Relmada Therapeutics Reports Second Quarter 2026 Financial Results and Provides Business Update

Description

- *Advancing NDV-01 toward IND filing expected by year-end 2026 with GMP manufacturing of clinical trial material underway. Initiation of the Phase 3 RESCUE registrational program upon IND clearance.*
- *Sepranolone IND filing expected by year-end 2026 and initiation of Phase 2 proof-of-concept study in Prader-Willi Syndrome upon IND clearance.*
- *Strengthened the leadership team with appointment of Bipin Dalmia as Chief Business Officer.*
- *Added to the Russell 2000® and Russell 3000® Indexes effective June 26, 2026.*
- *Cash balance of $217.7 million as of June 30, 2026, expected to fund operations through 2029, including completion of the NDV-01 Phase 3 RESCUE program.*
- *Management to host a conference call and webcast today at 4:30 PM ET.*

CORAL GABLES, Fla., Aug. 06, 2026 (GLOBE NEWSWIRE) — **Relmada Therapeutics, Inc.** (Nasdaq: RLMD, “Relmada” or the “Company”), a clinical-stage biotechnology company advancing innovative therapies for oncology and central nervous system disorders, today reported financial results for the second quarter ended June 30, 2026, and provided a business update.

“Relmada has entered a critical execution phase as we prepare NDV-01 for registrational development. With FDA alignment, a robust clinical dataset, an experienced leadership team, and capital expected to fund operations through completion of the Phase 3 RESCUE program, we believe the Company is well positioned to create significant long-term value,” said **Sergio Traversa, Chief Executive Officer of Relmada Therapeutics**. “Our immediate priority is manufacturing execution for NDV-01. Bringing a novel, sustained-release therapy of this kind into registrational development requires careful execution, and we are focused on completing the remaining activities needed to support the IND filing.”

Manufacturing and CMC Update

The Company is advancing manufacturing and chemistry, manufacturing, and controls (CMC) activities to support planned IND filings for both NDV-01 and sepranolone by year-end 2026. Each program is progressing along its own development path.

NDV-01: Manufacturing and CMC activities supporting the planned NDV-01 IND submission are ongoing. The Company expects to submit the NDV-01 IND by year-end 2026 and initiate the Phase 3 RESCUE registrational program upon IND clearance. Clinical trial sites are engaged and prepared to begin enrollment following IND clearance.

Sepranolone: Formulation development for sepranolone is complete, and the Company is finalizing the pre-filled syringe delivery system. This is the remaining step ahead of the sepranolone IND submission, which is expected by year-end 2026. The company expects to initiate the Phase 2 proof-of-concept study in Prader-Willi Syndrome following IND clearance.

Corporate Update

During the quarter, Relmada strengthened its leadership team with the appointment of Bipin Dalmia, PhD, MBA, as Chief Business Officer. He brings nearly three decades of biopharmaceutical leadership experience spanning business development, portfolio strategy, commercial planning, and uro-oncology, including leadership of the U.S. launch, indication expansion, global commercialization, and long-term manufacturing strategy for the first FDA-approved intravesical gene therapy for NMIBC.

“Since joining Relmada, I have become increasingly convinced that NDV-01 represents one of the most compelling opportunities in NMIBC,” said **Bipin Dalmia, Chief Business Officer of Relmada Therapeutics**. “As the NMIBC treatment landscape continues to evolve, patients and physicians are seeking therapies that deliver meaningful efficacy and durability without compromising convenience, tolerability, or ease of use. As we advance toward registrational development, NDV-01’s highly differentiated profile and potential applicability across multiple patient populations position it to become a foundational and best-in-class intravesical therapy across the NMIBC disease spectrum.”

Expected Upcoming Relmada Milestones:

NDV-01:

- NDV-01 United States IND filing – By YE26
- NDV-01 Phase 3 RESCUE program initiation – Upon IND Clearance

Sepranolone:

- Sepranolone United States IND filing – By YE26
- Sepranolone Phase 2 initiation in Prader-Willi Syndrome – Upon IND Clearance

Financial Results

Second Quarter 2026 Financial Results

- Research and development expense for the three months ended June 30, 2026, totaled $8.4 million, compared to $2.8 million for the three months ended June 30, 2025, an increase of $5.6 million. The increase was primarily attributable to higher NDV-01 and sepranolone study costs and increased manufacturing and drug storage costs, partially offset by lower employee compensation.
- General and administrative expense for the three months ended June 30, 2026, totaled $6.6 million compared to $7.4 million for the three months ended June 30, 2025, a decrease of approximately $0.8 million. The decrease was primarily driven by lower stock-based compensation and lower employee compensation, partially offset by higher stock appreciation rights expense and consulting services.
- Net cash used in operating activities for the three months ended June 30, 2026, totaled $9.6 million compared to $6.4 million for the three months ended June 30, 2025.
- The net loss for the three months ended June 30, 2026, was $12.9 million, or $0.11 per basic and diluted share, compared with a net loss of $9.9 million, or $0.30 per basic and diluted share, for the three months ended June 30, 2025.
- As of June 30, 2026, the Company’s cash, cash equivalents, and short-term investments balance were $217.7 million, compared to cash, cash equivalents, and short-term investments of

approximately $93.0 million at December 31, 2025.
- The Company's current cash, cash equivalents, and short-term investments as of June 30, 2026, are expected to provide sufficient resources to fund Company operations through 2029, including completion of the Phase 3 NDV-01 RESCUE program.
- The Company had 106,669,846 shares outstanding, as of August 4, 2026

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, August 6, 2026 at 4:30 PM ET
- Participant Dial-in (US): 1-800-717-1738
- Participant Dial-in (International): 1-646-307-1865
- Webcast Access: Click Here

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

About NDV-01

NDV-01 is a novel, sustained-release, intravesical formulation of gemcitabine and docetaxel (Gem/Doce) being developed for the treatment of non-muscle invasive bladder cancer (NMIBC). The formulation is engineered to provide prolonged bladder retention and sustained drug release over approximately 10 days. By forming a soft intravesical matrix, NDV-01 is designed to increase local drug exposure while limiting systemic toxicity. The treatment can be administered conveniently in an office setting in under 5 minutes without the need for anesthesia or specialized equipment. NDV-01 is encompassed by multiple patent applications that if issued, could provide protection until 2047.

About the NDV-01 Phase 3 RESCUE Registrational Pathways:

Relmada has received written FDA feedback confirming alignment on two registrational development pathways for NDV-01, including study design, patient populations, and primary endpoints. The Company expects to submit an IND by year-end 2026 and initiate the Phase 3 RESCUE program upon IND clearance.

About NMIBC

NMIBC represents 75-80% of all bladder cancer cases and is associated with high recurrence rates (50 – 80% over 5 years) and disease progression in a subset of these patients. With over 744,000 prevalent cases in the U.S. and limited treatment options, the market opportunity is significant. High-risk BCG-unresponsive disease represents the biggest unmet need in NMIBC, with limited and suboptimal bladder-sparing treatment options. Intermediate-risk NMIBC in the adjuvant setting has no currently approved therapies and patients with recurrence must undergo repeated surgical resections. NDV-01 has the potential to serve as a foundational frontline or salvage therapy across the NMIBC disease spectrum.

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 (PWS), 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. The Company expects to submit an IND by year-end 2026 and initiate the Phase 2 study in Prader-Willi syndrome upon IND clearance.

About Prader-Willi Syndrome (PWS)

PWS is a rare genetic disorder caused by chromosomal deletions on chromosome 15, leading to neurodevelopmental and behavioral complications. Global prevalence is estimated to be 350,000-400,000 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 and central nervous system conditions. Its lead candidates, NDV-01 and sepranolone, are advancing through 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 fail to progress, potential for Phase 2 NDV-01 data to fail to continue to deliver positive results supporting further development, potential for clinical trials to fail to deliver statistically and/or clinically significant evidence of efficacy and/or safety, failure of interim or 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 continue to secure FDA agreement on the regulatory path for NDV-01 and/or sepranolone, or that future NDV-01 and/or sepranolone clinical results will be acceptable to the FDA, failure to successfully execute manufacturing and CMC activities for NDV-01 and/or sepranolone, including GMP manufacture of clinical trial material, manufacturing scale-up, process validation, timing of completion of manufacturing activities, and regulatory acceptance of manufacturing-related submissions, failure to secure adequate NDV-01 and/or sepranolone drug supply, failure of pending patent applications to result in issued patents, or issued patents being challenged and invalidated by third parties or not providing us with any competitive advantages, the Company’s cash runway and sufficiency of the Company’s cash resources and uncertainties inherent in estimating the Company’s cash runway, future expenses and other financial results, including its ability to fund future

operations, including clinical trials, 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 are not a complete list.

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Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	As of June 30, 2026 (Unaudited)	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$11,334,370	$3,496,540
Short-term investments	206,396,805	89,509,710
Other receivable	10,912	–
Prepaid expenses	1,297,590	977,721
Total current assets	219,039,677	93,983,971
Other assets	19,500	19,500
Total assets	$ 219,059,177	$ 94,003,471
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable	$ 2,409,190	$ 1,568,944
Accrued expenses	5,011,583	4,861,583
Total current liabilities	7,420,773	6,430,527
Stock appreciation rights	5,080,081	1,060,931
Total liabilities	12,500,854	7,491,458
Commitments and Contingencies (See Note 8)		

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, 200,000,000 shares authorized, 106,669,846 and 73,333,622 shares issued and outstanding, respectively	106,670	73,333
Additional paid-in capital	936,684,992	784,705,878
Accumulated deficit	(730,233,339)	(698,267,198)
Total stockholders' equity	206,558,323	86,512,013
Total liabilities and stockholders' equity	$ 219,059,177	$ 94,003,471

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

	Three months ended June 30,		Six months ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$8,393,789	$2,819,377	$16,481,634	$14,770,400
General and administrative	6,617,238	7,401,929	17,991,147	13,669,342
Total operating expenses	15,011,027	10,221,306	34,472,781	28,439,742
Loss from operations	(15,011,027)	(10,221,306)	(34,472,781)	(28,439,742)
Other (expenses) income:				
Interest/investment income, net	2,301,394	321,458	3,261,156	761,745
Realized (loss) gain on short-term investments	(37,294)	47,203	(47,162)	110,156
Unrealized (loss) gain on short-term investments	(167,258)	(13,797)	(707,354)	141,934
Total other income	2,096,842	354,864	2,506,640	1,013,835
Net loss	$ (12,914,185)	$ (9,866,442)	$(31,966,141)	$(27,425,907)
Loss per common share – basic and diluted	$ (0.11)	$ (0.30)	$ (0.32)	$ (0.86)

Weighted average number of common shares outstanding – basic and diluted	112,375,941	33,191,622	99,327,509	31,807,943

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Three and Six months ended June 30, 2026				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2025	73,333,622	$73,333	$784,705,878	$(698,267,198)	$86,512,013
Stock based compensation	–	–	956,186	–	956,186
Proceeds from issuance of common stock, net	29,474,569	29,475	150,352,510	–	150,381,985
ATM Fees	–	–	(65,651)	–	(65,651)
Cashless exercise of pre-funded warrants for common stock	2,082,032	2,082	(2,082)	–	–
Net loss	–	–	–	(19,051,956)	(19,051,956)
Balance – March 31, 2026	104,890,223	104,890	935,946,841	(717,319,154)	218,732,577
Stock based compensation	–	–	902,903	–	902,903
ATM fees	–	–	(66,273)	–	(66,273)
Stock issuance costs	–	–	(199,879)	–	(199,879)
Exercise of pre-funded warrants for common stock	1,682,500	1,683	–	–	1,683
Options exercised	97,123	97	101,400	–	101,497
Net loss	–	–	–	(12,914,185)	(12,914,185)
Balance – June 30, 2026	106,669,846	$106,670	$936,684,992	$(730,233,339)	$206,558,323

	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

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

	Six months ended June 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$(31,966,141)	$(27,425,907)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,859,089	7,021,222
Stock appreciation rights compensation	4,019,150	27,649
Issuance of restricted common stock	–	905,226
Realized loss/(gain) on short-term investments	47,162	(110,156)
Unrealized loss/(gain) on short-term investments	707,354	(141,934)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(319,869)	411,834
Accounts payable	840,246	(2,768,652)
Accrued expenses	150,000	(2,388,191)
Other receivable	(10,912)	–
Net cash used in operating activities	(24,673,921)	(24,468,909)
Cash flows from investing activities		
Purchase of short-term investments	(174,270,466)	(809,375)
Sale of short-term investments	56,628,855	22,847,630
Net cash (used in)/provided by investing activities	(117,641,611)	22,038,255
Cash flows from financing activities		
Proceeds from issuance of common stock	159,999,996	–
Payment of fees for issuance of common stock	(9,817,890)	–
Proceeds from options exercised for common stock	101,497	–
Proceeds from warrants exercised for common stock	1,683	–
ATM fees	(131,924)	(73,021)
Net cash provided/(used in) by financing activities	150,153,362	(73,021)
Net increase/(decrease) in cash and cash equivalents	7,837,830	(2,503,675)
Cash and cash equivalents at beginning of the period	3,496,540	3,857,026
Cash and cash equivalents at end of the period	$ 11,334,370	$ 1,353,351

Non-cash investing and financing activities		
Cashless exercise of warrants for common stock	$ (2,082)	–

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