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

Description

- *Positive 12-Month Phase 2 data for NDV-01 demonstrated a 95% complete response (CR) rate at any time and a durable 76% CR rate at 12 months in high-risk non-muscle invasive bladder cancer (NMIBC), and a 94% CR rate at any time and a durable 80% CR rate at 12 months in the BCG-unresponsive subpopulation, reinforcing best-in-class potential in NMIBC*
- *On track to initiate Phase 3 RESCUE registrational program in second line (2L) BCG-unresponsive and adjuvant intermediate-risk NMIBC in mid-2026*
- *Filed provisional patent application with the USPTO in April 2026 covering NDV-01 pharmaceutical formulations and methods of treatment; if issued, patents claiming priority to the provisional filing would have a term until April 2047*
- *Relmada will feature two NDV-01 presentations at the American Urological Association Annual Meeting (AUA2026), highlighting the 12-month Phase 2 data and the Phase 3 RESCUE program design and rationale*
- *Cash balance of $234.0 million as of March 31, 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., May 12, 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 first quarter ended March 31, 2026 and provided a corporate update.

“We made significant progress in the first quarter, highlighted by the robust 12-month Phase 2 data for NDV-01 in NMIBC and the successful completion of a $160 million PIPE financing, which has well-capitalized our balance sheet to fund the NDV-01 RESCUE Phase 3 program through completion,” said **Sergio Traversa, Chief Executive Officer of Relmada Therapeutics**. “We remain on track to file the NDV-01 IND and initiate the Phase 3 RESCUE registrational program in mid-2026 – a milestone that would mark a major inflection point for Relmada and for the patients we aim to serve. We believe NDV-01 has the potential to be a best-in-class therapy for patients with NMIBC and remain focused on maximizing its potential for success. To this end, in April, we filed a provisional patent application in the U.S. directed to formulations and methods of treatment for NDV-01. This application, if issued, could form the basis for worldwide patent filings, and have a term into 2047.”

“The AUA2026 Annual Meeting provides an important opportunity to introduce NDV-01 to the broader urologic community,” said **Raj S. Pruthi, MD, Chief Medical Officer – Urology of Relmada**

Therapeutics. “Our presentations will highlight the 12-month Phase 2 data generated to date for NDV-01, including observed complete responses and safety findings. We will also be sharing the design and rationale for the Phase 3 RESCUE program. NDV-01 is a sustained-release gemcitabine and docetaxel (Gem/Doce) designed to support streamlined, in-office administration in less than five minutes. We believe AUA2026 provides an important national forum to increase awareness and engagement within the investigator community as we approach the initiation of the RESCUE program in mid-2026.”

Upcoming AUA2026 Presentations and NDV-01 Phase 2 Data Highlights:

Relmada will present two abstracts at AUA2026 including: (1) NDV-01 Phase 2 data (12-month follow-up), and (2) the Phase 3 RESCUE program design (Clinical Trials in Progress session). The presentations are intended to raise awareness of NDV-01 and build investigator interest in the RESCUE registrational program. Key data to be highlighted include:

- **95% complete response (CR) rate at any time and durable 76% CR rate at 12 months in high-risk NMIBC patients**
- **94% CR rate at any time and durable 80% CR rate at 12 months in BCG-unresponsive NMIBC patients**
- **No patient had progression to muscle-invasive disease, and no patient underwent a radical cystectomy**
- **Favorable overall tolerability** – no ? Grade 3 treatment-related adverse events and no treatment-related discontinuations or dose interruptions

NDV-01 Intellectual Property:

In April 2026, Relmada filed a provisional patent application with the United States Patent and Trademark Office (USPTO) directed to pharmaceutical formulations and methods of treatment related to NDV-01. The provisional filing has the potential to form the basis for a comprehensive world-wide patent filing program for NDV-01. If issued, patents claiming priority to the provisional filing will be expected to have a term until April 2047.

Expected Upcoming Relmada Milestones:

- NDV-01 United States IND filing – Mid-2026
- NDV-01 Phase 3 RESCUE Program initiation – Mid-2026
- Sepranolone Phase 2 initiation in Prader-Willi syndrome – Mid-2026
- Initial 3-month NDV-01 data from Phase 3 2L BCG-unresponsive study – YE 2026

Financial Results

First Quarter 2026 Financial Results

- Research and development expense for the three months ended March 31, 2026, totaled $8.1 million, compared to $12.0 million for the three months ended March 31, 2025, a decrease of $3.9

million. The decrease was primarily attributable to non-recurring costs associated with the acquisition of sepranolone and the license agreement of NDV-01 recognized in 2025. This 2026 decrease was partially offset by increased costs related to the start-up of the Phase 3 NDV-01 trials and Phase 2b sepranolone study and additional R&D personnel.

- General and administrative expense for the three months ended March 31, 2026, totaled $11.4 million compared to $6.3 million for the three months ended March 31, 2025, an increase of approximately $5.1 million. The increase was primarily driven by an increase in compensation costs partially offset by a decrease in stock-based compensation costs.
- Net cash used in operating activities for the three months ended March 31, 2026, totaled $15.1 million compared to $18.1 million for the three months ended March 31, 2025.
- The net loss for the three months ended March 31, 2026, was $19.1 million, or $0.22 per basic and diluted share, compared with a net loss of $17.6 million, or $0.58 per basic and diluted share, for the three months ended March 31, 2025.
- The Company's balance of $234.0 million in cash, cash equivalents, and short-term investments, includes net proceeds of approximately $150 million from the private placement financing announced March 9, 2026. This compares 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 March 31, 2026, is expected to provide sufficient resources to fund Company operations through 2029, including completion of the Phase 3 NDV-01 RESCUE program.
- The Company had 104,890,223 shares outstanding, as of May 7, 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: Tuesday, May 12, 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://www.relmada.com/investors/ir-calendar.

About NDV-01

NDV-01 is a ready-to-use, 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 controlled 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. It is encompassed

by multiple patent applications that if issued, could provide protection until 2047.

About the NDV-01 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 high-grade non-muscle invasive bladder cancer (HG-NMIBC). Patients are treated with NDV-01 in a biweekly induction phase, followed by monthly maintenance for up to one year. Patients were evaluated at 3-month intervals using cystoscopy and cytology, with biopsies performed at the treating physician's discretion. Time-to-event endpoints, including complete response (CR) and event free survival (EFS) rates, were analyzed as landmark events and using Kaplan–Meier (KM) analysis. The primary efficacy endpoints are safety and CR rate at 12 months, and secondary efficacy endpoints are duration of response (DOR) and EFS. Treatment-related adverse events (TRAEs) were graded according to CTCAE v5.0 (Common Terminology Criteria for Adverse Events, version 5.0).

About the NDV-01 Phase 3 RESCUE Registrational Pathways:

Relmada has received written feedback from the U.S. Food and Drug Administration (FDA) confirming alignment on two registrational development pathways for NDV-01, including study design, patient populations and primary endpoints. IND filing and program initiation remain on track for mid-2026.

Registration Pathway 1 – An open-label single-arm trial in second line (2L) BCG-unresponsive NMIBC with *carcinoma in situ (CIS)* patients who are currently refractory to approved or developmental therapies. Patients with BCG-unresponsive NMIBC with *CIS* who fail first line (1L) therapies, which we estimate to affect ~5,000 patients/year in the US, have few, if any, effective treatment alternatives to radical cystectomy. The primary endpoint of the study is complete response (CR) rate at any time.

Registrational Pathway 2 – An open label randomized controlled trial in intermediate-risk NMIBC of adjuvant therapy following TURBT (Transurethral Resection of Bladder Tumor, NDV-01 vs. observation). There are no approved adjuvant treatments for intermediate risk NMIBC, which we estimate affect ~75,000 patients/year in the US. The primary endpoint of the study is disease free survival (DFS).

About NMIBC

NMIBC represents 75-80% of all bladder cancer cases and is associated with high recurrence (50 – 80% over 5 years). With over 744,000 prevalent cases in the U.S. and limited treatment options, the market opportunity is significant. High-grade BCG-unresponsive disease represents one of the most difficult-to-treat NMIBC subtypes, with limited bladder-sparing options. Intermediate-risk NMIBC in the adjuvant setting has no currently approved therapies. 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. 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 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 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 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 March 31, 2026 (Unaudited)	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$9,776,400	$3,496,540
Short-term investments	224,186,743	89,509,710
Prepaid expenses	1,380,151	977,721
Total current assets	235,343,294	93,983,971
Other assets	19,500	19,500
Total assets	$ 235,362,794	$ 94,003,471
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,731,401	$ 1,568,944
Accrued expenses	7,160,233	4,861,583
Total current liabilities	12,891,634	6,430,527
Stock appreciation rights	3,738,583	1,060,931
Total liabilities	16,630,217	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, 150,000,000 shares authorized, 104,890,223 and 73,333,622 shares issued and outstanding, respectively	104,890	73,333
Additional paid-in capital	935,946,841	784,705,878
Accumulated deficit	(717,319,154)	(698,267,198)
Total stockholders' equity	218,732,577	86,512,013
Total liabilities and stockholders' equity	$ 235,362,794	$ 94,003,471

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

	Three months ended March 31,	
	2026	**2025**
Operating expenses:		
Research and development	$8,087,845	$11,951,023
General and administrative	11,373,909	6,267,412
Total operating expenses	19,461,754	18,218,435
Loss from operations	(19,461,754)	(18,218,435)
Other income:		
Interest/investment income, net	959,762	440,287
Realized (loss)/gain on short-term investments	(9,867)	62,952
Unrealized (loss)/gain on short-term investments	(540,097)	155,731
Total other income, net	409,798	658,970
Net loss	$(19,051,956)	$(17,559,465)
Loss per common share – basic and diluted	$ (0.22)	$ (0.58)
Weighted average number of common shares outstanding – basic and diluted	86,596,873	30,408,890

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

	Three months ended March 31, 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

	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

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

	Three months ended March 31,	
	2026	2025

Cash flows from operating activities		
Net loss	$(19,051,956)	$(17,559,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	956,186	3,572,769
Stock appreciation rights compensation	2,677,652	3,038
Issuance of restricted common stock	–	905,226
Realized loss/(gain) on short-term investments	9,867	(62,952)
Unrealized loss/(gain) on short-term investments	540,097	(155,731)
Change in operating assets and liabilities:		
Prepaid expenses	(402,430)	290,051
Accounts payable	1,762,457	(2,865,553)
Accrued expenses	(1,559,361)	(2,194,416)
Net cash used in operating activities	(15,067,488)	(18,067,033)
Cash flows from investing activities		
Purchase of short-term investments	(149,517,480)	(487,916)
Sale of short-term investments	14,290,483	15,847,629
Net cash (used in)/provided by investing activities	(135,226,997)	15,359,713
Cash flows from financing activities		
Proceeds from issuance of common stock	159,999,996	–
Payment of fees for issuance of common stock	(3,360,000)	–
ATM Fees	(65,651)	–
Net cash provided by financing activities	156,574,345	–
Net increase/(decrease) in cash and cash equivalents	6,279,860	(2,707,320)
Cash and cash equivalents at beginning of the period	3,496,540	3,857,026
Cash and cash equivalents at end of the period	$ 9,776,400	$ 1,149,706
Non-cash investing and financing activities:		
Cashless exercise of warrants for common stock	(2,082)	–
Fees for issuance of common stock included in accounts payable	2,400,000	–
Fees for issuance of common stock included in accrued expenses	3,858,011	

Source: Relmada Therapeutics

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