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): **January 11, 2023**

ORAMED PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

DELAWARE	**001-35813**	**98-0376008**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1185 Avenue of the Americas, Third Floor, New York, New York	**10036**
(Address of Principal Executive Offices)	(Zip Code)

844-967-2633
(Registrant's telephone number, including area code)

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:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value $0.012	**ORMP**	**The Nasdaq Capital Market, Tel Aviv Stock Exchange**

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 January 11, 2023, Oramed Pharmaceuticals Inc. (the "Company") announced Phase 3 results from its randomized, double-blind, placebo-controlled, multicenter clinical trial ("ORA-D-013-1") of its proprietary oral insulin capsule, ORMP-0801, comparing the efficacy of ORMD-0801 to placebo in patients with Type 2 Diabetes ("T2D") at 26 weeks. The trial did not meet its primary endpoint, which compared the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by the mean change from baseline in A1C at 26 weeks. The trial also did not meet its secondary endpoint, which assessed the mean change from baseline in fasting plasma glucose at 26 weeks. There were no serious drug-related adverse events. As a result, the Company expects to discontinue its oral insulin clinical activities for T2D.

In the ORA-D-013-1 trial, patients were randomized 2:2:1:1 into four groups: 8 mg dosed once-daily; 8 mg dosed twice-daily; placebo dosed once-daily; and placebo dosed twice-daily. Patients completed an initial 21-day screening period, followed by a 26-week double-blind treatment period.

Warning Concerning Forward-Looking Statements

This Current Report on Form 8-K contains statements which constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. These forward-looking statements are based upon the Company's present intent, beliefs or expectations, but forward-looking statements are not guaranteed to occur and may not occur for various reasons, including some reasons which are beyond the Company's control. For example, this Report discusses our discontinuation of clinical trial activities for ORMD-0801 and the potential safety and efficacy of ORMD-0801. These forward-looking statements are based on the current expectations of the management of the Company only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements, including the risk that the Company may not be able to successfully implement its strategic plans; the risks and uncertainties related to the progress, timing, cost and results of current and future clinical trials and product development programs; difficulties or delays in obtaining regulatory approval or patent protection for the Company's product candidates; competition from other pharmaceutical or biotechnology companies; and the Company's ability to obtain additional funding required to conduct its research, development and commercialization activities. In addition, the following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; delays or obstacles in launching the Company's clinical trials; changes in legislation; inability to timely develop and introduce new technologies, products and applications; lack of validation of the Company's technology as it progresses further and lack of acceptance of its methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of the Company's products; unforeseen scientific difficulties that may develop with its process; greater cost of final product than anticipated; loss of market share and pressure on pricing resulting from competition; laboratory results that do not translate to equally good results in real settings; the Company's patents may not be sufficient; that products may harm recipients; and other factors discussed in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, each of which is on file with the Securities and Exchange Commission and in other filings that the Company makes with the Securities and Exchange Commission in the future. All of these factors and uncertainties could cause the actual results or performance of the Company to differ materially from those contemplated in such forward-looking statements. For these reasons, among others, you should not place undue reliance upon the Company's forward-looking statements. Except as required by law, the Company undertakes no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this Report.

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.

ORAMED PHARMACEUTICALS INC.

By: /s/ Nadav Kidron
Name: Nadav Kidron
Title: President and CEO

January 11, 2023