Spero Therapeutics Announces Fourth Quarter and Full Year 2025 Operating Results and Provides a Business Update

- *Spero announced the resubmission of tebipenem HBr New Drug Application (NDA) to the FDA for complicated urinary tract infections (cUTI), including pyelonephritis in December 2025*
- *In February, Spero's licensing partner, GSK announced the FDA had set the PDUFA date as June 18, 2026*
- *Spero estimates cash and cash equivalents as of December 31, 2025 are sufficient to fund current operations into 2028*

CAMBRIDGE, Mass., March 26, 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 fourth quarter and full year ended December 31, 2025, and provided a business update.

"2025 was marked by important progress across the tebipenem HBr program in cUTI, including completion of the global Phase 3 trial and resubmission of the NDA," said Esther Rajavelu, President and CEO of Spero. "With our licensing partner GSK's global leadership in anti-infectives, tebipenem HBr, if approved, has the potential to address an important need and meaningfully improve treatment options for patients with cUTI. We look forward to the FDA's decision in late June as we continue to execute our business strategy to deliver innovative therapies."

Spero remains focused on completing its obligations under its License Agreement with GSK while advancing other corporate activities, including exploring opportunities to expand its 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 December 2025, GSK resubmitted the tebipenem HBr NDA to the FDA. In February 2026, GSK announced that the FDA set the Prescription Drug User Fee Act ("PDUFA") date as June 18, 2026. The NDA is supported by results from the successful Phase 3 PIVOT-PO trial that evaluated tebipenem HBr. The trial, which was stopped early for efficacy in May 2025, demonstrated 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. Detailed results were presented in a late-breaking oral abstract session at IDWeek 2025.
- 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.

Fourth Quarter and Full Year 2025 Financial Results

- Spero reported net income of $31.5 million for the fourth quarter of 2025 compared to a net loss of $(20.9) million

for the fourth quarter of 2024, or a diluted net gain and net income per share of common stock of $0.53 and a diluted net loss and net loss per share of common stock of $(0.38), respectively. Net income for the year ended December 31, 2025, was $8.6 million compared to a net loss for the year ended December 31, 2024, of $(68.6) million, or a diluted net gain per share of common stock of $0.15 and a diluted net loss per share of common stock of $(1.27), respectively.

- Total revenue for the fourth quarter of 2025 was $41.3 million, compared to total revenue of $15.0 million for the fourth quarter of 2024. The revenue increase for the fourth quarter of 2025 was primarily due to an increase in collaboration revenue from our agreements with GSK and Pfizer. Total revenue for the year ended December 31, 2025, was $66.8 million, compared to $48.0 million for the year ended December 31, 2024. The revenue increase for the year was primarily due to the aforementioned collaboration revenue related to our agreements with GSK and Pfizer.
- Research and development expenses for the fourth quarter of 2025 were $5.6 million, compared to $28.8 million of research and development expenses for the same period in 2024. Research and development expenses for the year ended December 31, 2025, were $38.5 million, compared to $96.8 million for the year ended December 31, 2024. The decrease in research and development expenses year-over-year was primarily due to decreased clinical trial activity related to the PIVOT-PO trial.
- General and administrative expenses for the fourth quarter of 2025 were $4.3 million, compared to $7.1 million of general and administrative expenses for the same period in 2024. This decrease was primarily due to decreased legal and personnel related costs. General and administrative expenses for the year ended December 31, 2025, were $21.2 million, compared to $23.7 million for the year ended December 31, 2024, with lower expenses in 2025 compared to 2024 primarily due to decreases in legal, consulting and personnel related costs.
- As of December 31, 2025, Spero had cash and cash equivalents of $40.3 million. Spero estimates that its cash and cash equivalents as of December 31, 2025 will be sufficient to fund current operations into 2028.
- In Q1 2026, Spero received a $25 milestone payment from GSK, triggered by the tebipenem HBr NDA resubmission.

For further details on Spero's financials, refer to Spero's Annual Report on Form 10-K, 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 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 December 31, 2025 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 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.

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

	December 31, 2025	December 31, 2024	Change
Cash, cash equivalents and marketable securities	$ 40,265	$ 52,889	$ (12,624)
Other assets	28,654	57,654	(29,000)
Total assets	**$ 68,919**	**$ 110,543**	**$ (41,624)**
Total liabilities	$ 9,898	$ 64,420	$ (54,522)
Total stockholder's equity	59,021	46,123	12,898
Total liabilities and stockholders' equity	**$ 68,919**	**$ 110,543**	**$ (41,624)**

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

	Three Months Ended December 31,		Year Ended December 31,		
	2025	**2024**	**2025**	**2024**	**$ Change**
Revenues:					
Grant revenue	$ 1,639	$ 5,688	$ 7,183	$ 20,581	$ (13,398)
Collaboration revenue - related party	27,084	9,304	47,033	27,025	20,008
Collaboration revenue	12,574	52	12,586	371	12,215
Total revenues	41,297	15,044	66,802	47,977	18,825
Operating expenses:					
Research and development	5,592	28,836	38,467	96,757	(58,290)
General and administrative	4,300	7,056	21,176	23,704	(2,528)
Impairment of long-term asset	-	-	587	-	587
Restructuring	-	877	258	877	(619)
Total operating expenses	9,892	36,769	60,488	121,338	(60,850)
Income (loss) from operations	31,405	(21,725)	6,314	(73,361)	79,675
Other income, net	376	1,127	2,519	4,795	(2,276)
Net income (loss) before income taxes	31,781	(20,598)	8,833	(68,566)	77,399
Income tax expense	(261)	(290)	(261)	-	(261)
Net income (loss) attributable to common shareholders of Spero Therapeutics, Inc.	$ 31,520	$ (20,888)	$ 8,572	$ (68,566)	$ 77,138
Net income (loss) per share attributable to common shareholders per share, basic	$ 0.56	$ (0.38)	$ 0.15	$ (1.27)	
Net income (loss) per share attributable to common shareholders per share, diluted	$ 0.53	$ (0.38)	$ 0.15	$ (1.27)	
Weighted average shares outstanding, basic:	56,020,363	54,538,547	56,020,363	54,037,917	
Weighted average shares outstanding, diluted:	59,368,159	54,538,547	59,039,225	54,037,917	

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