



## Spero Therapeutics Announces First Quarter 2023 Operating Results and Provides a Business Update

*Phase 2 trial of SPR720 in nontuberculous mycobacterial pulmonary disease (NTM-PD) on track for top line data readout in 1H 2024*

*Update on status of Special Protocol Assessment agreement for tebipenem HBr program expected mid-year 2023; initiation of Phase 3 trial in complicated urinary tract infection (cUTI) expected in 2H 2023*

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

CAMBRIDGE, Mass., May 11, 2023 (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 rare diseases and multi-drug resistant (MDR) bacterial infections, today announced financial results for the first quarter ended March 31, 2023, and provided a business update.

"Momentum continues to build across our late-stage programs, each of which targets a clear medical need in an indication with a robust market and a favorable commercial landscape, ripe for innovation," said Ankit Mahadevia, M.D., Chief Executive Officer of Spero. "SPR720's Phase 2 clinical proof of concept trial in NTM-PD continues to advance, with a top line data readout expected in the first half of 2024. In parallel, we continue to engage with the FDA on a Special Protocol Assessment agreement for a pivotal Phase 3 trial of tebipenem HBr in cUTI, expected to start later this year. We also expect to file an IND for SPR206 in the fourth quarter of this year, preparing for a Phase 2 trial in participants with hospital-acquired or ventilator-associated bacterial pneumonia."

### **Program Highlights and Upcoming Anticipated Milestones**

#### **SPR720:**

- The Phase 2 clinical trial of SPR720, a potential novel first-line oral therapy for nontuberculous mycobacterial (NTM) infections, continues to enroll participants with more than 15 active sites and top line data expected in the first half of 2024. The trial is expected to enroll up to 35 treatment-naïve or treatment-inexperienced participants with NTM-PD due to *Mycobacterium avium* complex. The primary endpoint of the trial evaluates changes in bacterial load in sputum samples from baseline to the end of the 56-day treatment period. Key secondary endpoints include assessments of clinical response, quality of life, SPR720 pharmacokinetics, and safety and tolerability. For more information on the trial and its design, see [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05496374) identifier [NCT05496374](https://clinicaltrials.gov/ct2/show/study/NCT05496374).

#### **Tebipenem HBr:**

- Spero continues to engage with the U.S. Food and Drug Administration (FDA) regarding a potential Special Protocol Assessment (SPA) agreement for a planned pivotal Phase 3 trial of tebipenem HBr, an investigational drug being developed as the first potential oral carbapenem antibiotic for the treatment of cUTI, including pyelonephritis, caused by certain bacteria. During a previously completed Type A meeting, the FDA indicated that positive results from the planned Phase 3 trial, supported by confirmatory nonclinical evidence of efficacy, could be sufficient to support the approval of tebipenem HBr for the treatment of cUTI, including pyelonephritis, for a limited use indication. Spero expects to provide an update on the status of the SPA agreement and details of the design of the Phase 3 trial in mid-year 2023. Initiation of the Phase 3 trial is expected in the second half of 2023.

- The tebipenem HBr program is the subject of an exclusive license agreement with GSK. Pursuant to the license agreement, Spero received a \$66 million upfront payment from GSK and is eligible to receive up to \$525 million in development, sales, and commercial milestones payments, as well as low single-digit to low double-digit tiered royalties on net product sales. Spero expects to provide additional details on the specific regulatory and development activities that may trigger milestone payments in mid-year 2023. Additional information on the license agreement is available [here](#).

#### **SPR206:**

- Spero is preparing to advance SPR206, a novel, investigational, intravenously administered next generation polymyxin antibiotic being developed to treat MDR Gram-negative bacterial infections, into a Phase 2 trial in participants with hospital-acquired or ventilator-associated bacterial pneumonia. Spero expects to submit an investigational new drug (IND) application to the FDA to support this Phase 2 trial in the fourth quarter of 2023.

#### **Medical Congress Engagement**

- In April 2023, two posters with data characterizing the *in vitro* activity of SPR206 and comparator compounds were presented at the 33<sup>rd</sup> European Congress of Clinical Microbiology and Infectious Diseases. Copies of the posters are available on the [Posters & Publications](#) page of the Spero corporate website.

#### **First Quarter 2023 Financial Results**

Spero reported a net loss for the first quarter ended March 31, 2023, of \$13.3 million or \$0.25 per share of common stock, compared to a net loss of \$32.8 million or \$1.01 per share of common stock reported for the same period in 2022.

Total revenues for the first quarter of 2023 were \$2.1 million, compared with revenues of \$2.1 million in the first quarter of 2022. Although total revenues for the year-over-year comparison are approximately the same, grant revenue was approximately \$493 thousand lower for 2023, while collaboration revenue was approximately \$493 thousand higher, due to recognition of revenue related to the GSK transaction.

Research and development expenses for the first quarter of 2023 were \$9.0 million, compared with \$17.0 million of research and development expenses for the same period in 2022. This year-over-year decrease was primarily due to lower direct costs related to the tebipenem HBr program, decreased clinical activity related to the SPR206 program and decreased research and development headcount associated with the strategic restructuring announced in May 2022.

General and administrative expenses for the first quarter of 2023 of \$7.3 million were lower than the \$15.3 million reported in the same period in 2022, primarily as a result of decreased personnel related costs associated with a reduction in headcount in commercial, general and administrative functions arising from the May 2022 strategic restructuring and a decrease in professional and consultant fees.

As of March 31, 2023, Spero had cash and cash equivalents of \$96.3 million. Based on its current operating plans, Spero believes that its cash and cash equivalents, together with other non-dilutive funding commitments, will be sufficient to fund its operating expenses and capital expenditures beyond 2024.

#### **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 1-855-327-6837 (domestic) or 1-631-891-4304 (international) and refer to conference ID 10021779, or click on this [link](#) and request a return call. The conference call will also be webcast live and a link to the webcast can be accessed [here](#) and on Spero's

website at [www.sperotherapeutics.com](http://www.sperotherapeutics.com) on the "Events and Presentations" page under the "Connect" tab. An archived webcast will be available on Spero's website for 30 days following the presentation.

### **Tebipenem HBr Research Support**

Select tebipenem HBr studies have 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 number HHSO100201800015C.

### **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, headquartered in Cambridge, Massachusetts, is a multi-asset, clinical-stage biopharmaceutical company focused on identifying, developing, and commercializing novel treatments for bacterial infections, including multi-drug resistant bacterial infections and rare diseases.

- Spero Therapeutics is developing SPR720 as a novel oral therapy candidate for the treatment of a rare, orphan pulmonary disease caused by non-tuberculous mycobacterial infections.
- Tebipenem HBr is an investigational drug in the United States being developed for the treatment of cUTI, including pyelonephritis, caused by certain bacteria, in adult patients who have limited treatment options; tebipenem HBr is not FDA-approved.
- Spero Therapeutics also has an IV-administered next generation polymyxin product candidate, SPR206, developed from its potentiator platform, which is in development 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 design, initiation, timing, progress and results of Spero's preclinical studies and clinical trials and its research and development programs, statements about the regulatory path forward for tebipenem HBr and potential FDA approval, the potential receipt of milestone payments or royalties on under Spero's various license and collaboration agreements, and Spero's cash runway. 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 tebipenem HBr 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 Spero will satisfy all of the pre-conditions to receipt of the milestone payments under its various license and collaboration agreements; the lengthy, expensive, and uncertain process of clinical drug development for SPR720 and SPR206; 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; 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)

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
Revenues:		
Grant revenue	\$1,329	\$1,822
Collaboration revenue	740	247
Total revenues	2,069	2,069
Operating expenses:		
Research and development	8,979	16,971
General and administrative	7,317	15,305
Total operating expenses	16,296	32,276
Loss from operations	(14,227 )	(30,207 )
Other income (expense)	961	(2,622 )
Net loss	\$(13,266 )	\$(32,829 )
Net loss attributable to common shareholders of Spero Therapeutics, Inc.	\$(13,266 )	\$(32,829 )
Net loss per share attributable to common shareholders per share, basic and diluted	\$(0.25 )	\$(1.01 )
Weighted average shares outstanding, basic and diluted:	52,527,018	32,606,715

**Spero Therapeutics, Inc.****Condensed Consolidated Balance Sheet Data**

(in thousands)

(unaudited)

	<b>March 31,</b>	<b>December 31,</b>
	<b>2023</b>	<b>2022</b>
Cash, cash equivalents and marketable securities	\$96,254	\$109,107
Other assets	16,292	15,695
<b>Total assets</b>	<b>\$112,546</b>	<b>\$124,802</b>
Total liabilities	47,707	48,868
Total stockholder's equity	64,839	75,934
<b>Total liabilities and stockholders' equity</b>	<b>\$112,546</b>	<b>\$124,802</b>