May 12, 2025

Relmada Therapeutics Reports First Quarter 2025 Financial Results and Provides Business Update

Positive initial Phase 2 proof-of-concept data for NDV-01 at AUA 2025 showing a 90% overall response rate at any time in non-muscle invasive bladder cancer (US prevalence 600K patients)

The Phase 2 study for NDV-01 continues with updates at 6, 9 and 12 month data follow-up over the course of 2025. Plans to start Phase III registration trial in H1 2026

Expecting to initiate a Phase 2 study for sepranolone in Prader-Willi syndrome in H1 2026 (US prevalence 20,000 patients)

Conference Call and Webcast Today at 4:30 PM ET

CORAL GABLES, Fla., May 12, 2025 (GLOBE NEWSWIRE) -- Relmada Therapeutics, Inc. (Nasdaq: RLMD, "Relmada" or the "Company"), a clinical-stage biotechnology company advancing innovative therapies for central nervous system and oncology indications, today reported financial results for the first quarter ended March 31, 2025, and provided a corporate and pipeline update.

"2025 is off to an outstanding start for Relmada," said Sergio Traversa, CEO of Relmada. "With the addition of NDV-01 and sepranolone, two differentiated Phase 2 product candidates targeting large, underserved markets, we've significantly enhanced our pipeline and long-term value proposition. The recently announced proof-of-concept data for NDV-01 presented at AUA 2025 reinforce its potential to become a best-in-class, bladder-sparing treatment for non-muscle invasive bladder cancer (NMIBC)."

"Our strategic focus remains on developing a diverse pipeline with strong scientific rationale, intellectual property protection, and capital-efficient development paths," added Mr. Traversa. "Looking ahead, we are prioritizing the advancement of NDV-01 and sepranolone into further clinical development."

"In the second half of 2025, we plan to complete the ongoing NDV-01 Phase 2 study and prepare for the initiation of a Phase III registration trial in the first half of 2026," said Maged Shenouda, CFO of Relmada. "We also expect to initiate a new Phase 2 study of sepranolone in Prader-Willi syndrome (PWS) in the first half of 2026."

Pipeline Highlights

NDV-01
A sustained-release intravesical formulation of gemcitabine and docetaxel (GEM/DOCE)

- **Indication**: High-Grade Non-Muscle Invasive Bladder Cancer (HG-NMIBC)

- **U.S. Market Opportunity**: ~600,000 prevalent cases
- **Current Status**: Phase 2 single-arm study actively enrolling
- **Recent Data (American Urological Association, AUA 2025)**:
  - 90% Overall Response Rate (18/20 patients)
  - 89% High-Grade Recurrence-Free Survival in papillary disease (16/18)
  - 100% Complete Response in carcinoma in situ (2/2)
- **Next Steps**:
  - FDA interactions and product supply scale-up in 2H 2025
  - Initiation of Phase 3 registration-track study in 1H 2026

Sepranolone
A first-in-class $GABA_A$ Modulating Steroid Antagonist (GAMSA)

- **Indications**: Prader-Willi Syndrome (PWS), Tourette Syndrome (TS), Essential Tremor, and other compulsivity-related disorders
- **US Prevalence**: Estimated 20,000 for PWS, orphan disease
- **Current Status**: Preparing for Phase 2 initiation in PWS
- **Supporting Data**:
  - In Tourette syndrome, Phase 2 trial showed a 28% reduction in tic severity (p=0.051) per YGTSS (Yale Global Tic Severity Scale)
  - Improvements in quality of life and symptom scales
  - Favorable safety profile with no CNS or systemic side effects
- **Next Steps**:
  - FDA engagement and manufacturing activities in 2025
  - Planned Phase 2 study launch in 1H 2026

First Quarter 2025 Financial Results

- **R&D Expense**: $11.9 million (vs. $13.3 million in Q1 2024), reflecting reduced REL-1017 trial costs, partially offset by new asset integration
- **G&A Expense**: $6.3 million (vs. $9.7 million), primarily due to lower stock-based compensation
- **Net Cash Used in Operations**: $18.1 million (vs. $13.0 million)
- **Net Loss**: $17.5 million or $0.58 per share (vs. $21.8 million or $0.72 per share)
- **Cash, Equivalents & Short-Term Investments**: $27.1 million as of March 31, 2025 (vs. $44.9 million at year-end 2024)
- **Shares Outstanding**: 33,191,622 as of May 7, 2025

Conference Call and Webcast
Relmada will host a conference call today, May 12, 2025, at 4:30 PM ET to discuss its Q1 results and pipeline progress.

- **Dial-in (U.S.)**: 1-877-407-0792
- **Dial-in (International)**: 1-201-689-8263
- **Conference ID**: 13753596
- **Webcast Access**: Click Here

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

About NDV-01

NDV-01 is a sustained-release, intravesical formulation of gemcitabine and docetaxel (GEM/DOCE), in development for the treatment of bladder cancer. It was designed to enable GEM/DOCE bladder retention and gradual drug release over 10 days. The formulation creates a soft matrix that enhances local exposure while minimizing systemic toxicity. NDV-01 is easy to administer in-office, in less than 10 minutes, and does not require anesthesia or specialized equipment. It is protected by patents through 2038.

About NMIBC

NMIBC represents ~75% of all bladder cancer cases and is associated with high recurrence (50–75% over 7 years). With over 600,000 prevalent cases in the U.S. and limited treatment options, the market opportunity is significant. NDV-01 has the potential to serve as a frontline or salvage therapy and could be applicable across multiple NMIBC subtypes.

About Sepranolone and GABA Modulation

Sepranolone, a synthetic isoallopregnanolone, selectively modulates $GABA_A$ receptors by antagonizing allopregnanolone (ALLO), without disrupting GABA signaling. It targets disorders linked to excess GABAergic activity such as Prader-Willi syndrome, Tourette syndrome, and Obsessive-Compulsive Disorder (OCD). More than 335 patients have been treated in trials to date, with an excellent safety profile.

About Prader-Willi Syndrome (PWS)

PWS is a rare genetic disorder caused by chromosomal deletions on chromosome 15, leading to neurodevelopmental and behavioral complications. US prevalence is estimated at 20,000 patients. Current treatments address symptoms but do not modify the underlying neurobehavioral pathology.

About Tourette Syndrome (TS)

TS affects more than 350,000 U.S. children and is marked by involuntary tics. Current therapies can have substantial side effects. Sepranolone is an investigational agent that offers a novel mechanism by modulating ALLO, potentially reducing compulsive symptoms more safely than existing dopaminergic therapies.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage biotechnology company focused on developing transformative therapies for central nervous system and oncology-related conditions. Its lead candidates, NDV-01 and sepranolone, are advancing through mid-stage clinical development with the potential to address significant unmet needs.

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 continue 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 March 31, 2025 (Unaudited)	As of December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 1,149,706	$ 3,857,026
Short-term investments	25,911,326	41,052,356
Prepaid expenses	596,410	886,461
Total current assets	27,657,442	45,795,843
Other assets	21,975	21,975
Total assets	$ 27,679,417	$ 45,817,818

Commitments and Contingencies (See Note 8)

Liabilities and Stockholders' Equity

Current liabilities:		
Accounts payable	$ 1,265,010	$ 4,130,563
Accrued expenses	3,966,411	6,160,827
Total current liabilities	5,231,421	10,291,390
Stock appreciation rights	7,505	4,467
Total liabilities	5,238,926	10,295,857
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, 33,191,622 and 30,174,202 shares issued and outstanding, respectively	33,191	30,174
Additional paid-in capital	680,848,800	676,373,822
Accumulated deficit	(658,441,500)	(640,882,035)
Total stockholders' equity	22,440,491	35,521,961
Total liabilities and stockholders' equity	$ 27,679,417	$ 45,817,818

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three months ended March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 11,951,023	$ 13,305,306
General and administrative	6,267,412	9,682,554
Total operating expenses	18,218,435	22,987,860
Loss from operations	(18,218,435)	(22,987,860)
Other income:		
Interest/investment income, net	440,287	1,055,888
Realized gain on short-term investments	62,952	53,133
Unrealized gain on short-term investments	155,731	50,713
Total other income	658,970	1,159,734
Net loss	$ (17,559,465)	$ (21,828,126)
Loss per common share – basic and diluted	$ (0.58)	$ (0.72)
Weighted average number of common shares outstanding – basic and diluted	30,408,890	30,132,170

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
(unaudited)

	Three months ended March 31, 2025

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance - December 31, 2024	30,174,202	$ 30,174	$ 676,373,822	$ (640,882,035)	$ 35,521,961
Stock based compensation	-	-	3,572,769	-	3,572,769
Issuance of Restricted Common Stock	3,017,420	3,017	902,209	-	905,226
Net loss	-	-	-	(17,559,465)	(17,559,465)
Balance – March 31, 2025	33,191,622	$ 33,191	$ 680,848,800	$ (658,441,500)	$ 22,440,491

	Three months ended March 31, 2024				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance - December 31, 2023	30,099,203	$ 30,099	$ 646,229,824	$ (560,902,681)	$ 85,357,242
Stock based compensation	-	-	8,295,468	-	8,295,468
Options exercised for common stock	74,999	75	246,672	-	246,747
ATM Fees	-	-	(25,000)	-	(25,000)
Net loss	-	-	-	(21,828,126)	(21,828,126)
Balance - March 31, 2024	30,174,202	$ 30,174	$ 654,746,964	$ (582,730,807)	$ 72,046,331

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Three months ended March 31,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (17,559,465)	$ (21,828,126)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,477,995	8,295,468
Realized gain on short-term investments	(62,952)	(53,133)
Unrealized gain on short-term investments	(155,731)	(50,713)
Change in operating assets and liabilities:		
Prepaid expenses	290,051	432,723
Accounts payable	(2,865,553)	1,683,092
Accrued expenses	(2,194,416)	(1,516,059)
Stock appreciation rights compensation	3,038	-
Net cash used in operating activities	(18,067,033)	(13,036,748)
Cash flows from investing activities		
Purchase of short-term investments	(487,916)	(7,013,933)
Sale of short-term investments	15,847,629	17,072,384
Net cash provided by investing activities	15,359,713	10,058,451
Cash flows from financing activities		
Proceeds from options exercised for common stock	-	246,747
ATM Fees	-	(25,000)
Net cash provided by financing activities	-	221,747
Net decrease in cash and cash equivalents	(2,707,320)	(2,756,550)
Cash and cash equivalents at beginning of the period	3,857,026	4,091,568

Cash and cash equivalents at end of the period	$ 1,149,706	$ 1,335,018

Source: Relmada Therapeutics