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 27, 2021

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 7.01 Regulation FD Disclosure.

On October 28, 2021, Spero Therapeutics, Inc. (the "Company") issued the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 hereto 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 that Section. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission (the "SEC") made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Items.

On October 28, 2021, the Company announced the submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for tebipenem HBr (tebipenem pivoxil hydrobromide) tablets for the treatment of complicated urinary tract infections, including pyelonephritis, caused by susceptible microorganisms. Based on standard FDA review timelines, the FDA has a 60-day period to determine whether the NDA is complete and acceptable for review.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated October 28, 2021.
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.

Dated: October 28, 2021

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

Exhibit 99.1

Spero Therapeutics Submits New Drug Application to U.S. FDA for Tebipenem HBr for the Treatment of Complicated Urinary Tract Infections including Pyelonephritis

CAMBRIDGE, Mass., October 28, 2021 — Spero Therapeutics, Inc. (Nasdaq: SPRO), a multi-asset clinical-stage biopharmaceutical company focused on identifying, developing and commercializing treatments in high unmet need areas involving multi-drug resistant bacterial infections and rare diseases, today announced the submission of a new drug application (NDA) to the U.S. Food and Drug Administration (FDA), seeking approval for tebipenem HBr tablets for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible microorganisms. If approved, tebipenem HBr would be the only oral carbapenem antibiotic available for use in cUTI.

“With the submission of this NDA, we have taken a major step towards potentially providing a substantial number of appropriate cUTI patients with an oral treatment option that could replace historical use of intravenous (IV) therapy,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “If approved, we believe tebipenem HBr could help patients significantly, and the avoidance of IV administration could lead to reduced healthcare resource utilization. We look forward to working with the FDA during the NDA review process as we prepare for tebipenem HBr’s anticipated launch in the second half of 2022.”

The NDA submission includes previously communicated positive data from the Phase 3 ADAPT-PO trial. This data showed that ADAPT-PO met its primary endpoint by demonstrating that oral tebipenem HBr was statistically non-inferior to IV ertapenem in the treatment of patients with cUTI and patients with acute pyelonephritis (AP).

About Spero Therapeutics Spero Therapeutics, Inc. is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multi-drug-resistant (MDR) bacterial infections and rare diseases.

Spero’s lead product candidate, tebipenem HBr (tebipenem pivoxil hydrobromide; formerly SPR994), is being developed as the first oral carbapenem antibiotic for use in cUTI, including pyelonephritis. In October 2021, Spero filed an NDA for tebipenem HBr tablets, which included positive top-line results from its Phase 3 ADAPT-PO clinical trial of tebipenem HBr in cUTI and AP.

Spero is also developing SPR720 as a novel oral therapy product candidate for the treatment of a rare, orphan pulmonary disease caused by non-tuberculous mycobacterial infections.

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

Tebipenem HBr is an investigational drug in the United States and is currently not approved for the treatment of complicated urinary tract infection, including pyelonephritis.

Tebipenem HBr Research Support

This project has 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 No. HHSO100201800015C.

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 approval of tebipenem HBr by the FDA; the timing of launch of tebipenem HBr; 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 anticipated shift from IV to oral administration. 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 any delays in acceptance and review of the NDA submission by the FDA for any reason, including the COVID-19 pandemic; the timing and content of advice given and decisions made by regulators, including the FDA; 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 develop and commercialize Spero’s product candidates, if approved; the potential impact of the COVID-19 pandemic;â€¯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 theâ€¯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 someâ€¯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 dateâ€¯subsequent toâ€¯the date of this press release.

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