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

Description

November 12, 2026 16:05 ET

- *NDV-01 CMC program on track to submit the IND by year-end 2026, with initiation of the registrational Phase 3 SPECTRUM program upon IND clearance*
- *Long-term extension NDV-01 Phase 2 data demonstrate continued durability of response: 86% of 12-month complete responders remained in complete response at 18 months, with no Grade ?3 treatment-related adverse events or discontinuations*
- *Registrational Phase 3 program renamed SPECTRUM; two independent registrational pathways in NMIBC remain unchanged*
- *Cash, cash equivalents and short-term investments of approximately $202.1 million as of September 30, 2026, expected to fund operations through 2029*

CORAL GABLES, Fla., Nov. 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 third quarter ended September 30, 2026, and provided a business update, including 18-month results from the NDV-01 Phase 2 study, the registrational Phase 3 SPECTRUM program, and continued progress toward the planned year-end 2026 Investigational New Drug (IND) submission for NDV-01 and sepranolone.

“Relmada has made significant progress in advancing the NDV-01 CMC program and remains on track to submit the NDV-01 IND by year-end 2026. Furthermore, we have established a manufacturing plan to provide uninterrupted clinical supply through the completion of the Phase 3 SPECTRUM program,” said Sergio Traversa, Chief Executive Officer of Relmada Therapeutics.

“Initial 18-month results from the ongoing NDV-01 Phase 2 study demonstrate extended durability of complete response and continued favorable tolerability,” added Bipin Dalmia, Chief Business Officer of Relmada Therapeutics. “Our Phase 3 program remains unchanged, with two independent registrational pathways in NMIBC, and we have renamed it SPECTRUM to reflect the potential breadth of NDV-01 across the NMIBC disease spectrum. We expect to begin the SPECTRUM program upon IND clearance.”

CMC and Manufacturing Update

NDV-01: NDV-01 CMC program is on track for IND submission by year-end 2026, with initiation of the registrational Phase 3 SPECTRUM program upon IND clearance. Furthermore, we have established a manufacturing plan to provide uninterrupted clinical supply through completion of the Phase 3 SPECTRUM program.

Sepranolone: The Company is finalizing the stability testing of the pre-filled syringe (PFS) delivery system to enable sepranolone IND submission, which is on track for year-end 2026. We expect to start

the Phase 2b trial in Prader-Willi Syndrome upon IND clearance.

NDV-01 Clinical Update

Phase 2 Study: Initial 18-month results from the ongoing Phase 2 TRGC-011 study of NDV-01 in high-risk NMIBC continue to support extended durability of NDV-01 complete responses and continued favorable tolerability profile.

- **Initial 18-month durability results:** 23 patients in complete response (CR) at 12 months continued into the long-term extension (LTE). 86% (12/14) of evaluable patients who reached 18 months remained in CR. In the BCG-unresponsive subgroup, 11 patients continued into the LTE, and 88% (7/8) of evaluable patients who reached 18 months remained in CR. Two BCG-naïve patients (T1 at study entry) progressed to muscle-invasive disease (T2a) at the Month 15 assessment.
- **Updated 12-month efficacy results:** Among 51 evaluable patients, the anytime CR rate was 94% (48/51) and the 12-month CR rate was 77% (24/31). In the BCG-unresponsive subgroup, the anytime CR rate was 96% (22/23) and 12-month CR rate was 73% (11/15). Through 12-months, both progression-free and cystectomy-free survival was 100%.
- **Safety and tolerability:** To date, there were no Grade ?3 treatment-related adverse events (TRAEs), no treatment-related serious adverse events, and no treatment-related discontinuations.

Phase 3 SPECTRUM Program: The NDV-01 Phase 3 program remains unchanged and is designed to pursue two independent registrational pathways in NMIBC:

1. A single-arm study in second-line (2L) high-risk BCG-unresponsive carcinoma in situ (CIS) ± Ta/T1 (Cohort 2UC), together with a separate single-arm 2L high-risk BCG-unresponsive Ta/T1 w/o CIS exploratory cohort (Cohort 2UP).
2. A randomized study evaluating NDV-01 as adjuvant therapy following transurethral resection of bladder tumor (TURBT) versus observation in low-grade intermediate-risk NMIBC (Cohort IRA).

The Company has changed the name of its Phase 3 program from RESCUE to SPECTRUM to better reflect the potential breadth of NDV-01 across the entire NMIBC disease spectrum. Clinical trial sites are engaged and preparing to initiate patient enrollment upon IND clearance.

Anticipated Upcoming Milestones

NDV-01:

- NDV-01 United States IND submission – By year-end 2026
- NDV-01 Phase 3 SPECTRUM program initiation – Upon IND clearance

Sepranolone:

- Sepranolone United States IND submission – By year-end 2026
- Sepranolone Phase 2b initiation in Prader-Willi Syndrome – Upon IND clearance

Financial Results

Third Quarter 2026 Financial Results

- Research and development expense for the three months ended September 30, 2026, totaled $9.2 million, compared to $4.0 million for the three months ended September 30, 2025, an increase of $5.2 million. The increase was primarily attributable to higher NDV-01 and sepranolone study preparation costs, increased manufacturing and drug storage costs and higher employee compensation, partially offset by lower stock-based compensation.
- General and administrative expense for the three months ended September 30, 2026, totaled $3.9 million compared to $6.3 million for the three months ended September 30, 2025, a decrease of approximately $2.4 million. The decrease was primarily driven by lower stock-based compensation and lower stock appreciation rights expense, partially offset by higher employee compensation and consulting services.
- Net cash used in operating activities for the three months ended September 30, 2026, totaled $12.6 million compared to $6.7 million for the three months ended September 30, 2025.
- The net loss for the three months ended September 30, 2026, was $13.9 million, or $0.12 per basic and diluted share, compared with a net loss of $10.1 million, or $0.30 per basic and diluted share, for the three months ended September 30, 2025.
- As of September 30, 2026, the Company's cash, cash equivalents, and short-term investments totaled $202.1 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 September 30, 2026, are expected to provide sufficient resources to fund Company operations through 2029, including completion of the two registrational cohorts of the NDV-01 Phase 3 SPECTRUM program.
- The Company had 106,694,846 shares outstanding, as of November 10, 2026.

Nine Months Ended September 30, 2026 Financial Results

- Research and development expense for the nine months ended September 30, 2026, totaled $25.7 million, compared to $18.8 million for the nine months ended September 30, 2025, an increase of $6.9 million. The increase was primarily attributable to increased manufacturing and drug storage costs, higher employee compensation and higher stock appreciation rights expense, partially offset by lower study costs and lower stock-based compensation.
- General and administrative expense for the nine months ended September 30, 2026, totaled $21.9 million compared to $20.0 million for the nine months ended September 30, 2025, an increase of approximately $1.9 million. The increase was primarily driven by higher employee compensation, stock appreciation rights expense and consulting services, partially offset by lower stock-based compensation.
- Net cash used in operating activities for the nine months ended September 30, 2026, totaled $37.3 million compared to $31.2 million for the nine months ended September 30, 2025.
- The net loss for the nine months ended September 30, 2026, was $45.8 million, or $0.44 per basic and diluted share, compared with a net loss of $37.5 million, or $1.16 per basic and diluted share,

for the nine months ended September 30, 2025.

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.

Date: Thursday, November 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://ir.relmada.com/investors/events/.

About NDV-01

NDV-01 is a novel, sustained-release, intravesical co-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 for up to 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 SPECTRUM Registrational Pathways:

Relmada has received written FDA feedback confirming alignment on two registrational 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 SPECTRUM 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 63,000 incident NMIBC cases per year 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. While four therapies are FDA-approved for first line BCG-unresponsive disease, there are no approved therapies in the second line or later. 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 intravesical 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 a favorable safety profile. The Company is on track to submit the sepranolone IND by year-end 2026 and expects to 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, potential changes to the design, size or timing of the Phase 3 SPECTRUM studies, including as a result of updated treatment guidelines or third-party clinical data, 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.

Investor Contact:
Brian Ritchie
LifeSci Advisors
britchie@lifesciadvisors.com

Media Inquiries:
Corporate Communications
media@relmada.com

Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	As of September 30, 2026 (Unaudited)	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$5,720,325	$3,496,540
Short-term investments	196,402,988	89,509,710
Other receivable	10,912	—
Prepaid expenses	2,915,011	977,721
Total current assets	205,049,236	93,983,971
Other assets	247,379	19,500
Total assets	$ 205,296,615	$ 94,003,471
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable	$ 2,538,585	$ 1,568,944
Accrued expenses	5,237,116	4,861,583
Total current liabilities	7,775,701	6,430,527
Stock appreciation rights	3,783,853	1,060,931
Total liabilities	11,559,554	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 and 150,000,000 shares authorized, respectively, 106,694,846 and 73,333,622 shares issued and outstanding, respectively	106,695	73,333
Additional paid-in capital	937,725,893	784,705,878
Accumulated deficit	(744,095,527)	(698,267,198)
Total stockholders' equity	193,737,061	86,512,013
Total liabilities and stockholders' equity	$ 205,296,615	$ 94,003,471

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

	Three months ended September 30,		Nine months ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 9,217,440	$ 4,036,267	$ 25,699,073	$ 18,806,667
General and administrative	3,878,983	6,291,079	21,870,130	19,960,421
Total operating expenses	13,096,423	10,327,346	47,569,203	38,767,088
Loss from operations	(13,096,423)	(10,327,346)	(47,569,203)	(38,767,088)
Other (expenses) income:				
Interest/investment income, net	2,274,541	247,013	5,535,697	1,008,758
Realized (loss) gain on short-term investments	(435,122)	(81,438)	(482,284)	28,717

Unrealized (loss) gain on short-term investments	(2,605,184)	70,275	(3,312,539)	212,210
Total other (expense) income – net	(765,765)	235,850	1,740,874	1,249,685
Net loss	$(13,862,188)	$(10,091,496)	$(45,828,329)	$(37,517,403)
Loss per common share – basic and diluted	$ (0.12)	$ (0.30)	$ (0.44)	$ (1.16)
Weighted average number of common shares outstanding – basic and diluted	112,437,710	33,191,622	103,745,599	32,274,238

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

	Three and Nine months ended September 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
Stock based compensation	—	—	1,023,176	—	1,023,176
Options exercised	25,000	25	17,725	—	17,750
Net loss	—	—	—	(13,862,188)	(13,862,188)
Balance – September 30, 2026	106,694,846	$106,695	$ 937,725,893	$(744,095,527)	$ 193,737,061

	Three and Nine months ended September 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
Stock-based compensation	—	—	3,607,554	—	3,607,554
Net loss	—	—	—	(10,091,496)	(10,091,496)
Balance – September 30, 2025	33,191,622	$33,191	$687,831,786	$(678,399,438)	$9,465,539

Date Created
2026/11/12