Spero Therapeutics Announces Third Quarter 2024 Operating Results and Provides a Business Update

Phase 3 PIVOT-PO trial of tebipenem HBr remains on track to complete enrollment in 2H 2025

Reiterate cash runway into mid-2026; Q3 2024 ending cash balance of $76.3M

CAMBRIDGE, Mass., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq: SPRO), a multi-asset clinical-stage biopharmaceutical company, focused on identifying and developing novel treatments for rare diseases and multi-drug resistant (MDR) bacterial infections, today announced financial results for the third quarter ended September 30, 2024, and provided a business update.

"Enrollment in the Phase 3 tebipenem HBr trial is progressing well, and we are on track to complete enrollment in the second half of 2025. Further, our work on the Phase 2 ready SPR206 program continues, contingent on availability of non-dilutive funding," said Sath Shukla, President and Chief Executive Officer of Spero. "With SPR720 development plans now suspended while we complete a review of the full dataset from the Phase 2a trial, our extended cash runway into mid-2026 and streamlined operations position us well to achieve our ultimate goal of delivering new therapies to patients in need."

Pipeline Update

Tebipenem HBr

Tebipenem HBr is an investigational oral carbapenem antibiotic being developed for the treatment of complicated urinary tract infections (cUTI) including acute pyelonephritis (AP) to help patients potentially avoid hospitalizations or reduce duration of in-patient therapy. Spero granted GSK an exclusive license to commercialize tebipenem HBr in all territories, except certain Asian territories.

- Enrollment on track in PIVOT-PO, the global Phase 3 clinical trial of tebipenem HBr in patients with cUTI. This randomized, double-blinded trial compares oral tebipenem HBr with intravenous imipenem cilastatin, in hospitalized adult patients with cUTI/AP. The primary endpoint is overall response (a combination of clinical cure and favorable microbiological response) at the Test-of-Cure (TOC) visit. Target enrollment for the trial is approximately 2,648 patients, with enrollment completion expected in the second half of 2025. For more information on PIVOT-PO, refer to ClinicalTrials.gov ID NCT06059846.

SPR206

SPR206 is an investigational, intravenously administered next-generation polymyxin that has shown antibiotic activity against MDR Gram-negative pathogens, including carbapenem-resistant Enterobacterales, *Acinetobacter baumannii* and *Pseudomonas aeruginosa* in preclinical studies.

- The U.S. Food and Drug Administration (FDA) has cleared the Company's IND for a Phase 2 trial in patients with hospital-acquired or ventilator-associated bacterial pneumonia (HABP/VABP). The Company maintains its guidance to initiate the trial contingent on availability of non-dilutive funding.

SPR720

SPR720 is an investigational oral, chemically stable phosphate ester prodrug that is converted rapidly in vivo to

SPR719, the active moiety. SPR719 targets the ATPase site of DNA gyrase B in mycobacteria.

- In October 2024, a planned interim analysis of the Phase 2a proof-of-concept study of SPR720 for the treatment of nontuberculous mycobacterial pulmonary disease (NTM-PD) demonstrated that the study did not meet its primary endpoint. While the data showed antimicrobial activity associated with SPR720, the interim analysis did not show sufficient separation from placebo and highlighted potential dose limiting safety issues in patients dosed at 1,000 mg orally once daily, including three cases of reversible grade 3 hepatotoxicity. In evaluating the totality of both the efficacy and safety data, the Company suspended its development program for SPR720 and will evaluate other potential paths forward as the remaining data are collected and analyzed.

Corporate Update

- In October 2024, following suspension of the current SPR720 development plans, Spero underwent a restructuring and reduction in force of approximately 39%, which extended the Company's cash runway into mid-2026.

Third quarter 2024 Financial Results

- Spero reported a net loss of $17.1 million, or ($0.32) per share of common stock, basic and diluted, for the third quarter ended September 30, 2024, compared with a net loss of $3.2 million, or ($0.06) per share of common stock, basic and diluted, for the third quarter ending September 30, 2023.
- Total revenue for the third quarter of 2024 was $13.5 million, compared with total revenue of $25.5 million for the third quarter of 2023. The revenue decrease for the third quarter of 2024 was primarily due to lower revenues related to ongoing collaborations.
- Research and development expenses for the third quarter of 2024 were $26.9 million, compared to $16.4 million of research and development expenses for the same period in 2023. The increase in research and development expenses year-over-year was primarily due to increased clinical trial expenses for PIVOT-PO.
- General and administrative expenses for the third quarter of 2024 were $5.2 million, compared to $5.7 million of general and administrative expenses for the same period in 2023. This year-over-year decrease was primarily due to decreased consulting and professional expenses.
- As of September 30, 2024, Spero had cash and cash equivalents of $76.3 million. Following the reduction in force and restructuring described above, Spero estimates that its existing cash and cash equivalents, together with earned and non-contingent development milestone payments from GSK, as well as other non-dilutive funding commitments, will be sufficient to fund its operating expenses and capital expenditures into mid-2026.

For further details on Spero's financials, refer to Spero's Quarterly Report on Form 10-Q, filed with the U.S. Securities and Exchange Commission (SEC) today.

About Spero Therapeutics

Spero Therapeutics, headquartered in Cambridge, Massachusetts, is a multi-asset clinical-stage biopharmaceutical company focused on identifying and developing novel treatments for rare diseases and MDR bacterial infections with high unmet need. For more information, visit www.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.

Tebipenem HBr Research Support

Select tebipenem HBr studies have been funded in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority, under contract number HHSO100201800015C.

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.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the timing, progress and results of Spero's preclinical studies, clinical trials and research and development programs; the potential benefits of any of Spero's current or future product candidates in treating patients; and Spero's strategy, goals and anticipated financial performance, milestones, business plans and focus. In some cases, forward-looking statements may be identified by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intent," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue," the negative of these terms or other similar expressions. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of important risks, uncertainties and other factors that may cause actual results to differ materially from those indicated by such forward looking statements, including whether tebipenem HBr, SPR720 and SPR206 will advance through the 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 FDA or equivalent foreign regulatory agencies; whether the FDA will ultimately approve tebipenem HBr and, if so, the timing of any such approval; whether the FDA will require any additional clinical data or place labeling restrictions on the use of tebipenem HBr that would delay approval and/or reduce the commercial prospects of tebipenem HBr; whether a successful commercial launch can be achieved and market acceptance of tebipenem HBr can be established; 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; Spero's need for additional funding; the ability to commercialize Spero's product candidates, if approved; Spero's ability to retain key personnel; Spero's leadership transitions; 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 SEC. The forward-looking statements included in this press release represent Spero's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Spero explicitly disclaims any obligation to update any forward-looking statements.

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

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 76,290	$ 76,333
Other assets	58,871	106,057
Total assets	**$ 135,161**	**$ 182,390**
Total liabilities	69,654	75,496
Total stockholder's equity	65,507	106,894
Total liabilities and stockholders' equity	**$ 135,161**	**$ 182,390**

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,	
	2024	2023	2024	2023
Revenues:				
Grant revenue	$5,650	$2,091	$14,893	$5,349
Collaboration revenue - related party	7,754	23,164	17,721	24,200
Collaboration revenue	65	218	319	710
Total revenues	13,469	25,473	32,933	30,259
Operating expenses:				
Research and development	26,864	16,393	67,921	34,883
General and administrative	5,198	5,708	16,648	19,121
Impairment of long-term asset	-	5,306	-	5,306
Total operating expenses	32,062	27,407	84,569	59,310
Loss from operations	(18,593)	(1,934)	(51,636)	(29,051)
Other income (expense)	1,156	940	3,668	2,877
Net loss	(17,437)	(994)	(47,968)	(26,174)
Income tax expense	290	(2,211)	290	(2,211)
Net loss	$(17,147)	$(3,205)	$(47,678)	$(28,385)
Net loss per share attributable to common shareholders per share, basic and diluted	$(0.32)	$(0.06)	$(0.89)	$(0.54)
Weighted average shares outstanding, basic and diluted:	54,124,862	52,710,280	53,869,824	52,603,709

SPERO THERAPEUTICS

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