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 3, 2019**

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** (Address of principal executive offices)	**02139** (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 7.01 Regulation FD Disclosure.

On October 3, 2019, Spero Therapeutics, Inc. (the "Company") issued a press release announcing that an independent review committee had evaluated interim pharmacokinetic plasma data from the Company's ongoing ADAPT-PO pivotal Phase 3 clinical trial of SPR994, the Company's oral carbapenem product candidate, and recommended that the Company continue the trial without modification of the protocol-defined dose. A copy of this press release is attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit 99.1 Press Release, dated October 3, 2019

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: October 3, 2019

By: /s/ Ankit Mahadevia, M.D.
Ankit Mahadevia, M.D.
Chief Executive Officer and President

Exhibit 99.1

Spero Therapeutics Announces Positive Recommendation to Continue Phase 3 Clinical Trial of SPR994 as Planned Following Independent Review Committee Analysis of SPR994 Treated Patients in Lead-in Cohort of Trial

CAMBRIDGE, Mass., October 3, 2019 - 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 (MDR) bacterial infections and rare diseases, today announced that an independent review committee evaluated pharmacokinetic data following enrollment of the first 70 patients in Spero's ongoing ADAPT-PO pivotal Phase 3 clinical trial of SPR994, Spero's oral carbapenem product candidate, and recommended that Spero continue the trial using the protocol-defined dose without modification.

"The Phase 3 trial is designed to evaluate whether an oral-only regimen of SPR994 can achieve an outcome similar to that observed with an intravenous antibiotic therapy in patients with complicated urinary tract infections. If SPR994 achieves this outcome and is ultimately approved, we believe it would represent a critical clinical and economic value proposition for the more than two million patients resistant to oral therapies currently used to treat such infections," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "A primary objective of the independent review committee was to confirm that plasma levels of SPR994 in patients in the Phase 3 trial support the selected treatment dose consistent with our goals for the trial. We are very pleased that the independent review committee, after reviewing data from 33 patients who had been randomized to SPR994 in the Phase 3 trial, determined that the plasma levels of SPR994 in those patients were suitable and recommended that we continue the trial without dose modification. This decision, based on patient data in context of our clinical trial, gives us additional confidence in SPR994's potential to meet the needs of patients with resistant infections. Enrollment continues to be on track, and we expect to report top-line data from the Phase 3 trial in the third quarter of 2020."

The independent review committee reviewed interim plasma concentration data from 33 patients who were randomized to SPR994 in the ongoing ADAPT-PO pivotal Phase 3 clinical trial for the treatment of complicated urinary tract infections (cUTI) and acute pyelonephritis (AP). ADAPT-PO is designed as a double-blind, double-dummy clinical trial to compare oral SPR994 dosed as 600 mg TID with a standard-of-care intravenous (IV) antibiotic, ertapenem, in approximately 1,200 patients with cUTI or AP, randomized 1:1 in each arm. The Phase 3 trial will continue as planned and Spero expects to report top-line data in the third quarter of 2020.

About SPR994

SPR994 is Spero's novel investigational oral formulation of tebipenem, a carbapenem-class antibiotic marketed by Meiji Seika Pharma Co. Ltd. (Meiji) in Japan as Orapenem® since 2009 for pediatric infections limited to pneumonia, otitis media and sinusitis. Carbapenems are an

important class of antibiotics because they have been observed to be safe and effective against drug-resistant Gram-negative bacterial infections. Spero is conducting a pivotal Phase 3 clinical trial of SPR994 entitled ADAPT-PO (a Phase 3, randomized, double-blind, double-dummy, multicenter, prospective study to assess the efficacy, safety and pharmacokinetics of orally administered tebipenem pivoxil hydrobromide (SPR994) compared to intravenous ertapenem in patients with complicated urinary tract infection (cUTI) or acute pyelonephritis (AP)). SPR994 has been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of cUTI.

About Spero

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

Spero's lead product candidate, SPR994, is designed to be the first oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections.

Spero is also advancing SPR720, its novel oral therapy product candidate designed for the treatment of rare, orphan disease caused by pulmonary non-tuberculous mycobacterial (NTM) infections.

Spero also has a platform technology known as its Potentiator Platform that it believes will enable it to develop drugs that will expand the spectrum and potency of existing antibiotics, including formerly inactive antibiotics, against Gram-negative bacteria. Spero's lead product candidates generated from its Potentiator Platform are two IV-administered agents, SPR206 and SPR741, designed to treat MDR Gram-negative infections in the hospital setting.

SPR994 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.

Forward Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about Spero's expectation that positive results from a single pivotal Phase 3 clinical trial of SPR994 and ancillary supportive studies to be conducted in parallel with the Phase 3 trial will support the approval of SPR994; the initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs; statements regarding management's assessment of the results of such preclinical studies and clinical trials; the timing of clinical data, including the availability of pharmacokinetic data from the lead-in cohort in the Phase 3 clinical trial of SPR994 and top-line data from the Phase 1 clinical

trial of SPR720 and the Phase 1 clinical trial of SPR206; and Spero's cash forecast and anticipated expenses, the sufficiency of its cash resources 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 the FDA will accept a single pivotal study for approval of SPR994; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Spero's product candidates will advance through the preclinical development and clinical trial process on a timely basis, or at all, taking into account the effects of possible regulatory delays, slower than anticipated patient enrollment, manufacturing challenges, clinical trial design and clinical outcomes; whether the results of such trials will warrant submission for approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; 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 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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