UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **April 28, 2025**

RELMADA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**001-39082**	**45-5401931**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2222 Ponce de Leon Blvd., Floor 3 **Coral Gables, FL**	**33134**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(212) 547-9591**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common stock, $0.001 par value per share	**RLMD**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 Current Report on Form 8-K, including the Exhibits hereto, 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 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 a trial, failure of planned or ongoing preclinical and clinical studies to demonstrate expected results, potential failure to secure FDA agreement on the regulatory path for sepranolone, and NDV-01, or that future sepranolone, or NDV-01 clinical results will be acceptable to the FDA, failure to secure adequate sepranolone, or NDV-01 drug supply, 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 should not be a complete list.

Item 7.01 Regulation FD Disclosure.

On April 28, 2025, Relmada Therapeutics, Inc. (the "Company") issued a press release announcing initial data from its Phase 2 study of NDV-01, a novel delivery formulation of a widely used chemotherapeutic regimen used to treat non muscle-invasive bladder cancer. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information set forth in Item 7.01 of this Current Report on Form 8-K and in the attached Exhibit 99.1 is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information set forth in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

On April 28, 2025, the Company presented at the American Urology Association 2025 (AUA2025) Annual Meeting positive initial data from the Company's Phase 2 study of NDV-01, showing that 90% of patients achieved high-grade disease-free status at any time point following treatment, demonstrating strong clinical activity and supporting further development of NDV-01 for the treatment of non-muscle invasive bladder cancer (NMIBC).

Highlights of Phase 2 data presented at AUA2025:

Efficacy Data:

3-month Assessment:

- Overall Response Rate (ORR): 85% (17/20 patients at 3 months)
- High-Grade Recurrence-Free Survival (HGRFS) in papillary disease: 83.3% (15/18 patients)
- Complete Response (CR) in CIS patients: 100% (2/2 patients)

At any time point:

- ORR: 90% (18/20 patients)
- HGRFS in papillary disease: 88.8% (16/18 patients)
- CR in CIS patients: 100% (2/2 patients)

Disease status at 6 months:

- 100% (n=7) of evaluable patients (1 CIS, 6 Ta/T1) achieved disease free status. One of these patients was re-treated at 3 months.

Overall:

The treatment effect of NDV-01 was consistent across all patient groups, demonstrating robust activity, regardless of prior BCG exposure (BCG-naïve and BCG-unresponsive) or disease pathology (including CIS or Ta/T1 papillary).

Safety:

NDV-01 was well tolerated, with no treatment related adverse events greater than Grade 1. The most common treatment emergent adverse events (TEAEs) were urinary urgency, flank pain, and dysuria, all of which were mild and transient, resolving in 24-28 hours. No patients discontinued treatment due to adverse events.

Study Overview:

- Open-label, single-arm, single-center Phase 2 study (NCT06663137) evaluating NDV-01 in patients with NMIBC (including BCG-naïve (n=8) and BCG-unresponsive (n=12))
- AUA 2025 data based on 20 enrolled patients with NMIBC, including 2 patients with carcinoma in situ (CIS) and 18 patients with papillary disease (Ta/T1)
- 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 study continues to actively enroll patients. As of the latest cut-off, a total of 26 patients have been enrolled: 20 patients have reached the 3-month assessment. Seven patients have reached 6-month assessment
- 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).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued on April 28, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 28, 2025

RELMADA THERAPEUTICS, INC.

By: */s/ Sergio Traversa*
Name: Sergio Traversa
Title: Chief Executive Officer

Exhibit 99.1

Relmada Therapeutics Presents Positive Initial Phase 2 NDV-01 Data at AUA2025

*90% of patients achieved high grade disease-free status at any time point with NDV-01, demonstrating strong proof-of-concept for sustained-release "GEM/DOCE" formulation**

NDV-01 showed promising clinical activity in BCG-naïve and BCG-unresponsive patients, with favorable overall tolerability

Data to be reviewed at Investor Event on April 28, 2025 at 4:30 PM ET

CORAL GABLES, FL, April 28, 2025 (GlobeNewswire) -- Relmada Therapeutics, Inc. (Nasdaq: RLMD, "Relmada", "the Company"), a clinical-stage biotechnology company, today announced that positive initial data from the Phase 2 study of NDV-01 showed that 90% of patients achieved high-grade disease-free status at any time point following treatment, demonstrating strong clinical activity and supporting further development of NDV-01 for the treatment of non-muscle invasive bladder cancer (NMIBC). The data were presented today at the American Urology Association 2025 (AUA2025) Annual Meeting with a data cutoff date of April 20, 2025. To register for the virtual Investor Event, click here.

Highlights of Phase 2 data presented at AUA2025:

Efficacy Data:

3-month Assessment:

- **Overall Response Rate (ORR): 85%** (17/20 patients at 3 months)
- **High-Grade Recurrence-Free Survival (HGRFS) in papillary disease: 83.3%** (15/18 patients)
- **Complete Response (CR) in CIS patients: 100%** (2/2 patients)

At any time point:

- **ORR: 90%** (18/20 patients)
- **HGRFS in papillary disease:** 88.8% (16/18 patients)
- **CR in CIS patients: 100%** (2/2 patients)

Disease status at 6 months:

- **100% (n=7) of evaluable patients (1 CIS, 6 Ta/T1) achieved disease free status.** One of these patients was re-treated at 3 months.

"I am impressed by these promising NDV-01 data reported at AUA2025. Gemcitabine and docetaxel (GEM/DOCE) have long shown clinical utility in NMIBC, but the complexity of administration has limited their broader use," said **Yair Lotan, MD**, Professor of Urology and Chief of Urologic Oncology at UT Southwestern Medical Center. "A formulation like NDV-01, which is designed to increase exposure to drug and simplify delivery and accessibility, has the potential to significantly change how we manage patients with NMIBC in routine practice."

"We believe NDV-01 has the potential to become the class-leading therapy for NMIBC across a wide spectrum of patients," said **Sergio Traversa**, CEO of Relmada. "The data presented at AUA2025 provide compelling proof-of-concept for NDV-01 as a bladder-sparing therapy. With its strong responses and tolerability combined with an administration time of less than 10 minutes, NDV-01 represents a potentially significant advance in outpatient bladder cancer treatment. We are enthusiastic about advancing this differentiated, ready-to-use GEM/DOCE formulation to improve patient outcomes and expand treatment options in NMIBC."

Overall:
The treatment effect of NDV-01 was consistent across all patient groups, demonstrating robust activity, regardless of prior BCG exposure (BCG-naïve and BCG-unresponsive) or disease pathology (including CIS or Ta/T1 papillary).

Safety:
NDV-01 was well tolerated, with no treatment related adverse events greater than Grade 1. The most common treatment emergent adverse events (TEAEs) were urinary urgency, flank pain, and dysuria, all of which were mild and transient, resolving in 24-28 hours. No patients discontinued treatment due to adverse events.

Study Overview:

- Open-label, single-arm, single-center Phase 2 study evaluating NDV-01 in patients with HG-NMIBC (including BCG-naïve (n=8) and BCG-unresponsive (n=12))
- AUA 2025 data based on 20 enrolled patients with HG-NMIBC, including 2 patients with carcinoma in situ (CIS) and 18 patients with papillary disease (Ta/T1)
- The study continues to actively enroll patients. As of the latest cut-off, a total of 26 patients have been enrolled: 20 patients have reached the 3-month assessment. Seven patients have reached 6-month assessment

* 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 NDV-01

NDV-01 is an innovative, investigational sustained-release formulation of two complementary chemotherapy agents, gemcitabine and docetaxel (GEM/DOCE). Designed for intravesical administration, NDV-01 forms a soft matrix within the bladder, gradually releasing drug over 10 days without requiring anesthesia or special equipment. NDV-01 is intended to simplify outpatient NMIBC treatment while maximizing local exposure, minimizing systemic toxicity, and improving patient convenience.

NDV-01 is protected by patents that extend to 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

More than 90% of the approximately 83,000 new U.S. cases of urothelial cancer are estimated to be bladder cancer. For the overall bladder cancer population, 5-year survival ranges from 70 to 96% of patients, moving to 6% for patients with advanced disease. Roughly 75% of bladder cancer cases are classified as non-muscle invasive (NMIBC) and approximately 50% of cases are classified as high-grade disease, considered to have increased risk of progression and recurrence. Sources indicate that NMIBC has a 50-75% recurrence rate (over seven years) and that the U.S. prevalence of NMIBC is approximately 600,000 patients.

The U.S. NMIBC market is estimated to be a multi-billion-dollar opportunity. Global numbers are higher, in line with projections for significant growth due to the increasing incidence of bladder cancer and the demand for effective, minimally invasive potential therapies like NDV-01. Approved treatment options remain limited (mainly the immunotherapy, BCG, which has been supply constrained for some time), with high recurrence rates leading to frequent re-treatment and progression. Other emerging programs include immunotherapy combinations, single agent chemotherapy formulations and targeted therapies. NDV-01 stands out based on the large body of published data that support the efficacy of treatment with gemcitabine and docetaxel, its ease of administration and potential for durability of action. Expansion beyond first-line treatment into use as a salvage treatment or in other subgroups of NMIBC, including naïve patients, could further increase the opportunity for NDV-01.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage biotechnology company committed to advancing innovative breakthrough therapies that have the potential to bring meaningful clinical benefits to targeted patient populations.

Lead investigational program, NDV-01, for High-Grade Non-Muscle Invasive Bladder Cancer, is being evaluated in a Phase 2 study. In addition, preparations are underway to advance sepranolone, a Phase 2b-ready investigational program for compulsion-related disorders including Tourette's Syndrome and Prader-Willi Syndrome, into further studies.

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 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 a trial, failure of planned or ongoing preclinical and clinical studies to demonstrate expected results, potential failure to secure FDA agreement on the regulatory path for sepranolone, and NDV-01, or that future sepranolone, or NDV-01 clinical results will be acceptable to the FDA, failure to secure adequate sepranolone, or NDV-01 drug supply, 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 should not be a complete list.

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