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): January 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 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 1.01 Entry into a Material Definitive Agreement.

On January 4, 2019, Spero Therapeutics, Inc. ("Spero"), through its wholly owned subsidiary New Pharma License Holdings Limited ("NPLH"), entered into a license agreement (the "License Agreement") with Everest Medicines II Limited ("Everest"), which License Agreement also includes an option granted by Spero's wholly owned subsidiary Spero Potentiator, Inc., a Delaware corporation ("Potentiator" and, together with NPLH, the "Company"). Under the terms of the License Agreement, the Company granted Everest an exclusive license to develop, manufacture and commercialize Spero's product candidate SPR206 (the "Compound") or products that contain the Compound (a "Licensed Product") in Greater China (which includes Mainland China, Hong Kong and Macau), South Korea and certain Southeast Asian countries (collectively, the "Territory"). The Company retains development, manufacturing and commercialization rights with respect to the Compound and Licensed Products in the rest of the world and also retains the right to develop or manufacture the Compound and Licensed Products in the Territory for use outside the Territory. In addition to the license grant to SPR206, the Company also granted Everest a 12-month exclusive option to negotiate with the Company for an exclusive license to develop, manufacture and commercialize Spero's product candidate SPR741 in the Territory.

Under the terms of the License Agreement, the Company is entitled to receive an upfront payment of $3 million. The Company may also receive up to an additional $59.5 million in milestone payments upon Everest's achievement of certain developmental, regulatory and sales milestone events related to SPR206, which achievement cannot be guaranteed. The Company is also entitled to receive high single-digit to low double-digit royalties on net sales, if any, of Licensed Products in the Territory following regulatory approval of the Compound. Everest has the right to sublicense to affiliates and third parties in the Territory.

Everest is responsible for all costs related to developing, obtaining regulatory approval of and commercializing the Compound and Licensed Products in the Territory, and is obligated to use commercially reasonable efforts to develop, manufacture and commercialize Licensed Products, including to achieve certain specified diligence milestones within agreed-upon periods. A joint development committee will be established between the Company and Everest to coordinate and review the development, manufacturing and commercialization plans with respect to Licensed Products in the Territory.

Unless earlier terminated due to certain material breaches of the contract, or otherwise, the License Agreement will expire on a jurisdiction-by-jurisdiction and Licensed Product-by-Licensed Product basis until the latest to occur of expiration of the last valid claim under a licensed patent in such jurisdiction, the expiration of regulatory exclusivity in such jurisdiction or ten years after the first commercial sale of such Licensed Product in such jurisdiction. The License Agreement may be terminated in its entirety by Everest upon 90 or 180 days' prior written notice, depending on the stage of development of the initial Licensed Product.

The foregoing description of the terms of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement, which Spero intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2019. Spero intends to seek confidential treatment for certain portions of the License Agreement pursuant to a Confidential Treatment Request to be submitted to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

On January 7, 2019, Spero issued a press release announcing the entry into the License Agreement, a copy of which is filed herewith as Exhibit 99.1 and incorporated by reference herein.

Item 8.01 Other Events.

On January 7, 2019, Spero issued a press release providing regulatory and clinical updates for its product candidate SPR994, a copy of which is filed herewith as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit 99.1 Press Release, dated January 7, 2019.

Exhibit 99.2 Press Release, dated January 7, 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: January 7, 2019

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

Exhibit 99.1

Spero Therapeutics Signs License Agreement with Everest Medicines to Develop, Manufacture and Commercialize SPR206 in Asia, with Option for SPR741 Rights, and Initiates SPR206 Phase 1 Clinical Trial

CAMBRIDGE, Mass., January 7, 2018 — Spero Therapeutics, Inc. (Nasdaq:SPRO), a multi-asset clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multidrug-resistant (MDR) bacterial infections, and Everest Medicines announced today that they have entered into a collaboration to develop, manufacture and commercialize SPR206 in Greater China, South Korea and certain Southeast Asian countries (the "Territory"), along with an exclusive option to rights to SPR741 in the Territory.

SPR206 and SPR741, two intravenous (IV)-administered product candidates from Spero's Potentiator Platform, are being developed as innovative options to treat MDR Gram-negative bacterial infections. Based on microbiological and *in vivo* testing, Spero believes that SPR206 has the potential to offer a broad-spectrum of activity, including against extensively drug-resistant (XDR) bacterial strains, together with improved safety and tolerability compared with other molecules in its class. Spero initiated a Phase 1 clinical trial of SPR206 in December 2018, designed as a double-blind, placebo-controlled, ascending dose, multi-cohort study in healthy subjects, and expects top-line data from this trial in the second half of 2019. Data from investigational new drug (IND)-enabling studies, together with data presented at the ESCMID/ASM Conference in September 2018, collectively demonstrate SPR206's favorable safety profile and *in vitro* activity against MDR Gram-negative pathogens, including carbapenem-resistant Enterobacteriaceae, *Acinetobacter baumannii* and *Pseudomonas aeruginosa*. SPR741 is a novel compound designed to expand the spectrum and enhance the potency of existing antibiotics. SPR741 completed a Phase 1b drug-drug interaction clinical trial in July 2018, which demonstrated safety and pharmacokinetic compatibility of SPR741 when co-administered with beta-lactam antibiotics.

Spero, through certain of its wholly owned subsidiaries, has granted Everest an exclusive license to develop, manufacture, and commercialize SPR206 in the Territory. Everest also has a 12-month exclusive option to rights to SPR741 in the Territory. A Joint Development Committee will be established between the companies to coordinate and review the development, manufacturing and commercialization plans with respect to SPR206 in the Territory. Spero will receive an upfront payment of $2 million and is eligible to receive milestone payments of up to an additional $59.5 million upon achievement of specified clinical, regulatory and commercial milestones related to SPR206, of which Spero anticipates receiving at least $2 million in near-term milestones during 2019. Furthermore, Spero will be eligible to receive high single-digit to low double-digit royalties on any sales of SPR206 products in the Territory following regulatory approval. Everest will also pay Spero a $1 million upfront fee for its exclusive 12-month option to rights to SPR741.

"We look forward to working with Everest Medicines to further develop and bring SPR206 to market in Greater China, South Korea and Southeast Asia in an effort to address the growing, global problem of antibiotic resistance," said Ankit Mahadevia, M.D., CEO of Spero Therapeutics. "Everest shares our passion and commitment to developing these important, novel medications. Having a local partner who understands the market dynamics and reimbursement landscape will significantly assist Spero's efforts to develop and commercialize these product candidates in Asia. Additionally, funding from this transaction will provide additional resources to advance our robust pipeline of products that address unmet medical needs."

"Bacterial drug resistance is a critical health issue and innovative new classes of antibiotics is an area of urgent unmet need," said Sean Cao, Interim CEO at Everest Medicines. "We partner with companies that develop innovative medicines and have large commercial potential in Asia. Development of safer polymyxins with a broad spectrum of antimicrobial activity including extensively resistant bacteria may provide a life-saving treatment to patients with limited or no alternative treatment options."

About the Spero Potentiator Platform – SPR206 and SPR741

The Potentiator Platform molecules are designed to treat Gram-negative bacterial infections through the molecule's interactions with the bacterium's outer membrane. The Potentiator Platform molecules exhibit this effect as a monotherapy or by co-administration with existing antibiotics. Spero currently has two Potentiator Platform drug candidates – SPR206, a direct acting IV-administered agent that has demonstrated broad Gram-negative antibacterial activity; and SPR741, an IV-administered agent that has demonstrated Gram-negative antibacterial activity when co-administered with existing antibiotics. Both have demonstrated activity against Gram-negative bacteria, including organisms identified by the Centers for Disease Control and Prevention and the World Health Organization as urgent and serious threats to human health. SPR206 is designed to have antibiotic activity as a single agent against MDR and XDR bacterial strains, including carbapenem-resistant *Pseudomonas aeruginosa, Acinetobacter baumannii* and Enterobacteriacea*e*. Spero initiated a Phase 1 trial of SPR206 in December 2018 and anticipates top-line data from the trial in the second half of 2019. In preclinical studies, SPR741 was able to potentiate over two-dozen existing antibiotics by expanding their activity against Gram-negative pathogens. SPR741 has been evaluated in two Phase 1 clinical trials in healthy volunteers supporting its safety and tolerability. Spero believes that its current intellectual property portfolio and pending patent applications will provide global protection, including China, the United States and Europe for SPR741 and SPR206 through 2038 and 2039, respectively.

About Everest Medicines

Everest Medicines is an emerging markets biopharmaceutical company focused on developing and commercializing transformative pharmaceutical products that address critical unmet medical needs for patients across Greater China and other Asian territories. The Everest Medicines team has deep expertise and an extensive track record of high-quality clinical development, regulatory affairs, CMC, business development and operations with leading global pharmaceutical companies, and in our territories of focus.

About Spero

Spero is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for MDR bacterial infections.

Spero'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.

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, that are 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 infection.

For more information, visit **https://sperotherapeutics.com**.

SPR206 Research Support

This project has been funded in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201500014C.

Forward-Looking Statements

This press release may contain forward-looking statements. These statements include, but are not limited to, statements about the future development or commercialization of SPR206 and SPR741 in Greater China, South Korea and certain Southeast Asian countries, the potential receipt of milestone payments, as well as royalties on potential future sales of SPR206, under the license with Everest Medicines, 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, including the availability of top-line data from the Phase 1 clinical trial of SPR206, 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 Spero's dependence on Everest Medicines to timely and successfully develop, manufacture and commercialize SPR206 in Greater China, South Korea and certain Southeast Asian countries; the fact that Spero may not receive any milestone or royalty payments from Everest Medicines; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Spero's product candidates, including SPR206, 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; Spero's ability to continue obtaining and maintaining intellectual property protection for its product candidates; 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.

Spero Investor and Media Contact:

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

Everest Medicines Media Contact:

James Heins
Senior Vice President
203-682-8251
James.Heins@icrinc.com

Exhibit 99.2

Spero Therapeutics Announces Positive Feedback from FDA Pre-Phase 3 Meeting for Oral SPR994 and Submission of IND for SPR994 in cUTI

- FDA meeting supports single pivotal Phase 3 clinical trial of SPR994 in cUTI
- SPR994 IND submitted and ADAPT-PO Phase 3 startup activities underway

CAMBRIDGE, Mass., January 7, 2018 (GLOBE NEWSWIRE) — 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 the results of its Type B / pre-IND / pre-Phase 3 meeting with the U.S. Food and Drug Administration (FDA) regarding SPR994 for the oral treatment of complicated urinary tract infections (cUTI). Based on its discussions with the FDA, Spero believes that positive results from a single pivotal Phase 3 clinical trial of SPR994 in cUTI demonstrating a 10% non-inferiority margin would support the approval of SPR994 for the treatment of cUTI. As a result of the meeting, Spero has submitted an Investigational New Drug (IND) application for SPR994 in cUTI with the FDA and begun startup activities for its ADAPT-PO Phase 3 clinical trial as well as ancillary supportive studies required for the approval of SPR994. The Company anticipates opening trial sites to support study enrollment in the first quarter of 2019.

“We have been very pleased by the informative and productive discussions with the FDA and our ability to obtain meaningful feedback on appropriate next steps for our planned pivotal Phase 3 trial of SPR994, ADAPT-PO,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. “The design of our Phase 3 program is consistent with our previous guidance and supports the key value proposition for SPR994 of demonstrating clinical equivalency of an oral versus intravenous carbapenem. We have completed the IND submission for SPR994 in cUTI. While we await the FDA’s acceptance of the IND, we have begun activities for our planned Phase 3 trial.”

Spero’s planned pivotal Phase 3 clinical trial of SPR994, ADAPT-PO, is designed as a double-blind, double-dummy trial to compare oral SPR994 with an existing standard of care intravenous (IV) antibiotic, ertapenem, in approximately 1,200 patients randomized 1:1 in each arm. As currently planned, the primary endpoint of the pivotal trial will be the combined clinical and microbiological response at the test of cure with a 10% non-inferiority margin versus IV ertapenem. The trial will incorporate a lead-in cohort of 70 patients with intensive pharmacokinetics assessment to confirm the dose and exposure in the cUTI patient population. Spero anticipates receiving interim pharmacokinetic data from the trial’s lead-in cohort in the second half of 2019. In addition to the planned pivotal Phase 3 trial, Spero will conduct routine ancillary clinical pharmacology studies in parallel with the Phase 3 trial, including a renal insufficiency study, a thorough QT prolongation study and a drug-drug interaction study.

Spero believes that its existing cash, cash equivalents and marketable securities as of September 30, 2018, together with initial committed funding of $15.7 million of the up to $54 million in funding awarded under its BARDA award, will fund its operations into the second half of 2020, including through top-line data readout of the planned pivotal Phase 3 clinical trial of SPR994.

About SPR994

SPR994 is Spero's novel investigational oral formulation of tebipenem, a carbapenem-class antibiotic marketed by Meiji Seika Pharma Co. Ltd. (Meiji) in Japan as Orapenem® since 2009 for pediatric infections limited to pneumonia, otitis media and sinusitis. Carbapenems are an important class of antibiotics because they have been demonstrated to be safe and effective against drug-resistant Gram-negative bacterial infections. Spero completed a Phase 1 clinical trial of SPR994 in Australia, designed as a double-blind, placebo-controlled, ascending dose, multi-cohort study to enable dose selection for Spero's planned pivotal Phase 3 clinical trial. Spero has submitted an IND for SPR994 in cUTI to the U.S. FDA and intends to open sites to support enrollment into the pivotal Phase 3 clinical trial of SPR994 entitled ADAPT-PO [(A Phase 3, Randomized, Double-blind, Double-dummy, Multicenter, Prospective Study to Assess the Efficacy, Safety and Pharmacokinetics of Orally Administered Tebipenem Pivoxil Hydrobromide (SPR994) Compared to Intravenous Ertapenem in Patients with Complicated Urinary Tract Infection (cUTI) or Acute Pyelonephritis (AP)] for the treatment of cUTI in the first quarter of 2019 in support of a new drug application (NDA). In preclinical studies, SPR994 has shown potent antibiotic activity against Gram-negative bacteria, including *E. coli*-producing extended-spectrum beta-lactamases (ESBLs) and ESBL-producing *Klebsiella pneumoniae*, similar to IV-administered ertapenem. Approximately 1,200 subjects have been dosed with tebipenem in clinical and pharmacologic studies conducted by Meiji during its development of tebipenem in Japan. In addition, available post-marketing outcomes data report of tebipenem in 3,540 pediatric patients with pneumonia, otitis media or sinusitis, and these data are consistent with the safety profile of tebipenem as observed in the clinical trial conducted by Meiji.

SPR994 Research Support:

This project has been funded in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201800015C.

About Spero Therapeutics

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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 our 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 planned 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, including the anticipated timing of the opening of sites to support enrollment into the planned pivotal Phase 3 clinical trial of SPR994; statements regarding management's assessment of the results of such preclinical studies and clinical trials; the timing of clinical data, including the availability of interim data from the Phase 3 trial's lead-in cohort; 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; that the Investigational New Drug (IND) application for SPR994 has been submitted to the FDA and there is the possibility that the initiation of the planned pivotal Phase 3 clinical trial of SPR994 may be delayed if the FDA raises any issues with the submission or because of a delay in the FDA's review of the IND due to the current shutdown of the U.S Government operations; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; the extent to which the FDA will permit Spero to rely in part on clinical data from clinical trials conducted by Meiji; whether Spero's product candidates, including SPR994, 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, clinical outcomes and findings of ancillary supportive studies to be conducted in parallel with the planned Phase 3 trial; 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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