

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 6, 2022

Entera Bio Ltd.

(Exact Name of Registrant as Specified in Its Charter)

Israel
(State or other jurisdiction
of incorporation)

001-38556
(Commission File Number)

00-000000
(I.R.S. Employer
Identification)

KIRYAT HADASSAH, MINRAV BUILDING – FIFTH FLOOR, JERUSALEM, Israel 9112002
(Address of principal executive offices) (Zip Code)

+972-2-532-7151
(Registrant's Telephone Number, Including Area Code)

(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 (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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, par value of NIS 0.0000769	ENTX	Nasdaq Capital Market
Warrants, each Warrant exercisable for half of an Ordinary Share at an exercise price of \$5.85 per Ordinary Share	ENTXW	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 8.01 Other Events.

On October 6, 2022, Entera Bio Ltd., a company organized under the laws of the State of Israel (the “Company”), announced the conclusion of its Type C meeting and agreement from the U.S. Food and Drug Administration (“FDA”) that a single Phase 3 placebo-controlled study could support a New Drug Application (“NDA”) submission of EB613 (oral hPTH (1-34), teriparatide tablets) under the 505(b)(2) regulatory pathway. The FDA also agreed that Total Hip Bone Mineral Density (“BMD”) could serve as the primary endpoint of the registrational study in post-menopausal osteoporosis patients.

The single pivotal Phase 3 clinical trial includes a 24-month placebo-controlled duration with change in Total Hip BMD assessed as the primary endpoint. The 2:1 randomization (EB613 vs. placebo) and planned 400 patients exposed to EB613 are expected to be sufficient to support both the safety and efficacy assessments for the NDA. Furthermore, the FDA agreed with the Company’s proposed enrollment of post-menopausal women with osteoporosis based on a BMD T-score of ≤ -2.5 to 3.0 and no major fracture history. This patient population is consistent with that studied during the Company’s Phase 2 6-month dose ranging study of EB613, which met all primary and key secondary endpoints of biochemistry and BMD. Finally, the Company intends to submit relative PK data comparing its oral tablet form of teriparatide, EB613 versus the subcutaneous injection of teriparatide, Forteo® to support the 505(b)(2) pathway. The Company expects to initiate patient enrollment for this Phase 3 clinical trial in 2023.

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 thereunto duly authorized.

ENTERA BIO LTD.

Date: October 6, 2022

By: /s/ Miranda J. Toledano
Name: Miranda J. Toledano
Title: Chief Executive Officer
