Spero Therapeutics Announces 3Q17 Operating Results and Pipeline Update

December 14, 2017

- Raised approximately $83.6 million in gross proceeds from Initial Public Offering
- Advanced pipeline with initiation of SPR994 Phase 1 trial in October 2017 and SPR741 Phase 1b trial in November 2017

CAMBRIDGE, Mass., Dec. 14, 2017 (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 financial results for the third quarter ended September 30, 2017 and provided a pipeline update.

“This has been a transformative period for Spero with the close of our initial public offering in November and recent initiation of two clinical trials, a Phase 1 trial for SPR994 and Phase 1b trial for SPR741, both focused on treating current and emerging drug-resistant infections,” said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics.

Third Quarter 2017 Financial Results

The Company reported a net loss of $(12.1) million, or basic and diluted net loss per common share of $(36.02), for the third quarter of 2017 versus a net loss of $(7.4) million and $(23.23) per common share, respectively, for the same period in 2016.

Revenue from government awards totaled $0.6 million for the third quarter of 2017, and was primarily due to reimbursement from CARB-X of SPR741 program expenses. Research and development expenses were $6.9 million for the third quarter of 2017, including non-cash share based compensation expense of $0.2 million, higher than third quarter of 2016 expenses of $6.0 million as expenses increased to support the advancement of the Company’s product pipeline. General and administrative expenses were $3.7 million for the third quarter of 2017, including non-cash share based compensation expenses of $0.7 million, higher than third quarter of 2016 expenses of $1.9 million due mainly to increased headcount and higher non-cash share based compensation. The Company expects that its research and development expenses will increase through the remainder of 2017 and throughout 2018 as it conducts additional clinical trials and other studies for its product candidates, achieves contingent milestones under its license agreement and invests in its pipeline. The Company expects general and administrative expenses to increase due to additional headcount to support its research and development activities and greater costs associated with operating as a public company.

As of September 30, 2017, the Company’s cash and cash equivalents totaled $25.4 million. In early November 2017, Spero completed its initial public offering in which it issued a total of approximately 6.0 million shares of common stock at a public offering price of $14.00 per share, for net proceeds before expenses of $77.7 million after deducting underwriting discounts and commissions.

Recent Highlights and Pipeline Update

In October 2017, Spero initiated a Phase 1 study of SPR994, an orally administered carbapenem antibiotic, in healthy subjects. The trial is designed as a double-blind, placebo-controlled, ascending dose, multi-cohort study to assess the safety, tolerability, food effect and pharmacokinetics of SPR994 in healthy subjects. The Company continues to guide to a rapid development plan for SPR994 with the initiation of a single pivotal Phase 3 trial in the second half of 2018 contingent upon a successful Phase 1 study outcome and subject to feedback from the U.S. Food and Drug Administration (FDA).

Spero announced today the initiation of a Phase 1b drug-drug interaction trial of SPR741, a novel investigational agent that is designed to expand the spectrum and increase the potency of a partner antibiotic when administered in combination. It is the first product candidate from Spero’s Potentiator Platform. The trial was initiated in the United Kingdom in November 2017 as previously planned following approval from the Medicines and Healthcare products Regulatory Agency (MHRA) and the Company’s pre-IND discussions with the FDA in late November 2017. The trial will study SPR741 administered in 30 healthy volunteers as a single dose in combination with compounds from the beta-lactam class of antibiotics, including cephalosporins (such as ceftazidime), monobactams (such as aztreonam) and beta-lactams/beta-lactamase inhibitors (such as pipercillin/tazobactam). The trial will assess the impact, if any, on the standalone pharmacokinetics of SPR741 or the standalone pharmacokinetics of the beta-lactam combination drug when the two are dosed together as a single dose. We continue to expect to receive top-line data from this trial in the first half of 2018. Following those results, we expect to be in a position to identify the most attractive partner antibiotic to take into a Phase 2 combination trial. That decision will be based on factors including results of our Phase 1b study, our selection of an antibiotic partner, current and future FDA feedback, and the status of other products in our portfolio such as SPR206. After we assess these factors, we expect to provide guidance on the initiation of our Phase 2 combination trial of SPR741.

About SPR994

SPR994 is a novel antibiotic with potential to be the first broad-spectrum oral carbapenem approved for use in adults. SPR994 is a novel, proprietary oral formulation of tebipenem pivoxil (tebipenem), a carbapenem-class antibiotic marketed by Meiji Seika Pharma Co. Ltd. in Japan as Orapenem® since 2009 for pediatric infections including pneumonia, otitis media and sinusitis and studied in approximately 1,200 subjects. SPR994 has demonstrated 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. While SPR994 has demonstrated a broad spectrum of activity against MDR Gram-negative bacteria, the initial trial will focus on the treatment of complicated urinary tract infections (cUTI). SPR994, enabled by Spero’s proprietary approach, has tailored release characteristics to potentially increase the efficacy of tebipenem for a given dose and reduce the frequency of dose administration.

About The Spero Potentiator Platform

Spero’s Potentiator Platform comprises novel compounds designed to specifically and potently interact with the lipopolysaccharide (LPS) in the outer membrane of Gram-negative bacteria. LPS acts as the persistent barrier to entry for many antimicrobial agents, including most Gram-positive antibiotics, and disruption of this barrier allows access to otherwise impermeable compounds. The Company’s product candidates generated from its Potentiator Platform are two IV-administered agents, SPR741 and SPR206, designed to treat MDR Gram-negative infections in the hospital setting. SPR741, its lead Potentiator candidate, has demonstrated *in vitro* the ability to expand the spectrum and increase the potency of a co-administered antibiotic against Gram-negative bacteria, including organisms identified by the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) as urgent and serious threats to human health. SPR741 has demonstrated an ability to potentiate over two dozen existing antibiotics by expanding their activity against Gram-negative pathogens. While previous attempts by others to develop agents that interact with the bacteria’s outer membrane using the mechanism of action employed by SPR741 have, to the Company’s knowledge, failed in preclinical testing and Phase 1 clinical trials due to safety concerns, data from the Company’s Phase 1 single- ascending dose and multiple-ascending dose clinical trial of SPR741 demonstrate it was well tolerated at single doses up to and including 800 mg and at doses up to and including 600 mg every 8 hours for 14 days. SPR206, Spero’s preclinical potentiator product candidate, is also designed to have antibiotic activity as a single agent against certain MDR and extremely drug resistant (XDR) bacterial strains.

About Spero

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

Spero is advancing SPR994, which is designed to be the first broad-spectrum oral antibiotic for use in adults to treat MDR Gram-negative infections.

Spero is also advancing its Potentiator Platform, which 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. The product candidates are two IV-administered agents, SPR741 and SPR206, designed to treat MDR Gram-negative infections in the hospital setting.

Spero is also developing 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 the Company's preclinical studies and clinical trials and the Company's research and development programs, the timing of clinical data, the Company's cash forecast and anticipated expenses and the sufficiency of the Company's cash resources. 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 the Company'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 United States Food and Drug Administration or equivalent foreign regulatory agencies; whether the Company'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" section of the Company's Registration Statement on Form S-1 initially filed with the Securities and Exchange Commission on October 6, 2017, as amended and in the form declared effective, and risks described in other filings the Company may make with the Securities and Exchange Commission in the future. The forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company 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 the Company's views as of any date subsequent to the date of this press release.

Spero Therapeutics
Condensed Consolidated Statement of Operations
(in thousand, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenue	$ 597	$ —	$ 986	$ —
Operating expenses:				
Research and development	6,910	6,005	20,366	19,406
General and administrative	3,653	1,909	8,350	5,005
Total operating expenses	10,563	7,914	28,716	24,411
Loss from operations	(9,966)	(7,914)	(27,730)	(24,411)
Other income (expense):	(2,110)	504	(3,597)	2816
Net loss attributable to common stockholders of Spero Therapeutics, Inc.	**$ (12,076)**	**$ (7,410)**	**$ (31,327)**	**$ (21,595)**
Net loss per share attributable to common stockholders, basic and diluted	**$ (36.02)**	**$ (23.23)**	**$ (93.96)**	**$ (70.15)**
Weighted average shares outstanding, basic and diluted	335,285	318,948	333,402	307,852

Spero Therapeutics
Condensed Consolidated Balance Sheet Data
(in thousand)
(Unaudited)

	September 30, 2017	**December 31, 2016**
Cash, cash equivalents and investments	$ 25,373	$ 10,315
Other assets	6,177	3,457
Total assets	**$ 31,550**	**$ 13,772**
Total liabilities	7,273	7,411
Total stockholder's equity	24,277	6,361
Total liabilities and stockholders' deficit	**$ 31,550**	**$ 13,772**

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Source: Spero Therapeutics, Inc.