

November 13, 2025

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

*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 2<sup>nd</sup> 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.](https://www.relmada.com) (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, 2<sup>nd</sup> 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  $\geq$  Grade 3 TRAE and no patients discontinued treatment due to AEs
- Of 36 enrolled patients receiving  $\geq 1$  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) | % (n/N)     |
|-------------------|----------------------------------|-------------|
| Complete Response |                                  |             |
| 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 for 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<sub>A</sub> 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](http://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.

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**Relmada Therapeutics, Inc.**  
**Condensed Consolidated Balance Sheets**

|                           | <b>As of<br/>September 30,<br/>2025<br/>(Unaudited)</b> | <b>As of<br/>December 31,<br/>2024</b> |
|---------------------------|---------------------------------------------------------|----------------------------------------|
| <b>Assets</b>             |                                                         |                                        |
| 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              | <u>\$ 14,876,244</u>                                    | <u>\$ 45,817,818</u>                   |

**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         | <u>5,410,705</u> | <u>10,295,857</u> |

Commitments and Contingencies (See Note 8)

**Stockholders' Equity:**

Preferred stock, \$0.001 par value, 200,000,000 shares authorized, none issued and outstanding

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Class A convertible preferred stock, \$0.001 par value, 3,500,000 shares authorized, none issued and outstanding

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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)**

|                     | <b>Three months ended<br/>September 30,</b> | <b>Nine months ended<br/>September 30,</b> |
|---------------------|---------------------------------------------|--------------------------------------------|
|                     | <b>2025</b>                                 | <b>2024</b>                                |
| 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                                                 | <u>10,327,346</u>      | <u>23,008,838</u>      | <u>38,767,088</u>      | <u>64,815,482</u>      |
| Loss from operations                                                     | <u>(10,327,346)</u>    | <u>(23,008,838)</u>    | <u>(38,767,088)</u>    | <u>(64,815,482)</u>    |
| 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                                | <u>70,275</u>          | <u>278,555</u>         | <u>212,210</u>         | <u>283,803</u>         |
| Total other (expense) income – net                                       | <u>235,850</u>         | <u>1,282,868</u>       | <u>1,249,685</u>       | <u>3,493,264</u>       |
| Net loss                                                                 | <u>\$ (10,091,496)</u> | <u>\$ (21,725,970)</u> | <u>\$ (37,517,403)</u> | <u>\$ (61,322,218)</u> |
| Loss per common share – basic and diluted                                | <u>\$ (0.30)</u>       | <u>\$ (0.72)</u>       | <u>\$ (1.16)</u>       | <u>\$ (2.03)</u>       |
| Weighted average number of common shares outstanding – basic and diluted | <u>33,191,622</u>      | <u>30,174,202</u>      | <u>32,274,238</u>      | <u>30,160,242</u>      |

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

**Three and Nine months ended September 30, 2025**

|                                     | Common Stock      |                  | Additional            | Accumulated             | Total               |
|-------------------------------------|-------------------|------------------|-----------------------|-------------------------|---------------------|
|                                     | Shares            | Par Value        | Paid-in Capital       | Deficit                 |                     |
| 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        | <u>33,191,622</u> | <u>\$ 33,191</u> | <u>\$ 687,831,786</u> | <u>\$ (678,399,438)</u> | <u>\$ 9,465,539</u> |

**Three and Nine months ended September 30, 2024**

|                                    | Common Stock |           | Additional      | Accumulated      | Total         |
|------------------------------------|--------------|-----------|-----------------|------------------|---------------|
|                                    | Shares       | Par Value | Paid-in Capital | Deficit          |               |
| 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 | <u>30,174,202</u> | <u>\$ 30,174</u> | <u>\$ 669,819,907</u> | <u>\$ (622,224,899)</u> | <u>\$ 47,625,182</u> |

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

|                                                                             | Nine months ended<br>September 30, |                     |
|-----------------------------------------------------------------------------|------------------------------------|---------------------|
|                                                                             | 2025                               | 2024                |
| <b>Cash flows from operating activities</b>                                 |                                    |                     |
| 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)         |
| <b>Net cash used in operating activities</b>                                | <u>(31,190,765)</u>                | <u>(42,956,164)</u> |
| <b>Cash flows from investing activities</b>                                 |                                    |                     |
| Purchase of short-term investments                                          | (1,043,307)                        | (11,424,986)        |
| Sale of short-term investments                                              | 29,834,551                         | 51,641,225          |
| <b>Net cash provided by investing activities</b>                            | <u>28,791,244</u>                  | <u>40,216,239</u>   |
| <b>Cash flows from financing activities</b>                                 |                                    |                     |
| Proceeds from options exercised for common stock                            | —                                  | 246,747             |
| ATM Expenses                                                                | (73,021)                           | (114,601)           |
| <b>Net cash (used in)/provided by financing activities</b>                  | <u>(73,021)</u>                    | <u>132,146</u>      |
| <b>Net decrease in cash and cash equivalents</b>                            | <u>(2,472,542)</u>                 | <u>(2,607,779)</u>  |
| <b>Cash and cash equivalents at beginning of the period</b>                 | <u>3,857,026</u>                   | <u>4,091,568</u>    |
| <b>Cash and cash equivalents at end of the period</b>                       | <u>\$ 1,384,484</u>                | <u>\$ 1,483,789</u> |



Source: Relmada Therapeutics