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 8, 2018

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 and 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 8, 2018, Spero Therapeutics, Inc. (the "Company") issued a press release announcing its results for the third quarter ended September 30, 2018. 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 8, 2018

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 8, 2018

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

Exhibit 99.1

Spero Therapeutics Announces Third Quarter 2018 Financial Results and Pipeline Overview

Pipeline rapidly advancing with three clinical trials planned to initiate by early 2019, including a SPR994 Phase 3 initiation around year-end 2018

CAMBRIDGE, Mass., November 8, 2018 — Spero Therapeutics, Inc. (Nasdaq:SPRO), a multi-asset clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multi-drug resistant (MDR) bacterial infections, today announced financial results for the third quarter ended September 30, 2018 and provided a pipeline overview.

"We continue to make significant progress across all of our product candidates," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "Positive news on all of our product candidates within the past six months, coupled with our recent follow-on offering and non-dilutive funding award from BARDA, puts us in a strong position to execute on our clinical plan and further our mission of developing new treatments to address the critical unmet need of drug-resistant infections. We look forward to starting the Phase 3 SPR994 trial and Phase 1 SPR206 trial around year-end 2018 followed by the Phase 1 SPR720 trial in early 2019."

Recent Clinical Highlights and Upcoming Milestones

SPR994:

The Company's lead product candidate, SPR994, is designed to be the first broad-spectrum oral carbapenem-class antibiotic for use in adults to treat MDR Gram-negative infections. In September 2018, Spero announced positive results from a final analysis of its single ascending dose (SAD) and multiple ascending dose (MAD) Phase 1 clinical trial of SPR994. Data demonstrated that repeat dose administration of both 300 mg and 600 mg of SPR994 was well tolerated, with a safety profile consistent with the carbapenem class of antibiotics. Final results demonstrated a linear and proportional increase in plasma exposure over the dose range tested, with peak urine concentrations approximately 50 to 100-fold higher than the maximum concentrations in plasma, supporting SPR994's potential utility as treatment for patients with complicated urinary tract infection (cUTI). Spero believes the data support the advancement of SPR994 at a dose of 600 mg administered three times per day (TID) into a pivotal Phase 3 clinical trial in cUTI. Following a scheduled pre-Phase 3 meeting with the U.S. Food and Drug Administration in the fourth quarter of 2018, Spero expects to submit an investigational new drug application (IND) and initiate a pivotal Phase 3 clinical trial of SPR994 for the treatment of cUTI around year-end 2018. To support clinical development of SPR994, in July 2018 the Biomedical Advanced Research and Development Authority (BARDA) and the Defense Threat Reduction Agency (DTRA) awarded the Company up to $54 million in non-dilutive funding and support over a five-year period.

Potentiator Platform (SPR206 and SPR741):

Spero's Potentiator Platform is an innovative approach to treating MDR Gram-negative bacterial infections and includes two IV-administered compounds, SPR741 and SPR206. SPR741 is designed to expand the spectrum and increase the potency of a partner antibiotic when administered in combination. SPR741 completed a positive Phase 1b drug-drug interaction clinical trial in May 2018, and data demonstrated pharmacokinetic compatibility and tolerability of SPR741 when co-administered with beta-lactam antibiotics. SPR206 is designed to have antibiotic activity as a single agent against MDR and extremely drug resistant (XDR) bacterial strains. Results from the SPR206 IND-enabling studies announced in May 2018 demonstrated the potential for wide therapeutic margins and broad antimicrobial spectrum as a single agent in the setting of serious hospital Gram-negative infections, supporting progression to clinical studies. Spero now plans to initiate a Phase 1 clinical trial for SPR206 around year-end 2018, earlier than its prior expectation of 2019. The Company continues to expect that data from a Phase 1 clinical trial of SPR206, together with the data from its completed Phase 1b clinical trial of SPR741, will enable the selection of a lead candidate from the Potentiator Platform to move forward into late stage development. Spero continues to assess clinical development strategies, partnering opportunities and non-dilutive funding for both Potentiator Platform product candidates.

SPR720:

SPR720 is an oral antibiotic designed for the treatment of an orphan disease, pulmonary non-tuberculous mycobacterial (NTM) infection. In early November 2018, Spero announced positive results from preclinical IND-enabling studies of SPR720. The data suggest that SPR720 has an acceptable safety profile, encouraging target pathogen efficacy, and a wide therapeutic margin. *In vitro* minimum inhibitory concentration (MIC) studies demonstrated potent activity for SPR720 against prevalent NTM pathogens, including *Mycobacterium avium* complex and *Mycobacterium abscessus*, and *in vivo* studies in murine models of pneumonia demonstrated favorable efficacy relative to standard-of-care comparator agents. These results, in conjunction with the recent regulatory interactions Spero has had, support the further development of SPR720. Spero plans to initiate a First-in-Human Phase 1 clinical trial of SPR720 in early 2019.

Third Quarter 2018 Financial Results

The Company reported a net loss of $(10.5) million, or $(0.60) per basic and diluted share, for the third quarter of 2018 versus a net loss of $(12.1) million and $(36.02) per common share, respectively, for the same period in 2017.

Revenue from government awards totaled $658,000 for the third quarter of 2018, higher than third quarter of 2017 revenue of $597,000, and was comprised of reimbursement of program expenses for SPR994 and SPR206. Research and development expenses were $8.5 million for the third quarter of 2018, higher than third quarter of 2017 expenses of $6.9 million, primarily due to higher spending on the SPR994 and SPR720 development programs. General and administrative expenses were $3.1 million for the third quarter of 2018, lower than third quarter of 2017 expenses of $3.7 million, largely due to lower professional and consultant fees.

The Company continues to expect that its research and development expenses will increase through the remainder of 2018 in connection with increased planned clinical and preclinical activities related to our product candidates as it prepares to initiate three clinical trials by early 2019, including the initiation of the Phase 3 SPR994 clinical trial around year-end 2018. The Company expects general and administrative expenses to increase through the remainder of 2018 due to additional headcount and consultant fees as it advances its clinical pipeline and incurs additional costs associated with operating as a public company.

As of September 30, 2018, the Company's cash, cash equivalents and marketable securities totaled $131.2 million. In early July 2018, Spero completed a follow-on offering in which it issued 3,780,000 shares of common stock at a price of $12.50 per share, and 2,220 shares of Series A Convertible Preferred Stock at a price of $12,500 per share, for net proceeds before expenses of $70.5 million after deducting underwriting discounts and commissions. Spero continues to believe that its existing cash, cash equivalents and marketable securities as of September 30, 2018, together with initial committed funding of $15.7 million under the BARDA award, will fund operations into the second half of 2020, including through top-line data readout of the planned pivotal Phase 3 clinical trial of SPR994.

About Spero Therapeutics

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.

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 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 intravenous (IV)-administered agents, SPR741 and SPR206, designed to treat MDR Gram-negative infections in the hospital setting.

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

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 initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs, including statements regarding management's assessment of the results of such preclinical studies and clinical trials, the timing of clinical data, 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 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; 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 we periodically make 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
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Grant revenue	$ 658	$ 597	$ 2,274	$ 986
Operating expenses:				
Research and development	8,459	6,910	24,758	20,366
General and administrative	3,134	3,653	9,238	8,350
Total operating expenses	11,593	10,563	33,996	28,716
Loss from operations	(10,935)	(9,966)	(31,722)	(27,730)
Other income (expense)	472	(2,110)	659	(3,597)
Net loss attributable to common stockholders of Spero Therapeutics, Inc.	$ (10,463)	$ (12,076)	$ (31,063)	$ (31,327)
Net loss per share attributable to common stockholders per share, basic and diluted	$ (0.60)	$ (36.02)	$ (2.01)	$ (93.96)
Weighted average shares outstanding, basic and diluted:	17,471,462	335,285	15,417,087	333,402

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

	September 30 2018	December 31, 2017
Cash, cash equivalents and marketable securities	$ 131,225	$ 87,288
Other assets	4,895	6,191
Total assets	**$ 136,120**	**$ 93,479**
Total liabilities	10,568	8,522
Total stockholder's equity	125,552	84,957
Total liabilities and stockholders' equity	**$ 136,120**	**$ 93,479**