Relmada Therapeutics Reports Second Quarter 2025 Financial Results and Announces NDV-01 6-Month Follow-up Safety and Efficacy Data in NMIBC

Description

6-month follow-up for NDV-01 showed a 91% overall response rate at any time in non-muscle invasive bladder cancer, with good overall safety

Enrollment in the Phase 2 study for NDV-01 continues, with updates expected at 9 and 12 month data follow-up. Preparations underway to start Phase III registration trial in 1H 2026

Expecting to initiate a Phase 2 study for sepranolone in Prader-Willi syndrome in 1H 2026

Conference Call and Webcast Today at 4:30 PM ET

CORAL GABLES, Fla., Aug. 07, 2025 (GLOBE NEWSWIRE) — Relmada Therapeutics, Inc. (Nasdaq: RLMD, “Relmada” or the “Company”), a clinical-stage biotechnology company advancing innovative therapies for oncology-related and central nervous system indications, today reported financial results for the second quarter ended June 30, 2025, announced 6-month follow-up data from the Phase 2 study of NDV-01 in bladder cancer and provided a corporate and pipeline update.

Highlights of the 6-month follow-up data from the Phase 2 study of NDV-01:

Table 1: Baseline characteristics (n=29)	
Gender	n (%)
Male	24 (83%)
Female	5 (17%)
Median Age (years) (range)	73 (54-93)
Median BCG Doses (range)	6 (0-18)
• BCG-naïve (n (%))	12 (41%)
• BCG exposed (n (%))	4 (14%)
• BCG unresponsive (n (%))	13 (45%)
Stage (n (%))	
Pure CIS	3 (10%)
Ta/T1 + CIS	4 (14%)
Ta	18 (62%)
T1	4 (14%)

Table 2: Clinical Results (Response Data)	
Complete Response	% (n/N)
Anytime	91% (21/23)
3 months	83% (19/23)
6 months	90% (19/21)

- One subject has reached the 9-month assessment and had a complete response (CR)
- No patient had progression to muscle invasive disease
- No patient underwent a radical cystectomy
- No patient had >= Grade 3 TRAE and no patients discontinued treatment due to AEs

“We are pleased to report that the six-month follow-up from the Phase 2 study of NDV-01, a gemcitabine/docetaxel (Gem/Doce) sustained release formulation, produced impressive results, with a 91% CR rate at any time point following NDV-01 treatment. The data reported today, in combination with the previously reported 3-month results, raise our confidence in NDV-01 as a potential durable treatment for bladder cancer,” said **Raj S. Pruthi, MD, CMO** of Relmada. “Gem/Doce have long shown clinical utility in non-muscle invasive bladder cancer (NMIBC), but the complexity of administration has limited their broader use. The sustained release formulation of NDV-01, which is designed to increase exposure to drug and simplify delivery and accessibility, has the potential to significantly change how we manage patients with NMIBC in routine practice.”

“As clinicians, we have embraced the combination of Gem/Doce as a highly effective therapy for many years,” said **Yair Lotan, MD, Chair of Relmada’s Clinical Advisory Board**. “However, it is difficult to formulate outside of the hospital setting, often creating a significant burden for patient and provider. NDV-01’s simple, ready-to-use sustained release formulation overcomes those burdens and could enable wider patient adoption transforming the care of NMIBC.”

Pipeline Highlights

NDV-01
A sustained-release intravesical formulation of gemcitabine and docetaxel (Gem/Doce)

- **Indication**: High-Grade/Intermediate-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
- **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 GABAA 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, an orphan disease
- **Current Status**: Preparing for Phase 2 initiation in PWS
- **Next Steps**:
  - FDA engagement and manufacturing activities in 2H 2025
  - Planned Phase 2 study launch in 1H 2026

Financial Results

Three Months Ended June 30, 2025 Results

- **R&D Expense**: $2.8 million (vs. $10.7 million in Q2 2024), primarily associated with the wind-down of REL-1017 trial costs and lower stock-based compensation, partially offset an increase in R&D employee compensation expense
- **G&A Expense**: $7.4 million (vs. $8.1 million), primarily due to lower stock-based compensation, partially offset by an increase in G&A employee compensation and consulting services expenses
- **Net Loss**: $9.9 million or $0.30 per share (vs. $17.8 million or $0.59 per share)

Six Month Ended June 30, 2025 Results

- **R&D Expense**: $14.7 million (vs. $24.0 million in 1H 2024), reflecting reduced REL-1017 trial costs and lower stock-based compensation, partially offset by an increase in costs associated with the NDV-01 and sepranolone acquisitions and an increase in R&D employee compensation expense
- **G&A Expense**: $13.7 million (vs. $17.8 million in 1H 2024), primarily due to lower stock-based compensation and use of consulting services, partially offset by an increase in G&A employee compensation expense
- **Net Cash Used in Operations**: $24.5 million (vs. $26.3 million)
- **Net Loss**: $27.4 million or $0.86 per share (vs. $39.6 million or $1.31 per share)
- **Cash, Equivalents & Short-Term Investments**: $20.6 million as of June 30, 2025 (vs. $44.9 million at year-end 2024)
- **Shares Outstanding**: 33,191,622 as of August 4, 2025

Conference Call and Webcast
Relmada will host a conference call today, August 7, 2025, at 4:30 PM ET to discuss its Q2 2025 results and pipeline progress.

- **Dial-in (U.S.)**: 1-877-407-0792
- **Dial-in (International)**: 1-201-689-8263
- **Conference ID**: 13754263
- **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 non-muscle invasive bladder cancer. It is 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 convenient 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 the Phase 2 Study

The Phase 2 study (NCT06663137) is an open-label, single-arm, single-center study evaluating the safety and efficacy of NDV-01 in patients with HG-NMIBC. Patients are treated with NDV-01 in a biweekly induction phase, follow by monthly maintenance for up to one year, with regular assessments via cystoscopy, cytology, and biopsy, as indicated. The primary efficacy endpoints are safety and complete response rate (CRR) at 12 months, and secondary efficacy endpoints are duration of response (DOR) and event free survival (EFS).

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 with sepranolone in clinical 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 to be 20,000 patients. Current treatments address symptoms but do not modify the underlying neurobehavioral pathology.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage biotechnology company focused on developing transformative therapies for oncology-related and central nervous system conditions. 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 Relmada's product candidates to progress, including the 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 NDV-01, and sepranolone, or that future NDV-01, or sepranolone, clinical results will be acceptable to the FDA, failure to secure adequate NDV-10, or sepranolone, 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 June 30, 2025 (Unaudited)	As of December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$1,353,351	$3,857,026
Short-term investments	19,266,190	41,052,356
Prepaid expenses	474,628	886,461

Total current assets	21,094,169	45,795,843
Other assets	21,975	21,975
Total assets	$ 21,116,144	$ 45,817,818

Liabilities and Stockholders' Equity

Current liabilities:		
Accounts payable	$ 1,361,911	$ 4,130,563
Accrued expenses	3,772,636	6,160,827
Total current liabilities	5,134,547	10,291,390
Stock appreciation rights	32,116	4,467
Total liabilities	$ 5,166,663	$ 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	684,224,232	676,373,822
Accumulated deficit	(668,307,942)	(640,882,035)
Total stockholders' equity	15,949,481	35,521,961
Total liabilities and stockholders' equity	$ 21,116,144	$ 45,817,818

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

	Three months ended June 30,		Six months ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$2,819,377	$10,721,089	$14,770,400	$24,026,395
General and administrative	7,401,929	8,097,695	13,669,342	17,780,249
Total operating expenses	10,221,306	18,818,784	28,439,742	41,806,644

Loss from operations	(10,221,306)	(18,818,784)	(28,439,742)	(41,806,644)
Other (expenses) income:				
Interest/investment income, net	321,458	963,013	761,745	2,018,901
Realized (loss) gain on short-term investments	47,203	133,114	110,156	186,247
Unrealized (loss) gain on short-term investments	(13,797)	(45,465)	141,934	5,248
Total other income	354,864	1,050,662	1,013,835	2,210,396
Net loss	$ (9,866,442)	$(17,768,122)	$(27,425,907)	$(39,596,248)
Loss per common share – basic and diluted	$ (0.30)	$ (0.59)	$ (0.86)	$ (1.31)
Weighted average number of common shares outstanding – basic and diluted	33,191,622	30,174,202	31,807,943	30,153,186

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

	Three and Six months ended June 30, 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
Stock based compensation	–	–	3,448,453	–	3,448,453
ATM Expenses	–	–	(73,021)	–	(73,021)
Net loss	–	–	–	(9,866,442)	(9,866,442)
Balance – June 30, 2025	33,191,622	$33,191	$684,224,232	$(668,307,942)	$ 15,949,481

	Three and Six months ended June 30, 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 Expenses	–	–	(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
Stock based compensation	–	–	7,213,419	–	7,213,419
Net loss	–	–	–	(17,768,122)	(17,768,122)
Balance – June 30, 2024	30,174,202	$30,174	$661,960,383	$(600,498,929)	$ 61,491,628

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

	Six months ended June 30,	
	2025	2024
Cash flows from operating activities		
Net loss	$(27,425,907)	$(39,596,248)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	7,926,448	15,508,887
Realized (gain) on short-term investments	(110,156)	(186,247)
Unrealized (gain) on short-term investments	(141,934)	(5,248)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	411,834	637,035
Accounts payable	(2,768,652)	668,559
Accrued expenses	(2,388,191)	(3,326,511)
Stock appreciation rights compensation	27,649	–
Net cash (used in) operating activities	(24,468,909)	(26,299,773)
Cash flows from investing activities		
Purchase of short-term investments	(809,375)	(8,313,312)
Sale of short-term investments	22,847,630	32,386,030

Net cash provided by investing activities	22,038,255	24,072,718
Cash flows from financing activities		
Proceeds from options exercised for common stock	–	246,747
ATM Expenses	(73,021)	(25,000)
Net cash (used in)/provided by financing activities	(73,021)	221,747
Net (decrease)/increase in cash and cash equivalents	(2,503,675)	(2,005,308)
Cash and cash equivalents at beginning of the period	3,857,026	4,091,568
Cash and cash equivalents at end of the period	$ 1,353,351	$ 2,086,260

Source: Relmada Therapeutics

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