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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 25, 2022

BONE BIOLOGICS CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**001-40899**	**42-1743430**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

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

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

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**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

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. ☐

Item 8.01 Other Events.

On October 25, 2022, the Company issued a press release with respect the CEO's Letter to Stockholders. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release Bone Biologics CEO Issues Letter to Stockholders, dated October 25, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 25, 2022

BONE BIOLOGICS CORPORATION

By: */s/ JEFFREY FRELICK*
Name: Jeffrey Frelick
Title: Chief Executive Officer

Exhibit 99.1

Bone Biologics CEO Issues Letter to Stockholders

BURLINGTON, Mass. (October 25, 2022) – Bone Biologics Corporation (NASDAQ: BBLG), a developer of orthobiologic products for spine fusion markets, today issued the following letter to stockholders from its President and Chief Executive Officer, Jeffrey Frelick.

To My Fellow Stockholders:

I am delighted to update you on Bone Biologics' development work with NELL-1 over the past year and to review our expected milestones over the coming months in anticipation of commencing our first-in-human pivotal study in 2023. As a reminder, NELL-1 is a recombinant human protein that we licensed through a technology transfer agreement with the UCLA Technology Development Group (UCLA TDG) for worldwide applications. NELL-1 combined with demineralized bone matrix (DBM) forms our product candidate, NB1.

NELL-1 has unique properties that suggest it will be ideal in treating spinal fusion, trauma, osteoporosis and other bone-related indications, and may be especially useful among "hard healers." This potential lies in its ability to provide rapid, specific and guided control over bone regeneration. We are optimistic that NB1 may provide an important alternative to a vexing clinical problem by improving the safety profile of an osteopromotive orthobiologic.

There is a large and established opportunity for NB1 with an estimated global market of $3 billion annually just for bone graft substitutes in spine fusion for products such as growth factors, DBM, synthetic materials, stem cells and allografts. This is the market Bone Biologics intends to address. Longer term, additional market opportunities await NB1 including the $11 billion annual market for treating osteoporosis and the $8 billion annual market for treating trauma patients.

A great deal of development work has been undertaken with NELL-1 in preparation for our first pilot clinical trial in Australia. Publications support NELL-1's mechanism of action and its potential for better bone formation, as preclinical animal data have been both extensive and compelling. Of particular importance is a study that evaluated the efficacy of NB1 as a novel bone graft material for interbody spine fusion in sheep, a phylogenetically advanced animal with spine fusion similarities to humans. That study found that NB1 safely and effectively promoted spine fusion.

With compelling preclinical data, we have moved forward with important activities to prepare for our human pilot study. Thus far in 2022, we entered into an agreement with MTF Biologics for supplying DBM as a carrier in our combination product. MTF Biologics, a highly regarded industry innovator, is a global nonprofit organization that provides one of the orthopedic industry's largest portfolios of allograft tissue. MTF Biologics' DBM will comprise half of our NB1 product.

Earlier this year we also engaged a contract development manufacturing organization (CDMO) that offers a global site network from process development to recombinant protein manufacturing. Because NELL-1 is a recombinant human protein that will be utilized in humans, it must be manufactured in specialized facilities, therefore engaging a CDMO was an important preparatory step.

Updated Agreement with UCLA

In 2006 we entered into an agreement with UCLA Technology Development Group to license NELL-1. This agreement is the foundation for Bone Biologics.

We most recently modified that agreement in May 2022 to enable us to preserve available capital and resources to develop our product. Under the modification, UCLA TDG will defer payment of the diligence fee until we (or any of our sublicensees) sell any product in accordance with the revised payment schedule.

Recent Equity Financing

We recently raised gross proceeds of $5.1 million in an underwritten public offering of units of common stock and warrants. We expect to use the net proceeds to fund our planned clinical trials, maintain and extend our patent portfolio, retain contract research organizations, and for working capital and other general corporate purposes. Importantly, these funds will allow us to begin our 30-patient pilot study with NB1 next year.

Expectations through 2023

As we look to the remainder of 2022, we are working toward several value-creating events:

- In preparation for the cGMP manufacturing run for product that will be used in our human clinical study, assays will be developed that characterize NELL-1 (including the potency assay, which quantitates the bone formation activity), a Master Cell Bank will be developed and scaling activities will be performed.
- We are building a quality system to meet the conditions of Essential Principles required by the Australian regulatory authorities prior to the initiation of human studies.
- We will also engage another CDMO that will perform fill/finish functions. This activity is required to ensure sterility, which is another requirement prior to human implantation.

Looking to 2023, we plan to commence a 30-patient clinical trial in Australia. This will be a multicenter, prospective, randomized pilot study evaluating the safety and preliminary effectiveness of NB1 in subjects with degenerative disc disease undergoing transforaminal lumbar interbody fusion.

As currently envisioned, the study will evaluate two concentrations of NB1 relative to the autograft control. The primary endpoints will include fusion success at 12 and 24 months after surgery, and change from the baseline Oswestry Disability Index, which is the Gold Standard tool to measure a patient’s permanent functional disability.

The Need for NELL-1 in a Compelling Market

The scientific basis for developing NB1 is the potential for increased safety and for better fusion rates. Spine fusion is a commonly performed surgical procedure in the treatment of numerous spinal diagnoses including degenerative disc disease, spinal stenosis, spondylolisthesis and other spinal deformities. A bony fusion is essential for restoring segmental stability, preventing or correcting deformity and improving long-term outcomes. Lumbar intervertebral fusion is achieved by creating an environment that’s conducive to the formation of a continuous osseous bridge across the involved spinal segments.

We are optimistic that spinal fusion patients will benefit from our solution to the problem of hard-to-heal bones, and we are very excited about the potential to help these patients as we advance NB1 along the development pathway. We believe our effort will be well-rewarded not only by patients, but also by caregivers and Bone Biologics stockholders. I extend thanks to all of our constituents for their ongoing support.

Sincerely,

Jeffrey Frelick
Chief Executive Officer

October 25, 2022

About Bone Biologics

Bone Biologics was founded to pursue regenerative medicine for bone. The Company is undertaking groundbreaking work with select strategic partners that builds on the preclinical research of the Nell-1 protein. Bone Biologics is currently focusing its development efforts for its bone graft substitute product on bone regeneration in spinal fusion procedures, while additionally having rights to trauma and osteoporosis applications. For more information, please visit www.bonebiologics.com.

Forward-looking Statements

Certain statements contained in this press release, including, without limitation, statements containing the words ‘‘believes,’’ ‘‘anticipates,’’ ‘‘expects’’ and words of similar import, constitute ‘‘forward-looking statements’’ within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve both known and unknown risks and uncertainties. The Company’s actual results may differ materially from those anticipated in its forward-looking statements as a result of a number of factors, including those including the Company’s ability to develop our lead product NELL-1 and other proposed products, its ability to obtain patent protection for its technology, its ability to obtain the necessary financing to develop products and conduct the necessary clinical testing, its ability to obtain Federal Food and Drug Administration approval to market any product it may develop in the United States and to obtain any other regulatory approval necessary to market any product in other countries, its ability to market any product it may develop, its ability to create, sustain, manage or forecast its growth; its ability to attract and retain key personnel; changes in the Company’s business strategy or development plans; competition; business disruptions; adverse publicity and international, national and local general economic and market conditions and risks generally associated with an undercapitalized developing company, as well as the risks contained under “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in the Company’s Form S-1, Form 10-K for the year ended December 31, 2021 and the Company’s other filings with the Securities and Exchange Commission. Except as required by applicable law, we undertake no obligation to revise or update any forward-looking statements to reflect any event or circumstance that may arise after the date hereof.

Contacts

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