Relmada Therapeutics Reports Fourth Quarter and Full Year 2025 Results and Provides Business Update

Description

- *Positive 12-month Phase 2 data for NDV-01 in non-muscle invasive bladder cancer (NMIBC) demonstrated a 95% complete response (CR) rate at any time and a durable 76% CR rate at 12 months, with favorable safety profile*
- *Completed an oversubscribed $160 million PIPE financing led by leading healthcare investors in March 2026, strengthens balance sheet to support NDV-01 Phase 3 development*
- *On track to initiate Phase 3 RESCUE registrational program in second line (2L) BCG-unresponsive and adjuvant intermediate-risk NMIBC in mid-2026*
- *Cash balance of $93.0 million as of December 31, 2025, plus gross proceeds of $160 million from March 2026 PIPE expected to fund operations through 2029, including completion of the NDV-01 RESCUE program*
- *Management to host a conference call and webcast today at 4:30 PM ET*

CORAL GABLES, Fla., March 19, 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 audited financial results for the fourth quarter and full year ended December 31, 2025 and provided a corporate update highlighting significant progress across its pipeline.**

"This has truly been a transformational year for Relmada, marked by significant progress with our lead program NDV-01," said **Sergio Traversa, Chief Executive Officer** of Relmada Therapeutics. "Our recently reported 12-month data for NDV-01 demonstrated durable complete responses with a favorable safety profile, reinforcing the program's potential to become a best-in-class therapy for patients with non-muscle invasive bladder cancer. With a successful $160 million PIPE financing and regulatory alignment with the FDA on two registrational pathways, we believe that we are well positioned to advance NDV-01 into the Phase 3 RESCUE program in mid-2026. Our team is now focused on executing this plan and initiating the RESCUE registrational program as we work to bring NDV-01 to patients as efficiently as possible."

"NDV-01's compelling efficacy, durability, and favorable safety profile, combined with operational ease-of-use are the cornerstone of its differentiated product profile and best-in-class potential," said **Raj S. Pruthi, MD, Chief Medical Officer-Oncology of Relmada Therapeutics**. "We continue to be encouraged by the high response rates and durable clinical benefit observed through 12 months, including in the BCG-unresponsive population, alongside a favorable safety profile with no ? Grade 3 treatment-related adverse events and no treatment-related discontinuations. Our clinical program builds on the urologic oncology community's comfort with conventional Gem/Doce's efficacy and safety profile with a sustained release product that could provide physicians and patients with a streamlined, less than 5-minute in-office

procedure. These results reinforce our confidence as we advance NDV-01 into the Phase 3 RESCUE registrational program in mid-2026."

Highlights of the 12-month follow-up data from the ongoing Phase 2 study of NDV-01:

In the 12-month follow-up of the Phase 2a study (March 9, 2026 Company press release) treatment with NDV-01 produced:

- **Durable 76% complete response (CR) rate at 12 months with 95% CR rate at any time in high-risk NMIBC**
- **BCG-unresponsive patients achieved an 80% CR rate at 12 months and 94% CR rate at any time**
- 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.

Phase 3 RESCUE Registrational Pathways:

As previously disclosed in the Company's January 12, 2026 regulatory update, 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.

Registrational Pathway 1 – An open label randomized controlled trial in intermediate-risk NMIBC of adjuvant therapy following TURBT (NDV-01 vs. observation). There are no approved treatments for adjuvant intermediate risk NMIBC, which we estimate affect ~75,000 patients/year in the U.S. The primary endpoint of the study is disease free survival (DFS).

Registration Pathway 2 – A 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 U.S., have few, if any, effective treatment alternatives to radical cystectomy. The primary endpoint of the study is complete response (CR) rate at any time.

Expected Upcoming Relmada Milestones:

- NDV-01 United States IND clearance – 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 expected by YE 2026

Financial Results

Fourth Quarter 2025 Financial Results

- Research and development expense for the three months ended December 31, 2025, totaled $8.1 million, compared to $11.0 million for the three months ended December 31, 2024, a decrease of $2.9 million. The decrease was primarily driven by a decrease in study costs associated with the completion of two Phase 3 trials for REL-1017, partially offset by increased costs related to the start-up 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 December 31, 2025, totaled $12.3 million compared to $8.1 million for the three months ended December 31, 2024, an increase of approximately $4.2 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 December 31, 2025, totaled $14.6 million compared to $8.8 million for the three months ended December 31, 2024.
- The net loss for the three months ended December 31, 2025, was $19.9 million, or $0.27 per basic and diluted share, compared with a net loss of $18.6 million, or $0.62 per basic and diluted share, for the three months ended December 31, 2024.

Twelve Month Ended December 31, 2025 Financial Results

- Research and development (R&D) expense for the 12 months ended December 31, 2025, totaled $26.9 million, compared to $46.2 million for the 12 months ended December 31, 2024, a decrease of $19.3 million. The decrease was primarily driven by a decrease in study costs associated with completion and conclusion of two Phase 3 trials for REL-1017, partially offset by increased costs related to the acquisition of NDV-01 and sepranolone, as well as the start-up of the Phase 3 NDV-01 trials and Phase 2b sepranolone study.
- General and administrative (G&A) expense for the 12 months ended December 31, 2025, totaled $32.2 million compared to $37.7 million for the 12 months ended December 31, 2024, a decrease of approximately $5.5 million. The decrease was primarily driven by a decrease in stock-based compensation expense and lower professional fees, partially offset by an increase in personnel-related costs.
- Net cash used in operating activities for the 12 months ended December 31, 2025, totaled $45.8 million compared to $51.8 million for the 12 months ended December 31, 2024.
- The net loss for the 12 months ended December 31, 2025, was $57.4 million, or $1.45 per basic and diluted share, compared with a net loss of $80.0 million, or $2.65 per basic and diluted share, for the 12 months ended December 31, 2024.
- The Company’s cash balance of $93.0 million in cash, cash equivalents, and short-term investments, includes net proceeds of approximately $94 million from an underwritten stock offering announced November 5, 2025. This compares to cash, cash equivalents, and short-term investments of approximately $44.9 million at December 31, 2024.
- On March 9, 2026, the Company announced a private financing with gross proceeds of $160 million. This financing, along with the cash, cash equivalents, and short-term investments as of December 31, 2025, 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 March 16, 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, March 19, 2026 at 4:30 PM ET
- Participant Dial-in (US): 1-877-407-0792
- Participant Dial-in (International): 1-201-689-8263
- 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 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. The NDV-01 formulation is ready to use, convenient to administer in-office in less than 5 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 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, 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 75-80% 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 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 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, 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 (Audited)

	As of December 31, 2025	As of December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$3,496,540	$3,857,026
Short-term investments	89,509,710	41,052,356
Prepaid expenses	977,721	886,461
Total current assets	93,983,971	45,795,843
Other assets	19,500	21,975
Total assets	$ 94,003,471	$ 45,817,818
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,568,944	$ 4,130,563
Accrued expenses	4,861,583	6,160,827
Total current liabilities	6,430,527	10,291,390
Stock appreciation rights	1,060,931	4,467
Total liabilities	7,491,458	10,295,857
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, 73,333,622 and 30,174,202 shares issued and outstanding, respectively	73,333	30,174
Additional paid-in capital	784,705,878	676,373,822
Accumulated deficit	(698,267,198)	(640,882,035)
Total stockholders' equity	86,512,013	35,521,961
Total liabilities and stockholders' equity	$ 94,003,471	$ 45,817,818

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

	2025	2024
Operating expenses:		
Research and development	$26,879,146	$46,175,512
General and administrative	32,221,054	37,715,524
Total operating expenses	59,100,200	83,891,036
Loss from operations	(59,100,200)	(83,891,036)
Other income (expenses):		
Interest/investment income, net	1,395,989	3,530,021
Realized (loss) gain on short-term investments	(79,207)	374,926
Unrealized gain on short-term investments	398,255	6,735
Total other income (expenses), net	1,715,037	3,911,682
Net loss	$ (57,385,163)	$ (79,979,354)
Net loss per common share – basic and diluted	$ (1.45)	$ (2.65)
Weighted average number of common shares outstanding – basic and diluted	39,479,694	30,163,751

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

	Common Stock		Additional Paid-in	Accumulated	
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 option	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
Stock-based compensation expense	–	–	13,905,181	–	13,905,181
Issuance of restricted common stock	3,017,420	3,017	902,209	–	905,226
Net proceeds from cash exercise options	40,142,000	40,142	93,597,687	–	93,637,829
ATM fees	–	–	(73,021)	–	(73,021)
Net loss	–	–	–	(57,385,163)	(57,385,163)
Balance – December 31, 2025	73,333,622	$73,333	$784,705,878	$(698,267,198)	$ 86,512,013

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

	2025	2024
Cash flows from operating activities		
Net loss	$(57,385,163)	$(79,979,354)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	13,905,181	30,184,414
Stock appreciation rights compensation	1,056,464	4,467
Issuance of restricted common stock	905,226	–
Realized (gain) loss on short-term investments	79,207	(374,926)
Unrealized gain on short-term investments	(398,255)	(6,735)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(88,785)	319,746
Accounts payable	(2,561,619)	624,554
Accrued expenses	(1,299,244)	(2,527,964)
Net cash used in operating activities	(45,786,988)	(51,755,798)
Cash flows from investing activities		
Purchase of short-term investments	(83,828,576)	(12,079,628)
Sale of short-term investments	35,690,270	63,641,225
Net cash (used in)/provided by investing activities	(48,138,306)	51,561,597

Cash flows from financing activities		
Proceeds from issuance of common stock, net	93,637,829	–
Payment of ATM fees	(73,021)	(287,088)
Proceeds from options exercised for common stock	–	246,747
Net cash provided by/(used in) financing activities	93,564,808	(40,341)
Net decrease in cash and cash equivalents	(360,486)	(234,542)
Cash and cash equivalents at beginning of the year	3,857,026	4,091,568
Cash and cash equivalents at end of the year	$ 3,496,540	$ 3,857,026

Source: Relmada Therapeutics

Released March 19, 2026

Date Created
2026/03/19