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): May 9, 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	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))

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. ☒

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**

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2019, Spero Therapeutics, Inc. (the "Company") issued a press release announcing its results for the quarter ended March 31, 2019. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, or incorporated by reference in any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit 99.1 Press Release, dated May 9, 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: May 9, 2019

By: /s/ Joel Sendek
Joel Sendek
Chief Financial Officer and Treasurer

Exhibit 99.1

Spero Therapeutics Announces First Quarter 2019 Operating Results and Provides Pipeline Review

SPR994 pivotal Phase 3 trial underway and screening patients; multiple clinical catalysts ahead in 2H19

CAMBRIDGE, Mass., May 9, 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 financial results for the first quarter ended March 31, 2019 and provided a pipeline review.

"We have made significant progress to date in 2019 advancing our pipeline candidates, including the initiation of our pivotal Phase 3 trial of oral SPR994 for the treatment of cUTI," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "We look forward to providing updates on the SPR994 Phase 3 trial, as well as reporting out Phase 1 data from our SPR720 and SPR206 clinical trials in the second half of 2019."

Recent Clinical Highlights and Upcoming Milestones

SPR994:

Spero's lead product candidate, SPR994, has the potential to be the first oral carbapenem antibiotic approved for use in adults to treat MDR Gram-negative infections. Following the FDA's acceptance of our investigational new drug (IND) application for SPR994 in complex urinary tract infection (cUTI), we initiated the single pivotal Phase 3 clinical trial required for approval of SPR994 in cUTI entitled ADAPT-PO. We opened clinical trial sites in April 2019 for the Phase 3 trial and are actively screening patients. The pivotal Phase 3 clinical trial is designed as a double-blind, double-dummy trial to compare oral SPR994 with an existing standard of care intravenous (IV) antibiotic, ertapenem, in approximately 1,200 patients with cUTI or acute pyelonephritis, randomized 1:1 in each arm. The Company expects to receive pharmacokinetic data from a lead-in cohort of 70 patients in the second half of 2019 to confirm the dose and exposure of SPR994 in the cUTI patient population. In March 2019, the FDA granted Fast Track Designation for SPR994 for the treatment of cUTI and acute pyelonephritis, a designation that provides opportunities for more frequent interaction with the FDA review team to expedite development and review as well as the potential for rolling review of the NDA upon request and agreement with the FDA.

SPR720:

SPR720 is an orally administered antimicrobial agent being developed for the treatment of a rare, orphan disease, non-tuberculous mycobacterial (NTM) infections. Pre-clinical *in vitro* and *in vivo* studies have demonstrated the potency of SPR720 against a range of bacteria that cause pulmonary NTM infections, including *Mycobacterium avium* complex and *Mycobacterium abscessus*. The collective data to date suggest that SPR720 has an acceptable safety profile, encouraging target pathogen efficacy, drug distribution to key sites of infection, such as the lung, and a wide therapeutic margin. In January 2019, Spero initiated a SPR720 Phase 1 clinical trial designed as a double-blind, placebo-controlled clinical trial to assess the safety, tolerability and pharmacokinetics of SPR720 in healthy volunteers. Spero continues to expect top-line data from the Phase 1 clinical trial in the second half of 2019.

SPR206:

SPR206 is an IV-administered product candidate from Spero's Potentiator Platform being developed as an innovative option to treat MDR Gram-negative bacterial infections. In preclinical studies, SPR206 showed activity as a single agent against MDR and extensively drug resistant (XDR) bacterial strains, including isolates of *Pseudomonas aeruginosa*, *Acinetobacter baumannii* and carbapenem-resistant *Enterobacteriaceae*, in both *in vitro* and *in vivo* models of infection. In the first quarter of 2019, SPR206 was the focus of a license agreement with Everest Medicines under which Spero granted Everest an exclusive

license to develop, manufacture and commercialize SPR206 in Greater China, South Korea and certain Southeast Asian countries in exchange for an upfront payment and royalties on net sales of products containing SPR206, if approved. In December 2018, Spero initiated a Phase 1 clinical trial of SPR206 designed as a double-blind, placebo-controlled, ascending dose, multi-cohort study in healthy subjects. Spero continues to expect top-line data from this trial in the second half of 2019.

First Quarter 2019 Financial Results

Spero reported a net loss for the first quarter ended March 31, 2019 of $5.1 million or $0.29 per common share, lower than the net loss reported for the same period in 2018 of $10.6 million or $0.74 per common share.

Grant revenue for the first quarter of 2019 totaled $3.9 million, higher than first quarter 2018 revenues of $1.2 million, primarily due to funding for SPR994 received under our BARDA contract announced in July 2018 that awarded Spero up to $44.2 million for qualified expenses for SPR994 development. Spero also recognized $3.8 million in collaboration revenue in the first quarter of 2019 related to upfront and milestone payments from the agreement with Everest that was announced in January 2019.

Research and development expenses for the first quarter of 2019 of $9.5 million were higher than $8.9 million for the same period of 2018 due to greater spend on the SPR994 and SPR720 programs, partially offset by lower spend on the Potentiator Platform product candidates. General and administrative expenses for the first quarter of 2019 of $3.9 million were higher than $3.0 million for the same period of 2018, primarily due to increased headcount and greater costs associated with operating as a public company.

The Company continues to expect that its research and development expenses will increase throughout 2019 due to greater planned clinical spend associated with the SPR994 pivotal ADAPT-PO trial as it enrolls patients, as well as the SPR720 and SPR206 Phase 1 clinical trials, along with increased personnel spend to support such programs. The Company continues to expect general and administrative expenses to increase in 2019 due to additional headcount and professional fees required to support SPR994 as it advances through a Phase 3 clinical trial and prepares for possible regulatory approval and commercialization.

As of March 31, 2019, the Company had cash and cash equivalents of $106.4 million. Consistent with previous guidance, Spero believes that its existing cash, cash equivalents and marketable securities, together with the initial funding committed under its BARDA award, will enable funding of operating expenses and capital expenditure requirements into the second half of 2020, including through the top-line data readout of the pivotal ADAPT-PO clinical trial of SPR994.

Upcoming Scientific and Investor Presentations

- Bank of America Merrill Lynch Health Care Conference 2019 on May 15, 2019 in Las Vegas, Nevada
- Oral and poster presentations at ASM Microbe from June 20 - 24, 2019 in San Francisco, California

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.

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 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 SPR206 and the Phase 1 clinical trial of SPR720; 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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Spero Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited, amounts in thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Grant revenue	$ 3,911	$ 1,153
Collaboration revenue	3,807	—
Total revenues	7,718	1,153
Operating expenses:		
Research and development	9,526	8,925
General and administrative	3,888	3,044
Total operating expenses	13,414	11,969
Loss from operations	(5,696)	(10,816)
Other income (expense)	624	172
Net loss attributable to common shareholders of Spero Therapeutics, Inc.	$ (5,072)	$ (10,644)
Net loss per share attributable to common shareholders per share, basic and diluted	$ (0.29)	$ (0.74)
Weighted average shares outstanding, basic and diluted:	17,221,120	14,369,182

Spero Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(Unaudited, amounts in thousands)

	March 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$106,392	$ 115,443
Other assets	18,258	13,563
Total assets	**$124,650**	**$ 129,006**
Total liabilities	11,321	13,151
Total stockholder's equity	113,329	115,855
Total liabilities and stockholders' equity	**$124,650**	**$ 129,006**