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): August 6, 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 August 6, 2020, Spero Therapeutics, Inc. (the "Company") issued a press release announcing its results for the quarter ended June 30, 2020. 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 August 6, 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: August 6, 2020

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

Exhibit 99.1

Spero Therapeutics Announces Second Quarter 2020 Operating Results and Provides Business Update

Top-line data for Phase 3 ADAPT-PO trial evaluating oral tebipenem HBr in complicated urinary tract infection expected in 3Q20

Conference call and live webcast at 4:30 p.m. EDT today

CAMBRIDGE, Mass., August 6, 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 second quarter ended June 30, 2020 and provided a business update.

“I am very pleased with our recent progress, as we are well positioned for the third quarter with top-line data from our Phase 3 ADAPT-PO clinical trial comparing oral tebipenem HBr to IV ertapenem expected before quarter end,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “We believe that tebipenem HBr, if approved, will have a significant benefit on the more than two million patients with avoidable hospitalizations for complicated urinary tract infections, and that the need for new, efficacious oral agents to keep patients out of the hospital has never been greater.”

Clinical Highlights and Upcoming Milestones

COVID-19 Update:

Spero remains committed to advancing its clinical programs while protecting the safety and well-being of patients, physicians and their staff. Spero is continuing to monitor and take steps to mitigate any effects of the COVID-19 pandemic on its business and clinical programs, while the U.S. Food and Drug Administration (FDA) is working with sponsors given the challenges the health crisis presents to conducting ongoing trials. Despite Spero’s best efforts to control the impact of the COVID-19 pandemic on its clinical trials and timelines, its clinical research organizations (CROs) are experiencing reduced capacity to conduct, validate and analyze trials, which Spero anticipates will have an effect on the timelines of its ongoing and planned Phase 1 clinical trials. Specifically, Spero believes a delay in Phase 1 trial readouts will affect the timing of the completion of its planned new drug application (NDA) submission for tebipenem HBr in complicated urinary tract infection (cUTI) as well as the initiation of its planned SPR206 Phase 1 bronchoalveolar lavage (BAL) clinical trial.

As a result of COVID-19, Spero now anticipates beginning a rolling submission of an NDA for tebipenem HBr for the treatment of cUTI to the FDA in the first quarter of 2021 and completion of the submission in the second quarter of 2021, pending positive data from its ongoing Phase 3 ADAPT-PO clinical trial and the FDA’s agreement with this submission approach. Spero expects to initiate its planned SPR206 Phase 1 BAL clinical trial in the first half of 2021.

Tebipenem HBr:

Spero's lead product candidate, tebipenem HBr, has the potential to be the first oral carbapenem antibiotic approved to treat MDR Gram-negative infections. Tebipenem HBr is currently being evaluated in the Phase 3 ADAPT-PO trial for the treatment of cUTI and acute pyelonephritis (AP). The trial completed enrollment of 1,372 patients in May 2020 and patient follow-up is complete. The trial remains blinded and Spero continues to expect to report top-line data in the third quarter of 2020.

ADAPT-PO compares an all oral regimen of tebipenem HBr with an existing standard of care intravenous (IV) antibiotic treatment, ertapenem, in patients with cUTI or AP, randomized 1:1 in each arm. The ADAPT-PO trial is supported by Phase 2 data in cUTI patients conducted by Spero's partner Meiji Seika, post-marketing data in Japan, and extensive pharmacokinetic and pharmacodynamic data, including pharmacokinetic data from the first 33 tebipenem HBr-treated ADAPT-PO patients. This pharmacokinetic data was analyzed by an independent review committee which recommended the ADAPT-PO trial continue without modifications to the protocol-defined dose.

Spero anticipates the COVID-19 pandemic will impact data validation and analysis for the ongoing Phase 1 trials that are required for the NDA submission of tebipenem HBr in cUTI. Spero expects to begin a rolling submission of an NDA for tebipenem HBr for the treatment of cUTI to the FDA in the first quarter of 2021, pending positive ADAPT-PO Phase 3 clinical data and the FDA's agreement on the approach, with a final submission planned for the second quarter of 2021 versus our previous guidance of the first quarter of 2021.

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*. Spero announced positive top-line data from its Phase 1 clinical trial of SPR720 in healthy volunteers in December 2019 and plans to 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, subject to the FDA's acceptance of an investigational new drug application. Spero met with the FDA in May and the agency acknowledged the Phase 2a clinical trial as designed was the appropriate next development step for SPR720.

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 results for SPR206 in healthy volunteers. These results showed that SPR206 was well-tolerated at doses likely to be within a therapeutic range for MDR Gram-negative bacterial infections. In conjunction with Everest Medicines, and through its grant from the U.S. Department of Defense awarded in July 2019, Spero expects to initiate a Phase 1 BAL clinical trial assessing the penetration of SPR206 into the pulmonary compartment in the first half of 2021 (versus its previous guidance of the second half of 2020) and initiate a renal impairment study of SPR206 in 2021.

Second Quarter 2020 Financial Results

Spero reported a net loss for the second quarter ended June 30, 2020 of $17.5 million or $0.85 per common share, compared to a net loss of $13.2 million or $0.74 per common share reported for the same period in 2019.

Total revenue for the second quarter of 2020 was $1.7 million, compared with revenues of $2.2 million in the second quarter of 2019. Reimbursement under Spero's contract with the Biomedical Advanced Research and Development Authority (BARDA) for qualified tebipenem HBr expenses was slightly higher in the second quarter of 2020 compared to the same period in 2019, however this increase was offset by lower funding received for SPR206 during the quarter under its contract with the U.S. National Institute of Allergy and Infectious Diseases (NIAID).

Research and development expenses for the second quarter of 2020 were $15.7 million, compared with $12.0 million of research and development expenses for the same period of 2019. This year-over-year increase was due to greater spending on the tebipenem HBr program. Spero continues to expect that its research and development expenses will increase in 2020 relative to 2019 due to the greater expense associated with progressing its pipeline.

General and administrative expenses for the second quarter of 2020 of $4.5 million were higher than the $3.8 million reported in the same period of 2019, primarily due to increased headcount. Spero continues to expect general and administrative expenses to increase through 2020 due to additional headcount and professional fees, and infrastructure required to support tebipenem HBr through a potential NDA filing, as well as support for Spero's other product candidates.

As of June 30, 2020, Spero had cash and cash equivalents of $71.4 million. Spero believes that its existing cash, cash equivalents and marketable securities, together with committed funding from the BARDA contract and other non-dilutive funding commitments, will be sufficient to fund its operating expenses and capital expenditure requirements into the first quarter of 2021.

Upcoming Investor and Clinical Presentations

- Corporate presentation at the Cantor Virtual Global Healthcare Conference 2020 being held September 15 – 17, 2020
- IDWeek 2020 Virtual Meeting being held October 21 – 25, 2020
- Corporate presentation at the Stifel Healthcare Conference being held November 17 – 18, 2020w

Conference Call and Webcast

Spero will host a conference call and webcast today at 4:30 p.m. EDT. To access the call, please dial (877) 705-6003 (domestic) or (201) 493-6725 (international) and refer to conference ID 13706063. The conference call will also be webcast live and a link to the webcast can be accessed here and also on Spero Therapeutics' website at www.sperotherapeutics.com in the "Investors and Media" section under "Events and Presentations." An archived webcast will be available on Spero's website for 30 days following the presentation.

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 an IV-administered next generation polymyxin product candidate, SPR206, developed from its potentiator platform that is 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 NDA submission with the FDA regarding tebipenem HBr, 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 final data from 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; the direct and indirect impact of the pandemic caused by an outbreak of a new strain of coronavirus on Spero's business and operations, including manufacturing, research and development costs, clinical trials, regulatory processes and employee expenses; 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 the FDA will accept a rolling NDA submission with respect to tebipenem HBr; 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:

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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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Grant revenue	$ 1,676	$ 2,089	$ 3,208	$ 6,000
Collaboration revenue	51	67	220	$ 3,874
Total revenues	1,727	2,156	3,428	9,874
Operating expenses:				
Research and development	15,656	12,026	36,092	21,552
General and administrative	4,547	3,782	8,633	7,670
Total operating expenses	20,203	15,808	44,725	29,222
Loss from operations	(18,476)	(13,652)	(41,297)	(19,348)
Other income (expense)	975	502	538	1,126
Net loss	$ (17,501)	$ (13,150)	$ (40,759)	$ (18,222)
Deemed dividend	$ —	$ —	$ (549)	$ —
Net loss attributable to common shareholders of Spero Therapeutics, Inc.	$ (17,501)	$ (13,150)	$ (41,308)	$ (18,222)
Net loss per share attributable to common shareholders per share, basic and diluted	$ (0.85)	$ (0.74)	$ (2.06)	$ (1.04)
Weighted average shares outstanding, basic and diluted:	20,633,402	17,667,620	20,095,415	17,445,600

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

	June 30, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$71,360	$ 82,045
Other assets	26,185	24,058
Total assets	**$97,545**	**$ 106,103**
Total liabilities	23,831	31,529
Total stockholder's equity	73,714	74,574
Total liabilities and stockholders' equity	**$97,545**	**$ 106,103**