Spero Therapeutics Announces First Quarter 2026 Operating Results and Provides Business Update

- *New Drug Application (NDA) for tebipenem HBr for complicated urinary tract infections (cUTI), including pyelonephritis, is under review at the FDA, with PDUFA date of June 18, 2026*
- *Spero maintains its cash runway guidance into 2028*

CAMBRIDGE, Mass., May 13, 2026 (GLOBE NEWSWIRE) -- Spero Therapeutics, Inc. (Nasdaq: SPRO), a clinical-stage biopharmaceutical company focused on identifying and developing novel treatments for rare diseases and diseases with high unmet need, today announced financial results for the first quarter ended March 31, 2026, and provided a business update.

"We continue to make solid progress on the tebipenem HBr program alongside our licensing partner, GSK, as we prepare for the FDA's decision expected in June," said Esther Rajavelu, President and CEO of Spero Therapeutics. "With GSK's leadership in anti-infectives, tebipenem HBr, if approved, has the potential to meaningfully improve treatment options for cUTI patients. Looking ahead, we are positioning the company for the next phase by advancing other corporate activities, including exploring opportunities to grow our portfolio of clinical-stage product candidates."

Program Update

Tebipenem HBr

Tebipenem HBr is an investigational oral carbapenem antibiotic being developed for the treatment of cUTI, including pyelonephritis, to provide an effective oral therapeutic alternative to IV carbapenems. Spero granted GSK an exclusive license to commercialize tebipenem HBr in all territories, except certain Asian territories where Meiji holds development and commercialization rights.

- In February 2026, GSK announced that the U.S. Food and Drug Association (FDA) set the Prescription Drug User Fee Act (PDUFA) date to complete the review of the tebipenem HBr NDA as June 18, 2026. The NDA was submitted by GSK in December 2025, supported by results from the Phase 3 PIVOT-PO trial. The trial was stopped early for efficacy in May 2025, demonstrating non-inferiority of tebipenem HBr compared to intravenous imipenem-cilastatin in hospitalized patients with cUTI, including pyelonephritis, based on the overall response (composite of clinical cure plus microbiological eradication of the bacteria causing the infection) at the test of cure visit.

- The safety and tolerability profile of tebipenem HBr in PIVOT-PO was consistent with results reported in other studies with tebipenem and in line with that of the carbapenem antibiotic class. The most frequently reported adverse events were diarrhea and headache; these events were all mild or moderate and non-serious.

- For more information on the PIVOT-PO trial, please refer to ClinicalTrials.gov ID NCT06059846.

First Quarter 2026 Financial Results

- Spero reported a net loss of $7.2 million for the first quarter of 2026 compared to a net loss of $13.9 million for the first quarter of 2025, or a diluted net loss per share of common stock of $0.13 and $0.25, respectively.

- Total revenue for the first quarter of 2026 was $0.3 million, compared to total revenue of $5.9 million for the first quarter of 2025.

- Research and development expenses for the first quarter of 2026 were $2.9 million, compared to $13.6 million of research and development expenses for the same period in 2025. The decrease was a result of decreased clinical activities related to our pivotal Phase 3 clinical trial of tebipenem HBr, which was stopped early for efficacy during the first half of 2025, and a decrease in personnel-related costs.

- General and administrative expenses for the first quarter of 2026 were $4.9 million, compared to $6.8 million of general and administrative expenses for the same period in 2025. The decrease was a result of decreased legal and personnel-related costs.

- As of March 31, 2026, cash and cash equivalents were $56.1 million.

- Spero maintains its cash runway guidance into 2028.

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.

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; and Biomedical Advanced Research and Development Authority, under contract number HHSO100201800015C.

About Spero Therapeutics

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

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 potential for tebipenem HBr to meaningfully improve treatment options for cUTI patients, if approved; the anticipated PDUFA date set by the FDA as June 18, 2026; Spero's exploration of opportunities to expand its portfolio of clinical stage product candidates; the potential of tebipenem HBr to be the first oral carbapenem antibiotic for US patients with cUTI, including pyelonephritis, and to set a new standard of care; the potential receipt of milestone payments under Spero's license and collaboration agreements; Spero's estimation that its cash and cash equivalents as of March 31, 2026 will be sufficient to fund operations into 2028; and the potential benefits of any of Spero's current or future product candidates in treating patients. 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 the FDA will ultimately approve tebipenem HBr and, if so, the timing of any such approval, taking into account the effects of possible regulatory delays; 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; Spero's reliance on third parties to manufacture, develop, and commercialize its product candidates, if approved; Spero's reliance on GSK, pursuant to the exclusive GSK License Agreement, to advance development of tebipenem HBr and GSK's right thereunder to determine, in its sole discretion, whether to further develop and commercialize tebipenem HBr; Spero's need for additional funding; Spero's ability to retain key personnel; whether Spero's cash resources will be sufficient to fund its continuing operations for the periods 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.

Investor Relations Contact:
Shai Biran, PhD
Spero Therapeutics
IR@Sperotherapeutics.com

Media Inquiries:
media@sperotherapeutics.com

-- Tables -

Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2026	December 31, 2025	$ Change
Cash and cash equivalents	$ 56,129	$ 40,265	$ 15,864
Other assets	2,892	28,654	(25,762)
Total assets	$ 59,021	$ 68,919	$ (9,898)
Total liabilities	6,087	9,898	(3,811)
Total stockholder's equity	52,934	59,021	(6,087)
Total liabilities and stockholders' equity	$ 59,021	$ 68,919	$ (9,898)

Spero Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,		
	2026	**2025**	**$ Change**
Revenues:			
Grant revenue	$ -	$ 763	$ (763)
Collaboration revenue - related party	258	5,099	(4,841)
Collaboration revenue	-	12	(12)
Total revenues	258	5,874	(5,616)
Operating expenses:			
Research and development	2,909	13,606	(10,697)
General and administrative	4,887	6,824	(1,937)
Restructuring	-	175	(175)
Total operating expenses	7,796	20,605	(12,809)
Loss from operations	(7,538)	(14,731)	7,193
Other income (expense)	335	865	(530)
Net loss	$ (7,203)	$ (13,866)	$ 6,663
Net loss per share attributable to common shareholders per share, basic and diluted	$ (0.13)	$ (0.25)	$ 0.12
Weighted average shares outstanding, basic and diluted:	57,281,570	55,376,188	1,905,382

SPERO THERAPEUTICS

5/13/2026 4:05:00 PM