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): **March 19, 2026**

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 2.02 Results of Operations and Financial Condition.

On March 19, 2026, Relmada Therapeutics, Inc. (the "Company") issued a press release providing a corporate update and reporting its financial results for the fiscal year ended December 31, 2025. The Company also announced that it would conduct a conference call and audio webcast on Thursday, March 19, 2026, at 4:30 PM EST / 1:30 PM PST, to discuss the update and results. The Company's complete audited financial statements and notes thereto as of, and for the years ended, December 31, 2025 and 2024, will be contained in its Annual Report on Form 10-K to be filed with the Securities and Exchange Commission. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On March 19, 2026, the Company 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 Exhibit 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*	Press release dated March 19, 2026, regarding corporate update and full year 2025 financial results
99.2*	Corporate Presentation dated March 19, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Furnished herewith

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: March 19, 2026

RELMADA THERAPEUTICS, INC.

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

Exhibit 99.1

Relmada Therapeutics Reports Fourth Quarter and Full Year 2025 Results and Provides Business Update

- *Positive 12-month Phase 2 data for NDV-01 in non-muscle invasive bladder cancer (NMIBC) demonstrated a 95% complete response (CR) rate at any time and a durable 76% CR rate at 12 months, with favorable safety profile*
- *Completed an oversubscribed $160 million PIPE financing led by leading healthcare investors in March 2026, strengthens balance sheet to support NDV-01 Phase 3 development*
- *On track to initiate Phase 3 RESCUE registrational program in second line (2L) BCG-unresponsive and adjuvant intermediate-risk NMIBC in mid-2026*
- *Cash balance of $93.0 million as of December 31, 2025, plus gross proceeds of $160 million from March 2026 PIPE expected to fund operations through 2029, including completion of the NDV-01 RESCUE program*
- *Management to host a conference call and webcast today at 4:30 PM ET*

CORAL GABLES, FL – March 19, 2026 (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 disorders, today reported audited financial results for the fourth quarter and full year ended December 31, 2025 and provided a corporate update highlighting significant progress across its pipeline.

"This has truly been a transformational year for Relmada, marked by significant progress with our lead program NDV-01", said **Sergio Traversa, Chief Executive Officer** of Relmada Therapeutics. "Our recently reported 12-month data for NDV-01 demonstrated durable complete responses with a favorable safety profile, reinforcing the program's potential to become a best-in-class therapy for patients with non-muscle invasive bladder cancer. With a successful $160M PIPE financing and regulatory alignment with the FDA on two registrational pathways, we believe that we are well positioned to advance NDV-01 into the Phase 3 RESCUE program in mid-2026. Our team is now focused on executing this plan and initiating the RESCUE registrational program as we work to bring NDV-01 to patients as efficiently as possible."

"NDV-01's compelling efficacy, durability, and favorable safety profile, combined with operational ease-of-use are the cornerstone of its differentiated product profile and best-in-class potential" said **Raj S. Pruthi, MD, Chief Medical Officer-Oncology of Relmada Therapeutics**. "We continue to be encouraged by the high response rates and durable clinical benefit observed through 12 months, including in the BCG-unresponsive population, alongside a favorable safety profile with no ≥ Grade 3 treatment-related adverse events and no treatment-related discontinuations. Our clinical program builds on the urologic oncology community's comfort with conventional Gem/Doce's efficacy and safety profile with a sustained release product that could provide physicians and patients with a streamlined, less than 5-minute in-office procedure. These results reinforce our confidence as we advance NDV-01 into the Phase 3 RESCUE registrational program in mid-2026."

Highlights of the 12-month follow-up data from the ongoing Phase 2 study of NDV-01:

In the 12-month follow-up of the Phase 2a study (March 9, 2026 Company press release) treatment with NDV-01 produced:

- **Durable 76% complete response (CR) rate at 12 months with 95% CR rate at any time in high-risk NMIBC**
- **BCG-unresponsive patients achieved an 80% CR rate at 12 months and 94% CR rate at any time**
- No patient had progression to muscle-invasive disease, and no patient underwent a radical cystectomy
- **Favorable overall tolerability** – no ≥ Grade 3 treatment-related adverse events and no treatment-related discontinuations or dose interruptions.

Phase 3 RESCUE Registrational Pathways:

As previously disclosed in the Company's January 12, 2026 regulatory update, Relmada has received written feedback from the U.S. Food and Drug Administration (FDA) confirming alignment on two registrational development pathways for NDV-01, including study design, patient populations and primary endpoints.

Registrational Pathway 1 – An open label randomized controlled trial in intermediate-risk NMIBC of adjuvant therapy following TURBT (NDV-01 vs. observation). There are no approved treatments for adjuvant intermediate risk NMIBC, which we estimate affect ~75,000 patients/year in the US. The primary endpoint of the study is disease free survival (DFS).

Registration Pathway 2 – A single-arm trial in second line (2L) BCG-unresponsive NMIBC with *carcinoma in situ (CIS)* patients who are currently refractory to approved or developmental therapies. Patients with BCG-unresponsive NMIBC with *CIS* who fail first line (1L) therapies, which we estimate to affect ~5,000 patients/year in the US, have few, if any, effective treatment alternatives to radical cystectomy. The primary endpoint of the study is complete response (CR) rate at any time.

Expected Upcoming Relmada Milestones:

- NDV-01 United States IND clearance – Mid-2026
- NDV-01 Phase 3 RESCUE Program initiation – Mid-2026
- Sepranolone Phase 2 initiation in Prader-Willi syndrome – Mid-2026
- Initial 3-month NDV-01 data from Phase 3 2L BCG-unresponsive study expected by YE 2026

Financial Results

Fourth Quarter 2025 Financial Results

- Research and development expense for the three months ended December 31, 2025, totaled $8.1 million, compared to $11.0 million for the three months ended December 31, 2024, a decrease of $2.9 million. The decrease was primarily driven by a decrease in study costs associated with the completion of two Phase 3 trials for REL-1017, partially offset by increased costs related to the start-up the Phase 3 NDV-01 trials and Phase 2b sepranolone study and additional R&D personnel.

- General and administrative expense for the three months ended December 31, 2025, totaled $12.3 million compared to $8.1 million for the three months ended December 31, 2024, an increase of approximately $4.2 million. The increase was primarily driven by an increase in compensation costs partially offset by a decrease in stock based compensation costs.

- Net cash used in operating activities for the three months ended December 31, 2025, totaled $14.6 million compared to $8.8 million for the three months ended December 31, 2024.

- The net loss for the three months ended December 31, 2025, was $19.9 million, or $0.27 per basic and diluted share, compared with a net loss of $18.6 million, or $0.62 per basic and diluted share, for the three months ended December 31, 2024.

Twelve Month Ended December 31, 2025 Financial Results

- Research and development (R&D) expense for the 12 months ended December 31, 2025, totaled $26.9 million, compared to $46.2 million for the 12 months ended December 31, 2024, a decrease of $19.3 million. The decrease was primarily driven by a decrease in study costs associated with completion and conclusion of two Phase 3 trials for REL-1017, partially offset by increased costs related to the acquisition of NDV-01 and sepranolone, as well as the start-up of the Phase 3 NDV-01 trials and Phase 2b sepranolone study.

- General and administrative (G&A) expense for the 12 months ended December 31, 2025, totaled $32.2 million compared to $37.7 million for the 12 months ended December 31, 2024, a decrease of approximately $5.5 million. The decrease was primarily driven by a decrease in stock-based compensation expense and lower professional fees, partially offset by an increase in personnel-related costs.

- Net cash used in operating activities for the 12 months ended December 31, 2025, totaled $45.8 million compared to $51.8 million for the 12 months ended December 31, 2024.

- The net loss for the 12 months ended December 31, 2025, was $57.4 million, or $1.45 per basic and diluted share, compared with a net loss of $80.0 million, or $2.65 per basic and diluted share, for the 12 months ended December 31, 2024.

- The Company’s cash balance of $93.0 million in cash, cash equivalents, and short-term investments, includes net proceeds of approximately $94 million from an underwritten stock offering announced November 5, 2025. This compares to cash, cash equivalents, and short-term investments of approximately $44.9 million at December 31, 2024.

- On March 9, 2026, the Company announced a private financing with gross proceeds of $160 million. This financing, along with the cash, cash equivalents, and short-term investments as of December 31, 2025, is expected to provide sufficient resources to fund Company operations through 2029, including completion of the Phase 3 NDV-01 RESCUE program.

- The Company had 104,890,223 shares outstanding, as of March 16, 2026

Conference Call and Webcast Information:

Relmada will host a conference call and webcast today at 4:30 PM ET to discuss recent business progress and financial results.

Conference Call and Webcast Information:

- Date: Thursday, March 19, 2026 at 4:30 PM ET
- Participant Dial-in (US): 1-877-407-0792
- Participant Dial-in (International): 1-201-689-8263
- Webcast Access: Click Here

A replay of the webcast will be available in 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 ready to use, convenient to administer in-office in less than 5 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 high-grade non-muscle invasive bladder cancer (HG-NMIBC). Patients are treated with NDV-01 in a biweekly induction phase, followed 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. High-grade BCG-unresponsive disease represents one of the most difficult-to-treat NMIBC subtypes, with limited bladder-sparing options. Intermediate-risk NMIBC in the adjuvant setting has no currently approved therapies. 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 interim or 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-01 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:

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Corporate Communications
media@relmada.com

Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets (Audited)

	As of December 31, 2025	As of December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 3,496,540	$ 3,857,026
Short-term investments	89,509,710	41,052,356
Prepaid expenses	977,721	886,461
Total current assets	93,983,971	45,795,843
Other assets	19,500	21,975
Total assets	$ 94,003,471	$ 45,817,818
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,568,944	$ 4,130,563
Accrued expenses	4,861,583	6,160,827
Total current liabilities	6,430,527	10,291,390
Stock appreciation rights	1,060,931	4,467
Total liabilities	7,491,458	10,295,857
Commitments and Contingencies (Note 10)		
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, 73,333,622 and 30,174,202 shares issued and outstanding, respectively	73,333	30,174
Additional paid-in capital	784,705,878	676,373,822
Accumulated deficit	(698,267,198)	(640,882,035)
Total stockholders' equity	86,512,013	35,521,961
Total liabilities and stockholders' equity	$ 94,003,471	$ 45,817,818

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

	2025	2024
Operating expenses:		
Research and development	$ 26,879,146	$ 46,175,512
General and administrative	32,221,054	37,715,524
Total operating expenses	59,100,200	83,891,036
Loss from operations	(59,100,200)	(83,891,036)
Other income (expenses):		
Interest/investment income, net	1,395,989	3,530,021
Realized (loss) gain on short-term investments	(79,207)	374,926
Unrealized gain on short-term investments	398,255	6,735
Total other income (expenses), net	1,715,037	3,911,682
Net loss	$ (57,385,163)	$ (79,979,354)
Net loss per common share – basic and diluted	$ (1.45)	$ (2.65)
Weighted average number of common shares outstanding – basic and diluted	39,479,694	30,163,751

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Audited)

	Common Stock		Additional Paid-in	Accumulated	
Balance – December 31, 2023	30,099,203	$ 30,099	$ 646,229,824	$ (560,902,681)	$ 85,357,242
Stock-based compensation expense	-	-	30,184,414	-	30,184,414
Net proceeds from cash exercise option	74,999	75	246,672	-	246,747
ATM fees	-	-	(287,088)	-	(287,088)
Net loss	-	-	-	(79,979,354)	(79,979,354)
Balance – December 31, 2024	30,174,202	30,174	676,373,822	(640,882,035)	35,521,961
Stock-based compensation expense	-	-	13,905,181	-	13,905,181
Issuance of restricted common stock	3,017,420	3,017	902,209	-	905,226
Net proceeds from cash exercise options	40,142,000	40,142	93,597,687	-	93,637,829
ATM fees	-	-	(73,021)	-	(73,021)
Net loss	-	-	-	(57,385,163)	(57,385,163)
Balance – December 31, 2025	73,333,622	$ 73,333	$ 784,705,878	$ (698,267,198)	$ 86,512,013

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

	2025	2024
Cash flows from operating activities		
Net loss	$ (57,385,163)	$ (79,979,354)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	13,905,181	30,184,414
Stock appreciation rights compensation	1,056,464	4,467
Issuance of restricted common stock	905,226	-
Realized (gain) loss on short-term investments	79,207	(374,926)
Unrealized gain on short-term investments	(398,255)	(6,735)
Change in operating assets and liabilities:		
Prepaid expenses and other assets	(88,785)	319,746
Accounts payable	(2,561,619)	624,554
Accrued expenses	(1,299,244)	(2,527,964)
Net cash used in operating activities	(45,786,988)	(51,755,798)
Cash flows from investing activities		
Purchase of short-term investments	(83,828,576)	(12,079,628)
Sale of short-term investments	35,690,270	63,641,225
Net cash (used in)/provided by investing activities	(48,138,306)	51,561,597
Cash flows from financing activities		
Proceeds from issuance of common stock, net	93,637,829	-
Payment of ATM fees	(73,021)	(287,088)
Proceeds from options exercised for common stock	-	246,747
Net cash provided by/(used in) financing activities	93,564,808	(40,341)
Net decrease in cash and cash equivalents	(360,486)	(234,542)
Cash and cash equivalents at beginning of the year	3,857,026	4,091,568
Cash and cash equivalents at end of the year	$ 3,496,540	$ 3,857,026

Exhibit 99.2

Relmada THERAPEUTICS

CORPORATE OVERVIEW

Unlocking Life Changing Therapies

March 2026

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 interim or 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.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

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Investment Thesis

- Innovative pipeline of **potential high-value assets**, led by NDV-01 for non-muscle invasive bladder cancer (NMIBC)
- NDV-01, **a late-stage** sustained-release Gem/Doce with **attractive commercial profile and well-defined regulatory pathway**
- **Improvement vs. conventional Gem/Doce**, positioning NDV-01 as a next-generation **standard-of-care** driven by ease and speed of administration, extended tumor exposure and physician familiarity
- **Proven efficacy** of conventional Gem/Doce supported by positive clinical response and tolerability profile for NDV-01 reduce mechanistic and regulatory risk
- **Experienced leadership team** supported by leading urology KOLs with direct NMIBC trial and practice experience

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Innovative Pipeline of Potential High-Value Assets

Focused on programs with positive proof-of-concept data

Candidate / Indication	Phase 1	Phase 2	Phase 3	Status / Potential Next Steps
NDV-01[1] High-Risk NMIBC (Study TRCG-001)				**2026**: Present data at upcoming medical meetings, continue enrollment
NDV-01 Intermediate-Risk NMIBC (RESCUE Cohort 1)			MID-2026	**Mid-2026**: Initiate RESCUE Phase 3 registrational Cohort 1
NDV-01 2L BCG-Unresponsive (RESCUE Cohort 2A)[2]			MID-2026	**Mid-2026**: Initiate RESCUE Phase 3 registrational Cohort 2A
NDV-01 2L BCG-Unresponsive (RESCUE Cohort 2B)[3]		MID-2026		**Mid-2026:** Initiate RESCUE Phase 2 exploratory Cohort 2B
Sepranolone Prader-Willi Syndrome (PWS)				**Mid-2026**: Initiate Phase 2b study **2026/27**: Identify next Indication

1. NDV-01: A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce); **2.** BCG-Unresponsive patients with CIS +/- Ta/T1 disease; Phase 3 Cohort 2A is a registrational cohort intended for regulatory approval. **3.** BCG-Unresponsive patients with high-grade Ta/T1 disease. Cohort 2B is an exploratory cohort and not intended for regulatory approval. **NMIBC:** Non-muscle invasive bladder cancer; **BCG:** Bacillus Calmette-Guérin; **2L:** Second Line

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NDV-01

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

1. Relmada press release March 9, 2025 **NMIBC:** Non-muscle invasive bladder cancer. The graphic is for artistic purposes only, not a factual representation

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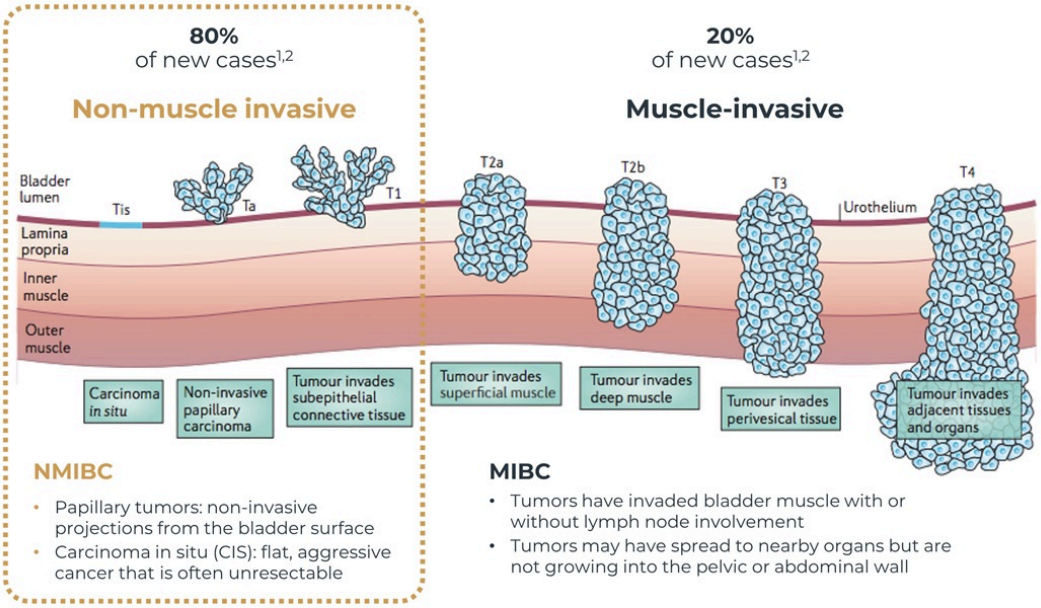
Our Focus: Non-Muscle Invasive Bladder Cancer (NMIBC)



NMIBC

- Papillary tumors: non-invasive projections from the bladder surface
- Carcinoma in situ (CIS): flat, aggressive cancer that is often unresectable

MIBC

- Tumors have invaded bladder muscle with or without lymph node involvement
- Tumors may have spread to nearby organs but are not growing into the pelvic or abdominal wall

1. Shih K et al. Aging Dis. 2021. **2.** Aldousari S et al. Can Urol Assoc J. 2013.

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NMIBC Represents Multi-Billion Dollar Market Opportunity

Key Highlights

High incidence[1]

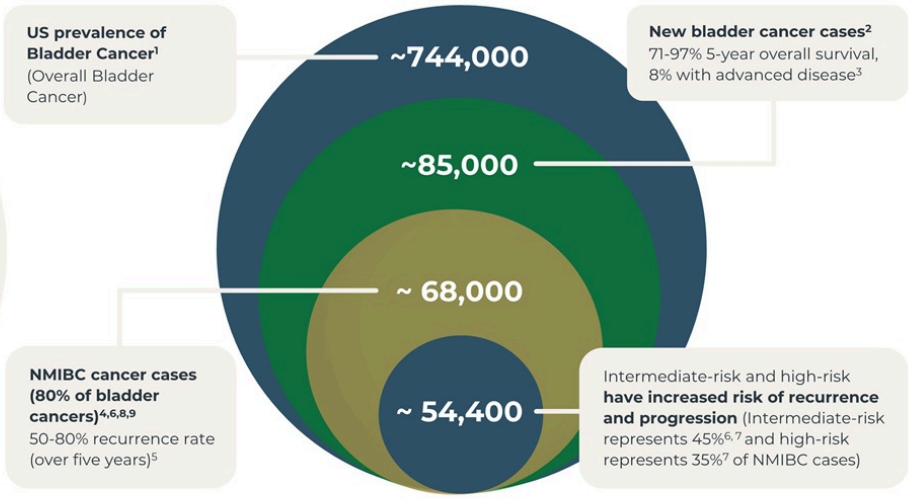
4.2% of all new cancer cases in the US

High recurrence[5]

~30%-61% of high-risk patients recur within one year.
Multiple treatment courses

High cost

Complex treatment pathways
$6.5B total annual cost (U.S.)[10]



1. National Cancer Institute (SEER). Cancer Stat Facts: Bladder Cancer. **2.** American Cancer Society. Key Statistics for Bladder Cancer. **3.** National Cancer Institute. Bladder Cancer Survival Data. **4.** American Urological Association / SUO. NMIBC Guidelines (2024 Amendment). **5.** Białek et al. EORTC Bladder Cancer Recurrence Calculator. 2024. **6.** Seo et al. J Prev Med Public Health. 2018. **7.** Nielsen et al. Cancer. 2013. **8.** Shih K et al. Aging Dis. 2021. **9.** Aldousari et al. Can Urol Assoc J. 2013. **10.** Clark O et al. Pharmacoecon Open. 2024. **NMIBC:** Non-muscle invasive bladder cancer

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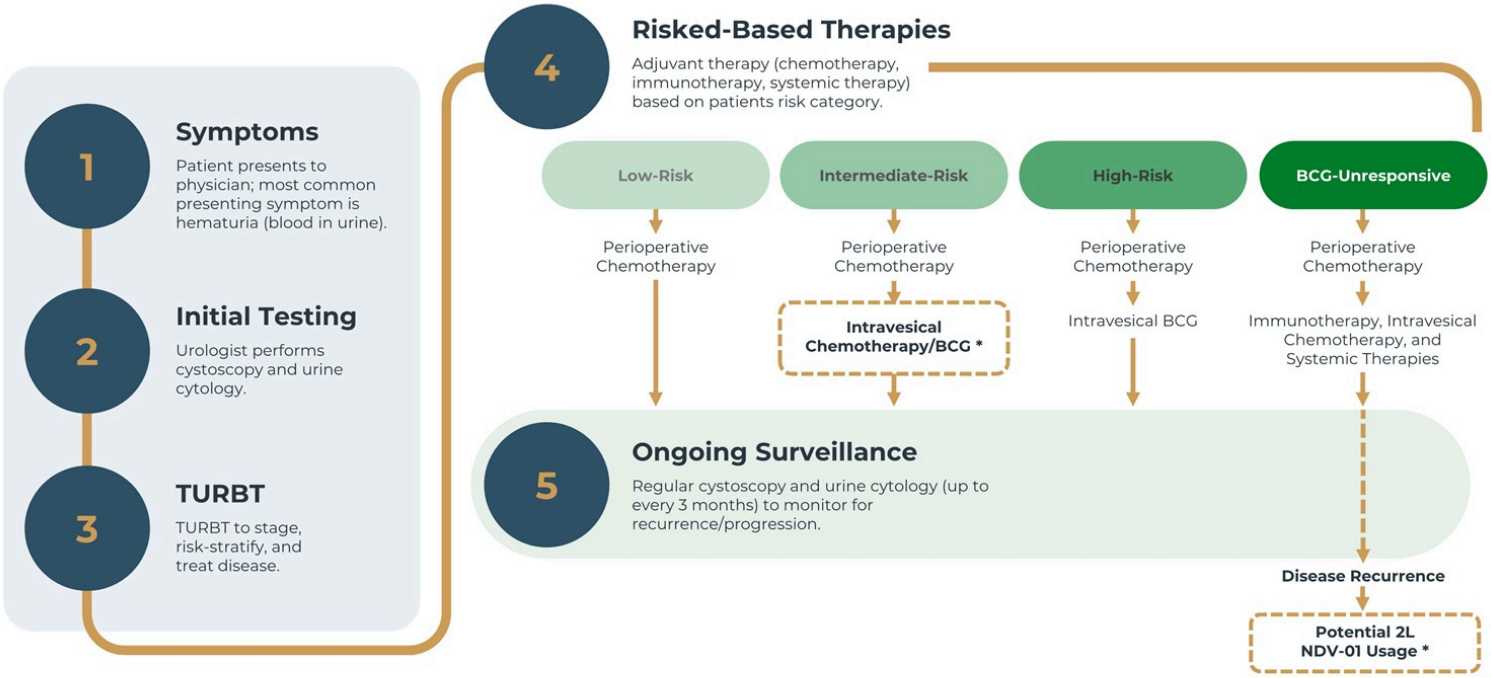
NMIBC Patient Journey

(*) Initial NDV-01 Registrational Pathways



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").
NMIBC: Non-muscle invasive bladder cancer; **BCG:** Bacillus Calmette Guérin; **TURBT:** Trans Urethral Resection of Bladder Tumor; **2L:** Second-line

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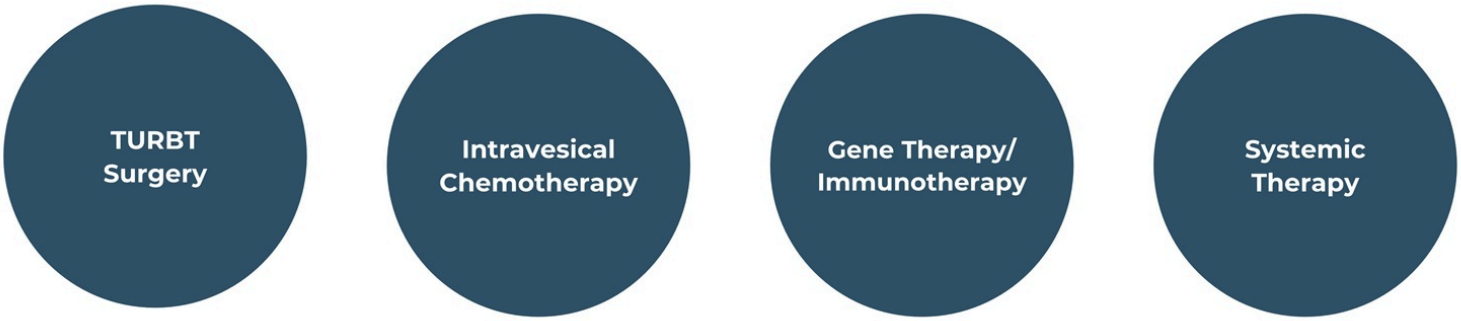
Overview of NMIBC Treatment Landscape

Approved and emerging treatments



TURBT Surgery

Complications (>15%)[1]

OR procedure under anesthesia

Patient burden

Intravesical Chemotherapy

Emerging dataset

Conventional Chemotherapies: mitomycin, gemcitabine, Gem/Doce

Sustained-Release: NDV-01 (Gem/Doce), INLEXZO™ (gemcitabine), ZUSDURI (mitomycin)

Gene Therapy/ Immunotherapy

Risk of recurrence (50-80%)[2]

Supply issues

Complex handling requirements

BCG, Adstiladrin®, Anktiva®, Cretostimogene, TARA-002, EG-70, TAR-210 (FGFR inhibitor)

Systemic Therapy

Risk of recurrence

Risk of immune-mediated or systemic side effects

KEYTRUDA® (anti-PD1), Sasanlimab (anti-PD1), TYRA-300 (oral FGFR3)

Relmada internal market research, 2025. **1.** Pycha A et al. Urology. 2003. **2.** Białek, Ł. (2024, August 1). *EORTC Bladder Cancer Recurrence and Progression Calculator*. Omni Calculator.
NMIBC: Non-muscle invasive bladder cancer; **TURBT:** Transurethral resection of bladder tumor; **BCG:** Bacillus Calmette-Guérin

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The Burden of Recurrences and TURBT is High

Frequent recurrences for IR NMIBC patients: ~ 1 recurrence / year[1]

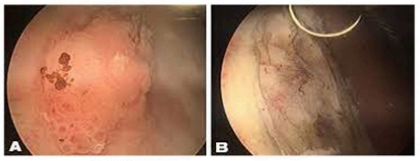
- 5-year risk of initial recurrence: 54.4%. After initial recurrence 60.1% of patients had a second recurrence by 2 years
- After 2nd recurrence, 51.5% of patients had a 3rd recurrence by 3 years

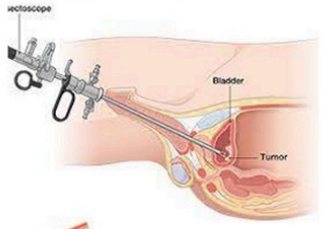
Increased risk of progression with more recurrences[1]

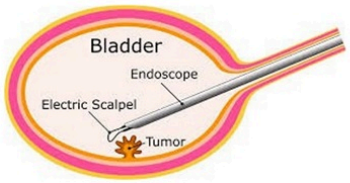
- The 5-year risk of progression: 9.5%, 21.9%, and 37.9% for patients with 1, 2, and 3+ recurrences, respectively

Recurrences typically require TURBT Invasive OR procedure with anesthesia

- Complication rate > 15%[2]
- Grade 3/4 complication rate = 9.4%[3]
- Readmission rate = 5%[4]
- Procedural Cost = $7,000-$10,000[5, 7]
- Worsening mental health, physical health and lower urinary tract symptom scores[6]







1. Sharma V et al. Urology. 2023. **2 .** Pycha A et al. Urology. 2003. **3.** Bansal A et al. Indian J Urol. 2016. **4.** Jindal T et al. Curr Urol. 2023. **5.** MediGence TURBT cost data. **6.** Lee LJ et al. Clinicoecon Outcomes Res. 2020. **7.** Kokkotos F et al. J Clin Oncol. 2022

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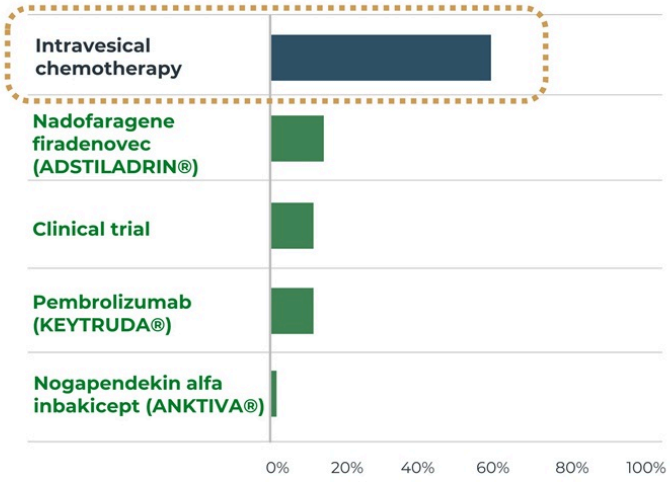
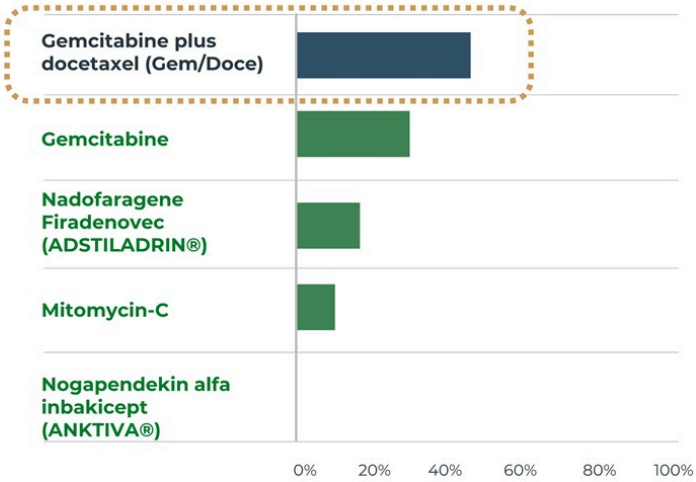
Gem/Doce Combination Stands Out in *Urology Times* Survey[1]

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.

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Significant Issues with Conventional Gem/Doce Intravesical Therapy for NMIBC

4-hour total procedure time	vs. **<5 minutes** for NDV-01
Requires **specialized pharmacy preparation**	vs. NDV-01 comes **ready for use** in two pre-filled plastic syringes
Utilization concentrated in **academic setting**	vs. NDV-01 which provides the **opportunity for community urologist** to deliver Gem/Doce
Limited drug exposure and dwell time	vs. NDV-01 which provides **sustained release** of Gem/Doce for up to 10 days

4-hour conventional Gem/Doce workflow

NMIBC: Non-muscle invasive bladder cancer; **Gem/Doce**: Gemcitabine plus Docetaxel

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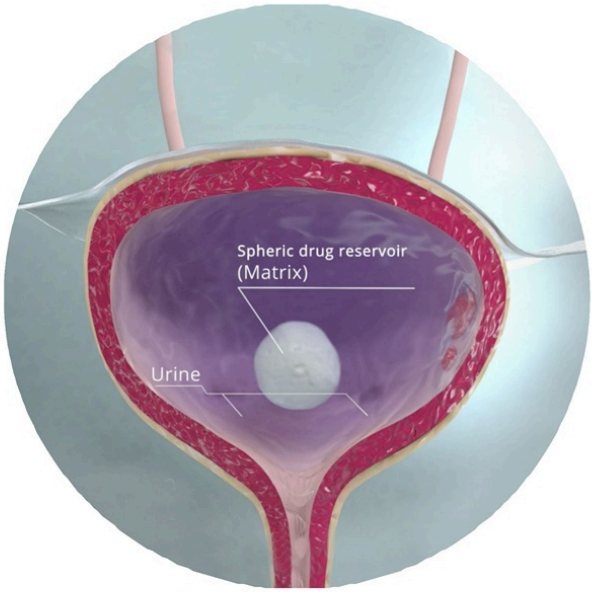
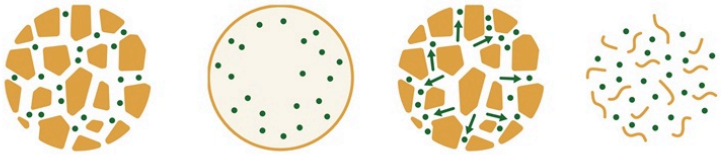
NDV-01 - Targeted Sustained-Release Intravesical Gem/Doce



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

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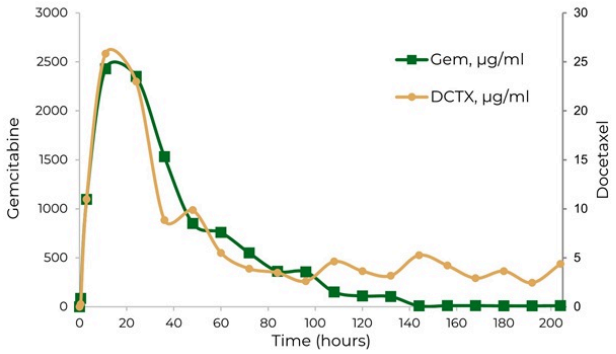
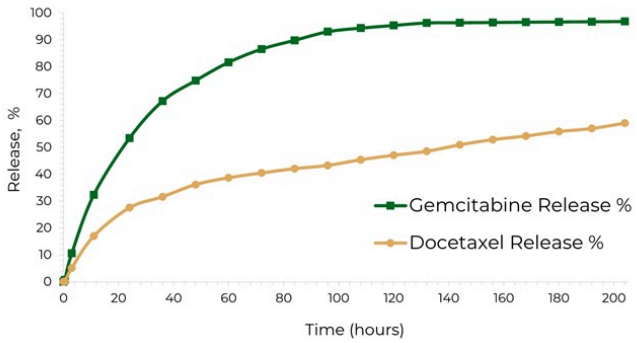
NDV-01 *in-vitro* Drug Concentrations Show Continuous & Optimized Drug Release

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

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NDV-01: Clinically De-Risked with Clear Competitive Advantages

Ready for Use: Rapid, Office-Based Administration

NDV-01 comes as two prefilled syringes instilled in **< 5 minutes**

Convenience: Unlocks Community-Based Treatment

In-office administration by MA/RN/LPN without specialized infusion infrastructure, supporting broad adoption in community urology practices where ~80% of NMIBC patients are treated

Derisked Based on Conventional Gem/Doce Usage

Conventional Gem/Doce is a **well-understood** and **most commonly used in academic practice**, providing familiarity and supporting a lower-risk clinical and regulatory pathway

Prolonged Intravesical Tumor Exposure

NDV-01 delivers continuous intravesical Gem/Doce inside the bladder enabling **sustained tumor exposure**

Favorable Safety & Clearance Profile

The NDV-01 biodegradable polymer gradually disintegrates and is **safely excreted in urine**, vs. Inlexzo™ which requires device extraction

Relmada internal market research 2025. **NMIBC:** Non-muscle invasive bladder cancer; **Gem/Doce**: Gemcitabine plus Docetaxel; **MA:** Medical assistant; **RN:** Registered Nurse; **LPN:** Licensed practical

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Study TRCG-011 for High-Risk NMIBC

An open-label, single-arm, single-center Phase 2a study to evaluate safety and efficacy of NDV-01 in HR NMIBC patients (NCT06663137)

HR: High Risk; **NMIBC:** Non-muscle invasive bladder cancer

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ONGOING TRCG-011 STUDY

Study Design

Inclusion Criteria

- High-risk disease with CIS, Ta/T 1 tumors[1, 2]
- BCG-naive, 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

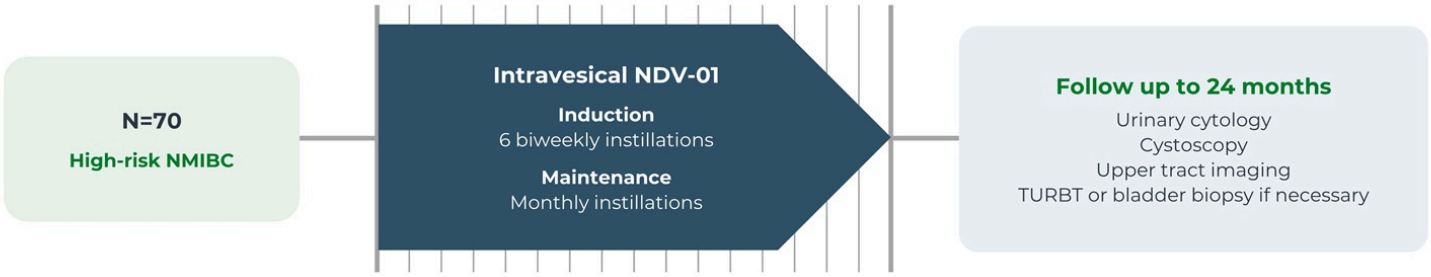
- Safety
- CR Rate at 12 months

Secondary Endpoint

- DOR
- EFS

Exploratory

- PK



1. The American Cancer Society. Bladder Cancer Stages. American Cancer Society, 12, Mar, 2024; **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. **CIS**: Carcinoma In Situ; **Ta**: Noninvasive papillary carcinoma; **T1:** Tumor invades lamina propria; **NMIBC:** Non-muscle invasive bladder cancer; **CR:** Complete Response; **DOR:** Duration of Response; **EFS:** Event Free Survival; **PK:** Pharmacokinetics; **TURBT:** Transurethral resection of bladder tumor **BCG:** Bacillus Calmette-Guérin

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ONGOING TRCG-011 STUDY

Demographic Data

Characteristics	N=48	%
Age		
Median (range)	75 (52-93) yr	
Sex		
Male	42	87.5%
Female	6	12.5%
BCG doses		
Median BCG doses (range)	9 (3-23)	
BCG-status		
BCG-naive	23	47.9%
BCG-exposed	5	10.4%
BCG-unresponsive	20	41.7%
Stage		
CIS +/- Ta/T1	12	25.0%
Ta HG	29	60.4%
T1 HG	7	14.6%

BCG: Bacillus Calmette-Guérin; **CIS:** Carcinoma In Situ; **Ta:** Noninvasive papillary carcinoma; **T1:** Tumor invades lamina propria; **HG:** High grade

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ONGOING TRCG-011 STUDY

NDV-01 Provided Durable Response Over Time

CR: Complete response; **BCG:** Bacillus Calmette-Guérin; **BCG-UR:** BCG-unresponsive; **KM:** Kaplan-Meier analysis

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ONGOING TRCG-011 STUDY

Efficacy and Tolerability

Efficacy Evaluable Patients[1] (Complete Response)

	n/N	%
Anytime	36/38	95%
3-month	33/38	87%
6-month	25/29	86%
9-month	22/26	85%*
12-month	19/25	76%*
12-month KM analysis	-	83%

- No patient had progression to muscle invasive disease
- No patient underwent a radical cystectomy
- 10 patients awaiting 3-month response assessment – Including 3 BCG-unresponsive CIS patients

BCG-UR Subpopulation (Complete Response)

	n/N	%
Anytime	16/17	94%
3-month	14/17	82%
6-month	12/14	86%
9-month	10/11	91%
12-month	8/10	80%
12-month KM analysis	-	84%

- n = 20 patients dosed in BCG-UR subpopulation
- BCG-UR defined by FDA definition[2]

1. Efficacy evaluable patients (n=38) includes patients with at least 3-month follow-up assessment. *Includes patients with CR after re-induction. 80% CR rate after re-induction;
2. https://www.fda.gov/media/101468/download; **BCG:** Bacillus Calmette-Guérin; **BCG-UR:** BCG-unresponsive; **KM:** Kaplan-Meier analysis

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ONGOING TRCG-011 STUDY

Treatment-Related AE and Tolerability

- **No patient had ≥ Grade 3 TRAE**
- **No patients discontinued treatment due to AEs**
- **Of the 48 patients who received ≥ 1 dose of NDV-01, 30 (63%) had a TRAE**
  - 54% transient uncomfortable urination (dysuria)
  - 8% asymptomatic positive urine culture
  - 8% hematuria

TRAE: Treatment-related adverse events; **AE:** Adverse events

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BCG-Unresponsive NMIBC: The Presence of CIS Does NOT Impact Gem/Doce RFS[1]

Steinberg et al. (2020): n=276; heavily-pre-treated with BCG

12-month RFS:

- Any CIS = 60%
- HG papillary alone = 61%

Table 3. *Kaplan-Meier estimates of various oncologic outcomes of patients treated with Gem/Doce*

Disease Type	No.*	% Time (95% CI) 6 Mos	12 Mos
RFS:			
All	276	77 (71–81)	60 (54–66)
Any CIS	173	76 (69–82)	60 (51–67)
Any papillary disease	169	76 (69–82)	62 (54–69)
CIS alone	107	78 (68–85)	57 (46–66)
HG papillary disease alone	72	78 (66–86)	61 (48–72)
Low grade papillary disease alone	31	76 (56–88)	60 (39–76)

THE JOURNAL of UROLOGY®

Multi-Institution Evaluation of Sequential Gemcitabine and Docetaxel as Rescue Therapy for Nonmuscle Invasive Bladder Cancer

Cox regression analysis for risk factors:

- Presence of CIS does NOT Impact RFS (p=0.15)

Presence of any CIS:			
Yes	173	1.31 (0.90–1.91)	0.15
No	103	Referent	

1. As demonstrated by third-party data: Steinberg et al. J Urol. 2020;203:902-909; **BCG:** Bacillus Calmette-Guérin; **CIS**: carcinoma in situ; **RFS:** recurrence-free survival; **HG:** High grade

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Rescue

Phase 3 Program

Recurrent / **E**ndovesical / **S**urgery-sparing / **C**ombination therapy for / **U**rothelial cancer / **E**ffectiveness

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PHASE 3 RESCUE TRIAL

Two Independent NDV-01 Approval Pathways Provide Significant Market Opportunity

Registrational Pathway 1

Single-arm trial in 2L BCG-unresponsive NMIBC with CIS who are refractory to approved or developmental therapies

~5k patients/annually in US[1] – based on 12-month CR rates of 19%-46%[3] for 1L BCG-unresponsive therapies

Registrational Pathway 2

Open label randomized controlled trial in intermediate-risk NMIBC – adjuvant therapy following TURBT (NDV-01 vs. observation)

~75k patients/annually in US[1] – with ~35%[2] of intermediate-risk patients receiving adjuvant therapy post-TURBT

1. Based on Internal estimates. **2.** Grabe-Heyne et al. Front Oncol. 2023. **3.** FDA approval summaries; company disclosures; published clinical trial data. **NMIBC:** Non-muscle invasive bladder cancer; **BCG:** Bacillus Calmette-Guérin (BCG); **TURBT:** Transurethral Resection of Bladder Tumor; **CIS**: carcinoma in situ; **1L:** first-line; **2L:** second-line; **CR**: Complete Response;

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PHASE 3 RESCUE TRIAL

Cohort 2A: 2L BCG-Unresponsive NMIBC

Open-label, single-arm study to evaluate safety and efficacy of NDV-01 in BCG-UR refractory to first-line therapy

Inclusion Criteria

- HR BCG-UR with CIS refractory to first-line therapy

Purpose

- Safety and efficacy of NDV-01 in patients with HR BCG-UR with CIS

Primary Endpoint

- CR anytime
- Safety

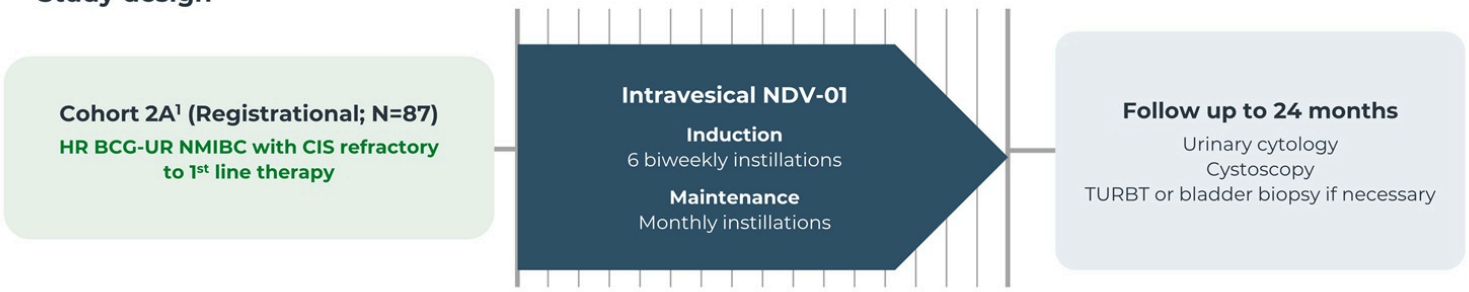
Secondary Endpoint

- DOR
- PFS
- RFS amongst responders

Other

- PK

Study design



1. BCG-Unresponsive patients with CIS +/- Ta/T1 disease. Phase 3 Cohort 2A is a registrational cohort intended for regulatory approval. **2.** BCG-Unresponsive patients with high-grade Ta/T1 disease. Phase 2 Cohort 2B is an exploratory cohort and not intended for regulatory approval. **HR:** High risk; **CIS:** Carcinoma In Situ; **CR:** Complete Response; **DOR:** Duration of Response; **RFS:** Recurrence Free Survival; **PFS:** Progression Free Survival; **PK:** Pharmacokinetics; **TURBT:** Transurethral resection of bladder tumor; **BCG:** Bacillus Calmette-Guérin **BCG-UR:** BCG-unresponsive

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PHASE 3 RESCUE TRIAL

Cohort 1: Adjuvant Intermediate-Risk NMIBC

Registrational Randomized study of TURBT + NDV-01 vs. TURBT in IR NMIBC

Inclusion Criteria

- IR NMIBC
- IBCG risk factors ≥ 1

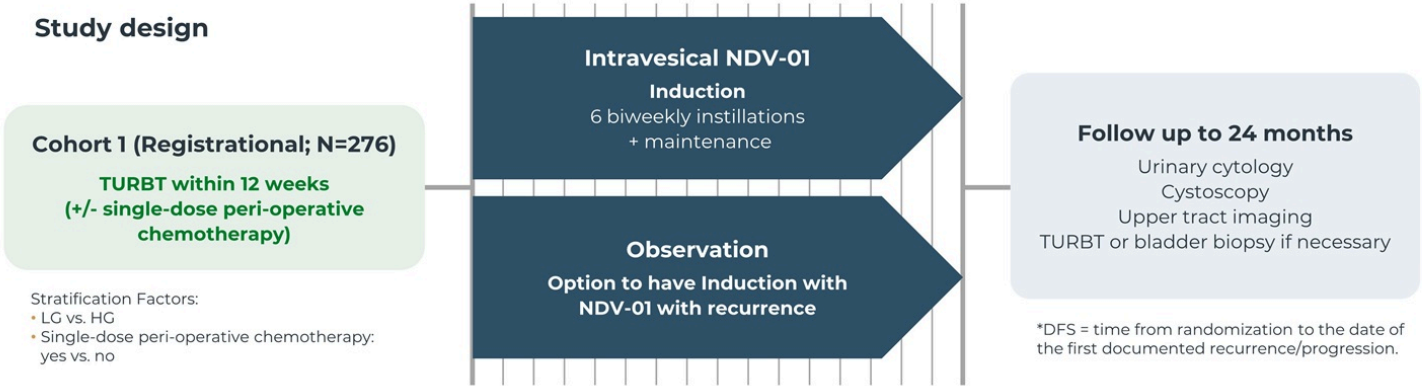
Primary Endpoint

- DFS*
- Safety

Secondary Endpoint

- HG-RFS
- PFS
- QOL

Study design



Stratification Factors:
- LG vs. HG
- Single-dose peri-operative chemotherapy: yes vs. no

*DFS = time from randomization to the date of the first documented recurrence/progression.

DFS: Disease Free Survival; **IR:** Immediate Risk; **HG-RFS:** High Grade Recurrence Free Survival; **PFS:** Progression Free Survival; **QOL:** Quality of Life Metrics; **TURBT**: Transurethral resection of bladder tumor; **IBCG:** International Bladder Cancer Group; **LG:** Low grade; **HG**: High grade

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Expecting to Advance NDV-01 Towards Registration-Track Studies in Mid-2026

Mid 2026

Initiate Phase 3 RESCUE Trials

Target two independent registrational pathways:

- 2L BCG-Unresponsive NMIBC patients
- Adjuvant Intermediate-Risk NMIBC patients

Q4 2026

Interim Phase 3 2L BCG-Unresponsive 3-month Data

Initial 3-month CR data + safety

BCG: Bacillus Calmette-Guérin (BCG); **NMIBC:** No muscle invasive bladder cancer; **IR:** Intermediate Risk

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Sepranolone

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

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Sepranolone Has the Potential to Normalize $GABA_A$ Receptor Activity

GABA (ϒ-aminobutyric acid) is the primary neurotransmitter, involved in anxiety and compulsive disorders[1,2]

Allopregnanolone (ALLO) typically enhances $GABA_A$ calming effects[3, 4]

In some individuals, ALLO exacerbates anxiety and compulsivity[5, 6]

Sepranolone normalizes $GABA_A$ receptor activity without interfering in GABA signaling[7,8]

1. Nuss P et al. Neuropsychiatr Dis Treat. 2015. **2.** Möhler H. Neuropharmacology. 2012. **3.** Belelli D et al. Nat Rev Neurosci. 2005. **4.** Majewska MD et al. Science. 1986. **5.** Girdler SS et al. Biol Psychiatry. 2001. **6.** Bixo M et al. Br J Psychiatry. 2025. **7.** Bixo M et al. Psychoneuroendocrinology. 2017. **8.** Bäckström T et al. Psychoneuroendocrinology. 2021. **$GABA_A$:** ϒ-aminobutyric acid type A; **ALLO:** Allopregnanolone

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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 and adults[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 AO. UpToDate. 2023. **2.** Crawford S et al. Neurology. 2020. **3.** Tinker SC et al. Psychiatry Res. 2022. **4.** International OCD Foundation epidemiology data. **PWS:** Prader-Willi syndrome; **ET:** Essential Tremor; **OCD:** Obsessive Compulsive Disorder

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Sepranolone: Highlights & Development Value

- **Differentiated therapeutic candidate** for compulsivity-related disorders, supported by positive proof-of-concept data in Tourette's syndrome
- **Phase 2 study in Prader-Willi syndrome (PWS)** planned for H1 2026, targeting a rare genetic disorder affecting 350,000–400,000 individuals worldwide
- **Program readiness:** Regulatory engagement and manufacturing activities are actively underway, supporting efficient trial initiation
- **Orphan/rare disease incentives:** Potential for orphan drug designation, including regulatory exclusivity, accelerated approval pathways, and enhanced commercial visibility
- **Strategic investor value:** Clear development milestones, potential for first-in-class differentiation, and meaningful opportunity in a high-unmet-need rare disease

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Expecting to Advance Sepranolone Towards Phase 2 Study in Prader-Willi Syndrome in Mid-2026

Mid 2026

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

PWS: Prader-Willi syndrome

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Corporate Summary

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Financial Overview

$93.0 million[1]

Cash, cash equivalents & short-term investments

As of December 31, 2025

$160 million PIPE[2]

Gross proceeds from PIPE (net ~$150M million)

Provides cash runway through 2029

~104.8 million[3]

Common shares outstanding

~127.9 million as converted – includes 15M outstanding options (weighted average exercise price of $12.51/share) and ~8.0M outstanding warrants

1. As of December 31, 2025; **2.** On March 9, 2026; **3.** Includes 29.5 million shares issued for PIPE on March 9, 2025

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Thank You!

Appendix

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 vs. BCG (NCT05538663)

1. Steinberg RL et al. J Urol. 2020; **2.** Garneau CA et al. Can Urol Assoc J. 2024; **3.** Yim K et al. Urol Oncol. 2023; **4.** McElree IM et al. J Urol. 2022; **5.** McElree IM et al. Urol Oncol. 2023; **6.** Tan WS et al. Eur Urol Oncol. 2023; **7.** Chevuru PT et al. Urol Oncol. 2023; **8.** Narayan VM et al. J Urol. 2024. **9**. Steinberg RL et al. J Urol. 2019; **RFS:** Relapse Free Survival; **BCG:** Bacillus Calmette-Guérin; **NMIBC:** Non-muscle invasive bladder cancer; **Gem/Doce**: Gemcitabine plus Docetaxel

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PHASE 3 RESCUE TRIAL

Cohort 2B: 2L BCG-Unresponsive NMIBC

Open-label, single-arm study to evaluate safety and efficacy of NDV-01 in BCG-UR refractory to first-line therapy

Inclusion Criteria

- HR BCG-UR papillary only refractory to first-line therapy

Purpose

- Safety and efficacy of NDV-01 in patients with HR BCG-UR with CIS

Primary Endpoint

- CR anytime
- Safety

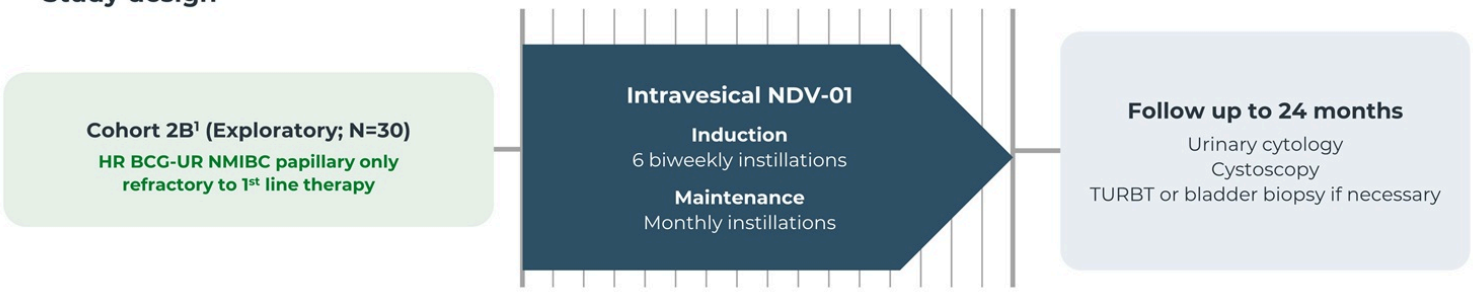
Secondary Endpoint

- DOR
- PFS
- RFS amongst responders

Other

- PK

Study design



1. BCG-Unresponsive patients with high-grade Ta/T1 disease. Phase 2 Cohort 2B is an exploratory cohort and not intended for regulatory approval. **CR:** Complete Response; **DOR:** Duration of Response; **RFS:** Recurrence Free Survival; **PFS:** Progression Free Survival; **BCG-UR:** BCG-unresponsive

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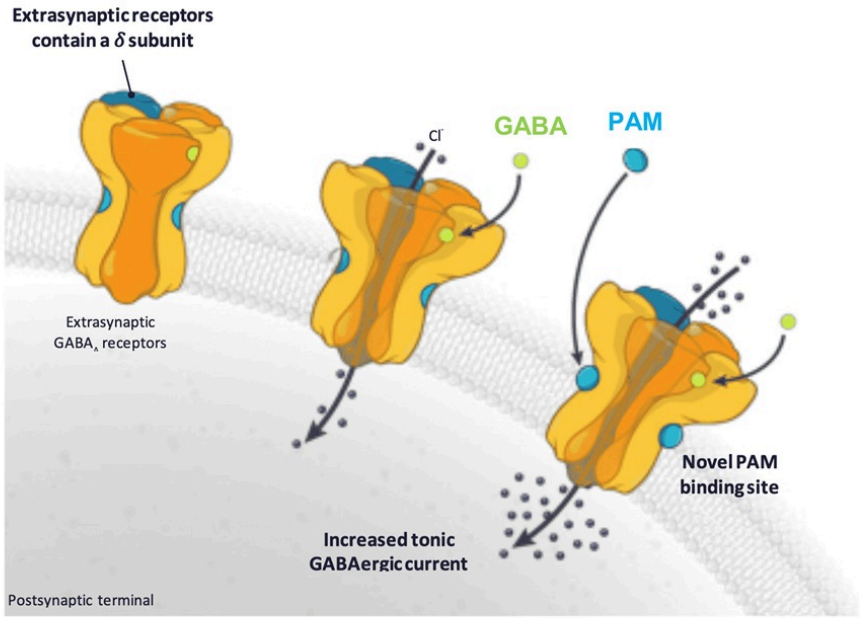
Sepranolone Has the Potential to Normalize $GABA_A$ Receptor Activity



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

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Management

Leadership

Sergio Traversa
Chief Executive Officer

Maged Shenouda
Chief Financial Officer

Chuck Ence
Chief Accounting and Compliance Officer

Paul Kelly
Chief Operating Officer

Raj S. Pruthi, MD
Chief Medical Officer

Board of Directors

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John Glasspool
Director

Fabiana Fedeli
Director

Sergio Traversa
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Paul Kelly
Chief Operating Officer

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