



Septerna Provides Corporate Overview and Reports Fourth Quarter and Full Year 2024 Financial Results

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Preclinical Work Advancing with Plans to Select a Next-Generation Oral Small Molecule PTH1R Agonist to Accelerate Toward the Clinic Later This Year

Phase 1 Trial for SEP-631, MRGPRX2 NAM Program for Mast Cell Diseases, Expected to Initiate in 2025

Well-Capitalized with \$420.8M Balance Sheet as of YE 2024 to Support Operating Runway into Early 2028

SOUTH SAN FRANCISCO, Calif., March 27, 2025 (GLOBE NEWSWIRE) -- [Septerna, Inc.](#) (Nasdaq: SEPN), a biotechnology company pioneering a new era of G protein-coupled receptor (GPCR) drug discovery, today provided a corporate overview complete with upcoming milestones and reported fourth quarter and full year 2024 financial results.

“Our Native Complex Platform™ continues to produce a deep pipeline of oral small molecule programs,” said Jeffrey Finer, M.D., Ph.D., chief executive officer and co-founder of Septerna. “Following the recent decision to discontinue our SEP-786 program, we remain focused on the opportunity to transform treatment for patients with hypoparathyroidism and are rapidly advancing multiple promising next-generation PTH1R agonists with the potential to select a next-generation candidate to advance toward the clinic later this year. In addition, SEP-631, our selective MRGPRX2 NAM for mast cell diseases, is on track to enter the clinic this year. We also continue to make good progress with our TSHR program for Graves’ disease and thyroid eye disease, as well as our single- and multi-acting incretin receptor agonist programs for metabolic diseases. With an experienced team, powerful platform and strong balance sheet, we believe we are well positioned to execute on our mission to develop multiple impactful GPCR medicines.”

Corporate Overview and Anticipated Milestones

- **PTH1R Agonist Program:**
 - In February 2025, Septerna discontinued its [Phase 1 clinical trial of SEP-786](#), an oral small molecule agonist of the parathyroid hormone 1 receptor (PTH1R) in development for hypoparathyroidism, following the observation of two unanticipated events of elevated unconjugated bilirubin in the multiple ascending dose (MAD) portion of the trial. The Grade 3 bilirubin elevations were reversible, without elevations in ALT, AST, and GGT liver enzyme levels and without liver injury, cholestasis or hemolysis. Non-clinical studies are underway to investigate the underlying mechanism of the observed effects. Observed early signals of on-target pharmacology in the MAD portion of the trial included increases in serum calcium and decreases in endogenous parathyroid hormone levels.
 - Septerna is advancing several lead compounds with distinct chemical structures unrelated to SEP-786 and favorable pharmacokinetics profiles. The Company plans to select a next-generation oral small molecule PTH1R agonist development candidate to accelerate toward clinical development by the end of 2025.
- **SEP-631 MRGPRX2 NAM Program:**
 - Septerna continues to advance SEP-631, a selective oral small molecule MRGPRX2 negative allosteric modulator (NAM), for the treatment of mast cell diseases, including chronic spontaneous urticaria. The company anticipates initiating a Phase 1 clinical trial in 2025 to assess safety, tolerability, pharmacokinetics, and pharmacodynamics of SEP-631 in healthy volunteers.
- **TSHR NAM Program:**
 - Septerna continues to progress several TSHR NAM lead compounds towards selection of a development candidate designed to be a disease-modifying treatment for Graves’ disease and thyroid eye disease.
- **Incretin Receptor Program:**
 - Septerna also continues to progress several incretin receptor agonist lead compounds, including single- and multi-acting GLP-1, GIP, or glucagon receptor agonists for the treatment of metabolic diseases, towards selection of one or more development candidates.
- **Corporate Updates:**
 - In January 2025, Septerna [appointed](#) Gil Labrucherie, CFA, J.D., as chief financial officer. Mr. Labrucherie is a seasoned biopharma executive with more than 25 years of senior leadership experience in finance and legal roles for public biopharmaceutical and technology companies.

Fourth Quarter and Full Year 2024 Financial Results

- **Cash Position:** Cash, cash equivalents, and marketable securities totaled \$420.8 million as of December 31, 2024. Septerna expects its current cash position to support its planned operations into early 2028.
- **R&D Expenses:** Research and development (R&D) expenses were \$19.3 million for the fourth quarter of 2024 and \$65.3 million for the full year ended December 31, 2024, compared to \$10.3 million for the fourth quarter of 2023 and \$36.0

million for year ended December 31, 2023.

- **G&A Expenses:** General and administrative (G&A) expenses were \$5.6 million for the fourth quarter of 2024 and \$16.6 million for the full year ended December 31, 2024, compared to \$3.1 million for the fourth quarter of 2023 and \$9.7 million for year ended December 31, 2023.
- **Net Loss:** Net loss totaled \$20.7 million for the fourth quarter of 2024 and \$71.8 million for the full year ended December 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.

From time to time, Septerna may use its website to distribute material information about the Company and for complying with its disclosure obligations under Regulation FD. Septerna's financial and other material information is routinely posted to and accessible on the Investors section of its website, available at www.Septerna.com. Investors are encouraged to review the Investors section of Septerna's website because it may post material information on that site that is not otherwise disseminated by the Company. Information that is contained in and can be accessed through Septerna's website or its social media are not incorporated into, and does not form a part of, this press release.

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 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 later 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 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 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 December 31,		Year Ended December 31,	
	2024	2023	2024	2023
Revenue	\$ 212	\$ 118	\$ 1,075	\$ 151
Operating expenses (income):				
Research and development	19,317	10,326	65,337	35,979
General and administrative	5,613	3,100	16,561	9,722
Gain on sale of non-financial asset	—	(47,625)	—	(47,625)
Total operating expenses (income)	24,930	(34,199)	81,898	(1,924)
(Loss) income from operations	(24,718)	34,317	(80,823)	2,075
Interest and other income, net	3,890	1,268	8,527	2,796
(Benefit) provision for income taxes	(160)	691	(498)	691
Net (loss) income	\$ (20,668)	\$ 34,894	\$ (71,798)	\$ 4,180
Net (loss) income attributable to common stockholders	\$ (20,668)	\$ 4,144	\$ (71,798)	\$ 567
Net (loss) income per share attributable to common stockholders:				
Basic	\$ (0.64)	\$ 1.95	\$ (7.26)	\$ 0.29
Diluted	\$ (0.64)	\$ 1.91	\$ (7.26)	\$ 0.29
Weighted-average shares outstanding:				
Basic	32,383,314	2,126,063	9,891,126	1,928,586
Diluted	32,383,314	2,455,078	9,891,126	2,177,124

SEPTERNA, INC.
Condensed Balance Sheets
(In thousands, except for share and per share data)
(Unaudited)

	December 31, 2024	September 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	\$ 420,789	\$ 137,512	\$ 88,483
Working capital ⁽¹⁾	343,975	120,180	105,764
Total assets	456,554	174,281	130,867
Total liabilities	36,507	37,532	20,026
Convertible preferred stock	—	224,157	149,215
Additional paid-in capital	538,321	10,119	8,199
Accumulated deficit	(118,374)	(97,706)	(46,576)
Total stockholders' equity (deficit)	\$ 420,047	\$ (87,408)	\$ (38,374)

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 Annual Report on Form 10-K for the year ended December 31, 2024 for further details regarding our current assets and current liabilities.