
**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): June 20, 2024

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

Delaware
(State or other jurisdiction
of incorporation)

001-40899
(Commission
File Number)

42-1743430
(IRS Employer
Identification No.)

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

01803
(Zip Code)

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

(Former name or former address, if changed since last report)

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:

- ☐ 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))

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	BBLG	Nasdaq Capital Market
Warrants to Purchase Common Stock, par value \$0.001 per share	BBLGW	Nasdaq Capital Market

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 7.01 Regulation FD Disclosure.

On June 20, 2024, Bone Biologics Corporation (the “Company”) issued a press release announcing that the first two patients have been treated in its pilot clinical study of the Company’s NB1 bone graft device in spine fusion. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under such section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated June 20, 2024
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.

BONE BIOLOGICS CORPORATION

Date: June 20, 2024

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



First Two Patients Treated in Pilot Clinical Study with Bone Biologics' NB1 Bone Graft Device in Spine Fusion

Reminder: Management "CEO Chat" with Zacks Small-Cap Research Analyst Begins Today at 11 a.m. Eastern Time

BURLINGTON, Mass. (June 20, 2024) — Bone Biologics Corporation ("Bone Biologics" or the "Company") (Nasdaq: BBLG, BBLGW), a developer of orthobiologic products for spine fusion markets, announces that the first two patients have been treated in the multicenter, prospective, randomized pilot clinical study of the Company's NB1 bone graft device. NB1 is NELL-1 protein combined with demineralized bone matrix (DBM) to provide rapid, specific and guided control over bone regeneration.

This pilot clinical study will evaluate NB1 in 30 adult subjects who undergo transforaminal lumbar interbody fusion (TLIF) to treat degenerative disc disease (DDD) and will evaluate safety and effectiveness, fusion success, pain, function improvement and adverse events. To be enrolled in the study, patients must have DDD at one level from L2-S1 and may also have up to Grade 1 spondylolisthesis or Grade 1 retrolisthesis at the involved level. These two patients were treated in Australia. The study design was previously reviewed and agreed upon by the U.S. Food and Drug Administration's Division of Orthopedic Devices in a Pre-submission to support progression to a pivotal clinical trial in the United States.

"We have worked diligently to prepare for this important milestone and are delighted that the first patients have been treated in our pilot clinical study," said Jeffrey Frelick, president and chief executive officer of Bone Biologics. "Preclinical animal studies demonstrated a strong safety profile, fusion success and bone healing of NB1, and we are optimistic that we will show fusion success in humans.

"There is clear need for a product that creates rapid, controlled and guided bone growth only in the presence of existing bone and not elsewhere in the body. We aim to demonstrate that NB1 will address this opportunity and compete in the \$3 billion annual global market for spine fusion products," he added.

Lumbar DDD is one of the most common causes of low back pain. DDD also leads to substantial disability, with many patients suffering from decreased ability to walk, sit, stand and/or sleep. For some people, DDD is part of the natural process of growing older and is a significant medical issue that is increasing as the global population ages.

“CEO Chat” Reminder

Bone Biologics reminds investors that Jeffrey Frelick, the Company’s president and chief executive officer, and Deina Walsh, chief financial officer, will be interviewed by Zacks Small-Cap Research analyst Brad Sorensen, CFA in a “CEO Chat” today at the Life Science Investor Forum with Virtual Investor Conference hosted by VirtualInvestorConferences.com.

The interview will begin at 11:00 a.m. Eastern time and can be viewed [here](#). Investors are encouraged to preregister to expedite participation and receive event updates, and are invited to ask questions during the event via a chat function.

About NB1

The Company’s product candidate NB1 combines the recombinant human NELL-1 (rhNELL-1) protein with demineralized bone matrix. 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 so-called “hard healers.” This potential lies in its ability to provide rapid, specific and guided control over bone regeneration.

For the NB1 bone graft device, the inclusion of rhNELL-1 provides an ancillary osteopromotive effect that is expected to increase the incidence. The proposed mechanism of action for rhNELL-1 to improve bone formation is based on published research and involves classic receptor binding and intracellular signaling transduction to the nucleus to promote osteogenic gene expression and bone formation.

There is a large and established opportunity for NB1 with an estimated global market of \$3 billion annually for bone graft substitutes in spine fusion for products such as growth factors, DBM, synthetic materials, stem cells and allografts. Additional longer-term market opportunities include the \$11 billion annual market for treating osteoporosis and the \$8 billion annual market for treating trauma.

About Bone Biologics

Bone Biologics was founded to pursue regenerative medicine for bone. The Company is undertaking work with select strategic partners that builds on the preclinical research of the NELL-1 protein. Bone Biologics is focusing 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 regarding the timing, implementation, and success of the company’s pilot clinical study, the ability of the company’s lead product candidate NB1 to provide rapid, specific and guided control over bone regeneration and show fusion success in humans, the ability of NB1 to compete in global markets, as well as statements containing the words “will,” “expect,” 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, but not limited to, market and other 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 Annual Report on Form 10-K for the year ended December 31, 2023 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.

Contact:

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