Relmada Issues Mid-Year CEO Letter to Shareholders

Description

CORAL GABLES, Fla., Sept. 10, 2025 (GLOBE NEWSWIRE) — Relmada Therapeutics, Inc. (Nasdaq: RLMD, “Relmada” or the “Company”), a clinical-stage biotechnology company advancing innovative therapies for oncology-related and central nervous system indications, today issued a Letter to Shareholders from Sergio Traversa, Chief Executive Officer.

Dear Fellow Shareholders:

2025 has been a truly transformational year for Relmada Therapeutics. With the year now well into its second half, I am pleased to share an update on our recent progress and to thank you for your continued support.

Strategic Review and Portfolio Expansion

Earlier this year, we completed a comprehensive strategic review that reaffirmed our mission to develop life-changing treatments while building a diversified portfolio. As a result, we added two differentiated Phase 2 product candidates that significantly strengthen Relmada’s long-term value proposition:

- **NDV-01,** a sustained-release formulation of gemcitabine and docetaxel in development for non-muscle invasive bladder cancer (NMIBC)
- **Sepranolone,** being developed for compulsivity disorders such as Prader-Willi Syndrome (PWS)

NDV-01: Strong Phase 2 Results and Path to Phase 3

Six-month follow-up data from our Phase 2 study of NDV-01 demonstrated impressive results, with **a 91% complete response (CR) rate** at any time point following treatment. These findings build on the positive three-month data presented at the **2025 American Urological Association Annual Meeting** and reinforce the potential of NDV-01 as a transformative, bladder-sparing therapy for NMIBC, a condition that affects approximately 600,000 patients in the U.S.

We are actively preparing to initiate a **Phase 3 registrational trial in the first half of 2026**, with key activities underway including regulatory filings and manufacturing scale-up.

Strengthening the NDV-01 Program

To further support NDV-01, we added two experts in bladder cancer to the Relmada team:

Raj S. Pruthi, MD as Chief Medical Officer–Oncology

Yair Lotan, MD as Chair of the Clinical Advisory Board

Their expertise will be invaluable as we advance the program toward late-stage development.

Sepranolone: Advancing in Prader-Willi Syndrome

Positive proof-of-concept data in Tourette's syndrome suggest that sepranolone may hold promise as a therapy for compulsive disorders. **In the first half of 2026,** we plan to initiate a **Phase 2 study in PWS**, a rare genetic disorder affecting 350,000–400,000 people worldwide and characterized by compulsive behaviors such as hyperphagia (obsessive eating). Preparations, including regulatory engagement and manufacturing activities, are underway.

Key Upcoming Milestones

NDV-01

- Phase 2 nine-month results (Q4 2025) and twelve months (Q1 2026)
- Product supply scale-up — 2H 2025
- U.S. IND clearance — 1H 2026
- Initiation of Phase 3 registrational trial — 1H 2026

Sepranolone

- FDA engagement and manufacturing activities — 2H 2025
- Initiation of Phase 2 PWS study — 1H 2026

Looking Ahead

As we begin the autumn season, we remain optimistic about Relmada's future. The progress of NDV-01 and sepranolone, combined with the expertise of our strengthened team, positions us well for value creation through disciplined execution and capital-efficient development.

On behalf of the entire Relmada team, thank you for your continued trust and confidence. We look forward to keeping you updated on our progress in the months ahead.

Sincerely,

Sergio Traversa

Chief Executive Officer

Relmada Therapeutics, Inc.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage biotechnology company focused on developing transformative therapies for oncology-related and central nervous system conditions. 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/Shareholder Letter 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 the 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, the 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 secure FDA agreement on the regulatory path for NDV-01, and sepranolone, or that future NDV-01, or sepranolone, clinical results will be acceptable to the FDA, failure to secure adequate NDV-10, or sepranolone, 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.

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

Media Inquiries:
Corporate Communications
media@relmada.com

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