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 6, 2021

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:

☐ 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 May 6, 2021, Spero Therapeutics, Inc. (the "Company") issued a press release announcing its results for the quarter ended March 31, 2021. 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.

99.1 Press Release, dated May 6, 2021

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 6, 2021

By: /s/ Tamara Joseph
Tamara Joseph
Chief Legal Officer

Exhibit 99.1

Spero Therapeutics Announces First Quarter 2021 Operating Results and Provides Business Update

Tebipenem HBr remains on track for NDA submission in the second half of 2021

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

CAMBRIDGE, Mass., May 6, 2021 — 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 first quarter ended March 31, 2021 and provided a business update.

“We are off to a strong start in 2021 and I am very pleased with the progress we have made across our pipeline,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “We recently completed a pre-NDA meeting for tebipenem HBr with the FDA and received feedback indicating that the format and content of the planned data package we intend to include in our NDA will be sufficient to support the submission. This regulatory milestone keeps us on track to submit the NDA in the second half of the year as we work to transition to a commercial-stage organization. Our Phase 3 ADAPT-PO data indicate that, if approved, tebipenem HBr may provide many of the over 2 million cUTI and acute pyelonephritis patients who would typically receive IV therapy the convenience of an oral treatment with comparable efficacy and safety. Replacing IV therapy with an oral option may help avoid unnecessary hospitalizations, delivering substantial value to payers, physicians, and most importantly, patients.”

Clinical Highlights and Upcoming Milestones

Tebipenem HBr:

Spero’s lead product candidate, tebipenem HBr, has the potential to be the first oral carbapenem antibiotic, if approved, to treat complicated urinary tract infection (cUTI), including acute pyelonephritis (AP). In September 2020, Spero announced positive data from the Phase 3 ADAPT-PO trial showing that oral tebipenem HBr was statistically non-inferior to intravenous ertapenem in the treatment of patients with cUTI and patients with AP.

In March 2021, Spero successfully completed a pre-new drug application (NDA) meeting with the United States Food and Drug Administration (FDA). The purpose of the meeting was to discuss the format and content of Spero’s planned NDA submission. Subject to FDA’s review of the full submission, Spero and the FDA achieved consensus that the NDA package as described during the course of the meeting would allow for FDA review, consistent with Spero’s expectations. Spero remains on track to make the NDA submission to the FDA in the second half of 2021.

In January 2021, Spero announced that the U.S. Patent and Trademark Office (USPTO) issued U.S. Patent No. 10,889,587, which covers a crystalline formulation of tebipenem HBr. This patent expires in February 2038. Tebipenem HBr has also been granted Qualified Infectious Disease Product (QIDP) and Fast Track designations by the FDA for the treatment of cUTI.

SPR720:

In December 2020, SPR720 advanced into a Phase 2a dose-ranging clinical trial in patients with nontuberculous mycobacterial pulmonary disease (NTM-PD) based on positive data from a Phase 1 clinical trial that evaluated the safety, tolerability and pharmacokinetics of oral SPR720, as well as supportive data from a series of non-clinical GLP toxicology and safety pharmacology studies, including investigational new drug application (IND)-enabling 28- and 31-day GLP studies in non-human primates and rats, respectively.

In February 2021, Spero received data from a chronic toxicology study in adult non-human primates in which mortalities with inconclusive causality to treatment were observed. As a precautionary measure, Spero paused dosing in its Phase 2a clinical trial and notified the FDA. The FDA then issued a verbal notification of a clinical hold on the clinical trial. Subsequently Spero received a formal clinical hold letter in which the FDA requested additional information from the non-human primate toxicology study, including a study report. To avoid incurring costs associated with the Phase 2a clinical trial while it was on hold and best facilitate potential future adjustments to the trial protocol, Spero decided to discontinue the Phase 2a clinical trial as it worked to understand the cause of the non-human primate mortalities. Spero has since completed the non-human primate toxicology study and is currently analyzing the data and preparing the study report. Based on available data to-date, Spero continues to believe there is a path forward for the SPR720 program. Spero expects to submit the study report to the FDA for its review in the third quarter of 2021.

SPR206:

SPR206 is an intravenously (IV)-administered product candidate being developed as an innovative option to treat multi-drug resistant (MDR) Gram-negative bacterial infections. In January 2020, Spero reported positive Phase 1 clinical trial results for SPR206 in healthy volunteers and subsequently received a $2.0 million milestone payment from Everest Medicines for the delivery of the Phase 1 Clinical Study Report in the fourth quarter of 2020.

Through its 2019 grant from the U.S. Department of Defense, and in conjunction with Everest Medicines, Spero expects to initiate two Phase 1 clinical trials of SPR206 in the second quarter of 2021. These trials include a bronchoalveolar lavage (BAL) clinical trial assessing the penetration of SPR206 into the pulmonary compartment and a renal impairment clinical trial. Data from the BAL and renal impairment clinical trials are expected by early 2022. For more information on the trials and their design, see ClinicalTrials.gov identifiers NCT04868292 (BAL trial) and NCT04865393 (renal impairment trial).

First Quarter 2021 Financial Results

Spero reported a net loss for the first quarter ended March 31, 2021 of $19.4 million or $0.66 per common share, compared to a net loss of $23.3 million or $1.22 per common share reported for the same period in 2020.

Total revenues for the first quarter of 2021 were $7.3 million, compared with revenues of $1.7 million in the first quarter of 2020. The increase was primarily due to grant revenue received through the BARDA contract for tebipenem HBr.

Research and development expenses for the first quarter of 2021 were $18.4 million, compared with $20.4 million of research and development expenses for the same period of 2020. This year-over-year decrease was due to winding down of Phase 3 activities for tebipenem HBr, offset in part by investment to support the NDA filing for tebipenem HBr.

General and administrative expenses for the first quarter of 2021 of $8.3 million were higher than the $4.1 million reported in the same period of 2020, primarily due to increased professional expenses and personnel costs to support the Company's precommercial efforts.

As of March 31, 2021, Spero had cash, cash equivalents, and marketable securities of $115.7 million. Spero believes that its existing cash, cash equivalents and marketable securities, together with committed funding from its BARDA contract and other non-dilutive funding commitments, will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2022, including through the submission of the NDA for tebipenem HBr.

Conference Call and Webcast

Spero will host a conference call and webcast today at 4:30 p.m. ET. To access the call, please dial 877-705-6003 (domestic) or 201-493-6725 (international) and refer to conference ID 13718122. 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 Therapeutics

Spero Therapeutics, Inc. is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multi-drug-resistant (MDR) bacterial infections and rare diseases.

Spero's lead product candidate, tebipenem HBr (tebipenem pivoxil hydrobromide; formerly SPR994), is being developed as the first oral carbapenem antibiotic for use in complicated urinary tract infections (cUTI) and acute pyelonephritis (AP). In September 2020, Spero announced positive top-line results from its Phase 3 ADAPT-PO clinical trial of tebipenem HBr in cUTI and AP.

Spero is also developing SPR720, its novel oral therapy product candidate being developed for the treatment of rare, orphan pulmonary disease caused by 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***.

Government Agency Research Support

The views expressed in this press release are those of the authors and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

Forward-Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about the initiation, timing and submission to the FDA of a NDA for tebipenem HBr and the potential approval of tebipenem HBr by the FDA; future commercialization, the potential number of patients who could be treated by tebipenem HBr and market demand for tebipenem HBr generally; expected broad access across payer channels for tebipenem HBr; the expected pricing of tebipenem HBr and the anticipated shift in treating patients from IV to oral administration; the plans for Spero's ongoing development of SPR720; the design, initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs, including the commencement of Spero's planned Phase 1 bronchoalveolar lavage (BAL) clinical trial assessing the penetration of SPR206 into the pulmonary compartment and its renal impairment study of SPR206; management's assessment of the results of such preclinical studies and clinical trials; the direct and indirect impact of the pandemic caused by an outbreak of a new strain of coronavirus (COVID-19) 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 Spero's ability to timely complete the NDA submission to the FDA for tebipenem HBr; the outcome of discussions with the FDA regarding the Phase 2a clinical trial of SPR720 and Spero's ability to proceed with such trial; Spero's need for additional funding; the lengthy, expensive, and uncertain process of clinical drug development; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; Spero's reliance on third parties to manufacture, develop, and commercialize its product candidates, if approved; the ability to develop and commercialize Spero's product candidates, if approved; the potential impact of the COVID-19 pandemic; Spero's ability to retain key personnel and to manage its growth; 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; 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.

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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,	
	2021	2020
Revenues:		
Grant revenue	$ 7,300	$ 1,532
Collaboration revenue	—	169
Total revenues	7,300	1,701
Operating expenses:		
Research and development	18,404	20,436
General and administrative	8,299	4,086
Total operating expenses	26,703	24,522
Loss from operations	(19,403)	(22,821)
Other income (expense)	(20)	(437)
Net loss	$ (19,423)	$ (23,258)
Deemed dividend	$ —	$ (549)
Net loss attributable to common shareholders of Spero Therapeutics, Inc.	$ (19,423)	$ (23,807)
Net loss per share attributable to common shareholders per share, basic and diluted	$ (0.66)	$ (1.22)
Weighted average shares outstanding, basic and diluted:	29,414,148	19,557,418

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

	March 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$115,676	$ 126,906
Other assets	27,764	26,545
Total assets	**$143,440**	**$ 153,451**
Total liabilities	24,594	21,411
Total stockholder's equity	118,846	132,040
Total liabilities and stockholders' equity	**$143,440**	**$ 153,451**