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): November 4, 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))

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 November 4, 2019, Spero Therapeutics, Inc. (the "Company") issued a press release announcing its results for the quarter ended September 30, 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 November 4, 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: November 4, 2019

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

Exhibit 99.1

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

SPR994 pivotal Phase 3 cUTI trial actively enrolling with data expected in the third quarter of 2020

CAMBRIDGE, Mass., November 4, 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 third quarter ended September 30, 2019 and provided a pipeline review.

“In the third quarter, we were pleased to announce a positive outcome from the SPR994 Phase 3 interim pharmacokinetic analysis where an independent data review committee determined that SPR994 plasma PK levels in patients were comparable to levels seen in the Phase 1 trial of healthy volunteers. As plasma exposure is a strong determinant of clinical efficacy, these data support the dose selected for the Phase 3 trial and give us additional confidence in SPR994’s activity in complicated urinary tract infections, a therapeutic area where a significant unmet need exists for effective oral agents that have the potency to fight resistant pathogens,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “We are in a strong financial position with approximately $94 million in cash as of the end of the third quarter of 2019 and we have upcoming clinical data for all of our clinical-stage pipeline programs scheduled to read out within the next 12 months, including top-line SPR994 Phase 3 data in the third quarter of 2020.”

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. A pivotal Phase 3 clinical trial of SPR994 for the treatment of complicated urinary tract infections (cUTI) entitled ADAPT-PO continues to enroll patients. This Phase 3 clinical trial compares an all oral regimen of 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. In October 2019, an independent review committee issued a positive recommendation to continue the trial using the protocol-defined dose without modification following its analysis of interim pharmacokinetic data from the first 33 patients dosed with SPR994 in the trial. The trial is enrolling well and Spero continues to expect to report top-line data from the Phase 3 clinical trial in the third quarter of 2020.

SPR720:

SPR720 is an orally administered antimicrobial agent being developed for the treatment of a rare, orphan disease, non-tuberculous mycobacterial (NTM) infections and other infections, including *Mycobacterium tuberculosis*. SPR720 is currently being evaluated in a double-blind, placebo-controlled Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of SPR720 in healthy volunteers. Spero expects to report top-line data from the Phase 1 clinical trial by year-end 2019. In June 2019, SPR720 was the focus of an equity investment by the Novo REPAIR Impact Fund for $10 million as well as a collaboration with Bill & Melinda Gates Medical Research Institute (Gates MRI) to further the development of SPR720 for tuberculosis (TB).

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 July 2019, the U.S. Department of Defense awarded $5.9 million to further clinical development of SPR206 against drug-resistant infections. SPR206 is currently being evaluated in a first-in-human Phase 1 clinical trial, designed as a double-blind, placebo-controlled, single and multiple ascending dose, multi-cohort study in healthy subjects. Spero expects to report top-line data from the Phase 1 clinical trial by year-end 2019.

Management Update

On October 31, 2019, Stephen J. DiPalma was appointed as interim Chief Financial Officer and Treasurer of Spero, effective November 8, 2019, to replace Joel Sendek, Spero's current Chief Financial Officer and Treasurer, who will depart the company on November 8, 2019 following his resignation announced on September 6, 2019. Mr. DiPalma is a Managing Director of Danforth Advisors, LLC, a financial consultancy firm that specializes in working with life sciences companies. Prior to and during his tenure at Danforth, Mr. DiPalma has served as interim Chief Financial Officer to several public and emerging life science companies. Mr. DiPalma joined Danforth in 2014 and served as Chief Financial Officer at Forum Pharmaceuticals from 2009 to 2014. He holds a B.S. from the University of Massachusetts and M.B.A. from Babson College.

Third Quarter 2019 Financial Results

Spero reported a net loss for the third quarter ended September 30, 2019 of $17.7 million or $0.95 per common share, greater than the net loss reported for the same period in 2018 of $10.5 million or $0.60 per common share.

Total revenue for the third quarter of 2019 totaled $4.6 million, higher than third quarter 2018 revenues of $658,000. The year-over-year increase was due to greater funding for SPR994 received under our BARDA contract awarded in July 2018 that allows for reimbursement of up to $46.7 million for qualified expenses for SPR994 development, $4.2 million of which was recognized during the third quarter of 2019.

Research and development expenses for the third quarter of 2019 of $18.5 million were higher than $8.5 million for the same period of 2018 due to greater spend on the SPR994 clinical program, partially offset by lower spend on the Potentiator Platform product candidates. General and administrative expenses for the third quarter of 2019 of $4.1 million were higher than $3.1 million for the same period of 2018, primarily due to increased headcount and facility-related costs.

Spero continues to expect that its research and development expenses will increase through year-end 2019 due to greater planned clinical spend associated with the SPR994 pivotal ADAPT-PO trial as enrollment scales, as well as the ongoing SPR720 and SPR206 Phase 1 clinical trials, along with increased personnel to support the clinical programs. Spero continues to expect general and administrative expenses to increase through year-end 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 September 30, 2019, Spero had cash and cash equivalents of $93.9 million, compared to $103.4 million as of June 30, 2019. In October 2019, Spero received an additional $5 million investment from Novo Holdings to complete the aggregate $10 million investment announced in June 2019. 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 its operating expenses and capital expenditure requirements for at least 12 months, which includes through the top-line data readout of the pivotal ADAPT-PO clinical trial of SPR994 expected in the third quarter of 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, 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.

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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Spero Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited, amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Grant revenue	$ 4,471	$ 658	$ 10,471	$ 2,274
Collaboration revenue	172	—	4,046	—
Total revenues	4,643	658	14,517	2,274
Operating expenses:				
Research and development	18,495	8,459	40,047	24,758
General and administrative	4,133	3,134	11,803	9,238
Total operating expenses	22,628	11,593	51,850	33,996
Loss from operations	(17,985)	(10,935)	(37,333)	(31,722)
Other income (expense)	268	472	1,394	659
Net loss attributable to common shareholders of Spero Therapeutics, Inc.	$ (17,717)	$ (10,463)	$ (35,939)	$ (31,063)
Net loss per share attributable to common shareholders per share, basic and diluted	$ (0.95)	$ (0.60)	$ (2.01)	$ (2.01)
Weighted average shares outstanding, basic and diluted:	18,659,079	17,471,462	17,859,829	15,417,087

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

	September 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 93,856	$ 115,443
Other assets	18,654	13,563
Total assets	**$ 112,510**	**$ 129,006**
Total liabilities	19,476	13,151
Total stockholder's equity	93,034	115,855
Total liabilities and stockholders' equity	**$ 112,510**	**$ 129,006**