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): **September 10, 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: **(786) 629-1376**

(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 Capital 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. ☐

Item 7.01 Regulation FD Disclosure.

On September 10, 2025, Relmada Therapeutics, Inc. (the "Company") issued a letter to its shareholders providing an update on the Company's recent progress, a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

On September 10, 2025, the Company also updated its corporate presentation, a copy of which is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibits 99.1 and 99.2, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1*	Letter to Shareholders dated September 10, 2025
99.2*	Corporate Presentation dated September 10, 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: September 10, 2025

RELMADA THERAPEUTICS, INC.

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

Exhibit 99.1

Relmada Issues Mid-Year CEO Letter to Shareholders

CORAL GABLES, FL – Sep 10, 2025 (GlobeNewswire) – 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

Exhibit 99.2

Relmada THERAPEUTICS

CORPORATE OVERVIEW

Unlocking Life Changing Therapies

August 2025

Disclosures

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 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 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.

Targeting life changing treatments with a diversified portfolio

Strategic pipeline development

Focused on innovative programs with early proof points, near-term milestone(s) and focused markets

Positive Phase 2a data for NDV-01, for NMIBC

Positive Phase 2a data showed 90% ORR at anytime[2]

Phase 3 trial planned for H1 2026

Strong team supported by ~$21 million cash

Proven team with strong development skills

$21M in cash, with no debt[1]

Sepranolone, for PWS, backed by POM data

Potential **use in Prader Willi syndrome (PWS)** backed by positive POM data in Tourette syndrome

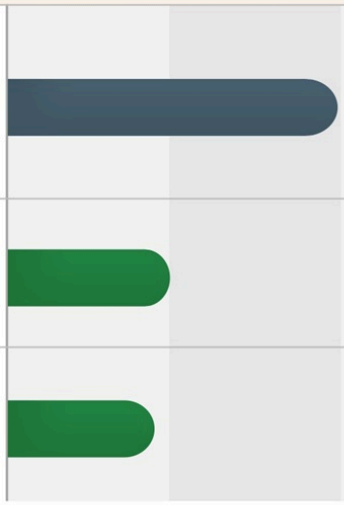
Phase 2b trial planned for H1 2026

1. Cash as of June 30, 2025; **2.** American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025 **NMIBC:** Non-Muscle Invasive Bladder Cancer; **ORR:** Overall Response Rate; **POM:** Proof-of-Mechanism

Innovative pipeline of potential high-value assets

Focused on programs with positive proof-of-concept data

Candidate / indication	Phase 1	Phase 2	Phase 3	Potential populations	Status / potential next steps
NDV-01[1] Non-muscle invasive bladder cancer (NMIBC)				68K new US patients with NMIBC[2] NMIBC US prevalence: 600K patients[3]	Q4 2025: 9 Month data Q1 2026: 12 Month data H2 2025: FDA interaction and product supply scale up 1H 2026: Initiate Phase 3 study
Sepranolone Prader-Willi Syndrome (PWS)				WW prevalence: 350K to 400K patients[4]	Q4 2025: Prep for next studies, including manufacturing H1 2026: Initiate Phase 2b study
Sepranolone Other indications				Including TS, Essential Tremor, OCD and other compulsivity-related indications	YE 2025: Identify next opportunity



1. NDV-01: A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce); **2.** Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); **3.** Markets, Research And. "Non-muscle Invasive Bladder Cancer (NMIBC) Epidemiology Forecasts to 2034." *GlobeNewswire News Room*, 25 Jan. 2024; **4.** Scheimann, Ann O. "Prader-Willi syndrome: Clinical features and diagnosis." *UpToDate*, edited by Mitchell E Geffner et al., 6 Feb. 2023. **NMIBC:** Non muscle invasive bladder cancer; **WW:** Worldwide; **TS:** Tourette Syndrome; **OCD:** Obsessive-Compulsive Disorder

NDV-01

A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce) for patients with NMIBC, with positive Phase 2a data[1]

1. American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025
NMIBC: Non-Muscle Invasive Bladder. The graphic is for artistic purposes only, not a factual representation

Class leading therapy in NMIBC

NMIBC needs new treatments

NMIBC affects >600,000[2] people in the US, with ~67,890[3] new patients each year

Supported by positive clinical data

Use of intravesical Gem/Doce high efficacy in BCG-naïve, -exposed, and -unresponsive disease[4-7]

NDV-01[1] PK data provide early proof-of-concept

Potent and durable cytotoxic activity and optimized drug exposure in the bladder

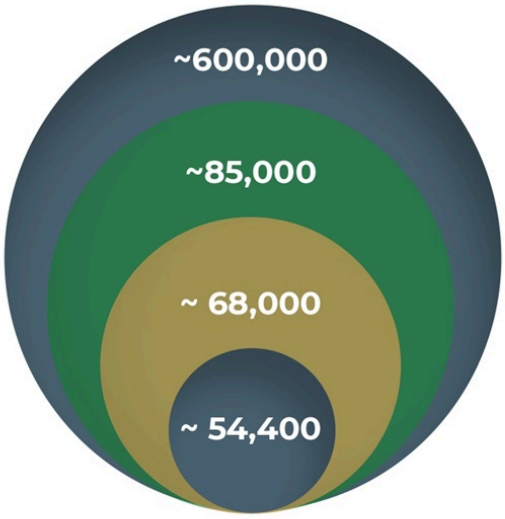
Phase 2 data presented at AUA 2025

Phase 2 data presented at AUA show 90% ORR at any time point[6]

1. NDV-01: A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce); **2.** "Non-muscle Invasive Bladder Cancer (NMIBC) Epidemiology Forecasts to 2034." *GlobeNewswire News Room*, 25 Jan. 2024; **3.** Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); **4.** McElree, Ian M., et al. "Comparison of Sequential Intravesical Gemcitabine and Docetaxel Vs Bacillus Calmette-Guérin for the Treatment of Patients With High-Risk Non–Muscle-Invasive Bladder Cancer." JAMA Network Open, vol. 6, no. 2, Feb. 2023, p. e230849; **5.** Chevuru PT, McElree IM, Mott SL, Steinberg RL, O'Donnell MA, Packiam VT. Long-term follow-up of sequential intravesical gemcitabine and docetaxel salvage therapy for non-muscle invasive bladder cancer. Urol Oncol. 2023 Mar;41(3):148.e1-148.e7; **6.** American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025; **7.** Kawada T, Yanagisawa T, Araki M, Pradere B, Shariat SF. Sequential intravesical gemcitabine and docetaxel therapy in patients with nonmuscle invasive bladder cancer: a systematic review and meta-analysis. Curr Opin Urol. 2023 May 1;33(3):211-218. **NMIBC:** Non-Muscle Invasive Bladder; **BCG:** Bacillus Calmette-Guérin; **ORR:** Objective Response Rate; **AUA:** American Urological Association; **PK:** Pharmacokinetic

NMIBC opportunity[1] — high prevalence and high recurrence rate

Supply issues for prior BCG-standard and gaps in care driving NMIBC innovation



US prevalence of NMIBC[1]
(non-muscle invasive bladder cancer)

New Bladder cancer cases[2]
70-96% 5-year overall survival, 6% with advanced disease[3]

NMIBC cancer cases (75-80% of bladder cancers)[4, 6]
50-80% recurrence rate (over five years)[5]

Intermediate-risk and high-risk have increased risk of recurrence and progression (Intermediate-risk represents 45%[6, 7] and high-risk represents 35%[7] of NMIBC cases)

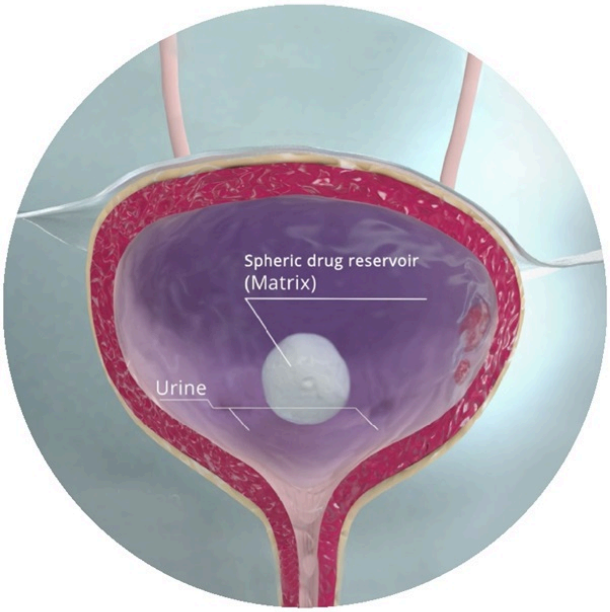
1. Markets, Research And. "Non-muscle Invasive Bladder Cancer (NMIBC) Epidemiology Forecasts to 2034." *GlobeNewswire News Room*, 25 Jan. 2024; **2.** The American Cancer Society medical and editorial content team. "Key Statistics for Bladder Cancer." American Cancer Society, www.cancer.org/cancer/types/bladder-cancer/about/key-statistics.html; **3.** American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025; **4.** Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); **5.** Białek, Łukasz. "EORTC Bladder Cancer Recurrence and Progression Calculator." Omni Calculator, 1 Aug. 2024, www.omnicalculator.com/health/eortc-bladder-cancer; **6.** Seo, Munseok, and James R. Langabeer II. "Demographic and Survivorship Disparities in Non–muscle-invasive Bladder Cancer in the United States." Journal of Preventive Medicine and Public Health, vol. 51, no. 5, Aug. 2018, pp. 242–47; **7.** Nielsen, Matthew E., et al. "Trends in Stage-specific Incidence Rates for Urothelial Carcinoma of the Bladder in the United States: 1988 to 2006." *Cancer*, vol. 120, no. 1, Oct. 2013, pp. 86–95, doi:10.1002/cncr.28397. **NMIBC:** Non-Muscle Invasive Bladder; **BCG:** Bacillus Calmette-Guérin

NMIBC patient care journey

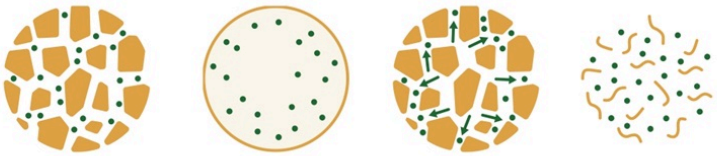
1. Physicians diagnose suspected cases of bladder cancer using cystoscopy and cytology. (Most common presenting symptom is blood in urine.)
2. Treatment begins with TURBT (transurethral resection of bladder tumor) surgery to stage, risk-stratify, and treat patients.
3. Following surgery, patients with HR-NMIBC typically receive intravesical BCG as primary treatment
4. Regular cystoscopies and urine cytology (up to every 3 months) are used to monitor patients and assess for recurrence
5. Following BCG therapy, for patients with recurrent disease, alternative intravesical treatments are used, including chemotherapies such as Gem/Doce

Based on AUA/SUO Practice Guidelines, 2024 (Event April 28, 2025 (Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment").
HR: High Risk; **NMIBC:** Non-Muscle Invasive Bladder; **BCG:** Bacillus Calmette Guérin; **TURBT:** Trans Urethral Resection of Bladder Tumor

Targeted intravesical therapy

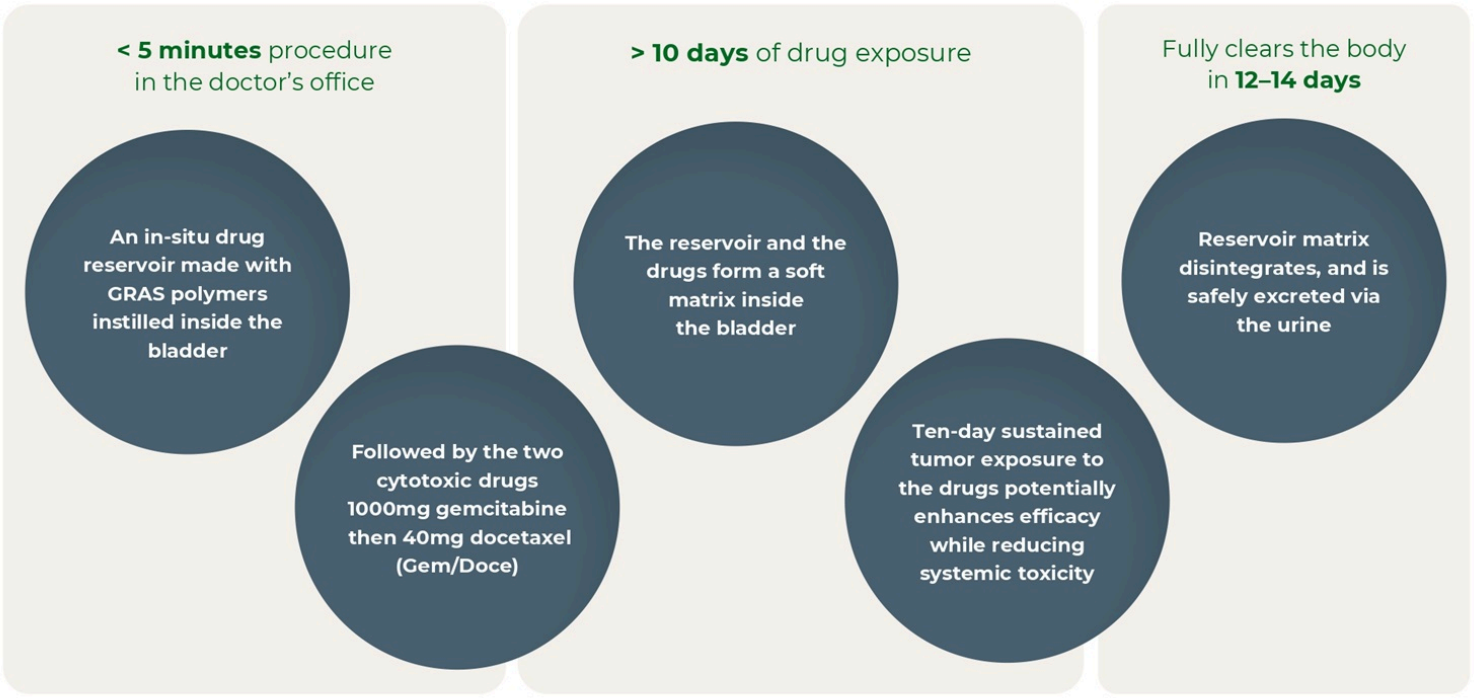


Bladder-targeted solid matrix enables prolonged tumor exposure to the cytotoxic drug combination via multiple delivery modalities



Diffusion through pores	Diffusion through the polymer	Osmotic pumping	Erosion

NDV-01’s innovative approach



GRAS: Generally Regarded as Safe

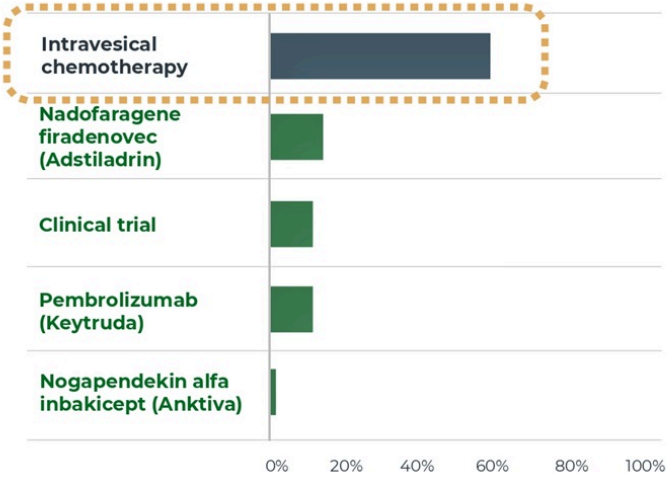
Gem/Doce combination has been embraced by the urologic oncology community

- Effective salvage treatment for patients who have **failed or are intolerant to BCG** with reported 2-year RFS ~50%[1, 2, 3]
- Gem/Doce is an effective alternative first-line agent in **high-risk BCG naïve** patients with 2-year RFS of 82%[4]
- Gem/Doce use expanding into **intermediate-risk and low-grade tumors** with reported 2-year RFS of 70-80%[5, 6]
- Gem/Doce **avoids/delays radical cystectomy**[7, 8]
- Large ongoing cooperative "BRIDGE" study (n=870) evaluating Gem/Doce combination v. BCG (NCT05538663)

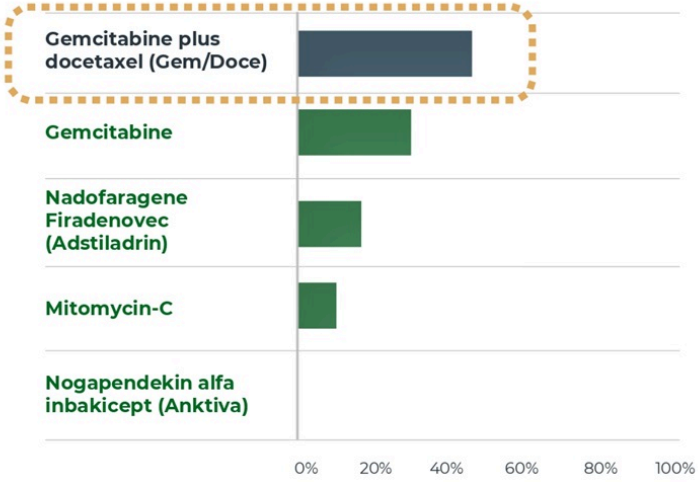
1. Steinberg RL, Thomas LJ, Brooks N, et al. Multi-Institution Evaluation of Sequential Gemcitabine/Docetaxel as Rescue Therapy for NMIBC. J Urol. 2020; **2.** Garneau CA, Marcotte N, Lacombe L, et al. Salvage therapy for BCG failure with intravesical sequential Gem/Doce in patients with recurrent NMIBC. Can Urol Assoc J J Assoc Urol Can. 2024; **3.** Yim K, Melnick K, Mott SL, et al. Sequential intravesical gemcitabine/docetaxel provides a durable remission in recurrent high-risk NMIBC following BCG therapy. Urol Oncol. 2023; **4.** McElree IM, Steinberg RL, Martin AC, et al. Sequential Intravesical gemcitabine/docetaxel for BCG-Naive High-Risk NMIBC. J Urol. 2022; **5.** McElree IM, Orzel J, Stubbee R, et al. Sequential intravesical gemcitabine/docetaxel for treatment-naive and previously treated intermediate-risk NMIBC. Urol Oncol. 2023; **6.** Tan WS, McElree IM, Davaro F, et al. Sequential Intravesical Gemcitabine/Docetaxel is an Alternative to BCG for the Treatment of Intermediate-risk NMIBC. Eur Urol Oncol. 2023; **7.** Chevuru PT, McElree IM, Mott SL, Steinberg RL, O'Donnell MA, Packiam VT. Long-term follow-up of sequential intravesical gemcitabine and docetaxel salvage therapy for NMIBC. Urol Oncol. 2023; **8.** Narayan VM, Boorjian SA, Alemozaffar M, et al. Efficacy of Intravesical Nadofaragene Firadenovec for Patients With BCG-Unresponsive NMIBC: 5-Year Follow-Up From a Phase 3 Trial. J Urol. 2024. **RFS:** Relapse Free Survival; **BCG:** Bacillus Calmette-Guérin; **NMIBC:** Non-muscle-Invasive Bladder Cancer

Gem/Doce combination stands out in *Urology Times* survey[1]

What is your preferred treatment for patients with BCG-unresponsive NMIBC?



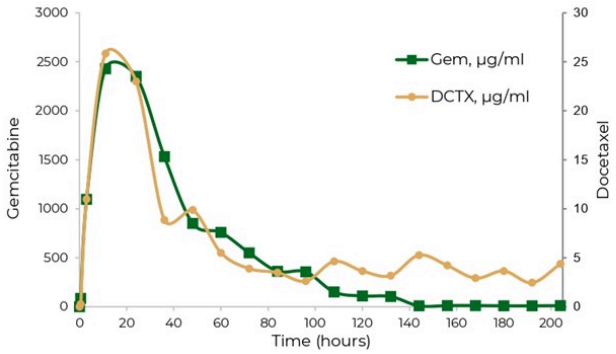
When selecting intravesical therapy after BCG-unresponsive NMIBC, which agent do you most commonly use?



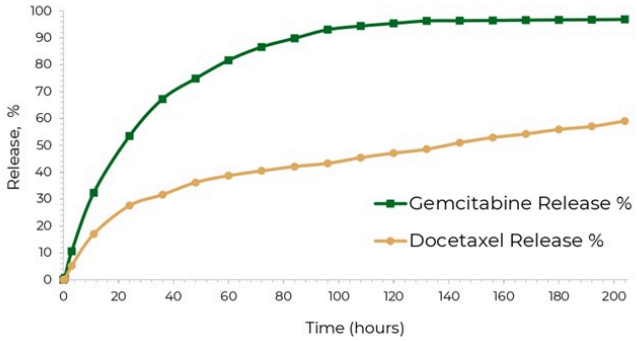
1. Derived from Urology Times: Survey on Treatment Patterns and Preferences in Non–Muscle Invasive Bladder Cancer, June 2025, based on responses from 42 practicing physicians (Saylor, Benjamin P. "Survey: New NMIBC Treatments Face Slow Uptake." *Urology Times*, 17 July 2025, www.urologytimes.com/view/survey-new-nmibc-treatments-face-slow-uptake.)

NDV-01 In-vitro drug concentrations show continuous & optimized drug release in the bladder

NDV-01 Gem/Doce concentration over time



NDV-01 cumulative release profile



In-vitro profiles demonstrate stable and predictable drug levels, minimizing peaks and troughs associated with systemic side effects.

Controlled drug exposure can potentially enhance anti-tumor activity while reducing the frequency of administration, enabling biweekly dosing.

Experimental overview: 12g NDV-01 with 10% gemcitabine, 0.25% docetaxel formulation was instilled into 10ml artificial urine (AUF) and kept in an orbital shaker incubator at 370C, 20 rpm. The AUF sample was withdrawn twice a day and replaced by fresh AUF. The drugs concertation in the UAF was quantitatively determined by HPLC

Study TRCG-011 high-risk NMIBC patients

An open-label, single-arm, single-center study to evaluate safety and efficacy of NDV-01 in HR NMIBC patients (NCT06663137)

American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025. **HR:** High Risk; **NMIBC:** Non muscle invasive bladder cancer

ONGOING TRCG-011 STUDY

Study design

Inclusion criteria

- High-risk disease with CIS/Tis, Ta, T 1 tumors[1, 2]
- BCG naïve, BCG-unresponsive, intolerant and experienced patients

Purpose

Evaluate the potential of NDV-01 as a safe and effective treatment for patients with high-risk NMIBC

Primary endpoint

- Safety
- CRR at 12 months

Secondary endpoint

- DOR
- EFS

Exploratory

- PK

1. The American Cancer Society. Bladder Cancer Stages. American Cancer Society, 12, Mar, 2024. https://www.cancer.org/cancer/types/bladder-cancer/detection-diagnosis-staging/staging.html; **2.** Holzbeierlein, Jeffrey M., et al. "Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment." The Journal of Urology, vol. 211, no. 4, Jan. 2024, pp. 533–38, doi:10.1097/ju.0000000000003846. **CIS**: Carcinoma In Situ; **Ta**: Noninvasive papillary carcinoma; **TI:** Tumor invades lamina propria; **CRR:** Complete Response Rate; **DOR:** Duration of Response. **EFS:** Event Free Survival; **PK:** Pharmacokinetics; **TURBT:** Transurethral resection of bladder tumor

ONGOING TRCG-011 STUDY

Demographic data

Characteristics	N=29	%
Age		
Median (range)	73 (54-93) yr	
Sex		
Male	24	83%
Female	5	17%
BCG doses		
Median BCG doses (range)	7 (0-18)	
BCG-status		
BCG-naive	12	41%
BCG-exposed	4	14%
BCG-unresponsive	13	45%
Stage		
CIS	3	10%
CIS + Ta/T1	4	14%
Ta HG	18	62%
T1 HG	4	14%

American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025. **ECOG:** Eastern Cooperative Oncology Group; **PS** Performance Status

ONGOING TRCG-011 STUDY

Treatment emergent AE and tolerability

Of the 28 patients who received >= 1 dose of NDV-01, 21 (72%) had a TRAE

77% dysuria

9% asymptomatic positive urine culture

4% hematuria

No patient had >= Grade 3 TRAE

No patients discontinued treatment due to AEs

American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025. **TRAE:** Treatment Related Adverse Events; **AE:** Adverse Event; **G1:** Grade 1; **BCG:** Bacillus Calmette-Guérin

ONGOING TRCG-011 STUDY

Efficacy

Complete response	n/N	%
Anytime	21/23	91%
3-month	19/23	83%
6-month	19/21[1]	90%

One subject has reached the 9-month assessment and had a CR

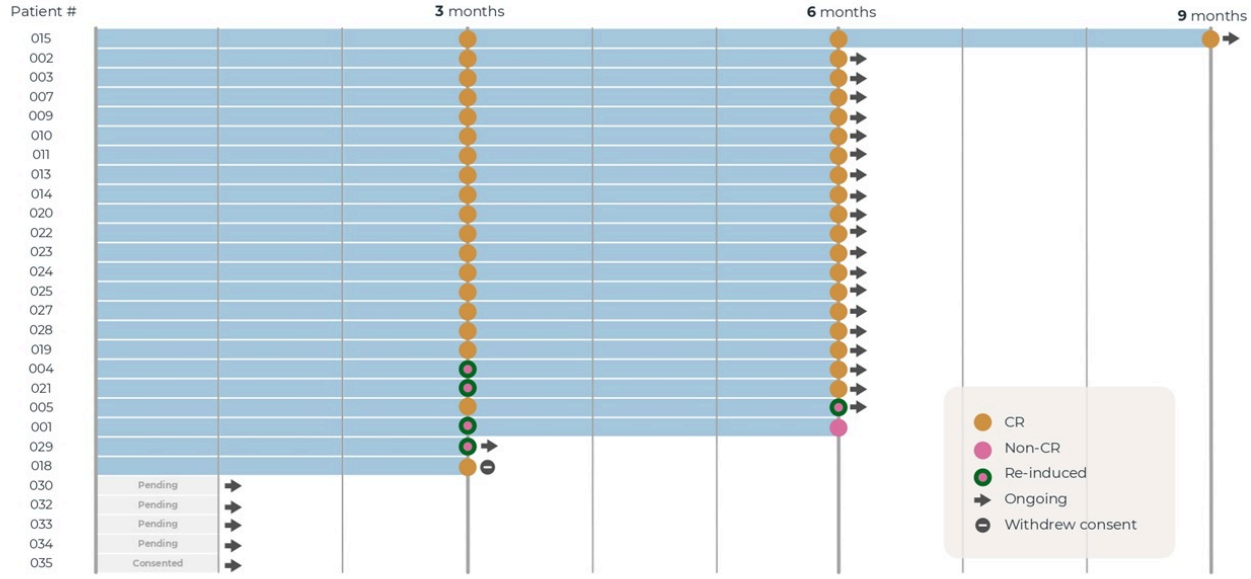
No patient had progression to muscle-invasive disease

No patient underwent a radical cystectomy

1. Includes 2 patients with CR after re-induction. 4 subjects underwent re-induction due to non-CR at 3 months, of which 3 had a 6-month assessment (1 pending). Of these 3 subjects, 2 had a 6-month CR (66% CR rate after re-induction)

ONGOING TRCG-011 STUDY

Demonstrated durable response over time



91%
Anytime CR rate

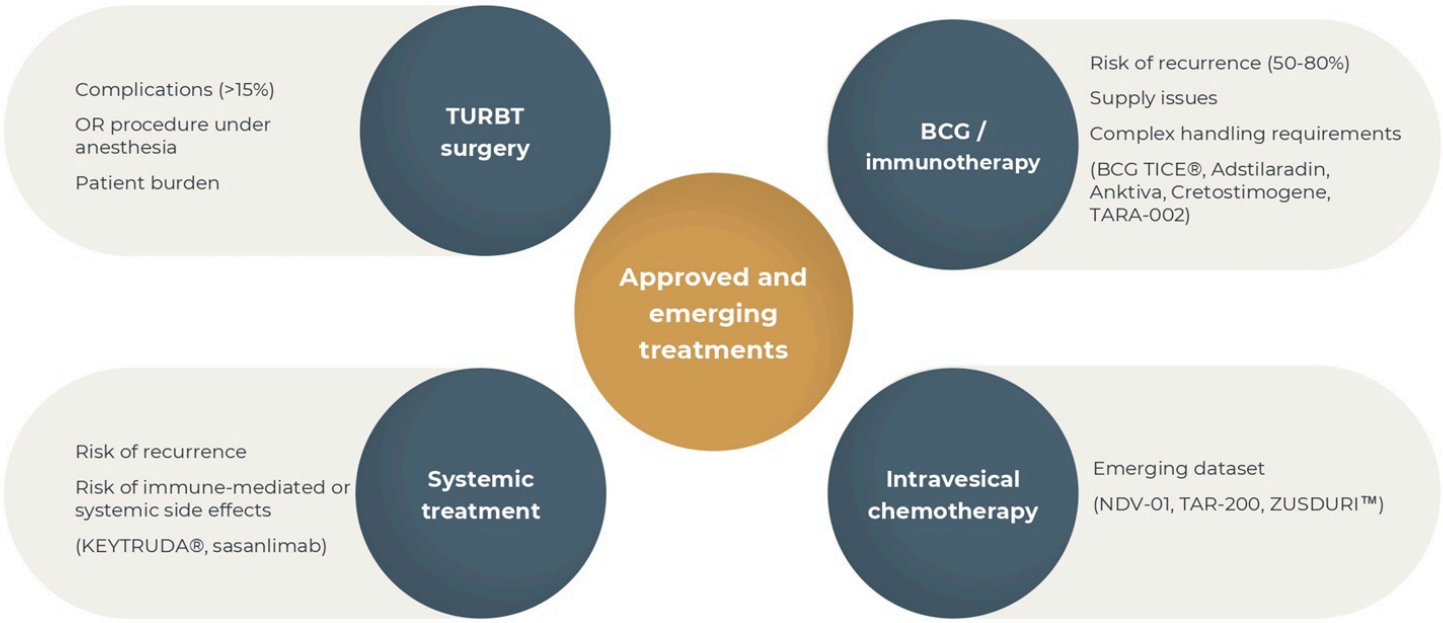
83%
3-month CR rate

90%
6-month CR rate

Pending completion

CR: Complete response

Overview of NMIBC treatment landscape



Relmada internal market research, 2025. **NMIBC**: Non-muscle-Invasive Bladder Cancer; **TURBT:** Transurethral resection of bladder tumor; **BCG:** Bacillus Calmette-Guérin

NDV-01: a differentiated intravesical approach

Product / product profile	NDV-01	TAR-200	ZUSDURI™
Sponsor	Relmada	Johnson & Johnson	UroGen
Active Agent	Gemcitabine/docetaxel (Gem/Doce)	Gemcitabine	Mitomycin C
NMIBC subtype	High-risk or intermediate-risk	High Risk	Low grade, intermediate risk
Phase	Phase 2	Phase 3	FDA approved
Dosing Format	Sustained-release hydrogel	Indwelling silicone delivery system	Reverse-thermal hydrogel
Presentation	Pre-filled syringe ready for intravesical delivery	Catheter-based insertion; cystoscopic removal	In-office dosing kit requires in-office reconstitution under chilled conditions
Requires device removal?	No	Yes, via cystoscope[1]	No

American Urological Association 2025 presentation. Relmada press release and Investor Event April 28, 2025. **1.** "TAR-200 - General Overview." *J&J Medical Connect*, 21 July 2025, www.jnjmedicalconnect.com/products/tar-200/medical-content/tar-200-general-overview. **NMIBC:** Non-muscle-Invasive Bladder Cancer

Competitive advantages

NDV-01 is an investigational intravesical therapy designed for the extended release of gemcitabine and docetaxel (Gem/Doce)

Ready for use

NDV-01 is supplied as prefilled syringe ready for use, easily instilled via catheter in **< 5 minutes**

Sustained release

NDV-01 releases Gem/Doce inside the bladder **continuously for 10 days**, resulting in sustained tumor exposure and meaningful improvement in patient outcome

Convenience

Patients are treated **in doctors' office**

Based on an existing effective treatment

Gem/Doce, **an existing, effective and well understood** treatment for NMIBC, is frequently used by urologists

Safely excreted

NDV-01 polymer biodegradable, gradually disintegrates, and is safely excreted via the urine

Relmada internal market research 2025. **NMIBC:** Non-muscle-Invasive Bladder Cancer

Expecting to advance NDV-01 towards registration-track studies in H1 2026

Q4 2025

Phase 2 data update
Results from 9-month follow-up

FDA Engagement
Including planned FDA interactions and manufacturing

Q1 2026

Phase 2 data update
Results from 12-month follow-up

H1 2026

Initiate Phase 3 study
Target population to be confirmed through FDA discussions

Sepranolone

A novel candidate, with potential to overcome the challenges of current therapies for compulsivity disorders

The graphic is for artistic purposes only, not a factual representation

Sepranolone has the potential to normalize $GABA_A$ receptor activity

GABA (ϒ-aminobutyric acid) is the primary neurotransmitter, involved in anxiety and compulsive disorders

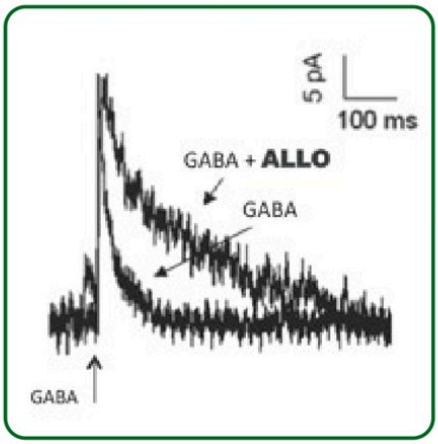
Allopregnanolone (ALLO) typically enhances $GABA_A$ calming effects

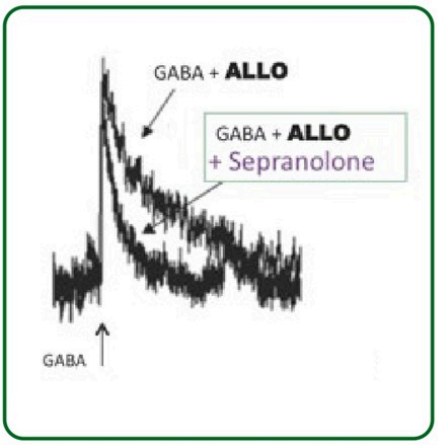
In some individuals, ALLO exacerbates anxiety and compulsivity

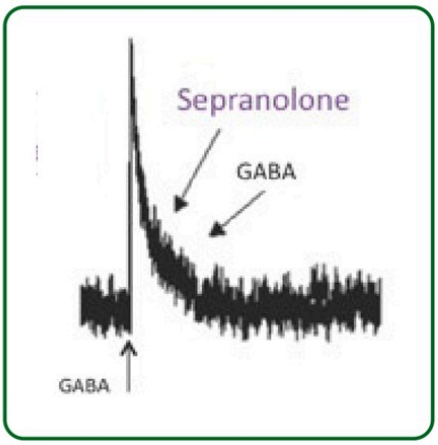
Sepranolone normalizes $GABA_A$ receptor activity without interfering in GABA signaling

$GABA_A$: ϒ-aminobutyric acid type A; **ALLO:** Allopregnanolone

Sepranolone normalizes $GABA_A$ receptor activity (in vitro)







Endogenous Sepranolone attenuates ALLO-enhanced GABA-activation of the $GABA_A$ receptor [1] in a dose-dependent manner, with with high specificity [2]

Sepranolone does not interfere with GABA signaling

1 Strömberg, J., et al. "Neurosteroid Modulation of Allopregnanolone and GABA Effect on the GABA-A Receptor." *Neuroscience*, vol. 143, no. 1, Aug. 2006, pp. 73–81, doi:10.1016/j.neuroscience.2006.07.031;
2. Lundgren et al, Brain Research 2003. Patch clamp experiment to evaluate receptor activity using electric current over the synaptic cleft. **$GABA_A$:** γ-aminobutyric acid type A; **ALLO:** Allopregnanolone

Topline sepranolone safety and efficacy data[1]

Sepranolone treatment produced a **28% drop in tic severity** (p=0.051), with consistent positive impact on secondary endpoints

Positive results across secondary Quality of Life measures, using widely accept scoring systems including the Gilles de la Tourette Syndrome Quality of Life total score (69% increase)

No CNS off-target or systemic side effects were observed

1. Sepranolone Phase 2 Tourette data, Relmada, Feb 06, 2025 press release. **CNS:** Central Nervous System

Positive Phase 2 data and unique MOA give sepranolone broad potential

Prader-Willi Syndrome

Genetic disorder often defined by persistent hunger and overeating

Global prevalence 350-400K people[1]

Tourette Syndrome

Neurological disorder characterized by repetitive, involuntary tics, with childhood onset

US prevalence 350-450K children[3]

Essential Tremors

Neurological disorder that causes involuntary, rhythmic shaking. Primarily notice during voluntary movements

US prevalence 6.4 MM people[2]

Obsessive-Compulsive Disorder and related disorders

OCD is characterized by intrusive, unwanted thoughts (obsessions) and repetitive behaviors (compulsions)

US prevalence 8.2M people[4]

1. Scheimann, Ann O. "Prader-Willi syndrome: Clinical features and diagnosis." UpToDate, edited by Mitchell E Geffner et al., 6 Feb. 2023, www.uptodate.com/contents/prader-willi-syndrome-clinical-features-and-diagnosis#H12; **2.** Crawford, Stephen, et al. "How Many Adults in the US Have Essential Tremor? Using Data From Epidemiological Studies to Derive Age-specific Estimates of Prevalence (4458)." *Neurology*, vol. 94, no. 15_supplement, Apr. 2020, doi:10.1212/wnl.94.15_supplement.4458; **3.** Tinker, Sarah C., et al. "Estimating the Number of People With Tourette Syndrome and Persistent Tic Disorder in the United States." *Psychiatry Research*, vol. 314, June 2022, p. 114684, doi:10.1016/j.psychres.2022.114684; **4.** International OCD Foundation. "International OCD Foundation | Who Gets OCD?" International OCD Foundation, 16 Dec. 2024, iocdf.org/about-ocd/who-gets-ocd. **PWS:** Prader-Willi syndrome; **ET:** Essential Tremor; **OCD:** Obsessive Compulsive Disorder

Impact on compulsivity could open the door to use in Prader-Willi Syndrome

Prader-Willis Syndrome is an unmet need

Prader-Willi syndrome (PWS) affects 350,000 to 400,000 people worldwide[1]

Sepranolone is a first-in-class candidate

Sepranolone's ability to target the $GABA_A$ and impact compulsivity disorders

Planning a Phase 2 study in 1H 2026

Advancing manufacturing scale-up and preparations to meet with FDA

1. Scheimann, Ann O. "Prader-Willi syndrome: Clinical features and diagnosis." UpToDate, edited by Mitchell E Geffner et al., 6 Feb. 2023, www.uptodate.com/contents/prader-willi-syndrome-clinical-features-and-diagnosis#H12. **$GABA_A$**: γ-aminobutyric acid type A

Expecting to advance sepranolone towards Phase 2 studies in Prader-Willi Syndrome in H1 2026

Q4 2025

Phase 2 PWS preparations
Including planned FDA interactions and further development of product supply

H1 2026

Initiation of Pilot Phase 2 study in Prader-Willi Syndrome
Focus on evaluating early proof-of-concept

PWS: Prader-Willi syndrome

Corporate summary

Financial overview

$20.6 million

Cash, cash equivalents & short-term investments

~33.2 million

Common shares outstanding (45.1 million as converted)

Unlevered balance sheet

No outstanding debt

As of June 30, 2025

NDV-01 and sepranolone poised to make important progress in 2025-2026

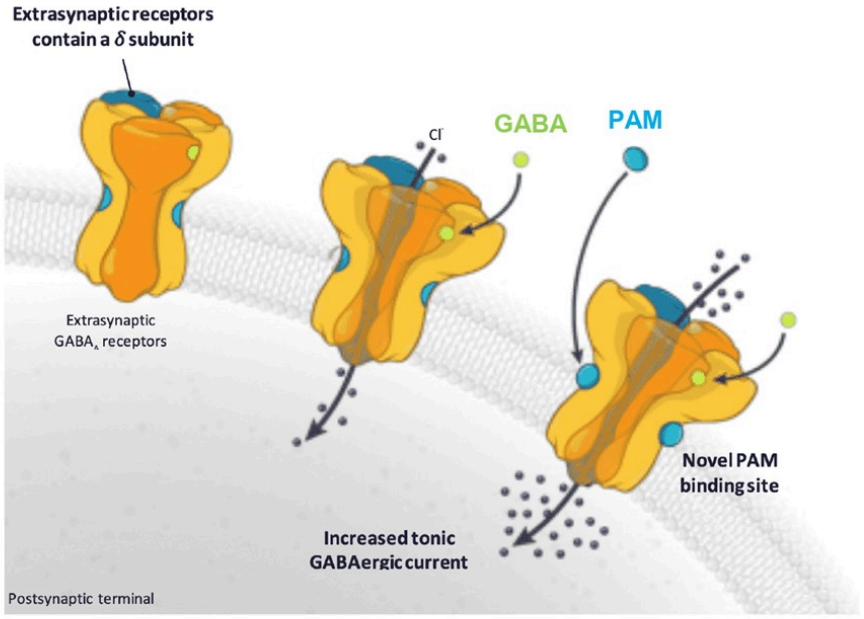
Q4 2025	**NDV-01**	Planned FDA interactions, manufacturing build-out
Q4 2025	**Sepranolone**	Planned FDA interactions, product supply expansion
H1 2026	**NDV-01**	Initiate registration-track study
H1 2026	**Sepranolone**	Initiate pilot PWS study

PWS: Prader-Willi syndrome

Thank you!

Appendix

Sepranolone has the potential to normalize $GABA_A$ receptor activity



https://asarinapharma.com/sepranolone/how-does-sepranolone-work/

