



Septerna Highlights Business Progress and Reports First Quarter 2025 Financial Results

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Announced Global Collaboration with Novo Nordisk to Develop Oral Small Molecules for Metabolic Diseases with Over \$2.2 Billion in Potential Milestone Payments

On Track to Select a Next-Generation Oral Small Molecule PTH1R Agonist to Accelerate Toward the Clinic Later in 2025

Expect to Initiate Phase 1 Trial for SEP-631, MRGPRX2 NAM Program for Mast Cell Diseases, in Third Quarter of 2025

Ended First Quarter 2025 with \$398.2 Million in Cash, Cash Equivalents and Marketable Securities; Novo Nordisk Collaboration to Significantly Extend Prior Runway Guidance of Early 2028

SOUTH SAN FRANCISCO, Calif., May 15, 2025 (GLOBE NEWSWIRE) -- Septerna, Inc. (Nasdaq: SEPN), a biotechnology company pioneering a new era of G protein-coupled receptor (GPCR) drug discovery, today highlighted key business updates and upcoming milestones and reported financial results for the first quarter ended March 31, 2025.

"Yesterday's landmark partnership announcement with Novo Nordisk to advance our incretin programs is an important validation of our GPCR Native Complex Platform™ and its potential to address major unmet needs in metabolic disease," said Jeffrey Finer, M.D., Ph.D., chief executive officer and co-founder of Septerna. "This collaboration provides a significant opportunity to create multiple potentially groundbreaking oral medicines, while also providing Septerna with substantial resources and operational flexibility to advance our diverse portfolio. In parallel, we continue to advance our wholly owned pipeline, including our next-generation oral small molecule PTH1R agonist for hypoparathyroidism, where we remain on track to select a development candidate to advance toward the clinic later this year. Additionally, our SEP-631 program targeting mast cell diseases is progressing well, with clinical trial initiation expected in the third quarter of this year. With a strong balance sheet, a differentiated technology platform, and a clear focus on execution, we believe we are well positioned to create long-term value for patients and shareholders."

Corporate Overview and Anticipated Milestones

- **PTH1R Agonist Program:**
 - Septerna continues to advance multiple lead compounds with distinct chemical structures unrelated to its first-generation oral small molecule, SEP-786, each with favorable pharmacokinetics (PK) profiles that support the potential for full-day calcium control in hypoparathyroidism patients with either once- or twice-daily dosing. Septerna plans to select a next-generation parathyroid hormone 1 receptor (PTH1R) agonist candidate to accelerate toward the clinic by the end of 2025.
- **SEP-631 MRGPRX2 NAM Program:**
 - Septerna anticipates initiating a Phase 1 clinical trial to assess safety, tolerability, PK, and pharmacodynamics (through an icatibant skin challenge) of SEP-631 in healthy volunteers in the third quarter of 2025. SEP-631 is a selective oral small molecule MRGPRX2 negative allosteric modulator (NAM) in development for the treatment of mast cell diseases, including chronic spontaneous urticaria.
- **TSHR NAM Program:**
 - Septerna continues to progress several TSHR NAM lead compounds, designed to be a disease-modifying treatment for Graves' disease and thyroid eye disease, towards selection of a development candidate.

Collaboration Agreement with Novo Nordisk

- On May 14, 2025, Septerna and Novo Nordisk [announced](#) a global collaboration agreement to discover, develop and commercialize multiple potential oral small molecule medicines for obesity, type 2 diabetes and other cardiometabolic diseases based on certain specified molecular targets. The companies will initially commence four simultaneous research and development (R&D) programs for small molecule therapies directed to one or more select GPCR targets, including the GLP-1, GIP and glucagon receptors.
- Under the terms of the agreement, Septerna is eligible to receive approximately \$2.2 billion from Novo Nordisk across an upfront payment and research, development and commercial milestone payments. This includes more than \$200 million in upfront and near-term milestone payments. Septerna is also eligible to receive tiered royalties on global net sales of marketed products.
- Novo Nordisk will cover all R&D expenses for partnered programs under the collaboration. In addition, Septerna has the right to opt-in to a worldwide profit-share for one program, in lieu of future milestones and royalties for that product candidate. More details can be found in the Current Report on [Form 8-K](#) filed on May 14, 2025.

First Quarter 2025 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities totaled \$398.2 million as of March 31, 2025. Septerna expects the upfront payment from the collaboration with Novo Nordisk to significantly extend its prior cash runway guidance of early 2028 and plans to provide updated guidance following the closing of the collaboration agreement.
- **R&D Expenses:** R&D expenses were \$19.3 million for the quarter ended March 31, 2025, compared to \$13.2 million for the quarter ended March 31, 2024.
- **G&A Expenses:** General and administrative (G&A) expenses were \$6.9 million for the quarter ended March 31, 2025, compared to \$2.7 million for the quarter ended March 31, 2024.
- **Net Loss:** Net loss was \$21.5 million for the quarter ended March 31, 2025, compared to \$14.2 million for the quarter ended March 31, 2024.

About Septerna

Septerna, Inc. is a biotechnology company pioneering a new era of GPCR drug discovery powered by its proprietary Native Complex Platform™. Its industrial-scale platform aims to unlock the full potential of GPCR therapies and has led to the discovery and development of its deep pipeline of oral small molecule product candidates focused initially on treating patients in three therapeutic areas: endocrinology, immunology and inflammation, and metabolic diseases. Septerna was launched by preeminent drug discovery company builders and scientific leaders in the biochemistry, structural biology, and pharmacology of GPCRs. For more information, please visit www.septerna.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, implied and express statements about Septerna's beliefs and expectations regarding: the expectations regarding the timing and closing of the collaboration agreement with Novo Nordisk, including the expiration or termination of the waiting period (and any extension thereof) under the Hart-Scott-Rodino Antitrust Improvements Act of 1976; the intended and potential benefits of the collaboration with Novo Nordisk, including the receipt of expected upfront payment upon the effectiveness of the collaboration agreement and potential milestone and royalty payments from commercial product sales, along with tiered royalties based on global net sales, if any; the continued development and advancement of Septerna's oral small molecule GPCR-targeted programs; its ability to demonstrate, and the timing of, preclinical proof-of-concept *in vivo* and *ex vivo* for multiple programs, including Septerna's plan to select a next-generation PTH1R product candidate to accelerate toward the clinic later this year; its ability to advance any product candidates that it may identify and successfully complete any clinical studies; the initiation, timing, progress, and results of conducting its research and development programs, including its plans to initiate a clinical trial for SEP-631 in the third quarter of this year; the potential of its proprietary Native Complex Platform™; its expectations regarding the implementation of its business model, strategic plans for its business, product candidates, and technology, and the accuracy of its estimates regarding expenses and capital requirements, including its expected cash runway being significantly beyond Septerna's prior guidance of into early 2028. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: uncertainties related to achieving the future potential research, development, and commercial milestones under the Novo Nordisk collaboration; uncertainties related to Septerna's product candidates entering clinical trials; the authorization, initiation, and successful completion of preclinical and Investigational New Drug (IND)-enabling studies to support future clinical development of potential product candidates (including those for the PTH1R program), including uncertainties related to opening INDs and obtaining regulatory approvals; risks related to clinical development outcomes including unexpected safety or efficacy findings; the results of preclinical studies, or clinical studies not being predictive of future results in connection with future studies; the scope of protection Septerna is able to establish and maintain for intellectual property rights covering its Native Complex Platform™ and its product candidates; Septerna's ability to identify and enter into future license agreements and collaborations; and general economic, industry and market conditions. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Septerna's Annual Report on Form 10-K for the year ended December 31, 2024, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Septerna's views only as of today and should not be relied upon as representing its views as of any subsequent date. Septerna explicitly disclaims any obligation to update any forward-looking statements subject to any obligations under applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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SEPTERNA, INC.

Condensed Statements of Operations
(In thousands, except for share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2025	2024
Revenue	\$ 219	\$ 317
Operating expenses:		
Research and development	19,271	13,153
General and administrative	6,858	2,654
Total operating expenses	<u>26,129</u>	<u>15,807</u>
Loss from operations	(25,910)	(15,490)
Interest and other income, net	4,434	1,231
Benefit for income taxes	—	93
Net loss attributable to common stockholders	<u>\$ (21,476)</u>	<u>\$ (14,166)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.49)</u>	<u>\$ (6.35)</u>
Weighted-average shares outstanding, basic and diluted	<u>43,937,410</u>	<u>2,232,246</u>

SEPTERNA, INC.

Condensed Balance Sheets
(In thousands)
(Unaudited)

	March 31, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	\$ 398,247	\$ 420,789
Working capital ⁽¹⁾	331,831	343,975
Total assets	434,020	456,554
Total liabilities	33,754	36,507
Additional paid-in capital	539,874	538,321
Accumulated deficit	(139,850)	(118,374)
Total stockholders' equity	<u>\$ 400,266</u>	<u>\$ 420,047</u>

1. Working capital is defined as total current assets less total current liabilities. See our financial statements and the related notes thereto included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025 for further details regarding our current assets and current liabilities.