Relmada Therapeutics Reports Fourth Quarter and Full Year 2024 Results and Provides Business Update

Description

Expect Topline Phase 2 data for NDV-01 for high-grade non-muscle invasive bladder cancer (HG-NMIBC), to be presented at AUA 2025 in April

Advancing novel neurosteroid, sepranolone, towards Phase 2b study in Tourette syndrome with plans for evaluation in other compulsion-related disorders, including Prader-Willi Syndrome

Cash balance of $44.8 million as of December 31 2024

Management hosting conference call and webcast today at 4:30 PM ET

CORAL GABLES, Fla., March 27, 2025 (GLOBE NEWSWIRE) — Relmada Therapeutics, Inc. (Nasdaq: RLMD, “Relmada”, “the Company”), a clinical-stage biotechnology company, today provided a corporate update and announced preliminary and unaudited financial results for the fourth quarter and full year ended December 31, 2024.

The Company’s conference call, planned for today, Thursday, March 27th, at 4:30 PM ET will include a brief review of the Phase 2 clinical pipeline including:

- **NDV-01**, a novel sustained-release intravesical formulation of gemcitabine and docetaxel (gem/doce) currently in a single-arm Phase 2 study for the treatment of high-grade Non-Muscle Invasive Bladder Cancer (NMIBC) (US prevalence of ~600,000 patients). *Topline Phase 2 data are expected to be reported at the American Urological Association meeting (AUA), being held April 26-29, 2025 in Las Vegas.*
- **Sepranolone**, a Phase 2b-ready neurosteroid in development for Tourette syndrome (US prevalence of ~350,000), with expanded potential for other compulsion-related disorders, including Prader-Willi syndrome (PWS, WW prevalence of 350,000 to 400,000 patients)

“At the end of last year, we initiated a process to transform the Company through the exploration of strategic product acquisition opportunities to maximize shareholder value. We are pleased to report excellent progress in this effort, with the recent acquisition of two high-potential Phase 2 programs NDV-01 and sepranolone. We believe each program represents exceptional value-creation opportunities for our investors,” said **Sergio Traversa, CEO** of Relmada Therapeutics. “Relmada’s growth strategy for 2025 will focus on advancing each of these programs through key development milestones, including plans to interact with the FDA to align on our regulatory strategy, complete production of the next batch of material, and finalize the design of the next studies, expected to begin around year-end this year or first quarter 2026.”

“An important dimension of our strategic options exploration has been the development of a portfolio of programs with near-term value drivers that can address under-served markets. While we maintain deep

expertise in diseases of the central nervous system, as we evaluate strategic opportunities, the broad drug development expertise of our Team provides flexibility to be opportunistic," commented **Maged Shenouda, CFO** of Relmada. "With a $44.8 million cash balance, as of December 31, 2024, and clean balance sheet, we begin the year with solid financial strength. As part of our prioritization efforts, we are re-evaluating further development of 'P11. While results of the Phase 1 study indicate that REL-P11 is well tolerated, our emphasis on focused patient populations, and the increasingly competitive clinical development landscape in metabolic disease have prompted our review."

Upcoming Milestones:

NDV-01

- Topline Phase 2 data: Expected to be reported at the American Urological Association meeting (AUA), being held April 26-29, 2025 in Las Vegas
- Phase 2 preparations, including planned FDA interactions and manufacturing: Q2-Q4 2025
- Initiation of registration-track study: late Q4 2025 to early 2026

Sepranolone

- Phase 2 preparations, including planned FDA interactions and further development our product supply plans: Q2-Q4 2025
- Initiation of second Phase 2 study (Tourette syndrome): late Q4 2025 to early 2026
- Initiation of Phase 2 study (Prader Willi syndrome): late Q4 2025 to early 2026

Financial Results

Fourth Quarter 2024 Financial Results

- Research and development expense for the three months ended December 31, 2024, totaled $11.0 million, compared to $14.7 million for the three months ended December 31, 2023, a decrease of $3.7 million. The decrease was primarily driven by a decrease in study costs associated with the completion of two Phase 3 trials and the long-term, open-label, safety trial (Study 310).
- General and administrative expense for the three months ended December 31, 2024, totaled $8.1 million compared to $12.1 million for the three months ended December 31, 2023, a decrease of approximately $4.0 million. The decrease was primarily driven by a decrease in stock-based compensation expense.
- Net cash used in operating activities for the three months ended December 31, 2024, totaled $8.8 million compared to $10.2 million for the three months ended December 31, 2023.
- The net loss for the three months ended December 31, 2024, was $18.6 million, or $0.62 per basic and diluted share, compared with a net loss of $25.1 million, or $0.84 per basic and diluted share, for the three months ended December 31, 2023.

Twelve Month Ended December 31, 2024 Financial Results

- Research and development expense for the 12 months ended December 31, 2024, totaled $46.2 million, compared to $54.8 million for the 12 months ended December 31, 2023, a decrease of $8.6 million. The decrease was primarily driven by a decrease in study costs associated with the completion and conclusion of two Phase 3 trials and the long-term, open-label, safety trial (Study 310).
- General and administrative expense for the 12 months ended December 31, 2024, totaled $37.7 million compared to $48.9 million for the 12 months ended December 31, 2023, a decrease of approximately $11.2 million. The decrease was primarily driven by cost-saving measures and a decrease in stock-based compensation expense.
- Net cash used in operating activities for the 12 months ended December 31, 2024, totaled $51.8 million compared to $51.7 million for the 12 months ended December 31, 2023.
- The net loss for the 12 months ended December 31, 2024, was $80 million, or $2.65 per basic and diluted share, compared with a net loss of $98.8 million, or $3.28 per basic and diluted share, for the 12 months ended December 31, 2024.
- As of December 31, 2024, the Company had cash, cash equivalents, and short-term investments of approximately $44.9 million, compared to cash, cash equivalents, and short-term investments of approximately $96.3 million at December 31, 2023. The company believes its cash balance is adequate to support planned operations through key milestones, into H1 2026.
- The Company had 33,191,622 shares outstanding, as of March 25, 2024

Conference Call and Webcast Information:
Relmada will host a conference call and webcast today at 4:30 PM ET to discuss recent business progress and financial results.

Conference Call and Webcast Information:

- Date: Thursday, March 27, 2025 at 4:30 PM ET
- Participant Dial-in (US): 1-877-407-0792
- Participant Dial-in (International): 1-201-689-8263
- Conference: 13751458
- Webcast Access: Click Here

A replay of the webcast will be available in the Investors section of the Relmada website at https://www.relmada.com/investors/ir-calendar.

About NDV-01
NDV-01 is an investigational, innovative sustained-release formulation of two complementary, well-established, chemotherapy agents, gemcitabine and docetaxel (gem/doce). It is designed for intravesical dosing and intended to be an in-office ready-to-use therapy that is administered rapidly and requires no anesthesia or new or dedicated equipment to employ. NDV-01 forms a spherical soft matrix within the bladder that sequesters drug and releases it as the matrix gradually dissolves.

NDV-01's formulation is specifically designed to maximize local drug concentration and prolong exposure to gem/doce, while minimizing systemic toxicity. Unlike conventional intravesical instillations, NDV-01 is

designed to avoid peaks and troughs in drug concentration, ensuring a gradual and sustained release of gem/doce over a 10-day period. This approach may potentially enhance overall efficacy, reduce side effects, reduce the frequency of dosing and improve patient compliance and outcomes. NDV-01 has the potential to be a first line (1L) therapy for HG-NMIBC, with further potential for use in patients who have failed other therapies, including BCG immunotherapy, and expansion into other NMIBC subtypes, including intermediate-grade disease.

NDV-01 is protected by several patents that go out to 2038.

About NMIBC

More than 90% of the approximately 83,000 new U.S. cases of urothelial cancer are estimated to be bladder cancer. For the overall bladder cancer population, 5-year survival ranges from 70 to 96% of patients, moving to 6% for patients with advanced disease. Roughly 75% of bladder cancer cases are classified as non-muscle invasive (NMIBC) and approximately 50% of cases are classified as high-grade disease, considered to have increased risk of progression and recurrence. Sources indicate that NMIBC has a 50-75% recurrence rate (over seven years) and that the U.S. prevalence of NMIBC is approximately 450,000 patients.

The U.S. NMIBC market is estimated to be a multi-billion opportunity. Global numbers are higher, in line with projections for significant growth due to the increasing incidence of bladder cancer and the demand for effective, minimally invasive potential therapies like NDV-01. Approved treatment options remain limited (mainly the immunotherapy, BCG, which has been supply constrained for some time), with high recurrence rates leading to frequent re-treatment and progression. Other emerging programs include immunotherapy combinations, single agent chemotherapy formulations and targeted therapies. NDV-01 stands out based on the large body of published data that support the efficacy of treatment with gemcitabine and docetaxel, its ease of administration and potential for durability of action. Expansion beyond first-line treatment into use as a salvage treatment or in other subgroups of NMIBC, including naïve patients, could further increase the opportunity for NDV-01.

About Neurotransmitter Modulators and Sepranolone

Sepranolone (isoallopregnanolone) is a first in class GAMSA, or $GABA_A$ Modulating Steroid Antagonist, that acts by selectively inhibiting GABA neurotransmitters including allopregnanolone (ALLO), considered to be an important player in the pathogenesis of compulsivity disorders like Tourette syndrome and obsessive compulsive disorder (OCD). The compound has been evaluated in several clinical neuro/hormonal indications and tested in more than 335 people, with good overall safety. Both sepranolone and allopregnalone are endogenous compounds.

Neurotransmitters are chemical messengers that carry essential signals between neurons, muscles and glands. GABA (-aminobutyric acid), the major inhibitory neurotransmitter, plays an important role in calming the nervous system and managing fear and anxiety. ALLO, a positive allosteric modulator of $GABA_A$, (PAM) enhances the inhibitory effects of GABA neurotransmitters, leading to greater anti-anxiety effects. In most people, this translates into lower stress, fear and anxiety. However, in some people with compulsion-related disorders, it appears that higher levels of ALLO have the opposite, or paradoxical, effect of increased anxiety, triggering compulsivity, including tics.

Sepranolone acts on ALLO through two $GABA_A$ receptor subtypes, alfa 2 and alfa 4, in a dose dependent and selective manner, without interfering with the GABA receptor itself. Preclinical data suggest that sepranolone normalizes $GABA_A$ receptor activity, and reduces ALLO-induced anxiety. These observations support the development of sepranolone as a potential treatment for Tourette syndrome and other compulsivity disorders.

Sepranolone is protected by multiple issued patents until 2038.

About Tourette syndrome (TS)

Tourette syndrome is a complex neurological condition characterized by involuntary tics. The Centers for Disease Control and Prevention (CDC) estimates that more than 350,000 children in the U.S. have TS, with onset typically occurring between ages five and ten. Though symptoms often improve in adulthood, many individuals experience chronic tics and associated psychosocial challenges. Existing treatments include dopamine D2 blockers, atypical antipsychotics, botulinum toxin injections, cognitive behavioral therapy (CBIT), and deep brain stimulation, but these options are often limited by significant side effects.

TS is believed to be influenced by genetic, environmental, and neurochemical factors, including the role of allopregnanolone in triggering compulsive behaviors. Current treatments target dopamine and other neurotransmitters, but the Company believes Sepranolone's modulation of Allopregnanolone offers a novel and potentially safer alternative.

About Prader-Willi Syndrome

Prader-Willi Syndrome (PWS) is a rare genetic disorder caused by a mutation or deletion on chromosome 15. The deletion prevents expression of certain genes that are essential for development. The syndrome affects 1 in 10,000 to 1 in 30,000 people, which translates to an estimated global prevalence of 350,000 to 400,000.

Poor muscle tone, cognitive impairment, and neuro/behavioral issues such as persistent hunger and over-eating are some of the early manifestations of PWS. There is no cure for PWS; treatments, intended to manage PWS' multiple symptoms and improve quality of life, focus on improving obsessive-compulsive behaviors, obesity, tantrums, seizures, height and other medical complications.

About Relmada Therapeutics, Inc.
Relmada Therapeutics is a clinical-stage biotechnology company committed to advancing innovative breakthrough therapies that have the potential to bring meaningful clinical benefits to targeted patient populations.

Lead investigational program, NDV-01, for High-Grade Non-Muscle Invasive Bladder Cancer, is being evaluated in a Phase 2 study. In addition, preparations are underway to advance sepranolone, a Phase 2b-ready investigational program for compulsion-related disorders including Tourette's Syndrome into further studies.

For more information, visit www.relmada.com.

Forward-Looking Statements:
The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by us or on our behalf. This press release contains statements which constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Any statement that is not historical in nature is a forward-looking statement and may be identified by the use of words and phrases such as "if", "may", "expects", "anticipates", "believes", "will", "will likely result", "will continue", "plans to", "potential", "promising", and similar expressions. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including potential for Phase 2 NDV-01 data to be presented at an upcoming medical conference, potential for Phase 2 NDV-01 data to deliver positive results supporting further development, potential for clinical trials to deliver statistically and/or clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure of planned or ongoing preclinical and clinical studies to demonstrate expected results, potential failure to secure FDA agreement on the regulatory path for sepranolone, and NDV-01, or that future sepranolone, or NDV-01 clinical results will be acceptable to the FDA, failure to secure adequate sepranolone, or NDV-01 drug supply and the other risk factors described under the heading "Risk Factors" set forth in the Company's reports filed with the SEC from time to time. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Relmada undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned that it is not possible to predict or identify all the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be a complete list.

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Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	As of December 31, 2024	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$3,857,026	$4,091,568
Short-term investments	41,052,356	92,232,292
Prepaid expenses	886,461	1,185,057

Total current assets	45,795,843	97,508,917
Other assets	21,975	43,125
Total assets	$ 45,817,818	$ 97,552,042
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,130,563	$ 3,506,009
Accrued expenses	6,160,827	8,688,791
Total current liabilities	10,291,390	12,194,800
Stock appreciation rights	4,467	–
Total liabilities	10,295,857	12,194,800
Commitments and Contingencies (Note 10)		
Stockholders' Equity:		
Preferred stock, $0.001 par value, 200,000,000 shares authorized, none issued and outstanding	–	–
Class A convertible preferred stock, $0.001 par value, 3,500,000 shares authorized, none issued and outstanding	–	–
Common stock, $0.001 par value, 150,000,000 shares authorized, 30,174,202 and 30,099,203 shares issued and outstanding, respectively	30,174	30,099
Additional paid-in capital	676,373,822	646,229,824
Accumulated deficit	(640,882,035)	(560,902,681)
Total stockholders' equity	35,521,961	85,357,242
Total liabilities and stockholders' equity	$ 45,817,818	$ 97,552,042

Relmada Therapeutics, Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2024 and 2023

	2024	2023
Operating expenses:		
Research and development	$46,175,512	$54,807,348
General and administrative	37,715,524	48,894,945
Total operating expenses	83,891,036	103,702,293
Loss from operations	(83,891,036)	(103,702,293)

Other income (expenses):		
Interest/investment income, net	3,530,021	5,151,704
Realized gain (loss) on short-term investments	374,926	(4,064,391)
Unrealized gain on short-term investments	6,735	3,823,234
Total other income (expenses), net	3,911,682	4,910,547
Net loss	$ (79,979,354)	$ (98,791,746)
Net loss per common share – basic and diluted	$ (2.65)	$ (3.28)
Weighted average number of common shares outstanding – basic and diluted	30,163,751	30,099,203

Relmada Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the Years Ended December 31, 2024 and 2023

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2022	30,099,203	$30,099	$602,517,138	$(462,110,935)	$140,436,302
Stock-based compensation expense	–	–	43,811,149	–	43,811,149
ATM fees			(98,463)	–	(98,463)
Net loss	–	–	–	(98,791,746)	(98,791,746)
Balance – December 31, 2023	30,099,203	30,099	646,229,824	(560,902,681)	85,357,242
Stock-based compensation expense	–	–	30,184,414	–	30,184,414
Net proceeds from cash exercise options	74,999	75	246,672	–	246,747
ATM fees	–	–	(287,088)	–	(287,088)
Net loss	–	–	–	(79,979,354)	(79,979,354)
Balance – December 31, 2024	30,174,202	$30,174	$676,373,822	$(640,882,035)	$ 35,521,961

Source: Relmada Therapeutics

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