operating activities		
Net loss	\$ (3,709,899)	\$ (689,499)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	44,764	152,844
Change in fair value of warrant liability	562,918	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	361,491	(279,128)
Accounts payable and accrued expenses	1,390,733	(44,996)
Net cash used in operating activities	(1,349,993)	(860,779)
Net decrease in cash	(1,349,993)	(860,779)
Cash, beginning of period	7,538,312	6,675,365
Cash, end of period	\$ 6,188,319	\$ 5,814,586
Supplemental information		
Income taxes paid	\$ -	\$ -
Non-cash financing activities		
Issuance of shares upon cashless exercise of warrants	\$ -	\$ -

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation
Notes to Unaudited Condensed Consolidated Financial Statements
For the three months ended March 31, 2023

1. The Company

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

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

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

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

Going Concern

The Company has no significant operating history and since inception to March 31, 2023 has incurred accumulated losses of approximately \$75.7 million. The Company will continue to incur significant expenses for development activities for its product NELL-1/DBM. Operating expenditures for the next twelve months are estimated at \$9.8 million. The accompanying consolidated financial statements for the three months ended March 31, 2023 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, the Company incurred a net loss of \$3.7 million, and used net cash in operating activities of \$1.3 million during the three months ended March 31, 2023. These factors raise substantial doubt about the Company’s ability to continue as a going concern within a reasonable period of time, which is considered to be one year from the issuance date of these financial statements. In addition, our independent registered public accounting firm, in its audit report to the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022, expressed substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

At March 31, 2023, we had cash of \$6.2 million. Available cash is expected to fund up to commencement of our pilot clinical study.

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

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

2. Summary of Significant Accounting Policies

Basis of Presentation

The interim condensed consolidated financial statements included herein reflect all material adjustments (consisting of normal recurring adjustments and reclassifications and non-recurring adjustments) which, in the opinion of management, are ordinary and necessary for a fair presentation of results for the interim periods. Certain information and footnote disclosures required under the accounting principles generally accepted in the United States of America (“GAAP”) have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”). The Company believes that the disclosures are adequate to make the information presented not misleading. The condensed consolidated balance sheet information as of December 31, 2022 was derived from the audited consolidated financial statements included in the Company’s Annual Report on Form 10-K filed with the SEC on March 30, 2023 (the “2022 Annual Report”). These condensed consolidated financial statements should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2022 and notes thereto included in the 2022 Annual Report.

The results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the entire fiscal year ended December 31, 2023 or for any other period.

Use of Estimates

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

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

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

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

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

Inflation

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

Cash

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

While the Company and its bank has not been directly affected by the recent failures of certain banks, the banking industry overall has experienced disruption and uncertainty, which could put additional pressures on the Company’s bank and other banks, and may negatively impact the availability and costs for various banking and investment offerings. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S., or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a failure or liquidity crisis.

Fair Value of Financial Instruments

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

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

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

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

The fair value of financial instruments measured on a recurring basis was as follows as of March 31, 2023:

Description	As of March 31, 2023			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	\$ 1,732,160	—	—	\$ 1,732,160
Total liabilities at fair value	\$ 1,732,160	—	—	\$ 1,732,160

The following table provides a roll-forward of the warrant liability measured at fair value on a recurring basis using unobservable level 3 inputs for the three period ended March 31, 2023 as follows:

	March 31, 2023
Warrant liability	
Balance as of beginning of period – December 31, 2022	\$ 1,659,468
Extinguishment of warrant liability upon exercise of warrants	(490,226)
Change in fair value	562,918
Balance as of March 31, 2023	\$ 1,732,160

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

Prepaid Expenses

At March 31, 2023, prepaid expenses consist of prepaid insurance and prepaid services. Prepaid expenses are amounts paid to secure the use of assets or the receipt of services at a future date or continuously over one or more future periods. When the prepaid expenses are eventually consumed, they are charged to expense. The Company had \$595,434 and \$956,925 in prepaid expenses as of March 31, 2023 and December 31, 2022, respectively.

Stock Based Compensation

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

Loss per Common Share

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

Since the effects of outstanding options and warrants are anti-dilutive for the three months ended March 31, 2023 and 2022, 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 March 31, 2023 and 2022:

	March 31,	
	2023	2022
Warrants	12,443,428	1,827,650
Stock options	509,454	342,294
	12,952,882	2,169,944

New Accounting Standards

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

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

3. Warrant Liability

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

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

	March 31, 2023	December 31, 2022
Warrant liability:		
Risk-free interest rate	3.67%	4.26%
Expected volatility	115.06%	112.58%
Expected life (in years)	4.54	4.78
Expected dividend yield	-	-
Fair Value:		
Warrant liability	\$ 1,732,160	\$ 1,659,468

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

4. Stockholders’ Equity

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 March 31, 2023 and December 31, 2022, the Company had an aggregate of 16,702,912 and 15,301,986 shares of common stock outstanding, respectively.

In February 2023, 1,400,926 Series C warrants were exchanged for 1,400,926 shares of common stock.

5. Common Stock Warrants

A summary of warrant activity for the three months ended March 31, 2023 is presented below:

Subject to Exercise	Number of Warrants	Weighted Average Exercise Price	Weighted Average Life (Years)
Outstanding as of December 31, 2022	13,844,354	\$ 1.78	4.65
Granted – 2023	-	-	-
Forfeited/Expired – 2023	-	-	-
Exercised – 2023	(1,400,926)	4.54	4.78
Outstanding as of March 31, 2023	12,443,428	\$ 1.98	4.39

As of March 31, 2023, the Company had outstanding vested and unexercised Common Stock Warrants as follows:

Date Issued	Exercise Price	Number of Warrants	Expiration date
October 2021	\$ 6.30	1,827,650	October 13, 2026
October 2022	\$ 1.62	4,522,703	October 12, 2027
October 2022	\$ 1.35	4,333,815	October 12, 2027
October 2022	\$ 0.00	1,759,260	October 12, 2027
Total outstanding warrants at March 31, 2023		12,443,428	

Based on a fair market value of \$0.26 per share on March 31, 2023, there 1,759,260 exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, the intrinsic value attributed to exercisable but unexercised common stock warrants at March 31, 2023 was \$454,769.

6. Stock-based Compensation

2015 Equity Incentive Plan

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

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

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

A summary of stock option activity for the three months ended March 31, 2023 is presented below:

Subject to Exercise	Number of Options	Weighted Average Exercise Price	Weighted Average Life (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	452,829	\$ 16.84	5.60	\$ -
Granted – 2023	56,625	0.24	2.00	-
Forfeited/Expired – 2023	-	-	-	-
Exercised – 2023	-	-	-	-
Outstanding as of March 31, 2023	509,454	\$ 15.00	4.82	\$ 1,048
Options vested and exercisable at March 31, 2023	481,821	\$ 15.76	4.55	\$ 1,048

As of March 31, 2023, the Company had outstanding stock options as follows:

Date Issued	Exercise Price	Number of Options	Expiration date
August 2015	\$ 39.75	41,624	December 27, 2025
September 2015	\$ 39.75	8,000	December 27, 2025
November 2015	\$ 39.75	48,986	December 27, 2025
December 2015	\$ 39.75	2,228	December 27, 2025
January 2016	\$ 39.75	51,032	January 9, 2026
May 2016	\$ 51.25	10,766	May 26, 2026
September 2016	\$ 51.25	3,973	May 31, 2026
January 2017	\$ 51.25	2,142	January 1, 2027
January 2018	\$ 49.25	1,566	January 1, 2028
January 2019	\$ 2.35	21,964	January 1, 2029
October 2021	\$ 5.25	48,847	October 26, 2031
January 2022	\$ 3.52	26,166	January 1, 2032
January 2022	\$ 3.72	50,000	January 1, 2024
January 2022	\$ 3.72	25,000	January 3, 2024
August 2022	\$ 1.61	110,535	August 23, 2032
January 2023	\$ 0.24	56,625	January 25, 2025
Total outstanding options at March 31, 2023		509,454	

Based on a fair value of \$0.26 per share on March 31, 2023, 56,625 exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, the intrinsic value attributed to exercisable but unexercised common stock warrants at March 31, 2023 was \$1,048.

There were 56,625 options granted during the three months ended March 31, 2023 with a fair value of \$11,948. Vesting of options differs based on the terms of each option. During the three months ended March 31, 2023 and 2022, the Company had stock-based compensation expense of \$44,764 and \$152,844, respectively, related to the vesting of stock options granted to the Company’s employees and directors included in our reported net loss. Our policy is to account for forfeitures of the unvested portion of option grants when they occur; therefore, these forfeitures are recorded as a reversal to expense, which can result in a credit balance in the statement of operations.

The Company utilized the Black-Scholes option-pricing model. The assumptions used for the three months ended March 31, 2023 are as follows:

	March 31, 2023
Risk free interest rate	4.67%
Expected life (in years)	1
Expected Volatility	136.03%
Expected dividend yield	0%

At March 31, 2023, management determined that the Company has limited trading history by which to determine the volatility of its own common stock price. Accordingly, the fair value of the options was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. The risk-free interest rate used in the calculations is based on the implied yield available on U.S. Treasury issues with an equivalent term approximating the expected life of the options as calculated using the simplified method. The expected life of the options used was based on the contractual life of the option granted. Stock-based compensation is a non-cash expense because we settle these obligations by issuing shares of our common stock from our authorized shares instead of settling such obligations with cash payments.

As of March 31, 2023, total unrecognized compensation cost related to unvested stock options was \$22,140. The cost is expected to be recognized over a weighted average period of 0.25 years.

7. Commitments and Contingencies

UCLA TDG Exclusive License Agreement

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

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

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

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

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

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

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

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

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

As of March 31, 2023, none of the above milestones has been met.

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

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

Payments to UCLA TDG under the Amended License Agreement for the three months ended March 31, 2023 and 2022 were \$16,606 and \$22,149, respectively.

Development Contracts

The Company has two contracts with one vendor for development activities of NELL-1. As of March 31, 2023, there was \$28,200 of prepaid expenses and \$2,132,791 in accounts payable for this vendor. Amounts remaining for services contained within the contracts was \$3,648,991 as of March 31, 2023.

At March 31, 2021 there exists a concentration of payables to one vendor of approximately 96% of the Company's payables.

Contingencies

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

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

NASDAQ Notice

On November 17, 2022, the Company received a written notice from the NASDAQ Stock Market LLC ("Nasdaq") that the Company has not been in compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for a period of 30 consecutive business days. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum closing bid price of \$1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company is provided a compliance period of 180 calendar days from the date of the Notice, or until May 16, 2023, to regain compliance with the minimum closing bid price requirement. If the Company does not regain compliance during the compliance period ending May 16, 2023, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify for the second compliance period, the Company must (i) meet the continued listing requirement for market value of publicly-held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum closing bid price requirement and (ii) notify Nasdaq of its intent to cure the deficiency. As of March 31, 2023, the Company did not meet the initial listing standard for stockholders' equity applicable for the second compliance period. Accordingly, the Company expects that it will receive a notice that the Company's securities will be subject to delisting. If such notice is received, the Company plans to appeal the delisting determination to the Nasdaq Listing Qualifications Panel. The Company can achieve compliance with the minimum closing bid price requirement if, during the appeal process, the minimum closing bid price per share of the Company's common stock is at least \$1.00 for a minimum of 10 consecutive business days. The Company anticipates that its shares of common stock will continue to be listed and traded on the Nasdaq Capital Market during any compliance period(s) or during the appeal process.

In connection with regaining compliance, on May 1, 2023, the Company received the approval of the requisite number of holders of the shares of our common stock to amend our certificate of incorporation to effect a reverse split of the shares of our common stock at a ratio of 1-for-20 to 1-for-50 (or any number in between), with the exact ratio to be set within such range in the discretion of our board of directors without further approval or authorization of our stockholders. We believe that the reverse split should increase our bid price such that we meet the minimum bid requirement required for maintaining our listing requirements for the Nasdaq Capital Market, although no assurance can be given that such reverse split will be sufficient to satisfy the minimum bid price requirements. Once the Company regains compliance with the minimum bid price requirement, the Company will then be subject to the continuing listing requirements regarding stockholders' equity which the Company currently satisfies. If our common stock is delisted from Nasdaq, our common stock may be eligible for trading on the over-the-counter market. If we are not able to obtain a listing on another stock exchange or quotation service for our common stock, it may be extremely difficult or impossible for stockholders to sell the shares.

8. Subsequent Events

On May 1, 2023, the Company received the approval of the requisite number of holders of the shares of our common stock to amend our certificate of incorporation to effect a reverse split of the shares of our common stock at a ratio of 1-for-20 to 1-for-50 (or any number in between), with the exact ratio to be set within such range in the discretion of our board of directors without further approval or authorization of our stockholders. As of the date of the filing of these financial statements in the Company's quarterly report for the period ended March 31, 2023, on Form 10-Q, the reverse stock split has not been approved by the board of directors.

Item 2. Management’s Discussion and Analysis.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and audited consolidated financial statements for the years ended December 31, 2022 and 2021 and the related notes included in our Annual Report on Form 10-K filed for the fiscal year ended December 31, 2022, with the SEC on March 30, 2023. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See “Note Regarding Forward-Looking Statements” for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors.

Overview

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

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

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

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

UCLA TDG Exclusive License Agreement

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

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

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

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In connection with regaining compliance, on May 1, 2023, we received the approval of the requisite number of holders of the shares of our common stock to amend our certificate of incorporation to effect a reverse split of the shares of our common stock at a ratio of 1-for-20 to 1-for-50 (or any number in between), with the exact ratio to be set within such range in the discretion of our board of directors without further approval or authorization of our stockholders. We believe that the reverse split should increase our bid price such that we meet the minimum bid requirement required for maintaining our listing requirements for the Nasdaq Capital Market, although no assurance can be given that such reverse split will be sufficient to satisfy the minimum bid price requirements. Once the Company regains compliance with the minimum bid price requirement, the Company will then be subject to the continuing listing requirements regarding stockholders’ equity which the Company currently satisfies. If our common stock is delisted from Nasdaq, our common stock may be eligible for trading on the over-the-counter market. If we are not able to obtain a listing on another stock exchange or quotation service for our common stock, it may be extremely difficult or impossible for stockholders to sell the shares.

Results of Operations

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

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

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

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

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.

Three Months ended March 31, 2023 compared to the Three Months ended March 31, 2022

	Three-months ended March 31, 2023	Three-months ended March 31, 2022	% Change
Operating expenses			
Research and development	\$ 2,590,645	\$ 36,400	7017.16%
General and administrative	556,892	653,099	(14.73)%
Total operating expenses	3,147,537	689,499	356.50%
Loss from operations	(3,147,537)	(689,499)	356.50%
Change in fair value of warrant liability	(562,918)	-	100.00%
Interest income	556	-	100.00%
Net loss	\$ (3,709,899)	\$ (689,499)	438.06%

Research and Development

Our research and development decreased from \$36,400 during the three months ended March 31, 2022 to \$2,590,645 during the three months ended March 31, 2023. The increase of \$2,554,245 is primarily due to development activities for our Nell-1 protein. We will continue to incur significant expenses for development activities for NELL-1 in the future.

General and Administrative

Our general and administrative expenses decreased from \$653,099 during the three months ended March 31, 2022 to \$556,892 during the three months ended March 31, 2023. The \$96,207 decrease was due to the fair value of options issued in 2022.

Change in fair value of warrant liability

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

The change in fair value of warrant liability represents the re-measurement of the outstanding warrants at March 31, 2023.

Liquidity and Capital Resources

We have no significant operating history and since inception to March 31, 2023 has incurred accumulated losses of approximately \$75.7 million. We will continue to incur significant expenses for development activities for our product NELL-1/DBM. Operating expenditures for the next twelve months are estimated at \$9.8 million. The accompanying consolidated financial statements for the three months ended March 31, 2023 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, the Company incurred a net loss of \$3,709,899, and used net cash in operating activities of \$1,349,993 during the three months ended March 31, 2023. These factors raise substantial doubt about the Company’s ability to continue as a going concern within a reasonable period of time, which is considered to be one year from the issuance date of these financial statements. In addition, our independent registered public accounting firm, in its audit report to the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022, expressed substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

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

At March 31, 2023 and December 31, 2022, we had cash of \$6,188,319 and \$7,538,312, respectively.

On October 12, 2022, we completed a public equity offering, generating net proceeds to us of \$4,429,860. Available cash is expected to fund up to commencement of our pilot clinical study.

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

Cash Flows

Operating activities

During the three months ended March 31, 2023 and 2022, cash used in operating activities was \$1,349,993 and \$860,779, respectively. Cash expenditures for the three months ended March 31, 2023 increased primarily due to development activities for our Nell-1 protein.

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 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

Item 4. 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 March 31, 2023. Based upon that evaluation, our Chief Financial Officer and Chief Executive Officer concluded that as of March 31, 2023, our disclosure controls and procedures were effective.

As of March 31, 2023, management assessed the effectiveness of our internal control over financial reporting and based on that assessment, our Chief Financial Officer and Chief Executive Officer concluded that as of March 31, 2023, our internal control over financial reporting was effective.

Changes in Internal Controls

There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

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

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

Item 1A. Risk Factors.

Not applicable.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

Not Applicable

Item 5. Other Information.

None

Item 6. Exhibits.

(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit	Description
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-Q for the quarter ended March 31, 2023.*
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-Q for the quarter ended March 31, 2023.*
32.1	Certification of the Company’s Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certification of the Company’s Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed Herewith

SIGNATURES

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

BONE BIOLOGICS CORPORATION

Dated: May 15, 2023

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

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

I, Jeffrey Frelick, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Bone Biologics Corporation
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. As the registrant’s Principal Financial Officer, I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and I have:
 - a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 15, 2023

/s/ Jeffrey Frelick
Jeffrey Frelick
Principal Executive Officer

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

I, Deina H. Walsh, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Bone Biologics Corporation
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. As the registrant’s Principal Financial Officer, I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and I have:
 - a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: May 15, 2023

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

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

In connection with the Report of Bone Biologics Corporation (the “Company”) on Form 10-Q for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Jeffrey Frelick, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jeffrey Frelick

Jeffrey Frelick
Principal Executive Officer

May 15, 2023

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

In connection with the Report of Bone Biologics Corporation (the “Company”) on Form 10-Q for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Deina H. Walsh, Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Deina H. Walsh

Deina H. Walsh
Principal Financial Officer

May 15, 2023
