# Spero Therapeutics Announces Third Quarter 2021 Operating Results and Provides Business Update

November 10, 2021

*Submitted NDA to U.S. FDA for tebipenem HBr for the treatment of complicated urinary tract infections, including pyelonephritis*

*Entered into a non-dilutive revenue interest financing agreement with HealthCare Royalty Partners® for up to $125 million*

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

CAMBRIDGE, Mass., Nov. 10, 2021 (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 bacterial infections and rare diseases, today announced financial results for the third quarter ended September 30, 2021, and provided a business update.

"During the quarter, we strengthened both our leadership team and financial position, while moving tebipenem HBr closer to a point where cUTI patients may soon have a solution to their existing unmet need," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero Therapeutics. "Chief among these accomplishments was our recent NDA submission for tebipenem HBr, which, if approved, would make it the first oral carbapenem antibiotic available for use in cUTI. We also entered into a revenue interest financing agreement with HealthCare Royalty Partners®, providing us with non-dilutive capital to support tebipenem HBr's anticipated launch and the development of our early-stage programs."

**Clinical Highlights and Upcoming Milestones**

**Tebipenem HBr:**

In October 2021, Spero submitted a new drug application (NDA) to the United States Food and Drug Administration (FDA), seeking approval for tebipenem HBr tablets for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by susceptible microorganisms. The NDA submission includes previously communicated positive data from ADAPT-PO showing the Phase 3 trial met its primary endpoint by demonstrating that oral tebipenem HBr was statistically non-inferior to intravenous (IV) ertapenem in the treatment of patients with cUTI and patients with acute pyelonephritis (AP). If approved, tebipenem HBr would be the only oral carbapenem antibiotic available for use in cUTI.

The Company expects a commercial launch for tebipenem HBr in the second half of 2022, subject to its approval by the FDA.

**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.

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. Spero then informed the FDA it had paused dosing in its Phase 2a clinical trial as a precautionary measure. In response, the Company subsequently 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 completed the non-human primate toxicology study in the third quarter, has finalized the study report, and initiated engagement with the FDA in the fourth quarter.

**SPR206:**

SPR206 is an IV-administered next generation polymyxin antibiotic candidate being developed as an innovative option to treat multi-drug resistant (MDR) Gram-negative bacterial infections. Data from a prior Phase 1 clinical trial showed that SPR206 was generally well tolerated with a lack of nephrotoxicity at predicted therapeutic dose levels.

SPR206 is currently being evaluated in two ongoing Phase 1 trials. 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 in early 2022. Funding for these studies is provided by the United States Department of Defense under Award Number W81XWH-1910295.

The SPR206 program is also supported by funding from the National Institute of Allergy and Infectious Diseases and is the subject of a license agreement with Pfizer Inc., which was made alongside Pfizer's previously announced $40 million equity investment in Spero. Pursuant to the licensing agreement between the parties, Spero granted Pfizer the rights to develop, manufacture, and commercialize SPR206 in ex-U.S. and ex-Asia territories. In exchange for these rights, Spero is eligible to receive up to $80 million in development and sales milestones, and high single digit to low double-digit royalties on net sales of SPR206 in these territories.

For more information on the BAL and renal impairment trials and their design see ***ClinicalTrials.gov*** identifiers ***NCT04868292*** (BAL trial) and ***NCT04865393*** (renal impairment trial).

**Corporate Highlights**

In September 2021, Spero entered into a non-dilutive revenue interest financing agreement with HealthCare Royalty Partners® for up to $125 million. Per the agreement, Spero received a $50 million upfront payment in October 2021. The Company is also due to receive an additional $50 million upon FDA approval of tebipenem HBr for a cUTI indication, and an additional $25 million upon the attainment of a prespecified commercial milestone and mutual agreement between Spero and HealthCare Royalty Partners®.

**Management Highlights**

Kathleen Tregoning joined Spero's Board of Directors on October 12, 2021. She has more than two decades of experience in biotechnology and public policy. Ms. Tregoning is currently the Chief Corporate Affairs Officer at Cerevel Therapeutics, with previous service at Sanofi, Biogen, and as a professional staff member for multiple committees in the United States Congress.

Jamie Brady joined Spero as Chief Human Resource Officer (CHRO) on September 20, 2021. He has nearly thirty years of senior human resources leadership experience within the life science space, including deep experience guiding companies building towards commercialization. Mr. Brady most recently served as CHRO of uniQure, with previous service at Intarcia Therapeutics and Genzyme.

David Musselman joined Spero as Senior Vice President, Sales and Market Access on October 6, 2021. He brings over twenty-three years of pharmaceutical and biotech experience and has extensive urology and commercial launch experience. Mr. Musselman most recently served as Vice President of Specialty Sales at Urovant, where he was responsible for building and executing on Urovant's first product launch. David also spent 13 years at Astellas where he was the Area Vice President and was responsible for leading a team of 275 sales professionals. He was also a Director of Regional Accounts at Astellas, where he led the payer team and was responsible for contracting and negotiation strategy across the company's urology, oncology, transplant, and antifungal franchises.

**Medical Congress Engagement**

Spero participated in three medical meetings during the quarter. In July 2021, Spero attended the 31st European Congress of Clinical Microbiology & Infectious Diseases, with a poster presentation, examining the effect of renal impairment on the PK of oral tebipenem, and another poster highlighting "Characterization of Resistance to DNA Gyrase Inhibitor SPR719 in Mycobacterium avium." In September 2021, Spero attended the American Urological Associations' 2021 Annual Meeting, as Spero launched its unbranded disease state campaign. Spero also attended The Infectious Diseases Society of America's (IDSA) IDWEEK™ 2021 in late September 2021, with twenty-three poster presentations, showcasing *in vitro* and *in vivo* studies of tebipenem HBr, and highlighting additional research on the epidemiology and management of cUTI.

**Third Quarter 2021 Financial Results**

Spero reported a net loss for the third quarter ended September 30, 2021, of $22.5 million or $0.70 per common share, compared to a net loss of $18.9 million or $0.86 per common share reported for the same period in 2020.

Total revenues for the third quarter of 2021 were $3.1 million, compared with revenues of $4.0 million in the third quarter of 2020. The revenue decrease was primarily due to a decrease in qualified expenses, incurred under the BARDA contract for tebipenem

HBr, partially offset by an increase in funding under our DoD agreement relating to SPR206.

Research and development expenses for the third quarter of 2021 were $14.4 million, compared with $17.7 million of research and development expenses for the same period of 2020. This year-over-year decrease was due to the completion of significant activities in the Phase 3 clinical trial for tebipenem HBr and decreased spending associated with the clinical hold on the Phase 2a clinical trial for SPR720, offset partially by increased clinical study costs for SPR206 and an increase in personnel costs associated with additional research and development headcount.

General and administrative expenses for the third quarter of 2021 of $11.2 million were higher than the $5.3 million reported in the same period of 2020, primarily due to an increase in headcount in commercial, general, and administrative functions, as well as an increase in professional and consultant fees, to support potential commercialization of tebipenem HBr.

As of September 30, 2021, Spero had cash, cash equivalents, and marketable securities of $123.4 million. Based on current projections, 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 fourth quarter of 2022. This forecast does not include either the $50 million in upfront proceeds from the revenue interest financing agreement with HealthCare Royalty Partners®, which were received after the quarter end, nor the additional $50 million milestone payment for potential approval of tebipenem HBr in 2022. These additional sources of liquidity, if approval for tebipenem HBr is achieved in 2022, should provide Spero with sufficient funding into the second half of 2023.

**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 800-263-0877 (domestic) or 646-828-8143 (international) and refer to conference ID 5314099. 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***. An archived webcast will be available on Spero's website for 30 days following the presentation.

**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.

**Department of Defense**
Select SPR206 studies are supported by the Office of the Assistant Secretary of Defense for Health Affairs, through the Joint Warfighter Medical Research Program under Award No. W81XWH 19 1 0295. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

**National Institute of Allergy and Infectious Disease**
Select SPR206 studies have been funded in whole or 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. 75N93021C00022.

**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 cUTI, including pyelonephritis. In October 2021, Spero filed an NDA for tebipenem HBr tablets, which included positive top-line results from its Phase 3 ADAPT-PO clinical trial of tebipenem HBr in cUTI and AP.

Tebipenem HBr is an investigational drug in the United States and is currently not approved for the treatment of complicated urinary tract infection, including pyelonephritis.

Spero is also developing SPR720 as a novel oral therapy product candidate for the treatment of a rare, orphan pulmonary disease caused by non-tuberculous mycobacterial infections.

Spero also has an IV-administered next generation polymyxin product candidate, SPR206, developed from its potentiator platform, which 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 the potential approval of tebipenem HBr by the FDA; the timing of launch of tebipenem HBr; the potential number of patients who

could be treated by tebipenem HBr and market demand for tebipenem HBr generally; the effectiveness of tebipenem HBr and its potential impact on healthcare resource utilizations; the anticipated shift from IV to oral administration, and the length of time for which Spero's cash resources are expected to be sufficient. 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 any delays in acceptance and review of the NDA submission by the FDA for any reason, including the COVID-19 pandemic; the timing and content of advice given and decisions made by regulators, including the FDA; 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'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**
**(in thousands, except share and per share data)**
**(unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Revenues: | | | | |
| Grant revenue | $ 2,356 | $ 3,957 | $ 12,698 | $ 7,165 |
| Collaboration revenue | 708 | 38 | 2,814 | 258 |
| Total revenues | 3,064 | 3,995 | 15,512 | 7,423 |
| Operating expenses: | | | | |
| Research and development | 14,436 | 17,706 | 47,301 | 53,798 |
| General and administrative | 11,152 | 5,309 | 28,680 | 13,942 |
| Total operating expenses | 25,588 | 23,015 | 75,981 | 67,740 |
| Loss from operations | (22,524) | (19,020) | (60,469) | (60,317) |
| Other income (expense) | 3 | 84 | (47) | 622 |
| Net loss | $ (22,521) | $ (18,936) | $ (60,516) | $ (59,695) |
| Deemed dividend | $ — | $ — | $ — | $ (549) |
| Net loss attributable to common shareholders of Spero Therapeutics, Inc. | $ (22,521) | $ (18,936) | $ (60,516) | $ (60,244) |
| Net loss per share attributable to common shareholders per share, basic and diluted | $ (0.70) | $ (0.86) | $ (1.99) | $ (2.91) |
| Weighted average shares outstanding, basic and diluted: | 32,132,500 | 21,933,922 | 30,417,305 | 20,712,720 |

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 123,417 | $ 126,906 |
| Other assets | 21,274 | 26,545 |
| **Total assets** | **$ 144,691** | **$ 153,451** |
| | | |
| Total liabilities | 32,796 | 21,411 |
| Total stockholder's equity | 111,895 | 132,040 |
| **Total liabilities and stockholders' equity** | **$ 144,691** | **$ 153,451** |

Source: Spero Therapeutics, Inc.