

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 September 30, 2022

☐ 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 November 2, 2022, there were 15,301,986 shares of the issuer's common stock, \$0.001 par value, outstanding.

Bone Biologics Corporation
- INDEX -

	Page
<u>PART I – FINANCIAL INFORMATION:</u>	
<u>Item 1. Financial Statements.</u>	F-1
Unaudited Condensed Consolidated Financial Statements	
<u>Unaudited Condensed Consolidated Balance Sheets</u>	F-1
<u>Unaudited Condensed Consolidated Statements of Operations</u>	F-2
<u>Unaudited Condensed Consolidated Statement of Stockholders’ Equity (Deficit)</u>	F-3
<u>Unaudited Condensed Consolidated Statements of Cash Flows</u>	F-5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	F-6
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	4
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	9
<u>Item 4. Controls and Procedures</u>	9
<u>PART II – OTHER INFORMATION:</u>	9
<u>Item 1. Legal Proceedings</u>	9
<u>Item 1A. Risk Factors</u>	9
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	9
<u>Item 3. Defaults Upon Senior Securities</u>	10
<u>Item 4. Mine Safety Disclosures</u>	10
<u>Item 5. Other Information</u>	10
<u>Item 6. Exhibits</u>	10
<u>Signatures</u>	11

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, 2021, filed with the Securities and Exchange Commission (“SEC”) on March 15, 2022.

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, 2022</u> (unaudited)	<u>December 31, 2021</u>
Assets		
Current assets		
Cash	\$ 5,059,243	\$ 6,675,365
Prepaid expenses	<u>141,734</u>	<u>-</u>
Total assets	<u>\$ 5,200,977</u>	<u>\$ 6,675,365</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued expenses	<u>\$ 799,475</u>	<u>\$ 99,909</u>
Total liabilities	<u>799,475</u>	<u>99,909</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, 2022 and December 31, 2021	-	-
Common stock, \$0.001 par value per share; 100,000,000 shares authorized; 10,350,579 and 10,350,574 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	10,350	10,350
Additional paid-in capital	77,244,839	77,040,713
Accumulated deficit	<u>(72,853,687)</u>	<u>(70,475,607)</u>
Total stockholders' equity	<u>4,401,502</u>	<u>6,575,456</u>
Total liabilities and stockholders' equity	<u>\$ 5,200,977</u>	<u>\$ 6,675,365</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Condensed Consolidated Statements of Operations

	Three Months Ended September 30, 2022 (unaudited)	Three Months Ended September 30, 2021 (unaudited)	Nine Months Ended September 30, 2022 (unaudited)	Nine Months Ended September 30, 2021 (unaudited)
Revenues	\$ -	\$ -	\$ -	\$ -
Cost of revenues	-	-	-	-
Gross profit	-	-	-	-
Operating expenses				
Research and development	769,410	-	823,410	47,516
General and administrative	449,867	229,789	1,553,070	595,078
Total operating expenses	1,219,277	229,789	2,376,480	642,594
Loss from operations	(1,219,277)	(229,789)	(2,376,480)	(642,594)
Other expenses				
Interest expense, net – related party	-	(279,514)	-	(790,354)
Loss before provision for income taxes	(1,219,277)	(509,303)	(2,376,480)	(1,432,948)
Provision for income taxes	-	-	1,600	-
Net Loss	\$ (1,219,277)	\$ (509,303)	\$ (2,378,080)	\$ (1,432,948)
Weighted average shares outstanding – basic and diluted	10,350,579	2,911,333	10,350,579	2,911,333
Loss per share – basic and diluted	\$ (0.12)	\$ (0.17)	\$ (0.23)	\$ (0.49)

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Condensed Consolidated Statement of Stockholders' Equity (Deficit)
For the three and nine months ended September 30, 2022
(unaudited)

	<i>Common Stock</i>		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
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	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	-	-	-	(469,304)	(469,304)
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	-	-	-	(1,219,277)	(1,219,277)
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 Statement of Stockholders' Equity (Deficit)
For the three and nine months ended September 30, 2021
(unaudited)

	<i>Common Stock</i>		Additional	Accumulated	Total
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u> <u>Capital</u>	<u>Deficit</u>	<u>Stockholders'</u> <u>Deficit</u>
Balance at December 31, 2020	12,273,036	\$ 12,273	\$ 55,160,339	\$(68,864,922)	\$ (13,692,310)
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>(431,747)</u>	<u>(431,747)</u>
Balance at March 31, 2021	12,273,036	12,273	55,160,339	(69,296,669)	(14,124,057)
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>(491,898)</u>	<u>(491,898)</u>
Balance at June 30, 2021	12,273,036	12,273	55,160,339	(69,788,567)	(14,615,955)
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>(509,303)</u>	<u>(509,303)</u>
Balance at September 30, 2021	<u>12,273,036</u>	<u>\$ 12,273</u>	<u>\$ 55,160,339</u>	<u>\$(70,297,870)</u>	<u>\$ (15,125,258)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

Bone Biologics Corporation

Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine Months Ended September 30, 2022 (unaudited)	Nine Months Ended September 30, 2021 (unaudited)
Cash flows from operating activities		
Net loss	\$ (2,378,080)	\$ (1,432,948)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	204,126	-
Interest payable – related party	-	790,354
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(141,734)	(49,019)
Accounts payable and accrued expenses	699,566	(395,121)
Deferred compensation	-	45,000
Net cash used in operating activities	(1,616,122)	(1,041,734)
Cash flows from financing activities		
Bank overdraft	-	(10,609)
Proceeds from credit facilities – related party	-	1,055,717
Net cash provided by financing activities	-	1,045,108
Net increase (decrease) in cash	(1,616,122)	3,374
Cash, beginning of period	6,675,365	-
Cash, end of period	\$ 5,059,243	\$ 3,374
Supplemental information		
Interest paid - related party	\$ -	\$ -
Income taxes paid	\$ 1,600	\$ -

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, 2022 and 2021
(unaudited)

1. The Company

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

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

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

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

On October 12, 2021, an amendment to our certificate of incorporation for a reverse split of the Company’s outstanding common stock at a ratio of 1 for 2.5 became effective. All share and per share amounts have been retro-actively restated as of the reverse split occurred at the beginning of the earliest period presented.

Going Concern and Liquidity

The Company has no significant operating history and since inception to September 30, 2022 has incurred accumulated losses of approximately \$72.9 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 \$11.5 million. The accompanying consolidated financial statements for the nine months ended September 30, 2022 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, the Company incurred a net loss of \$2,378,080, and used net cash in operating activities of \$1,616,122 during the nine months ended September 30, 2022. 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, 2021, 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, 2022, we had cash of \$5,059,243. On October 12, 2022, the Company completed a public offering generating gross proceeds to the Company of \$5,100,000, and net proceeds, after underwriters discounts and expenses of approximately \$4,454,000 (see Note 6). 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.

For the past several years, we have depended on our relationship with Hankey Capital for working capital to fund our operations, which has been raised in the form of both debt and equity capital. Hankey Capital, directly and indirectly, controls approximately 70% of our issued and outstanding shares of common stock as of September 30, 2022. However, no assurance can be given that any future financing from Hankey Capital will be available or, if available, that it will be on terms that are satisfactory to the Company. In the absence of financing from other sources, the inability to obtain additional financing from Hankey Capital will result in the scaling back or discontinuance of our product development programs or operations entirely.

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, 2021 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 15, 2022 (the "2021 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, 2021 and notes thereto included in the 2021 Annual Report.

The results of operations for the nine months ended September 30, 2022 are not necessarily indicative of the results to be expected for the entire fiscal year ended December 31, 2022 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 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 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 which will be conducting the clinical trials for the Company are that such clinical trials are being delayed or extended for several months as a result of the coronavirus pandemic. There is also significant uncertainty as to the effect that the coronavirus may have on the amount and type of financing available to the Company in the future.

Inflation

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

Cash

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

Fair Value of Financial Instruments

The Company’s financial instruments consist of cash and accounts payable. The recorded values of cash and accounts payable approximate their fair values based on their short-term nature.

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.

Stock Based Compensation

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

Loss per Common Share

The Company utilizes FASB ASC Topic No. 260, *Earnings per Share*. Basic loss per share is computed by dividing loss available to common shareholders by the weighted-average number of common shares outstanding. Shares issued for collateral for outstanding loans of -0- and 9,361,702 at September 30, 2022 and 2021, respectively are excluded from weighted average shares outstanding. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. Diluted loss per common share reflects the potential dilution that could occur if convertible debentures, options and warrants were to be exercised or converted or otherwise resulted in the issuance of common stock that then shared in the earnings of the entity.

Since the effects of outstanding options, warrants, and the conversion of convertible debt are anti-dilutive for the period ended September 30, 2022 and 2021, shares of common stock underlying these instruments have been excluded from the computation of loss per common share.

The following sets forth the number of shares of common stock underlying outstanding options, warrants, and convertible debt as of September 30, 2022 and 2021:

	September 30,	
	2022	2021
Warrants	1,827,650	-
Stock options	452,829	192,281
Convertible promissory notes	-	5,923,950
	2,280,479	6,116,231

New Accounting Standards

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

3. Stockholders’ Equity (Deficit)

Common Stock Warrants

A summary of warrant activity for the period ended September 30, 2022 is presented below:

Subject to Exercise	Number of Warrants	Weighted Average Exercise Price	Weighted Average Life (Years)
Outstanding as of December 31, 2021	1,827,650	\$ 6.30	4.79
Granted – 2022	-	-	-
Forfeited/Expired – 2022	-	-	-
Exercised – 2022	-	-	-
Outstanding as of September 30, 2022	1,827,650	\$ 6.30	4.29

As of September 30, 2022, the Company had outstanding vested and unexercised Common Stock Warrants as follows:

Date Issued	Exercise Price	Number of Warrants	Expiration date
October 2021	\$ 6.30	1,737,023	October 13, 2026
October 2021	\$ 6.30	90,627	October 13, 2026
Total outstanding warrants at September 30, 2022		1,827,650	

Based on a fair market value of \$1.05 per share on September 30, 2022, there were no exercisable but unexercised in-the-money common stock warrants on that date. Accordingly, there was no intrinsic value attributed to exercisable but unexercised common stock warrants at September 30, 2022.

4. Stock-based Compensation

A summary of stock option activity for the period ended September 30, 2022, 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, 2021	241,128	\$ 32.76	5.43	\$ 9,445
Granted – 2022	211,701	2.60	7.17	-
Forfeited/Expired – 2022	-	-	-	-
Exercised – 2022	-	-	-	-
Outstanding as of September 30, 2022	452,829	\$ 16.82	5.86	\$ -
Options vested and exercisable at September 30, 2022	369,927	\$ 20.29		-

As of September 30, 2022, the Company had outstanding stock options as follows:

Date Issued	Exercise Price	Number of Options	Expiration date
August 2015	\$ 39.75	41,624	December 27, 2025
September 2015	\$ 39.75	8,000	December 27, 2025
November 2015	\$ 39.75	48,986	December 27, 2025
December 2015	\$ 39.75	2,228	December 27, 2025
January 2016	\$ 39.75	51,032	January 9, 2026
May 2016	\$ 51.25	10,766	May 26, 2026
September 2016	\$ 51.25	3,973	May 31, 2026
January 2017	\$ 51.25	2,142	January 1, 2027
January 2018	\$ 49.25	1,566	January 1, 2028
January 2019	\$ 2.35	21,964	January 1, 2029
October 2021	\$ 5.25	48,847	October 26, 2031
January 2022	\$ 3.52	26,166	January 1, 2032
January 2022	\$ 3.72	50,000	January 1, 2024
January 2022	\$ 3.72	25,000	January 3, 2024
August 2022	\$ 1.61	110,535	August 23, 2032
Total outstanding options at September 30, 2022		452,829	

Based on a fair value of \$1.05 per share on September 30, 2022, there was no intrinsic value attributed to exercisable but unexercised stock options at September 30, 2022.

There were 211,701 options granted during the nine month period ended September 30, 2022 with a fair value of \$321,592. Vesting of options differs based on the terms of each option. During the nine month periods ended September 30, 2022 and 2021, the Company had stock-based compensation expense of \$204,126 and \$-0-, 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 periods ended September 30, 2022 and 2021 are as follows:

	September 30, 2022	September 30, 2021
Risk free interest rate	0.39% - 3.157%	-%
Expected life (in years)	1.00 - 5.87	-
Expected Volatility	96.24% - 112.54%	-%
Expected dividend yield	-%	-%

As of the issuance of these consolidated financial statements, there was no active public market for the Company’s shares. Accordingly, the fair value of the options was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. The risk-free interest rate used in the calculations is based on the implied yield available on U.S. Treasury issues with an equivalent term approximating the expected life of the options as calculated using the simplified method. The expected life of the options used was based on the contractual life of the option granted. Stock-based compensation is a non-cash expense because we settle these obligations by issuing shares of our common stock from our authorized shares instead of settling such obligations with cash payments.

As of September 30, 2022, total unrecognized compensation cost related to unvested stock options was \$117,466. The cost is expected to be recognized over a weighted average period of 0.37 years.

5. Commitments and Contingencies

UCLA TDG Exclusive License Agreement

Effective April 9, 2019, the Company 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 Technology Development Group on behalf of UC Regents (“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, UCLA TDG has continued to grant the Company exclusive rights to develop and commercialize NELL-1 (the “Licensed Product”) for spinal fusion, 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 to pay certain royalties to UCLA TDG under the Amended License Agreement at the rate of 3.0% of net sales of licensed products through the life of the patents. We must pay the royalties to UCLA TDG on a quarterly basis. Upon a first commercial sale, we also must pay between \$50,000 and \$250,000, depending on the calendar year which is after the first commercial sale. If we are required to pay any third party any royalties as a result of us making use of UCLA TDG patents, then we may reduce the royalty owed to UCLA TDG by 0.333% for every percentage point paid to a third party. If we grant sublicense rights to a third party to use the UCLA TDG patent, then we will pay to UCLA TDG 10% to 20% of the sublicensing income we receive from such sublicense.

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

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

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

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

The Company’s obligation to pay the Diligence Fee will survive termination or expiration of the agreement and the Company is prohibited from assigning, selling, or otherwise transferring any of its assets related to any Licensed Product unless the Company’s foregoing Diligence Fee obligation is assigned, sold, or transferred along with such assets, or unless the Company pays 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, 2022, none of the above milestones has been met.

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

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

Payments to UCLA TDG under the Amended License Agreement for the nine months ended September 30, 2022 and 2021 were \$10,000 and \$45,500, respectively.

Other

On April 7, 2022, the Company entered into a contract with Wuxi Biologics USA LLC (“Wuxi”) for the development of recombinant protein NELL 1, as defined. Total costs of this agreement are estimated to be \$2,088,500. During the nine-months ended September 30, 2022, the Company incurred costs of \$634,900 pursuant to this agreement.

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. 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.

6. Subsequent Events

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

The warrants are subject to certain adjustment and cashless exercise provisions as described herein. The shares of common stock and warrants may be transferred separately immediately upon issuance. Holders of the Series C warrants may execute such warrants on a “cashless” basis upon the earlier of (i) one Trading Day from the issuance date of such warrant or (ii) the time when \$10.0 million of volume is traded in the our common stock, if the volume weighted average price (“VWAP”) of our common stock on any trading day on or after the closing date fails to exceed the exercise price of the Series C warrant (subject to adjustment for any stock splits, stock dividends, stock combinations, recapitalizations and similar events).

The Series A, B and C 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 will classify the fair value of the warrants of approximately \$7.6 million as a current liability at the date of closing.

The offering of 3,777,778 units was made pursuant to an underwriting agreement with WallachBeth Capital LLC, as representative of the underwriters named therein (the “Representative”). Pursuant to the underwriting agreement, the Company granted to the Representative a 45-day option to purchase up to 566,666 additional shares of Common Stock and/or 566,666 warrants to cover over-allotments, if any. The Representative has exercised its option with respect to 556,037 of warrants. In addition, the Company agreed to grant the Representative a warrant to purchase an aggregate of 188,888 shares of common stock, at an exercise price of \$1.62 per share, and exercisable commencing on a date which is six months from October 12, 2022, and expiring on October 12, 2027.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

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, 2021 and 2020 and the related notes included in our Annual Report on Form 10-K filed for the fiscal year ended December 31, 2021 with the SEC on March 15, 2022. 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/DBM. The NELL-1/DBM combination product is an osteostimulative recombinant protein that provides target specific control over bone regeneration. The protein, as part of the UCB-1 technology platform has been licensed exclusively for worldwide applications to us through a technology transfer from UCLA Technology Development Group on behalf of UC Regents (“UCLA TDG”). UCLA TDG and the Company received guidance from the FDA that NELL-1/DBM will be classified as a combination product with a device lead.

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

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

The negative impact of the COVID-19 pandemic and the impact on the global economy and capital markets resulting from the geopolitical instability caused in part by the ongoing military conflict between Russia and Ukraine, including inflation and Federal Reserve interest rate increases, have contributed to global supply chain issues and economic uncertainty, which could negatively affect our operations. Additionally, the general consensus among economists suggests that we should expect a higher recession risk to continue over the next year, which could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect our operations.

UCLA TDG Exclusive License Agreement

Effective April 9, 2019, the Company 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 Technology Development Group on behalf of UC Regents (“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, UCLA TDG has continued to grant the Company exclusive rights to develop and commercialize NELL-1 (the “Licensed Product”) for spinal fusion, 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 to pay certain royalties to UCLA TDG under the Amended License Agreement at the rate of 3.0% of net sales of licensed products through the life of the patents. We must pay the royalties to UCLA TDG on a quarterly basis. Upon a first commercial sale, we also must pay between \$50,000 and \$250,000, depending on the calendar year which is after the first commercial sale. If we are required to pay any third party any royalties as a result of us making use of UCLA TDG patents, then we may reduce the royalty owed to UCLA TDG by 0.333% for every percentage point paid to a third party. If we grant sublicense rights to a third party to use the UCLA TDG patent, then we will pay to UCLA TDG 10% to 20% of the sublicensing income we receive from such sublicense.

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

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

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

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

The Company’s obligation to pay the Diligence Fee will survive termination or expiration of the agreement and the Company is prohibited from assigning, selling, or otherwise transferring any of its assets related to any Licensed Product unless the Company’s foregoing Diligence Fee obligation is assigned, sold, or transferred along with such assets, or unless the Company pays 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, 2022, none of the above milestones has been met.

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

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

Results of Operations

Impact of the Novel Coronavirus (COVID-19) and other Macroeconomic Factors 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 which will conduct 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.

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.

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, 2022 compared to the Three Months ended September 30, 2021

	Three-months ended September 30, 2022	Three-months ended September 30, 2021	% Change
Operating expenses			
Research and development	\$ 769,410	\$ -	100.00%
General and administrative	449,867	229,789	95.77%
Total operating expenses	1,219,277	229,789	430.61%
Loss from operations	(1, 219,277)	(229,789)	430.61%
Interest expense, related party	-	(279,514)	(100.00)%
Net loss	\$ (1, 219,277)	\$ (509,303)	139.40%

Research and Development

Our research and development expense increased from \$-0- during the three months ended September 30, 2021 to \$769,410 during the three months ended September 30, 2022. We continue to implement research activities after curtailing our operations during 2021. We will continue to incur significant expenses for development activities for NELL-1 in the future.

General and Administrative

Our general and administrative expenses increased from \$229,789 during the three months ended September 30, 2021 to \$449,867 during the three months ended September 30, 2022. The \$220,078 increase was due to resuming operations in 2022. Significant expenses incurred during 2022 were Directors and Officers insurance, directors’ compensation, the revised CFO employment agreement for full-time services and the services of an investor relations firm. We also incurred stock based compensation expense for our directors and management team totaling \$32,534.

Interest Expense

Our interest expense decreased from \$279,514 for the three months ended September 30, 2021 to \$-0- during the three months ended September 30, 2022. All the outstanding convertible notes were converted in October 2021.

Nine Months ended September 30, 2022 compared to the Nine Months ended September 30, 2021

	Nine-months ended September 30, 2022	Nine-months ended September 30, 2021	% Change
Operating expenses			
Research and development	\$ 823,410	\$ 47,516	1632.91%
General and administrative	1,553,070	595,078	160.99%
Total operating expenses	2,376,480	642,594	269.83%
Loss from operations	(2, 376,480)	(642,594)	269.83%
Interest expense, related party	-	(790,354)	(100.00)%
Provision for income taxes	1,600	-	100.00%
Net loss	\$ (2,378,080)	\$ (1,432,948)	65.96%

Research and Development

Our research and development expense increased from \$47,516 during the nine months ended September 30, 2021 to \$823,410 during the nine months ended September 30, 2022. We continue to implement research activities after curtailing our operations during 2021. We will continue to incur significant expenses for development activities for NELL-1 in the future.

General and Administrative

Our general and administrative expenses increased from \$595,078 during the nine months ended September 30, 2021 to \$1,553,070 during the nine months ended September 30, 2022. The \$957,992 increase was due to resuming operations in 2022. Significant expenses incurred during 2022 were Directors and Officers insurance, directors’ compensation, the revised CFO employment agreement for full-time services and the services of an investor relations firm. We also incurred stock based compensation expense for our directors and management team totaling \$204,126.

Interest Expense

Our interest expense decreased from \$790,354 for the nine months ended September 30, 2021 to \$-0- during the nine months ended September 30, 2022. All the outstanding convertible notes were converted in October 2021.

Liquidity and Capital Resources

The Company has no significant operating history and since inception to September 30, 2022 has incurred accumulated losses of approximately \$72.9 million. The Company will continue to incur significant expenses for development activities for their lead product NELL-1/DBM. Operating expenditures for the next twelve months are estimated at \$11.5 million. The accompanying consolidated financial statements for the nine months ended September 30, 2022 have been prepared assuming the Company will continue as a going concern. As reflected in the financial statements, the Company incurred a net loss of \$2,378,080, and used net cash in operating activities of \$1,616,122 during the nine months ended September 30, 2022. 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 the 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 10K for the year ended December 31, 2021, 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, 2022, we had cash of \$5,059,243. On October 12, 2022, the Company completed a public offering generating gross proceeds to the Company of \$5,100,000, and net proceeds, after underwriters discounts and expenses of approximately \$4,454,000. 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.

For the past several years, we have depended on our relationship with Hankey Capital for working capital to fund our operations, which has been raised in the form of both debt and equity capital. Hankey Capital, directly and indirectly, controls approximately 70% of our issued and outstanding shares of common stock. However, no assurance can be given that any future financing from Hankey Capital will be available or, if available, that it will be on terms that are satisfactory to the Company. In the absence of financing from other sources, the inability to obtain additional financing from Hankey Capital will result in the scaling back or discontinuance of our product development programs or operations entirely.

Cash Flows

Operating activities

During the nine months ended September 30, 2022 and 2021, cash used in operating activities was \$1,616,122 and \$1,041,734, respectively. Cash expenditures for the nine months ended September 30, 2022 increased primarily due to directors' compensation, the revised CFO employment agreement for full-time services and investor relation services.

Financing activities

During the nine months ended September 30, 2022, there were no financing activities. During the nine months ended September 30, 2021, cash provided by financing activities of \$1,045,108 resulted primarily from draws on our second and third credit facilities with Hankey Capital.

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 Estimates

In preparing our condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the SEC, we make assumptions, judgments and estimates that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. We evaluate our assumptions, judgments and estimates on a regular basis. We also discuss our critical accounting policies and estimates with the Audit Committee of the Board of Directors.

We believe that the assumptions, judgments and estimates involved in the accounting for revenue recognition, business combinations and income taxes have the greatest potential impact on our condensed consolidated financial statements. These areas are key components of our results of operations and are based on complex rules requiring us to make judgments and estimates, and consequently, we consider these to be our critical accounting policies. Historically, our assumptions, judgments and estimates relative to our critical accounting policies have not differed materially from actual results.

There have been no significant changes in our critical accounting policies and estimates during the nine months ended September 30, 2022, as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2021.

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 September 30, 2022. Based upon that evaluation, our Chief Financial Officer and Chief Executive Officer concluded that as of September 30, 2022, our disclosure controls and procedures were effective.

As of September 30, 2022, 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 September 30, 2022, 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 September 30, 2022 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. 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 September 30, 2022.*
31.2	Certification of the Company’s Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, with respect to the registrant’s Report on Form 10-Q for the quarter ended September 30, 2022.*
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: November 14, 2022

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 Executive 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: November 14, 2022

/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: November 14, 2022

/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, 2022 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, 2022

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, 2022 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, 2022
