



Septerna Highlights Company Progress and Reports Third Quarter 2025 Financial Results

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SEP-479 Selected as Next-Generation Oral PTH1R Agonist Development Candidate

SEP-631 (MRGPRX2 NAM) Phase 1 Clinical Trial in Healthy Volunteers Ongoing

Robust Financial Position of \$561.6 Million Expected to Support Operations at Least into 2029

SOUTH SAN FRANCISCO, Calif., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Septerna, Inc. (Nasdaq: SEPN), a clinical-stage 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 quarter ended September 30, 2025.

"In the third quarter, we made meaningful progress across our portfolio, highlighted by the selection of SEP-479 as our next-generation PTH1R agonist development candidate for hypoparathyroidism and the initiation of our Phase 1 clinical trial for SEP-631 which targets MRGPRX2 for mast cell-driven diseases," said Jeffrey Finer, M.D., Ph.D., chief executive officer and co-founder of Septerna. "Both programs exemplify the power of our Native Complex Platform™ to generate differentiated oral small-molecule GPCR therapies with the potential to address serious diseases across a range of indications. With multiple milestones anticipated in the first half of 2026, we are executing with focus and momentum as we work to deliver meaningful therapies for patients."

Corporate Overview and Anticipated Milestones

- **SEP-479 PTH1R Agonist for Hypoparathyroidism:**
 - In September, Septerna announced the selection of SEP-479 as its next-generation, oral PTH1R agonist development candidate. In a seven-day study in healthy cynomolgus monkeys, SEP-479 demonstrated robust, dose-dependent increases in serum calcium and decreases in endogenous parathyroid hormone levels. Based on preclinical studies from multiple species, SEP-479 is projected to have a human half-life supportive of once-daily dosing, aligned with the company's goal of providing full-day calcium control for patients with hypoparathyroidism.
 - Following the successful completion of the remaining preclinical development activities, Septerna plans to initiate a Phase 1 clinical trial for SEP-479 in the first half of 2026.
- **SEP-631 MRGPRX2 NAM for Mast Cell Diseases:**
 - A Phase 1 clinical trial of SEP-631, an oral small-molecule MRGPRX2 negative allosteric modulator (NAM) for the treatment of mast cell diseases including chronic spontaneous urticaria, is ongoing in healthy volunteers. The study is evaluating safety, tolerability, pharmacokinetics, and pharmacodynamics (through an icatibant skin challenge), with initial single-ascending-dose and multiple-ascending-dose data expected in the first half of 2026.
- **TSHR NAM Program:**
 - Septerna continues to make progress toward the selection of a development candidate for its TSHR NAM program, with the goal of delivering a potential disease-modifying oral treatment for Graves' disease and thyroid eye disease.
- **Discovery Programs:**
 - The company also continues to advance discovery-stage programs utilizing its Native Complex Platform™ across multiple therapeutic areas.

Business Highlights

- In July, Septerna's global collaboration and license agreement with Novo Nordisk formally commenced, with joint research and development activities underway to discover and develop oral small-molecule therapies for obesity, type 2 diabetes, and other cardiometabolic diseases.
- In September, Septerna appointed Keith Gottesdiener, M.D., to its Board of Directors, where he will serve as chairperson of the newly formed R&D Committee. Dr. Gottesdiener brings more than 30 years of experience advancing medicines from discovery through commercialization, including leadership roles at Prime Medicine, Rhythm Pharmaceuticals, and Merck Research Laboratories. His appointment further strengthens Septerna's scientific and strategic leadership as the company advances its pipeline of potential GPCR-targeted therapies.

Third Quarter 2025 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities totaled \$561.6 million as of September 30, 2025,

reflecting receipt of the \$195.0 million upfront payment from Novo Nordisk and a \$12.5 million milestone payment from Vertex. Septerna expects its existing cash runway to fund operations into at least 2029.

- **Revenue:** Revenue was \$21.5 million for the quarter ended September 30, 2025, compared to \$0.2 million for the quarter ended September 30, 2024. For the quarter ended September 30, 2025, revenue included the amortization of \$12.8 million of the \$195.0 million upfront payment received from Novo Nordisk in July 2025, as well as \$8.5 million for research services associated with the Novo Nordisk collaboration.
- **R&D Expenses:** Research and development (R&D) expenses were \$24.3 million for the quarter ended September 30, 2025, compared to \$17.8 million for the quarter ended September 30, 2024.
- **G&A Expenses:** General and administrative (G&A) expenses were \$7.1 million for the quarter ended September 30, 2025, compared to \$4.9 million for the quarter ended September 30, 2024.
- **Net Income (Loss):** Net income was \$8.2 million for the quarter ended September 30, 2025, compared to \$20.5 million in net loss for the quarter ended September 30, 2024.

About Septerna

Septerna, Inc. is a clinical-stage biotechnology company with a world-class team of GPCR experts and drug developers advancing cutting-edge science to unlock the full potential of GPCR therapies for patients with significant unmet needs. The company's proprietary Native Complex Platform™ is designed to enable new approaches to GPCR drug discovery and has led to the development of a diverse pipeline of novel oral small molecule drug candidates. Septerna is advancing programs in endocrinology, immunology and inflammation, metabolic diseases and additional therapeutic areas, both independently and with partners. 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 continued advancement of Septerna's PTH1R agonist program, including the planned initiation of a Phase 1 clinical trial for SEP-479 in the first half of 2026, subject to successful completion of preclinical activities and regulatory submissions; the continued development and advancement of SEP-631, including the ongoing Phase 1 clinical trial and timing of initial data expected in the first half of 2026 for the Phase 1 single-ascending-dose and multiple-ascending-dose cohorts; its ability to demonstrate, and the timing of, preclinical proof-of-concept *in vivo* and *ex vivo* for multiple programs; 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 advance multiple lead TSHR NAM program compounds toward development candidate selection; the potential of its proprietary Native Complex Platform™; the collaboration with Novo Nordisk, including its to jointly discover, develop and commercialize multiple potential oral small molecule therapies for obesity, type 2 diabetes, and other cardiometabolic diseases; 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 at least into 2029. 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: Septerna's product candidates successfully entering and advancing through clinical trials (including SEP-479 and SEP-631); 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 SEP-479), including uncertainties related to opening INDs and other 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 clinical outcomes; risks related to the timing of initiating clinical studies and future availability of clinical data; 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 maintain existing collaborations, identify and enter into future license agreements and collaborations, and realize the intended and potential benefits thereof; unanticipated future expense levels and capital requirements; 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	\$ 21,495	\$ 176	\$ 21,833	\$ 863
Operating expenses:				
Research and development	24,264	17,832	65,723	46,020
General and administrative	7,117	4,894	20,884	10,948
Gain on sale of non-financial asset	(12,500)	—	(12,500)	—
Total operating expenses	<u>18,881</u>	<u>22,726</u>	<u>74,107</u>	<u>56,968</u>
Income (loss) from operations	2,614	(22,550)	(52,274)	(56,105)
Interest and other income, net	5,559	1,891	14,133	4,637
Benefit for income taxes	—	136	—	338
Net income (loss) attributable to common stockholders	<u>\$ 8,173</u>	<u>\$ (20,523)</u>	<u>\$ (38,141)</u>	<u>\$ (51,130)</u>
Net income (loss) per share attributable to common stockholders, basic	<u>\$ 0.18</u>	<u>\$ (8.40)</u>	<u>\$ (0.86)</u>	<u>\$ (21.87)</u>
Net income (loss) per share attributable to common stockholders, diluted	<u>\$ 0.18</u>	<u>\$ (8.40)</u>	<u>\$ (0.86)</u>	<u>\$ (21.87)</u>
Weighted-average shares outstanding, basic	<u>44,343,085</u>	<u>2,443,678</u>	<u>44,150,041</u>	<u>2,337,891</u>
Weighted-average shares outstanding, diluted	<u>45,602,099</u>	<u>2,443,678</u>	<u>44,150,041</u>	<u>2,337,891</u>

Condensed Balance Sheets

(In thousands)
(Unaudited)

	September 30, 2025	December 31, 2024
Cash, cash equivalents and marketable securities	\$ 561,558	\$ 420,789
Working capital ⁽¹⁾	416,399	343,975
Total assets	606,653	456,554
Total liabilities	217,922	36,507
Additional paid-in capital	544,826	538,321
Accumulated deficit	(156,515)	(118,374)
Total stockholders' equity	388,731	420,047

1. Working capital is defined as total current assets less total current liabilities. See our condensed financial statements and the related notes thereto included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025 for further details regarding our current assets and current liabilities.