

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 Capital Market
Warrants to Purchase Common stock, \$0.001 par value per share	BBLGW	The Nasdaq Capital Market

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, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

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

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

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

☐ Yes ☒ No

As of November 10, 2023, there were 3,134,391 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 and subsequent Quarterly Reports on Form 10-Q or other reports filed with the SEC.

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>September 30, 2023</u>	<u>December 31, 2022</u>
	(unaudited)	
Assets		
Current Assets		
Cash	\$ 4,452,586	\$ 7,538,312
Prepaid expenses	<u>523,758</u>	<u>956,925</u>
Total assets	<u>\$ 4,976,344</u>	<u>\$ 8,495,237</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable and accrued expenses	\$ 1,102,721	\$ 888,461
Warrant liability	<u>80,514</u>	<u>1,659,468</u>
Total current liabilities	<u>1,183,235</u>	<u>2,547,929</u>
Total liabilities	<u>1,183,235</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 September 30, 2023 and December 31, 2022	-	-
Common stock, \$0.001 par value per share; 100,000,000 shares authorized; 3,134,391 and 510,065 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	3,135	510
Additional paid-in capital	83,149,047	77,907,025
Accumulated deficit	<u>(79,359,073)</u>	<u>(71,960,227)</u>
Total stockholders' equity	<u>3,793,109</u>	<u>5,947,308</u>
Total liabilities and stockholders' equity	<u>\$ 4,976,344</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 September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenues	\$ -	\$ -	\$ -	\$ -
Cost of revenues	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>
Gross profit	-	-	-	-
Operating expenses				
Research and development	1,574,850	769,410	6,460,747	823,410
General and administrative	<u>506,040</u>	<u>449,867</u>	<u>1,807,548</u>	<u>1,554,670</u>
Total operating expenses	<u>2,080,890</u>	<u>1,219,277</u>	<u>8,268,295</u>	<u>2,378,080</u>
Loss from operations	(2,080,890)	(1,219,277)	(8,268,295)	(2,378,080)
Other expenses				
Change in fair value of warrant liability	160,645	-	867,930	-
Interest income	<u>536</u>	<u>-</u>	<u>1,519</u>	<u>-</u>
Net Loss	<u>\$ (1,919,709)</u>	<u>\$ (1,219,277)</u>	<u>\$ (7,398,846)</u>	<u>\$ (2,378,080)</u>
Loss per share – basic and diluted	<u>\$ (0.61)</u>	<u>\$ (3.53)</u>	<u>\$ (4.68)</u>	<u>\$ (6.89)</u>
Weighted average shares outstanding – basic and diluted	<u>3,134,391</u>	<u>345,019</u>	<u>1,582,397</u>	<u>345,019</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Consolidated Statement of Stockholders' Equity
For the Three and Nine Months ended September 30, 2023
(unaudited)

	<u>Common Stock</u>		Additional	Accumulated	Total
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Equity</u>	<u>Stockholders'</u>
			<u>Capital</u>		<u>Equity</u>
Balance at December 31, 2022	510,065	\$ 510	\$ 77,907,025	\$(71,960,227)	\$ 5,947,308
Fair value of vested stock options issued to employees and directors	-	-	44,764	-	44,764
Exercise of warrants	46,698	47	(47)	-	-
Extinguishment of warrant liability upon exercise of warrants	-	-	490,226	-	490,226
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>(3,709,899)</u>	<u>(3,709,899)</u>
Balance at March 31, 2023	556,763	557	78,441,968	(75,670,126)	2,772,399
Fair value of vested stock options issued to employees and directors	-	-	16,670	-	16,670
Exercise of warrants	39,506	40	(40)	-	-
Extinguishment of warrant liability upon exercise of warrants	-	-	220,798	-	220,798
Proceeds from sale of common stock in public offering, net of offering costs \$547,837	2,538,071	2,538	4,449,625	-	4,452,163
Share adjustment for stock split rounding	51	-	-	-	-
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>(1,769,238)</u>	<u>(1,769,238)</u>
Balance at June 30, 2023	3,134,391	3,135	83,129,021	(77,439,364)	5,692,792
Fair value of vested stock options issued to employees and directors	-	-	20,026	-	20,026
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>(1,919,709)</u>	<u>(1,919,709)</u>
Balance at September 30, 2023	<u>3,134,391</u>	<u>\$ 3,135</u>	<u>\$ 83,149,047</u>	<u>\$(79,359,073)</u>	<u>\$ 3,793,109</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Consolidated Statement of Stockholders' Equity
For the Three and Nine Months ended September 30, 2022
(unaudited)

	<i>Common Stock</i>		Additional	Accumulated	Total
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Deficit</u>	<u>Stockholders'</u>
			<u>Capital</u>		<u>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	<u>-</u>	<u>-</u>	<u>-</u>	<u>(689,499)</u>	<u>(689,499)</u>
Balance at March 31, 2022	10,350,579	10,350	77,193,557	(71,165,106)	6,038,801
Fair value of vested stock options issued to employees and directors	-	-	18,748	-	18,748
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>(469,304)</u>	<u>(469,304)</u>
Balance at June 30, 2022	10,350,579	10,350	77,212,305	(71,634,410)	5,588,245
Fair value of vested stock options issued to employees and directors	-	-	32,534	-	32,534
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>(1,219,277)</u>	<u>(1,219,277)</u>
Balance at September 30, 2022	<u>10,350,579</u>	<u>\$ 10,350</u>	<u>\$ 77,244,839</u>	<u>\$(72,853,687)</u>	<u>\$ 4,401,502</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Condensed Consolidated Statements of Cash Flows

	<u>Nine Months Ended September 30, 2023</u> (unaudited)	<u>Nine Months Ended September 30, 2022</u> (unaudited)
Cash flows from operating activities		
Net loss	\$ (7,398,846)	\$ (2,378,080)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	81,460	204,126
Change in fair value of warrant liability	(867,930)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	433,167	(141,734)
Accounts payable and accrued expenses	214,260	699,566
Net cash used in operating activities	(7,537,889)	(1,616,122)
Cash flows from financing activities		
Proceeds from sale of common stock in public offering, net of offering costs	4,452,163	-
Net cash provided by financing activities	4,452,163	-
Net decrease in cash	(3,085,726)	(1,616,122)
Cash, beginning of period	7,538,312	6,675,365
Cash, end of period	\$ 4,452,586	\$ 5,059,243
Supplemental information		
Income taxes paid	\$ -	\$ -
Non-cash financing activities		
Extinguishment of warrant liability upon exercise of warrants	\$ 711,024	\$ -

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation
Notes to Unaudited Condensed Consolidated Financial Statements
For the Three and Nine Months ended September 30, 2023 and 2022

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.

The Company is a medical device company that is currently focused on bone regeneration in spinal fusion using the recombinant human protein known as NELL-1. NELL-1 in combination with DBM, demineralized bone matrix, is an osteopromotive recombinant protein that provides target specific control over bone regeneration. The NELL-1 technology platform has been licensed exclusively for worldwide applications to the Company through a technology transfer from the UCLA Technology Development Group on behalf of UC Regents (“UCLA TDG”). UCLA TDG and the Company received guidance from the Food and Drug Administration 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 are subject to extensive regulation by numerous governmental authorities in the United States. Prior to marketing in the United States, any combination product developed by the Company must undergo rigorous preclinical (animal) and clinical (human) testing and an extensive regulatory approval process implemented by the FDA under the Food, Drug and Cosmetic Act. There can be no assurance that the Company will not encounter problems in clinical trials that will cause the Company or the FDA to delay or suspend clinical trials.

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

On June 5, 2023, an amendment to the Company’s certificate of incorporation for a reverse split of the Company’s outstanding common stock at a ratio of 1-for-30 became effective. All share and per share amounts have been retro-actively restated as if the reverse split occurred at the beginning of the earliest period presented.

Going Concern

The Company has no significant operating history and since inception to September 30, 2023 has incurred accumulated losses of approximately \$79.4 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 \$5.1 million. The accompanying unaudited condensed consolidated financial statements for the nine months ended September 30, 2023, have been prepared on the basis that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. As reflected in the financial statements, during the nine months ended September 30, 2023, the Company incurred a net loss of \$7.4 million, and used net cash in operating activities of \$7.5 million. 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 September 30, 2023, we had cash of \$4.5 million. Available cash is expected to fund our operations until the second quarter of 2024 when we expect to announce data reporting from our pilot clinical study.

We anticipate that we will require approximately \$5.9 million to complete first in man studies, and an estimated additional \$27 million to achieve FDA approval for a spine interbody fusion indication.

On June 16, 2023, the Company completed a public offering generating net proceeds to the Company of \$4.5 million.

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 nine months ended September 30, 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 the warrant liability, 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.

Inflation

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

Cash

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

Fair Value of Financial Instruments

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

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

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

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

The fair value of financial instruments measured on a recurring basis was as follows as of September 30, 2023:

Description	As of September 30, 2023			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	\$ 80,514	—	—	\$ 80,514
Total liabilities at fair value	\$ 80,514	—	—	\$ 80,514

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 nine period ended September 30, 2023 as follows:

	September 30, 2023
Warrant liability	
Balance as of beginning of period – December 31, 2022	\$ 1,659,468
Extinguishment of warrant liability upon exercise of warrants	(711,024)
Change in fair value	(867,930)
Balance as of September 30, 2023	\$ 80,514

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 September 30, 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 \$523,758 and \$956,925 in prepaid expenses as of September 30, 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 nine months ended September 30, 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 and warrants as of September 30, 2023 and 2022:

	September 30,	
	2023	2022
Warrants	375,296	60,922
Stock options	274,284	15,094
	649,580	76,016

New Accounting Standards

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

3. Warrant Liability

In October 2022, the Company completed a public equity offering, which included the issuance of 433,382 warrants. Upon the occurrence of certain transactions (“Fundamental Transactions,” as defined in the warrant agent agreement), the warrants provide for a value determined using a Black Scholes model with inputs calculated as described in the warrant agreement which includes a 100% floor on the volatility input to be utilized. 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:

	September 30, 2023	December 31, 2022
Warrant liability:		
Risk-free interest rate	4.74%	4.26%
Expected volatility	134.17%	112.58%
Expected life (in years)	4.03	4.78
Expected dividend yield	-	-
Fair Value of warrant liability	\$ 80,514	\$ 1,659,468

The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant. We determine expected volatility based upon the historical volatility of our common stock since listing on The Nasdaq Capital Market. We do not believe that the future volatility of our common stock over an option’s expected term is likely to differ significantly from the past. The expected term of the warrants granted are determined based on the duration of time the warrants are expected to be outstanding. The dividend yield on the Company’s warrants is assumed to be zero as the Company has not historically paid dividends.

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 as of September 30, 2023 and December 31, 2022.

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 September 30, 2023 and December 31, 2022, the Company had an aggregate of 3,134,391 and 510,065 shares of common stock outstanding, respectively.

In February 2023, 46,698 Series C warrants were exchanged for 46,698 shares of common stock.

In May 2023, 39,506 Series C warrants were exchanged for 39,506 shares of common stock.

On June 14, 2023, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with EF Hutton, division of Benchmark Investments, LLC (“EF Hutton”) acting as representatives of the several underwriters in connection with a public offering (the “Offering”) of an aggregate of 2,538,071 shares of its common stock. The public offering price was \$1.97 per share and the underwriters agreed to purchase 2,538,071 shares at a 7% discount to the public offering price. The Company granted EF Hutton a 45-day option to purchase up to 380,710 additional shares, to cover over-allotments, if any, which was not exercised. The Offering closed on June 16, 2023, resulting in gross proceeds of \$5 million, before deducting underwriting discounts and commissions and other offering expenses. The net proceeds in relation to the Offering were \$4,452,163.

5. Common Stock Warrants

A summary of warrant activity for the nine months ended September 30, 2023 is presented below:

Subject to Exercise	Number of Warrants	Weighted Average Exercise Price	Weighted Average Life (Years)
Outstanding as of December 31, 2022	461,500	\$ 53.40	4.65
Granted – 2023	-	-	-
Forfeited/Expired – 2023	-	-	-
Exercised – 2023	(86,204)	-	4.29
Outstanding as of September 30, 2023	375,296	\$ 65.66	3.87

As of September 30, 2023, the Company had outstanding vested and unexercised Common Stock Warrants as follows:

Date Issued	Exercise Price	Number of Warrants	Expiration date
October 2021	\$ 189.00	60,934	October 13, 2026
October 2022	\$ 48.60	144,464	October 12, 2027
October 2022	\$ 40.50	150,761	October 12, 2027
October 2022	\$ 0.00	19,137	October 12, 2027
Total outstanding warrants at September 30, 2023		375,296	

Based on a fair market value of \$0.71 per share on September 30, 2023, there 19,137 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 September 30, 2023 was \$13,587.

6. Stock-based Compensation

2015 Equity Incentive Plan

The Company has 5,035,918 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. In September 2023, the Company's stockholders approved an amendment to the 2015 Equity Incentive Plan that, among other items, increased the number of shares available under the 2015 Equity Incentive Plan by 5,000,000 shares. Appropriate adjustments were made in the number of authorized shares and other numerical limits in 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 nine months ended September 30, 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	15,106	\$ 505.20	5.60	\$ -
Granted – 2023	259,178	0.68	9.94	18,010
Forfeited/Expired – 2023	-	-	-	-
Exercised – 2023	-	-	-	-
Outstanding as of September 30, 2023	274,284	\$ 29.08	8.62	\$ 18,010
Options vested and exercisable at September 30, 2023	16,995	\$ 459.70	4.32	\$ -

As of September 30, 2023, the Company had outstanding stock options as follows:

Date Issued	Exercise Price	Number of Options	Expiration date
August 2015	\$ 1,192.50	1,387	December 27, 2025
September 2015	\$ 1,192.50	268	December 27, 2025
November 2015	\$ 1,192.50	1,634	December 27, 2025
December 2015	\$ 1,192.50	75	December 27, 2025
January 2016	\$ 1,192.50	1,701	January 9, 2026
May 2016	\$ 1,537.50	359	May 26, 2026
September 2016	\$ 1,537.50	135	May 31, 2026
January 2017	\$ 1,537.50	72	January 1, 2027
January 2018	\$ 1,477.50	53	January 1, 2028
January 2019	\$ 70.50	732	January 1, 2029
October 2021	\$ 157.50	1,630	October 26, 2031
January 2022	\$ 105.60	873	January 1, 2032
January 2022	\$ 111.60	1,667	January 1, 2024
January 2022	\$ 111.60	833	January 3, 2024
August 2022	\$ 48.30	3,687	August 23, 2032
January 2023	\$ 7.20	1,889	January 25, 2025
September 2023	\$ 0.64	257,289	September 12, 2033
Total outstanding options at September 30, 2023		274,284	

Based on a fair value of \$0.71 per share on September 30, 2023. There were no exercisable but unexercised in-the-money common stock warrants on that date.

There were 259,178 options granted during the nine months ended September 30, 2023 with a fair value of \$161,948. Vesting of options differs based on the terms of each option. During the nine months ended September 30, 2023 and 2022, the Company had stock-based compensation expense of \$81,460 and \$204,126, 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 nine months ended September 30, 2023 are as follows:

	September 30, 2023
Risk free interest rate	4.39%
Expected Volatility	135.49%
Expected life (in years)	5.86
Expected dividend yield	0%

The expected volatility is a measure of the amount by which our stock price is expected to fluctuate during the expected term of options granted. We determine the expected volatility based upon the historical volatility of our common stock since listing on The Nasdaq Capital Market. We do not believe that the future volatility of our common stock over an option’s expected term is likely to differ significantly from the past. The risk-free interest rate used in the calculations is based on the implied yield available on U.S. Treasury issues with an equivalent term approximating the expected life of the options as calculated using the simplified method. The expected life of the options used was based on the contractual life of the option granted. Stock-based compensation is a non-cash expense because 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 September 30, 2023, total unrecognized compensation cost related to unvested stock options was \$135,445. The cost is expected to be recognized over a weighted average period of 0.38 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, which was subsequently 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 Amended License Agreement and we are prohibited from assigning, selling, or otherwise transferring any of its assets related to any Licensed Product unless our Diligence Fee obligation is assigned, sold, or transferred along with such assets, or unless we pay UCLA TDG the Diligence Fee within ten (10) days of such assignment, sale or other transfer of such rights to any Licensed Product.

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

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

As of September 30, 2023, none of the above milestones have 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. We are required to meet certain diligence milestone deadlines pursuant to the Amended License Agreement. Applicable for the current year, we are required to spend at least \$1,000,000 per calendar year on pre-clinical or clinical development until the date that we complete a Phase III pivotal study. If we fail to meet this or the other diligence milestone deadlines, UCLA TDG has the right to either terminate the license or reduce the license to a non-exclusive license.

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 nine months ended September 30, 2023 and 2022 were \$23,238 and \$35,235, respectively.

Development Contracts

The Company has two contracts with one vendor for development activities of NELL-1. As of September 30, 2023, there were no prepaid expenses and \$955,076 in accounts payable for this vendor. Amounts remaining for services contained within the contracts was \$487,640 as of September 30, 2023.

At September 30, 2023 there exists a concentration of payables to one vendor of approximately 98% 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 Stroeve ("Stroeve"), John Booth ("Booth"), Stephen LaNeve ("LaNeve", and together with Stroeve 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 Notices

On November 17, 2022, the Company received a deficiency letter from The Nasdaq Stock Market LLC's ("Nasdaq") notifying it that, because the bid price of its common stock closed below \$1.00 per share for 30 consecutive business days, it was no longer in compliance with Nasdaq's minimum bid price rule, which is a requirement for continued listing on the Nasdaq Capital Market. On June 28, 2023, the Company received a letter from Nasdaq confirming the decision of a Nasdaq Hearings Panel, that while the Company demonstrated compliance with the minimum bid price at that time, based on its recent bid price history the panel imposed a "Panel Monitor," as defined by Nasdaq Listing Rule 5815(d)(4)(A), through June 27, 2024.

On September 27, 2023, the Company received a written notice (the "Notice") from the staff of Nasdaq notifying the Company that it failed to comply with the \$1.00 per share minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2). As a result of the imposition of a mandatory Panel Monitor, the Company is not eligible for a compliance period to regain compliance with the minimum bid price requirement. Accordingly, the Nasdaq staff has determined to delist the Company's securities from Nasdaq (the "Staff Determination").

The Company timely requested a hearing before a Nasdaq Hearings Panel (the "Panel"), to appeal the Staff Determination, which request stayed any delisting action pending the issuance of the Panel's determination. The Panel hearing is scheduled for November 30, 2023.

At the hearing, the Company expects to present its plan for regaining and sustaining compliance with all applicable requirements for continued listing on The Nasdaq Capital Market. There can be no assurance that the Panel will grant the Company any additional time to regain compliance or that the Company will ultimately regain and sustain compliance for listing of its securities on Nasdaq. In the event the Company's securities are delisted from Nasdaq, the Company expects that its securities should be eligible to trade on the over-the-counter OTC Markets platform. The Company is evaluating several alternatives to regain compliance with the minimum bid price requirement.

8. Subsequent Events

The Company has evaluated subsequent events through November 14, 2023, the date which the consolidated financial statements were available to be issued. There were no additional subsequent events noted that would require adjustment to or disclosure in these consolidated financial statements.

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. We believe our platform technology has application in delivering improved outcomes in the surgical specialties of spinal, orthopedic, general orthopedic, plastic reconstruction, neurosurgery, interventional radiology, and sports medicine. Lead product development and clinical studies are targeted on spinal fusion surgery, one of the larger segments in the orthopedic market.

We are a development stage entity. The production and marketing of our products and ongoing research and development activities are subject to extensive regulation by numerous governmental authorities in the United States. Prior to marketing in the United States, any combination product developed by us must undergo rigorous preclinical (animal) and clinical (human) testing and an extensive regulatory approval process implemented by the FDA under the 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, which was subsequently 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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Our obligation to pay the Diligence Fee will survive termination or expiration of the Amended License Agreement and we are prohibited from assigning, selling, or otherwise transferring any of its assets related to any Licensed Product unless our Diligence Fee obligation is assigned, sold, or transferred along with such assets, or unless we pay UCLA TDG the Diligence Fee within ten (10) days of such assignment, sale or other transfer of such rights to any Licensed Product.

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

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As of September 30, 2023, none of the above milestones have 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. We are required to meet certain diligence milestone deadlines pursuant to the Amended License Agreement. Applicable for the current year, we are required to spend at least \$1,000,000 per calendar year on pre-clinical or clinical development until the date that we complete a Phase III pivotal study. If we fail to meet this or the other diligence milestone deadlines, UCLA TDG has the right to either terminate the license or reduce the license to a non-exclusive license.

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 nine months ended September 30, 2023 and 2022 were \$ 23,238 and \$35,235, respectively.

NASDAQ Notices

On November 17, 2022, we received a deficiency letter from The Nasdaq Stock Market LLC's ("Nasdaq") notifying us that, because the bid price of our common stock closed below \$1.00 per share for 30 consecutive business days, we were no longer in compliance with Nasdaq's minimum bid price rule, which is a requirement for continued listing on the Nasdaq Capital Market. On June 28, 2023, the Company received a letter from Nasdaq confirming the decision of a Nasdaq Hearings Panel that while the Company demonstrated compliance with the minimum bid price rule at that time, based on our recent bid price history the panel imposed a "Panel Monitor," as defined by Nasdaq Listing Rule 5815(d)(4)(A), through June 27, 2024.

On September 27, 2023, the Company received a written notice (the "Notice") from the staff of Nasdaq notifying the Company that it failed to comply with the \$1.00 per share minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2). As a result of the imposition of a mandatory Panel Monitor, the Company is not eligible for a compliance period to regain compliance with the minimum bid price requirement. Accordingly, the Nasdaq staff has determined to delist the Company's securities from Nasdaq (the "Staff Determination").

The Company timely requested a hearing before a Nasdaq Hearings Panel (the "Panel"), to appeal the Staff Determination, which request stayed any delisting action pending the issuance of the Panel's determination. The Panel hearing is scheduled for November 30, 2023.

At the hearing, the Company expects to present its plan for regaining and sustaining compliance with all applicable requirements for continued listing on The Nasdaq Capital Market. There can be no assurance that the Panel will grant the Company any additional time to regain compliance or that the Company will ultimately regain and sustain compliance for listing of its securities on Nasdaq. In the event the Company's securities are delisted from Nasdaq, the Company expects that its securities should be eligible to trade on the over-the-counter OTC Markets platform. The Company is evaluating several alternatives to regain compliance with the minimum bid price requirement.

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.

Three Months ended September 30, 2023 compared to the Three Months ended September 30, 2022

	Three-months ended September 30, 2023	Three-months ended September 30, 2022	% Change
Operating expenses			
Research and development	\$ 1,574,850	\$ 769,410	104.68%
General and administrative	506,040	449,867	12.49%
Total operating expenses	2,080,890	1,219,277	70.67%
Loss from operations	(2,080,890)	(1,219,277)	70.67%
Change in fair value of warrant liability	160,645	-	100.00%
Interest income	536	-	100.00%
Net loss	\$ (1,919,709)	\$ (1,219,277)	57.45%

Research and Development

Our research and development costs increased from \$769,410 during the three months ended September 30, 2022 to \$1,574,850 during the three months ended September 30, 2023. The increase of \$805,440 is primarily due to development activities for our Nell-1 protein as we prepare for our pilot clinical study. We will continue to incur significant expenses for development activities for NELL-1 in the future.

General and Administrative

Our general and administrative expenses increased from \$449,867 during the three months ended September 30, 2022 to \$506,040 during the three months ended September 30, 2023. The \$56,173 increase was primarily due to consultants for the annual proxy and to assist with the NASDAQ notice. The incentive bonus accruals were based on performance targets established for each fiscal year.

Change in fair value of warrant liability

In October 2022, we completed a public equity offering, which included the issuance of 433,382 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 September 30, 2023.

Nine Months ended September 30, 2023 compared to the Nine Months ended September 30, 2022

	Nine-months Ended September 30, 2023	Nine-months Ended September 30, 2022	% Change
Operating expenses			
Research and development	\$ 6,460,747	\$ 823,410	684.63%
General and administrative	1,807,548	1,554,670	16.27%
Total operating expenses	8,268,295	2,378,080	247.69%
Loss from operations	(8,268,295)	(2,378,080)	247.69%
Change in fair value of warrant liability	867,930	-	100.00%
Interest income	1,519	-	100.00%
Net loss	\$ (7,398,846)	\$ (2,378,080)	211.13%

Research and Development

Our research and development costs increased from \$823,410 during the nine months ended September 30, 2022 to \$6,460,747 during the nine months ended September 30, 2023. The increase of \$5,637,337 is primarily due to development activities for our Nell-1 protein as we prepare for our pilot clinical study. We will continue to incur significant expenses for development activities for NELL-1 in the future.

General and Administrative

Our general and administrative expenses increased from \$1,554,670 during the nine months ended September 30, 2022 to \$1,807,548 during the nine months ended September 30, 2023. The \$252,878 increase was due to increased legal expenditures offset by a decrease in the fair value of options issued in 2023 verses 2022.

Change in fair value of warrant liability

In October 2022, we completed a public equity offering, which included the issuance of 433,382 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 September 30, 2023.

Liquidity and Capital Resources

Since inception to September 30, 2023 we have incurred accumulated losses of approximately \$79.4 million. We 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 \$5.1 million. The accompanying consolidated financial statements for the nine months ended September 30, 2023 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, we incurred a net loss of \$7.4 million, and used net cash in operating activities of \$7.5 million during the nine months ended September 30, 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 our product development programs, or obtain funds if available (although there can be no certainties) through strategic alliances that may require us to relinquish rights to our technology or substantially reduce or discontinue our operations entirely. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to us. Even if we are able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in the case of equity financing.

On June 14, 2023, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with EF Hutton, division of Benchmark Investments, LLC (“EF Hutton”) acting as representatives of the several underwriters in connection with a public offering (the “Offering”) of an aggregate of 2,538,071 shares of its common stock. The public offering price was \$1.97 per share and the underwriters agreed to purchase 2,538,071 shares at a 7% discount to the public offering price. The Company granted EF Hutton a 45-day option to purchase up to 380,710 additional shares, to cover over-allotments, if any, which was not exercised. The Offering closed on June 16, 2023, resulting in gross proceeds of \$5 million, before deducting underwriting discounts and commissions and other offering expenses. The net proceeds in relation to the Offering were \$4,452,163 thousand.

At September 30, 2023 and December 31, 2022, we had cash of \$4,452,586 and \$7,538,312, respectively.

Available cash is expected to fund our operations through the second quarter of 2024.

We anticipate that we will require approximately \$5.9 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 nine months ended September 30, 2023 and 2022, cash used in operating activities was \$7,537,889 and \$1,616,122, respectively. Cash expenditures for the nine months ended September 30, 2023 increased primarily due to development activities for our Nell-1 protein as we prepare for our pilot clinical study.

Financing activities

During the nine months ended September 30, 2023, cash provided by financing activities of \$4,452,163 resulted from the net proceeds of our June 14, 2023 public offering of common stock.

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.

Critical Accounting Policies and Use of Estimates

See our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2022 for a discussion of our critical accounting policies and use of estimates. There have been no material changes to our critical accounting policies and use of estimates discussed in such report.

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, as amended (Exchange Act)) as of September 30, 2023. Based upon that evaluation, our Chief Financial Officer and Chief Executive Officer concluded that as of September 30, 2023, our disclosure controls and procedures were effective.

Changes in Internal Controls

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) that occurred during the quarter ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

There have been no material developments with respect to the information previously reported under Part I, Item 3 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Item 1A. Risk Factors.

For a discussion of the Company's potential risks or uncertainties, please see "Part I—Item 1A—Risk Factors" and "Part II—Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC, and "Part I—Item 2—Management's Discussion and Analysis of Financial Condition and Results of Operations" herein. There have been no material changes from the risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022, and subsequent Quarterly Reports on Form 10-Q, except as noted herein.

We ceased to be in compliance with the Nasdaq minimum bid price rule while subject to a Nasdaq Panel Monitor and have requested a hearing with a Nasdaq Hearing Panel in response to a delisting notice. If the Hearing Panel does not grant us additional time to regain compliance with the minimum bid price rule,, and if we are unable to regain and maintain compliance with the Nasdaq listing rules, our common stock may be delisted from trading on the Nasdaq Stock Market, which could have a material adverse effect on us and our stockholders.

On November 17, 2022, we received a deficiency letter from Nasdaq notifying us that, because the bid price of our common stock closed below \$1.00 per share for 30 consecutive business days, we were no longer in compliance with Nasdaq's minimum bid price rule, which is a requirement for continued listing on the Nasdaq Capital Market. We filed an expedited review request and on June 28, 2023, we received a letter from Nasdaq confirming the decision of a Nasdaq Hearing Panel that while the Company demonstrated compliance with the minimum bid price rule at that time, based on our recent bid price history, the panel imposed a "Panel Monitor," as defined by Nasdaq Listing Rule 5815(d)(4)(A), through June 27, 2024.

On September 27, 2023, the Company received a written notice (the "Notice") from the staff of Nasdaq notifying the Company that it failed to comply with the \$1.00 per share minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2). As a result of the imposition of a mandatory Panel Monitor, the Company is not eligible for a compliance period to regain compliance with the minimum bid price requirement. Accordingly, the Nasdaq staff has determined to delist the Company's securities from Nasdaq (the "Staff Determination").

The Company timely requested a hearing before a Nasdaq Hearings Panel (the "Panel"), to appeal the Staff Determination, which request stayed any delisting action pending the issuance of the Panel's determination. The Panel hearing is scheduled for November 30, 2023.

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

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.

During the three months ended September 30, 2023, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits.

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

Exhibit	Description
10.1	First Amendment to the Bone Biologics Corporation 2015 Equity Incentive Plan (Incorporated by reference to Annex B to the registrant’s Proxy Statement on Schedule 14A filed August 3, 2023).
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 September 30, 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 September 30, 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
** Furnished 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: November 14, 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. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 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. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 14, 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 September 30, 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

November 14, 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 September 30, 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

November 14, 2023
