Relmada Therapeutics Reports Third Quarter 2025 Financial Results and Provides Key Clinical, Regulatory, and Corporate Updates

Description

Positive 9-month follow-up data for NDV-01 showed a 92% overall response rate at any time in non-muscle invasive bladder cancer (NMIBC), with favorable overall safety

Secured FDA alignment on key elements of Phase 3 program with two independent paths for approval in two separate NMIBC indications: High-risk 2nd line BCG-unresponsive, and Intermediate-risk patients in the adjuvant setting; Studies expected to begin H1 2026

Completed $100M underwritten offering of common stock and pre-funded warrants on November 5th to support planned operations into 2028

Conference Call and Webcast Today at 4:30 PM ET

CORAL GABLES, Fla., Nov. 13, 2025 (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 indications, today reported financial results for the third quarter ended September 30, 2025, and provided business highlights including updates for the NDV-01 program for non-muscle invasive bladder cancer (NMIBC) and completion of an underwritten financing providing $100 million in gross proceeds.

"Relmada's outstanding progress this year has significantly de-risked our lead program, NDV-01 for NMIBC, and established a strong foundation for future success. Positive 9-month data showing a 92% complete response (CR) rate at any time point and the positive outcome of our Type B meeting with the FDA further reinforce our confidence in NDV-01's potential to become a best-in-class treatment for NMIBC," said **Sergio Traversa, Chief Executive Officer** of Relmada Therapeutics. "The recent $100M underwritten financing provides the resources to drive forward the planned registrational studies for NDV-01, advance development of sepranolone for Prader-Willi Syndrome (PWS) and support the future growth of Relmada."

NDV-01 Program Update:

- As previously announced, FDA Type B pre-IND meeting secured FDA alignment on key elements of planned Phase 3 registrational program (specific study design details to be further discussed with the agency):
  - **In high-risk, 2nd line BCG-unresponsive setting**, FDA stated that a single arm trial might be acceptable in a more refractory patient population.
  - **In the intermediate-risk NMIBC setting**, FDA agreed that a proposal to randomize patients post-TURBT (transurethral resection of bladder tumor) to adjuvant NDV-01 vs observation, evaluating a time-to-event endpoint, is generally acceptable.

- **Further non-clinical studies are not required**. FDA indicated that no further non-clinical studies are required to support a 505(b)(2) New Drug Application (NDA).

- **9-month follow-up for NDV-01 showed a 92% complete response rate (CRR) at any time**, with favorable overall safety

Clinical Results (Response Data)

Complete Response	% (n/N)
Anytime	92% (23/25)
3 months	84% (21/25)
6 months	87% (20/23)*
9 months	85% (17/20)*

**Includes patients with CR after re-induction. 60% CR rate after re-induction*

- Two subjects have reached 12-month assessment, and both have a CR
- No patient had progression to muscle-invasive disease
- No patient underwent a radical cystectomy
- No new safety signals in terms of type, number, or degree of AEs — with no patients having a ? Grade 3 TRAE and no patients discontinued treatment due to AEs
- Of 36 enrolled patients receiving ? 1 dose, 22 (61%) experienced a treatment-related adverse event (AE). Among treatment-related AEs, 62% were transient (< 24 hours) grade 1 uncomfortable urination (dysuria), 9% were asymptomatic positive urine culture and 7% were hematuria.

Efficacy in BCG-Unresponsive Subpopulation:**

Clinical Results (Response Data)

Complete Response	% (n/N)
Anytime	91% (10/11)
3 months	82% (9/11)
6 months	78% (7/9)
9 months	88% (7/8)

n = 18 patients in BCG-UR subpopulation, BCG-UR defined by FDA definition**
**https://www.fda.gov/media/101468/download,
BCG-UR, Bacillus Calmette-Guérin (BCG) – Unresponsive

Additional NDV-01 Update:

- **Relmada announced the appointment of Max Kates, MD to the Company's Clinical Advisory Board**. Dr. Kates, Associate Professor of Urology and Oncology at Johns Hopkins University School of Medicine, is a distinguished urologic oncologist who brings a wealth of experience, from chairing the landmark Phase 3 BRIDGE trial and leading several other practice-changing studies.

“Positive 9-mo data and alignment with the FDA on the Phase 3 pivotal program are key milestones for the NDV-01 program. We are pleased that ongoing Phase 2 follow-up data continue to support the opportunity for NDV-01 to transform the treatment of NMIBC, by providing patients and physicians with a potential bladder-sparing, in-office, ready-to-use, safe, effective and durable, best-in-class therapy,” said **Raj S. Pruthi, MD, Chief Medical Officer-Oncology.** “Securing FDA alignment for two distinct registrational paths provides a clear path to advance NDV-01 for patients with NMIBC who currently have limited options. We believe a single-arm registrational study in high-risk, refractory BCG-unresponsive patients offers a rapid route to potential approval, while alignment on a separate, second pivotal study in intermediate-risk NMIBC could enable an additional indication and broader clinical adoption. We look forward to working with the FDA to establish the final study design and initiate the registrational program in the first half of 2026.”

Expected Upcoming Milestones:

- NDV-01 Twelve-month data from ongoing Phase 2 NMBIC Study – Q1 2026
- NDV-01 United States IND clearance – 1st Half 2026
- NDV-01 High-risk, 2nd line BCG-unresponsive NMIBC Phase 3 Trial Initiation – 1st Half 2026
- NDV-01 Intermediate Risk in the Adjuvant Setting Phase 3 Trial Initiation – 1st Half 2026
- Sepranolone – Initiation of phase 2, proof of concept clinical trial in PWS – 1st Half 2026

Financial Results

Three Months Ended September 30, 2025 Results

- **R&D Expense**: $4.0 million (vs. $11.1 million in Q3 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**: $6.3 million (vs. $11.9 million in Q3 2024), primarily due to lower stock-based compensation and consulting services expenses
- **Net Loss**: $10.1 million or $0.30 per share (vs. $21.7 million or $0.72 per share in Q3 2024)

Nine Months Ended June 30, 2025 Results

- **R&D Expense**: $18.8 million (vs. $35.2 million for the nine months ended September 30, 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**: $20.0 million (vs. $29.6 million or the nine months ended September 30, 2024), primarily due to lower stock-based compensation, G&A employee compensation and use of consulting services
- **Net Cash Used in Operations**: $31.2 million (vs. $43.0 million)
- **Net Loss**: $37.5 million or $1.16 per share (vs. $61.3 million or $2.03 per share)
- **Cash, Equivalents & Short-Term Investments**: $13.9 million as of September 30, 2025 (vs. $44.9 million at December 31, 2024), excluding net proceeds of approximately $94.0 million for an underwritten offering of common stock and pre-funded warrants which the Company closed and settled on November 5, 2025. Based on current plans, the Company believes that its current cash balance, including net proceeds from the offering, is sufficient to support planned expenses into

2028.
- **Shares Outstanding**: 73,333,622 as of November 10, 2025

Conference Call and Webcast

Relmada will host a conference call today, November 13, 2025, at 4:30 PM ET to discuss its Q3 2025 results and pipeline progress.

- **Dial-in (U.S.)**: 1-877-407-0792
- **Dial-in (International)**: 1-201-689-8263
- **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. The NDV-01 formulation is a ready to use, 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 75-80% 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. 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 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-10 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.

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, 2025 (Unaudited)	As of December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$1,384,484	$3,857,026
Short-term investments	12,502,040	41,052,356
Prepaid expenses	967,745	886,461
Total current assets	14,854,269	45,795,843
Other assets	21,975	21,975
Total assets	$ 14,876,244	$ 45,817,818
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,453,102	$ 4,130,563
Accrued expenses	3,736,496	6,160,827
Total current liabilities	5,189,598	10,291,390
Stock appreciation rights	221,107	4,467
Total liabilities	5,410,705	10,295,857
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, 33,191,622 and 30,174,202 shares issued and outstanding, respectively	33,191	30,174
Additional paid-in capital	687,831,786	676,373,822
Accumulated deficit	(678,399,438)	(640,882,035)

Total stockholders' equity	9,465,539	35,521,961
Total liabilities and stockholders' equity	$ 14,876,244	$ 45,817,818

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

	Three months ended September 30,		Nine months ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$4,036,267	$11,149,136	$18,806,667	$35,175,531
General and administrative	6,291,079	11,859,702	19,960,421	29,639,951
Total operating expenses	10,327,346	23,008,838	38,767,088	64,815,482
Loss from operations	(10,327,346)	(23,008,838)	(38,767,088)	(64,815,482)
Other (expenses) income:				
Interest/investment income, net	247,013	856,478	1,008,758	2,875,379
Realized (loss) gain on short-term investments	(81,438)	147,835	28,717	334,082
Unrealized gain on short-term investments	70,275	278,555	212,210	283,803
Total other (expense) income – net	235,850	1,282,868	1,249,685	3,493,264
Net loss	$ (10,091,496)	$ (21,725,970)	$ (37,517,403)	$(61,322,218)
Loss per common share – basic and diluted	$ (0.30)	$ (0.72)	$ (1.16)	$ (2.03)
Weighted average number of common shares outstanding – basic and diluted	33,191,622	30,174,202	32,274,238	30,160,242

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

	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

	Three and Nine months ended September 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 exercises 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
Stock-based compensation	–	–	7,949,125	–	7,949,125
ATM Expenses	–	–	(89,601)	–	(89,601)
Net loss	–	–	–	(21,725,970)	(21,725,970)
Balance – September 30, 2024	30,174,202	$ 30,174	$669,819,907	$(622,224,899)	$ 47,625,182

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

	Nine months ended September 30,	
	2025	2024
Cash flows from operating activities		

Net loss	$(37,517,403)	$(61,322,218)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	11,534,002	23,458,012
Realized gain on short-term investments	(28,717)	(334,082)
Unrealized gain on short-term investments	(212,210)	(283,803)
Fair value changes on stock appreciation rights	216,640	12,562
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(81,285)	(378,596)
Accounts payable	(2,677,461)	(1,160,468)
Accrued expenses	(2,424,331)	(2,947,571)
Net cash used in operating activities	(31,190,765)	(42,956,164)
Cash flows from investing activities		
Purchase of short-term investments	(1,043,307)	(11,424,986)
Sale of short-term investments	29,834,551	51,641,225
Net cash provided by investing activities	28,791,244	40,216,239
Cash flows from financing activities		
Proceeds from options exercised for common stock	–	246,747
ATM Expenses	(73,021)	(114,601)
Net cash (used in)/provided by financing activities	(73,021)	132,146
Net decrease in cash and cash equivalents	(2,472,542)	(2,607,779)
Cash and cash equivalents at beginning of the period	3,857,026	4,091,568
Cash and cash equivalents at end of the period	$ 1,384,484	$ 1,483,789

Source: Relmada Therapeutics

Released November 13, 2025

Date Created
2025/11/13