



Spero Therapeutics Announces Second Quarter 2019 Operating Results and Provides Pipeline Update

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SPR994 pivotal Phase 3 cUTI trial enrollment continues; multiple clinical pipeline catalysts expected in 2H19

CAMBRIDGE, Mass., Aug. 08, 2019 (GLOBE NEWSWIRE) -- 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 (MDR) bacterial infections and rare diseases, today announced financial results for the second quarter ended June 30, 2019 and provided a pipeline review.

"In the second quarter we continued to advance our industry-leading pipeline through the initiation of enrollment in our SPR994 Phase 3 trial in cUTI and the expansion of our strategic partnerships and alliances to provide additional financial and research support for our pipeline products, SPR720 and SPR206," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "We had a significant presence in June at the ASM Microbe 2019 medical conference with twenty-two presentations, and we look forward to additional data announcements from our pipeline compounds in the second half of 2019."

Recent Clinical Highlights and Upcoming Milestones

SPR994:

Spero's lead product candidate, SPR994, has the potential to be the first oral carbapenem antibiotic approved for use in adults to treat MDR Gram-negative infections. A pivotal Phase 3 clinical trial of SPR994 for the treatment of complicated urinary tract infections (cUTI) entitled ADAPT-PO is currently enrolling patients. This Phase 3 clinical trial 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 with cUTI or acute pyelonephritis, randomized 1:1 in each arm. The Company continues to expect to receive pharmacokinetic data from a lead-in cohort of 70 patients in the second half of 2019 to confirm the dose and exposure of SPR994 in the cUTI patient population.

SPR720:

SPR720 is an orally administered antimicrobial agent being developed for the treatment of a rare, orphan disease, non-tuberculous mycobacterial (NTM) infections and other infections, including *Mycobacterium tuberculosis*. SPR720 is currently being evaluated in a double-blind, placebo-controlled Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics of SPR720 in healthy volunteers. Spero continues to expect to report top-line data from the Phase 1 clinical trial in the second half of 2019. Preclinical *in vitro* and *in vivo* studies have demonstrated the potency of SPR720 against clinically important mycobacteria, including NTM species *Mycobacterium avium* complex and *Mycobacterium abscessus*. In June 2019, SPR720 was the focus of an equity investment by the Novo REPAIR Impact Fund for up to \$10 million. Spero also entered into a collaboration with Bill & Melinda Gates Medical Research Institute (Gates MRI) to further the development of SPR720 for tuberculosis (TB) under which Gates MRI will conduct and fund preclinical and clinical studies for the development of SPR720 against TB as well as certain collaborative activities in furtherance of Gates MRI's charitable purposes.

SPR206:

SPR206 is an IV-administered product candidate from Spero's Potentiator Platform being developed as an innovative option to treat MDR Gram-negative bacterial infections. In preclinical studies, SPR206 showed activity as a single agent against MDR and extensively drug resistant (XDR) bacterial strains, including isolates of *Pseudomonas aeruginosa*, *Acinetobacter baumannii* and carbapenem-resistant *Enterobacteriaceae*, in both *in vitro* and *in vivo* models of infection. In July 2019, the U.S. Department of Defense awarded \$5.9 million to further clinical development of SPR206 against drug-resistant infections. SPR206 is currently being evaluated in a first-in-human Phase 1 clinical trial, designed as a double-blind, placebo-controlled, single and multiple ascending dose, multi-cohort study in healthy subjects. Spero continues to expect to report top-line data from this trial in the second half of 2019.

Second Quarter 2019 Financial Results

Spero reported a net loss for the second quarter ended June 30, 2019 of \$13.2 million or \$0.74 per common share, greater than the net loss reported for the same period in 2018 of \$10.0 million or \$0.69 per common share.

Total revenue for the second quarter of 2019 totaled \$2.1 million, higher than second quarter 2018 revenues of \$463,000, primarily due to funding for SPR994 received under our BARDA contract announced in July 2018 that awarded Spero up to \$44.2 million for qualified expenses for SPR994 development. In May 2019, Spero's contract with Biomedical Advanced Research and Development Authority (BARDA) was modified to include additional funding of \$2.5 million for SPR994, increasing the overall potential award to \$46.7 million.

Research and development expenses for the second quarter of 2019 of \$12.0 million were higher than \$7.4 million for the same period of 2018 due to greater spend on the SPR994, partially offset by lower spend on the Potentiator Platform product candidates. General and administrative expenses for the second quarter of 2019 of \$3.8 million were higher than \$3.1 million for the same period of 2018, primarily due to increased headcount and facility-related costs.

The Company continues to expect that its research and development expenses will increase throughout 2019 due to greater planned clinical spend

associated with the SPR994 pivotal ADAPT-PO trial as enrollment scales, as well as the SPR720 and SPR206 Phase 1 clinical trials, along with increased personnel spend to support such programs. The Company continues to expect general and administrative expenses to increase in 2019 due to additional headcount and professional fees required to support SPR994 as it advances through a Phase 3 clinical trial and prepares for possible regulatory approval and commercialization.

As of June 30, 2019, the Company had cash and cash equivalents of \$103.4 million, compared to \$106.4 million as of March 31, 2019. Consistent with previous guidance, Spero believes that its existing cash, cash equivalents and marketable securities, together with the initial funding committed under its BARDA award, will enable funding of operating expenses and capital expenditure requirements into the second half of 2020, including through the top-line data readout of the pivotal ADAPT-PO clinical trial of SPR994.

Upcoming Investor and Scientific Presentations

- Janney Healthcare Conference on September 10, 2019 in New York, NY
- Oppenheimer Fall Summit focused on Specialty Pharma & Rare Disease on September 23 – 24, 2019 in New York, NY
- 2019 Cantor Global Healthcare Conference on October 2 – 4, 2019 in New York, NY
- IDWeek 2019 on October 2 – 6, 2019 in Washington, DC
- Stifel Healthcare Conference on November 19 – 20, 2019 in New York, NY

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, 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 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, designed 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 SPR994 and ancillary supportive studies to be conducted in parallel with the 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; statements regarding management's assessment of the results of such preclinical studies and clinical trials; the timing of clinical data, including the availability of pharmacokinetic data from the lead-in cohort in the Phase 3 clinical trial of SPR994 and top-line data from the Phase 1 clinical trial of SPR720 and the Phase 1 clinical trial of SPR206; 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; 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 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 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
Senior Director, Investor Relations
857-242-1547
IR@sperotherapeutics.com

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,	
	2019	2018	2019	2018
Revenues:				

Grant revenue	\$ 2,089	\$ 463	\$ 6,000	\$ 1,616
Collaboration revenue	67	—	3,874	—
Total revenues	2,156	463	9,874	1,616
Operating expenses:				
Research and development	12,026	7,374	21,552	16,299
General and administrative	3,782	3,060	7,670	6,104
Total operating expenses	15,808	10,434	29,222	22,403
Loss from operations	(13,652)	(9,971)	(19,348)	(20,787)
Other income (expense)	502	15	1,126	187
Net loss attributable to common shareholders of Spero Therapeutics, Inc.	\$ (13,150)	\$ (9,956)	\$ (18,222)	\$ (20,600)
Net loss per share attributable to common shareholders per share, basic and diluted	\$ (0.74)	\$ (0.69)	\$ (1.04)	\$ (1.43)
Weighted average shares outstanding, basic and diluted:	17,667,620	14,376,529	17,445,600	14,372,876

Spero Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(Unaudited, Amounts In Thousands)

	June 30, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	\$ 103,408	\$ 115,443
Other assets	19,081	13,563
Total assets	\$ 122,489	\$ 129,006
Total liabilities	12,820	13,151
Total stockholder's equity	109,669	115,855
Total liabilities and stockholders' equity	\$ 122,489	\$ 129,006



Source: Spero Therapeutics, Inc.