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): April 6, 2022

SPERO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38266**	**46-4590683**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

675 Massachusetts Avenue, 14th Floor Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 242-1600

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(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**SPRO**	**The Nasdaq Global Select 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 April 6, 2022, Spero Therapeutics, Inc. issued a press release titled "Spero Therapeutics Tebipenem Pivoxil Hydrobromide Phase 3 Data Published in *The New England Journal of Medicine*". A copy of the press release is furnished as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release, dated April 6, 2022, furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

SPERO THERAPEUTICS, INC.

Date: April 6, 2022

By: /s/ Tamara Joseph
Tamara Joseph
Chief Legal Officer

Exhibit 99.1

Spero Therapeutics Tebipenem Pivoxil Hydrobromide Phase 3 Data Published in *The New England Journal of Medicine*

CAMBRIDGE, Mass., April 6, 2022 — Spero Therapeutics, Inc. (Nasdaq: SPRO) today announced publication in *The New England Journal of Medicine* (NEJM) of the results from the Phase 3 ADAPT-PO clinical trial for its investigational oral carbapenem antibiotic, tebipenem pivoxil hydrobromide (tebipenem HBr). The paper, titled "Oral Tebipenem Pivoxil Hydrobromide in Complicated Urinary Tract Infection," is available online at the New England Journal of Medicine (NEJM).

"ADAPT-PO was a landmark trial that is the first Phase 3 head-to-head comparison of an all-oral versus all-IV treatment regimen in complicated urinary tract infection (cUTI) or acute pyelonephritis," said Angela Talley, M.D., Senior Vice President, Clinical Development at Spero Therapeutics, and senior author of the NEJM paper.

"We are honored to have the results of our global Phase 3 trial published in *The New England Journal of Medicine* and we are grateful to the patients and investigators who participated in this trial," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics.

In September 2020, Spero Therapeutics announced the topline data from the Phase 3 ADAPT-PO clinical trial and, in October 2021, included the results from the completed trial in a New Drug Application (NDA) filed with the U.S. Food and Drug Administration (FDA). Earlier this year, Spero Therapeutics announced that the FDA accepted the NDA for substantive review and granted Priority Review designation. The NDA, which is currently under FDA regulatory review, seeks approval for tebipenem pivoxil oral tablets (tebipenem HBr) for the treatment of cUTI, including pyelonephritis, caused by certain microorganisms, in adult patients who have limited oral treatment options. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target date of June 27, 2022.

About Spero Therapeutics

Spero Therapeutics is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing, and commercializing novel treatments for bacterial infections, including multidrug resistant bacterial infections and rare diseases.

- The NDA for tebipenem pivoxil oral tablets (tebipenem HBr), Spero Therapeutics' lead product candidate, is currently being reviewed by the FDA; tebipenem HBr is not FDA-approved.
- Tebipenem HBr is an investigational drug in the United States being developed for the treatment of complicated urinary tract infection, including pyelonephritis, caused by certain microorganisms, in adult patients who have limited oral treatment options.
- Spero Therapeutics is also developing SPR720 as a novel candidate oral therapy for the treatment of a rare, orphan pulmonary disease caused by non-tuberculous mycobacterial infections.

- Spero Therapeutics also has an IV-administered next generation polymyxin product candidate, SPR206, developed from its potentiator platform, which is in development to treat multidrug resistant Gram-negative infections in the hospital setting.

For more information, visit ***https://sperotherapeutics.com***.

Tebipenem HBr Research Support

This project has been funded in part with Federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201800015C.

Forward Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, potential approval of tebipenem HBr by the FDA and the timing thereof; Spero's anticipated commercial launch of tebipenem HBr following FDA approval and the timing thereof; the sufficiency of Spero's cash resources and Spero's anticipated expenses; potential payments under Spero's agreement with BARDA; the ability of the Company to receive payments under the HCR financing facility; future clinical trials for pediatric use of tebipenem HBr; future use of tebipenem HBr for pediatric patients; the potential number of patients who could be treated by tebipenem HBr and market demand for tebipenem HBr generally; the effectiveness of tebipenem HBr and its potential impact on healthcare resource utilizations;; and the availability of additional non-dilutive funding from governmental agencies beyond any initially funded awards . In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intent," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including whether Spero's NDA for tebipenem HBr, for which Spero is currently engaged in discussions with the FDA, is sufficient for approval of tebipenem HBr, including the resolution of any deficiencies identified in such review; whether any additional information we provide to the FDA during the NDA review process may cause delays or extend the PDUFA goal action date; whether the FDA will require any additional clinical data or place labeling restrictions on the use of tebipenem HBr that would add costs for us, delay approval and/or reduce the commercial prospects of tebipenem HBr; Spero's readiness for an anticipated launch of tebipenem HBr if approval is obtained; if the NDA for tebipenem HBr is not approved by December 31, 2022, Spero's obligation to repay $50 million in upfront proceeds received under its revenue interest financing agreement; the COVID-19 pandemic; Spero's need for additional funding; the lengthy, expensive, and uncertain process of clinical drug development; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; Spero's reliance on third parties to manufacture, develop, and commercialize its product candidates, if approved; the ability to commercialize Spero's product candidates, if approved; Spero's ability to retain key personnel and to manage its growth; whether Spero's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; and other factors discussed in the "Risk Factors" set forth in filings that Spero periodically makes with the U.S. Securities and Exchange

Commission. The forward-looking statements included in this press release represent Spero's views as of the date of this press release. Spero anticipates that subsequent events and developments will cause its views to change. However, while Spero may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Spero's views as of any date subsequent to the date of this press release.

Investor Relations Contact:

Ted Jenkins
Vice President, Investor Relations
Tjenkins@sperotherapeutics.com
(617) 798-4039

Media Contact:

Jacqueline Pomfret Kirby
Vice President, Corporate Affairs
Jkirby@sperotherapeutics.com
(617) 798-4074