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): March 16, 2020

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 2.02. Results of Operations and Financial Condition.

On March 16, 2020, Spero Therapeutics, Inc. (the "Company") issued a press release announcing its results for the fourth quarter and full year ended December 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 March 16, 2020

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: March 16, 2020

By: /s/ Stephen DiPalma
Stephen DiPalma
Interim Chief Financial Officer and Treasurer

Exhibit 99.1

Spero Therapeutics Announces Fourth Quarter and Full-Year 2019 Operating Results and Provides Pipeline Update

2020 catalysts include tebipenem HBr pivotal Phase 3 top-line cUTI data in 3Q20 and SPR720 Phase 2a NTM trial initiation in 2H20

CAMBRIDGE, Mass., March 16, 2020 — 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 financial results for the fourth quarter and full-year ended December 31, 2019 and provided a pipeline update.

“In 2019 and continuing into 2020, we have made significant clinical progress with positive clinical data reported for all of our pipeline programs, all of which are designed to address serious unmet needs and to treat multi-drug resistant infections,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “We have a solid cash position heading into 2020 bolstered by proceeds from our $30 million rights offering that closed in early March 2020, and we look forward to an eventful 2020 that includes top-line data from our pivotal Phase 3 clinical trial of tebipenem HBr in complicated urinary tract infections (cUTI) expected in the third quarter of 2020.”

Recent Clinical Highlights and Upcoming Milestones

Tebipenem HBr:

Spero’s lead product candidate, tebipenem HBr, has the potential to be the first oral carbapenem antibiotic approved for use in adults to treat MDR Gram-negative infections. Spero’s pivotal Phase 3 clinical trial of tebipenem HBr for the treatment of cUTI, ADAPT-PO, is currently enrolling patients. The ADAPT-PO trial compares an all oral regimen of tebipenem HBr 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. In October 2019, an independent review committee analyzed interim pharmacokinetic (PK) data from the first 33 patients dosed with tebipenem HBr and recommended the continuation of the trial using the protocol-defined dose without modification. Spero continues to expect to report top-line data from the ADAPT-PO trial in the third quarter of 2020. To support continued clinical development of tebipenem HBr, in February 2020 the Biomedical Advanced Research and Development Authority (BARDA) exercised a $15.9 million option under its existing contract with Spero, bringing the total committed funding under the award to $44.0 million in non-dilutive funding, inclusive of $10.0 million in funding from the Defense Threat Reduction Agency (DTRA).

SPR720:

SPR720 is an orally administered antimicrobial agent being developed by Spero for the treatment of non-tuberculous mycobacterial (NTM) disease, a rare orphan disease, as well as other infections, including *Mycobacterium tuberculosis*. In December 2019, Spero reported positive preliminary results from its Phase 1 clinical trial of SPR720 in healthy volunteers indicating that SPR720 was generally well-tolerated at doses up to 1000 mg over the maximum studied duration of 14 days, with a PK profile that Spero believes supports its further development as an oral agent for the treatment of NTM pulmonary disease. The Phase 1 clinical trial was designed as a double-blind, placebo-controlled clinical trial to assess the safety, tolerability and pharmacokinetics of SPR720 at single and multiple ascending doses in healthy volunteers. In March 2020, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation for SPR720, a designation that is given to drugs intended to treat a rare disease or condition that affects fewer than 200,000 persons in the United States. Spero expects to present final data from the SPR720 Phase 1 clinical trial at a medical conference in 2020. Spero plans to meet with the FDA in the first half of 2020, submit an investigational new drug (IND) application for SPR720 to the FDA in the second half of 2020, and subject to FDA acceptance of the IND, initiate a dose-ranging Phase 2a clinical trial evaluating SPR720 in patients with NTM disease due to *Mycobacterium avium* complex (MAC) in the second half of 2020.

SPR206:

SPR206 is an IV-administered product candidate being developed as an innovative option to treat MDR Gram-negative bacterial infections. In January 2020, Spero reported positive preliminary Phase 1 clinical trial data for SPR206 in healthy volunteers demonstrating that SPR206 was well-tolerated at doses likely to be within a therapeutic range for MDR Gram-negative bacterial infections. The Phase 1 clinical trial was designed as a double-blind, placebo-controlled, single and multiple ascending dose, multi-cohort study in healthy volunteers. Spero expects to present final data from the Phase 1 clinical trial in the first half of 2020. In conjunction with Everest Medicines, and through its grant from the U.S. Department of Defense awarded in July 2019, Spero plans to conduct a Phase 1 bronchoalveolar lavage (BAL) clinical trial assessing the penetration of SPR206 into the pulmonary compartment in the second half of 2020 and initiate a renal impairment study of SPR206.

Fourth Quarter and Full-Year 2019 Financial Results

Spero reported a net loss for the fourth quarter and year ended December 31, 2019 of $25.2 million and $60.9 million, or $1.32 and $3.35 per common share, respectively. Net loss for the fourth quarter and year ended December 31, 2018 was $10.6 million and $41.7 million, or $0.60 and $2.60 per common share, respectively.

Total revenue for the fourth quarter and year ended December 31, 2019 was $3.6 million and $18.1 million, respectively, and was comprised of reimbursement for all of Spero's pipeline programs. Grant revenue for the year ended December 31, 2019 was $14.2 million higher than the same period of 2018 due to greater funding for tebipenem HBr received under the BARDA contract awarded in July 2019 that allows for reimbursement for prequalified expenses.

Research and development expenses for the fourth quarter 2019 of $25.7 million were higher than $9.1 million for the same period of 2018 due to higher direct clinical trial expense primarily from the ongoing ADAPT-PO Phase 3 trial that began enrolling patients in the first quarter of 2019. Research and development expenses for the year ended December 31, 2019 were $65.8 million compared to $33.9 million for the year ended December 31, 2018, with increased expenses in 2019 versus 2018 due to greater spend on tebipenem HBr and as well as SPR720 program expenses, partially offset by lower spend on Spero's Potentiator Platform product candidates. Spero expects that its research and development expenses will increase in 2020 due to greater planned spend associated with the ADAPT-PO Phase 3 clinical trial and preparation of a potential New Drug Application (NDA) filing for tebipenem HBr, as well as the initiation of a Phase 2a clinical trial for SPR720 in NTM, along with increased research and development personnel to support the ongoing and planned programs.

General and administrative expenses for the fourth quarter 2019 of $3.8 million were slightly higher than $3.6 million for the same period of 2018, primarily due to increased headcount. General and administrative expenses for the year ended December 31, 2019 were $15.6 million compared to $12.9 million for the year ended December 31, 2018, with the increased expenses in 2019 versus 2018 primarily due to an increase in headcount, professional fees and facility-related expenses. Spero expects general and administrative expenses to increase in 2020 due to additional headcount and professional fees required to support tebipenem HBr as it advances towards regulatory approval as well as increased facility-related expenses to support the expanding headcount.

As of December 31, 2019, Spero had cash, cash equivalents and marketable securities of $82.0 million. Subsequent to year-end 2019, on March 5, 2020 Spero announced the closing of its rights offering for $30 million in gross proceeds. Spero believes that its existing cash, cash equivalents and marketable securities as well as proceeds from the completed rights offering, together with committed funding from our BARDA contract and other non-dilutive funding commitments, will enable funding of its operating expenses and capital expenditure requirements into the first quarter of 2021, including through the filing of an NDA for tebipenem HBr.

Upcoming Scientific and Investor Presentations

- Multiple scientific presentations at the 30th European Congress of Clinical Microbiology and Infectious Diseases from April 18-21, 2020
- Corporate presentation at the H. C. Wainwright Annual Global Life Sciences Conference from April 20-21, 2020
- Corporate presentation at the 2020 Bank of America Merrill Lynch Health Care Conference from May 12-14, 2020

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, tebipenem HBr (tebipenem pivoxil hydrobromide; formerly 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 includes an IV-administered product candidate, SPR206, being developed 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 tebipenem HBr and ancillary supportive studies to be conducted in parallel with the Phase 3 trial will support the approval of tebipenem HBr; the design, initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs, including the timing of Spero's regulatory meeting with the FDA regarding SPR720, the timing of Spero's IND submission with the FDA regarding SPR720, the commencement of Spero's planned Phase 2a clinical trial of SPR720 and the commencement of Spero's planned Phase 1 bronchoalveolar lavage (BAL) clinical trial assessing the penetration of SPR206 into the pulmonary compartment; 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 tebipenem HBr, final data from the Phase 1 clinical trial of SPR720 and final data from the Phase 1 clinical trial of SPR206; and Spero's cash forecast and anticipated expenses, anticipated payments under Spero's agreement with Everest Medicines, potential payments under Spero's agreement with BARDA, 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 tebipenem HBr; 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 will satisfy all of the pre-conditions to receipt of the development milestone payment under its agreement with Everest Medicines; whether BARDA elects to exercise its second option under Spero's agreement with BARDA; whether Spero's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; whether Spero's clinical and preclinical development programs are delayed or disrupted due to the coronavirus; 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.

Spero Investor and Media Contact:

Sharon Klahre
Senior Director, Investor Relations
857-242-1547
IR@sperotherapeutics.com

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

	December 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 82,045	$ 115,443
Other assets	24,058	13,563
Total assets	**$ 106,103**	**$ 129,006**
Total liabilities	31,529	13,151
Total stockholder's equity	74,574	115,855
Total liabilities and stockholders' equity	**$ 106,103**	**$ 129,006**

Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Grant revenue	$ 2,934	$ 1,692	$ 13,405	$ 3,966
Collaboration revenue	696	—	4,742	—
Total revenues	3,630	1,692	18,147	3,966
Operating expenses:				
Research and development	25,728	9,127	65,775	33,885
General and administrative	3,785	3,649	15,588	12,887
Total operating expenses	29,513	12,776	81,363	46,772
Loss from operations	(25,883)	(11,084)	(63,216)	(42,806)
Other income (expense)	674	485	2,291	1,144
Net loss attributable to common shareholders of Spero Therapeutics, Inc.	$ (25,209)	$ (10,599)	$ (60,925)	$ (41,662)
Net loss per share attributable to common shareholders per share, basic and diluted	$ (1.32)	$ (0.60)	$ (3.35)	$ (2.60)
Weighted average shares outstanding, basic and diluted:	19,052,827	17,736,996	18,160,525	16,001,832