Septerna Highlights Business Progress and Reports First Quarter 2026 Financial Results

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Compelling Phase 1 Data for SEP-631 (MRGPRX2 NAM) in Healthy Volunteers Support Phase 2b Development, Initially in Chronic Spontaneous Urticaria (CSU) in Second Half of 2026

Phase 1 Clinical Trial Initiated for SEP-479, Oral Small Molecule PTH1R Agonist for Hypoparathyroidism

Cash Position of $522.1 Million Expected to Support Operating Plans at Least into 2029

SOUTH SAN FRANCISCO, Calif., May 11, 2026 (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 pipeline progress and anticipated milestones and reported financial results for the first quarter ended March 31, 2026.

“In the first quarter, we continued to make meaningful progress across our pipeline, highlighted by positive Phase 1 clinical results for SEP-631 and the initiation of our Phase 1 clinical trial for SEP-479,” said Jeffrey Finer, M.D., Ph.D., chief executive officer and co-founder of Septerna. “These advances further validate our Native Complex Platform® and its ability to efficiently generate differentiated oral small molecules against historically challenging GPCR targets. As our clinical programs continue to advance, we believe Septerna is increasingly well positioned to unlock the broad therapeutic potential of GPCR-targeted medicines for patients with significant unmet need.”

Recent Portfolio Progress and Anticipated Milestones

- **SEP-479 PTH1R Agonist for Hypoparathyroidism:**
  - In April 2026, Septerna initiated a Phase 1 clinical trial of SEP-479, its potent, selective oral small molecule PTH1R agonist for the treatment of hypoparathyroidism. The single-ascending dose and multiple-ascending dose study is evaluating safety, tolerability, pharmacokinetics and pharmacodynamics (including serum calcium and endogenous serum PTH) in healthy volunteers, with data expected in late 2026 or early 2027.
- **SEP-631 MRGPRX2 NAM for Mast Cell-Driven Diseases:**
  - In March 2026, Septerna presented positive Phase 1 clinical results for SEP-631, its oral small molecule MRGPRX2 negative allosteric modulator (NAM), supporting advancement into Phase 2 development. SEP-631 was well tolerated, demonstrated a pharmacokinetic profile supportive of once-daily oral dosing and produced robust, dose-dependent suppression of icatibant-induced skin wheal formation.
  - Septerna continues preparations to initiate a Phase 2b trial of SEP-631 in chronic spontaneous urticaria (CSU) in the second half of 2026, following completion of long-term toxicology studies. The Company expects to subsequently evaluate SEP-631 in an open-label study in chronic inducible urticaria patients with symptomatic dermatographism. Septerna is also assessing additional mast cell-driven diseases characterized by high unmet need.
- **TSHR NAM Program:**
  - Septerna continues to progress toward development candidate selection for its TSHR NAM program, with the goal of delivering a potential disease-modifying oral treatment for Graves’ disease and thyroid eye disease.
- **Additional Programs:**
  - Septerna continues to advance and achieve research milestones from its global collaboration with Novo Nordisk to discover, develop and commercialize multiple potential oral small molecule medicines for obesity, type 2 diabetes and other cardiometabolic diseases based on specified GPCR targets.
  - The Company also continues to advance wholly-owned discovery-stage programs utilizing its Native Complex Platform® across multiple therapeutic areas.

Corporate Update

- Septerna’s Chief Medical Officer, Jae Kim, M.D., has informed the Company of his decision to pursue a new opportunity located in Southern California near his primary residence. Septerna has initiated a search for a successor, and Dr. Kim will continue to serve in an advisory capacity during the transition period.

First Quarter 2026 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities totaled $522.1 million as of March 31, 2026. Septerna expects its existing cash runway to fund operations at least into 2029.
    - **Revenue:** Revenue from the Novo Nordisk collaboration was $26.5 million for the quarter ended March 31, 2026, compared to $0.2 million from Vertex for the quarter ended March 31, 2025. Revenue for the quarter ended March 31, 2026, included the amortization of $15.7 million of the $195.0 million from the upfront payment and $0.5 million from the achievement of $2.0 million in research milestones in addition to $10.3 million for research services associated with the collaboration.
- **R&D Expenses**: Research and development (R&D) expenses were $29.5 million for the quarter ended March 31, 2026, compared to $19.3 million for the quarter ended March 31, 2025.
- **G&A Expenses:** General and administrative (G&A) expenses were $10.3 million for the quarter ended March 31, 2026, compared to $6.9 million for the quarter ended March 31, 2025.
- **Net Loss:** Net loss was $8.6 million for the quarter ended March 31, 2026, compared to $21.5 million for the quarter ended March 31, 2025.

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 potential of SEP-479 preclinical data to translate into similar clinical safety, pharmacokinetic, and pharmacodynamic findings; the estimated availability of SEP-479 Phase 1 clinical data in late 2026 or early 2027; the potential for SEP-479 to be a differentiated once-daily oral therapy for patients with hypoparathyroidism; the potential of its proprietary Native Complex Platform®; the continued advancement of SEP-631, including the plan to initiate a Phase 2b clinical study in CSU in the second half of 2026 subject to the successful completion of long-term preclinical toxicology studies; the role of MRGPRX2 in mast cell-driven diseases; the potential of SEP-631 to provide a convenient oral treatment option for patients with CSU and other mast cell-driven diseases; expectations regarding the anticipated once-daily dosing frequency of SEP-631; the ability of the SEP-631 Phase 1 safety and efficacy observations to successfully translate into clinical outcomes in patients; the continued development of its TSHR NAM program; the advancement of its discovery-stage programs across multiple therapeutic areas; the size and growth potential of the markets for its current and future product candidates; its expectations regarding strategic plans for its business, product candidates, and technology; its expectations regarding the company's uses of capital, expenses and financial results, including its expected cash runway at least into 2029; and the scope of protection it is able to establish and maintain for intellectual property rights covering its Native Complex Platform® and its product candidates. 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 those for SEP-479 and SEP-631) including uncertainties related to opening INDs and obtaining other regulatory approvals; risks related to clinical development outcomes including unexpected safety or efficacy findings; the results of preclinical studies including the long-term toxicology studies for SEP-479 and SEP-631, 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; and 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, 2025, 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)

	March 31,	
	2026	**2025**
Revenue	$ 26,523	$ 219
Operating expenses:		
Research and development	29,535	19,271
General and administrative	10,288	6,858
Total operating expenses	39,823	26,129
Loss from operations	(13,300)	(25,910)
Interest and other income, net	5,000	4,434
Provision for income taxes	(337)	—
Net loss attributable to common stockholders	$ (8,637)	$ (21,476)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.19)	$ (0.49)
Weighted-average shares outstanding, basic and diluted	44,758,800	43,937,410

SEPTERNA, INC.

Condensed Balance Sheets
(In thousands)
(Unaudited)

	March 31, 2026	**December 31, 2025**
Cash, cash equivalents and marketable securities	$ 522,092	$ 548,658
Working capital[(1)]	289,893	324,033
Total assets	569,688	596,187
Total liabilities	191,230	214,261
Additional paid-in capital	554,872	548,517
Accumulated deficit	(175,890)	(167,253)
Total stockholders' equity	$ 378,458	$ 381,926

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, 2026 for further details regarding our current assets and current liabilities.