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 27, 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 (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
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 June 27, 2022, Spero Therapeutics, Inc. (the "Company") issued a press release announcing that it has received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration (the "FDA") for its New Drug Application ("NDA") seeking approval for tebipenem HBr oral tablets for treatment of adult patients with complicated urinary tract infection ("cUTI"), including pyelonephritis. In the CRL, the FDA communicated that it had completed its review of the NDA and determined that the NDA could not be approved in its present form. The FDA ultimately concluded that the Company's Phase 3 cUTI study of tebipenem HBr (ADAPT-PO) was insufficient to support approval and that additional clinical study would be required. The Company intends to promptly request a Type A meeting with the FDA, to gain further insights as to the pathway forward towards a potential regulatory approval for tebipenem HBr.

The full text of the press release issued in connection with this announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release, dated June 27, 2022
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: June 27, 2022

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

Exhibit 99.1

Spero Therapeutics Receives Complete Response Letter from U.S. Food and Drug Administration for Tebipenem HBr New Drug Application

CAMBRIDGE, Mass., June 27, 2022 — Spero Therapeutics, Inc. (Nasdaq: SPRO) today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its New Drug Application (NDA) seeking approval for tebipenem HBr oral tablets for treatment of adult patients with complicated urinary tract infection (cUTI), including pyelonephritis. The FDA had set a Prescription Drug User Fee Act (PDUFA) target action date of June 27, 2022.

In the CRL, the FDA communicated that it had completed its review of the NDA and determined that the NDA could not be approved in its present form. As previously disclosed in Spero's May 3, 2022 press release, the CRL was anticipated based on feedback received at the late cycle meeting, in which the agency outlined potential deficiencies in the application. In the CRL, the FDA ultimately concluded that Spero's Phase 3 cUTI study of tebipenem HBr (ADAPT-PO) was insufficient to support approval and that additional clinical study would be required. Spero intends to promptly request a Type A meeting with the FDA, to gain further insights as to the pathway forward towards a potential regulatory approval for tebipenem HBr.

"We are disappointed with the FDA's decision, but we look forward to our continued dialogue, addressing the agency's concerns and outlining a clear path forward for tebipenem HBr," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "With this development, we continue to believe that tebipenem HBr offers patients and their providers an important new treatment option, that if approved, has the potential to address the critical unmet need for a new oral antibiotic for patients with cUTI."

Dr. Mahadevia continued, "Our commitment to the development of effective new agents to address unmet medical needs remains strong, as we seek to identify the optimal path forward for tebipenem's regulatory approval, commercialization, and value creation, potentially through external partnerships. Tebipenem HBr remains an important part of the Spero pipeline and a complement to our SPR720 and SPR206 programs, which we continue to advance towards key clinical and regulatory milestones."

Tebipenem HBr Research Support

Select tebipenem HBr studies have been funded in part with federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number HHSO100201800015C.

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 multi-drug resistant bacterial infections and rare diseases.

- Spero Therapeutics is developing SPR720 as a novel oral therapy candidate 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 multi-drug resistant Gram-negative infections in the hospital setting.
- Tebipenem HBr is an investigational drug in the United States being developed for the treatment of cUTI, including pyelonephritis, caused by certain microorganisms, in adult patients who have limited treatment options; tebipenem HBr is not FDA-approved.

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

Forward Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about the potential regulatory path forward for tebipenem HBr and the potential approval of tebipenem HBr by the FDA and the timing thereof; the potential value of tebipenem HBr; the potential for a partnership of the tebipenem HBr franchise; the future development and commercialization of tebipenem HBr, SPR206 and SPR720; the design, initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs; and management's assessment of the results of such preclinical studies and clinical trials. 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 the FDA will ultimately approve tebipenem HBr and, if so, the timing of any such approval; whether the FDA will require any additional clinical data or place labeling restrictions on the use of tebipenem HBr that would add costs for Spero, delay approval and/or reduce the commercial prospects of tebipenem HBr; whether any third parties would be interested in partnering with Spero to pursue continued efforts to obtain FDA approval of tebipenem HBr, or acquiring rights to the tebipenem HBr program from Spero through a partnership arrangement; the COVID-19 pandemic; Spero's need for additional funding; the risk that Spero may not be able to address the FDA's concerns with respect to tebipenem HBr; the lengthy, expensive, and uncertain process of clinical drug development for SPR720 and SPR206; 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; 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.

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