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): **May 12, 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 May 12, 2026, Relmada Therapeutics, Inc. (the "Company") issued a press release providing a corporate update and reporting its financial results for the three months ended March 31, 2026. The Company also announced that it would conduct a conference call and audio webcast on Tuesday, May 12, 2026, at 4:30 PM EST / 1:30 PM PST, to discuss the update and results. The Company's complete unaudited condensed consolidated financial statements and notes thereto as of March 31, 2026, and December 31, 2025, and for the three months ended March 31, 2026 and 2025, will be contained in its Quarterly Report on Form 10-Q 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 May 12, 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 May 12, 2026, regarding corporate update and full year 2025 financial results
99.2*	Corporate Presentation dated May 12, 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: May 12, 2026

RELMADA THERAPEUTICS, INC.

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

Exhibit 99.1

Relmada Therapeutics Reports First Quarter 2026 Financial Results and Provides Business Update

- *Positive 12-Month Phase 2 data for NDV-01 demonstrated a 95% complete response (CR) rate at any time and a durable 76% CR rate at 12 months in high-risk non-muscle invasive bladder cancer (NMIBC), and a 94% CR rate at any time and a durable 80% CR rate at 12 months in the BCG-unresponsive subpopulation, reinforcing best-in-class potential in NMIBC*
- *On track to initiate Phase 3 RESCUE registrational program in second line (2L) BCG-unresponsive and adjuvant intermediate-risk NMIBC in mid-2026*
- *Filed provisional patent application with the USPTO in April 2026 covering NDV-01 pharmaceutical formulations and methods of treatment; if issued, patents claiming priority to the provisional filing would have a term until April 2047*
- *Relmada will feature two NDV-01 presentations at the American Urological Association Annual Meeting (AUA2026), highlighting the 12-month Phase 2 data and the Phase 3 RESCUE program design and rationale*
- *Cash balance of $234.0 million as of March 31, 2026 expected to fund operations through 2029, including completion of the NDV-01 Phase 3 RESCUE program*
- *Management to host a conference call and webcast today at 4:30 PM ET*

CORAL GABLES, FL – May 12, 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 financial results for the first quarter ended March 31, 2026 and provided a corporate update.

"We made significant progress in the first quarter, highlighted by the robust 12-month Phase 2 data for NDV-01 in NMIBC and the successful completion of a $160 million PIPE financing, which has well-capitalized our balance sheet to fund the NDV-01 RESCUE Phase 3 program through completion," said **Sergio Traversa, Chief Executive Officer of Relmada Therapeutics**. "We remain on track to file the NDV-01 IND and initiate the Phase 3 RESCUE registrational program in mid-2026 – a milestone that would mark a major inflection point for Relmada and for the patients we aim to serve. We believe NDV-01 has the potential to be a best-in-class therapy for patients with NMIBC and remain focused on maximizing its potential for success. To this end, in April, we filed a provisional patent application in the U.S. directed to formulations and methods of treatment for NDV-01. This application, if issued, could form the basis for worldwide patent filings, and have a term into 2047."

"The AUA2026 Annual Meeting provides an important opportunity to introduce NDV-01 to the broader urologic community," said **Raj S. Pruthi, MD, Chief Medical Officer – Urology of Relmada Therapeutics**. "Our presentations will highlight the 12-month Phase 2 data generated to date for NDV-01, including observed complete responses and safety findings. We will also be sharing the design and rationale for the Phase 3 RESCUE program. NDV-01 is a sustained-release gemcitabine and docetaxel (Gem/Doce) designed to support streamlined, in-office administration in less than five minutes. We believe AUA2026 provides an important national forum to increase awareness and engagement within the investigator community as we approach the initiation of the RESCUE program in mid-2026."

Upcoming AUA2026 Presentations and NDV-01 Phase 2 Data Highlights:

Relmada will present two abstracts at AUA2026 including: (1) NDV-01 Phase 2 data (12-month follow-up), and (2) the Phase 3 RESCUE program design (Clinical Trials in Progress session). The presentations are intended to raise awareness of NDV-01 and build investigator interest in the RESCUE registrational program. Key data to be highlighted include:

- **95% complete response (CR) rate at any time and durable 76% CR rate at 12 months in high-risk NMIBC patients**
- **94% CR rate at any time and durable 80% CR rate at 12 months in BCG-unresponsive NMIBC patients**
- **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

NDV-01 Intellectual Property:

In April 2026, Relmada filed a provisional patent application with the United States Patent and Trademark Office (USPTO) directed to pharmaceutical formulations and methods of treatment related to NDV-01. The provisional filing has the potential to form the basis for a comprehensive world-wide patent filing program for NDV-01. If issued, patents claiming priority to the provisional filing will be expected to have a term until April 2047.

Expected Upcoming Relmada Milestones:

- NDV-01 United States IND filing – 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 – YE 2026

Financial Results

First Quarter 2026 Financial Results

- Research and development expense for the three months ended March 31, 2026, totaled $8.1 million, compared to $12.0 million for the three months ended March 31, 2025, a decrease of $3.9 million. The decrease was primarily attributable to non-recurring costs associated with the acquisition of sepranolone and the license agreement of NDV-01 recognized in 2025. This 2026 decrease was partially offset by increased costs related to the start-up of 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 March 31, 2026, totaled $11.4 million compared to $6.3 million for the three months ended March 31, 2025, an increase of approximately $5.1 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 March 31, 2026, totaled $15.1 million compared to $18.1 million for the three months ended March 31, 2025.

- The net loss for the three months ended March 31, 2026, was $19.1 million, or $0.22 per basic and diluted share, compared with a net loss of $17.6 million, or $0.58 per basic and diluted share, for the three months ended March 31, 2025.

- The Company's balance of $234.0 million in cash, cash equivalents, and short-term investments, includes net proceeds of approximately $150 million from the private placement financing announced March 9, 2026. This compares to cash, cash equivalents, and short-term investments of approximately $93.0 million at December 31, 2025.

- The Company's current cash, cash equivalents, and short-term investments as of March 31, 2026, 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 May 7, 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: Tuesday, May 12, 2026 at 4:30 PM ET

- Participant Dial-in (US): 1-800-717-1738

- Participant Dial-in (International): 1-646-307-1865

- 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 ready-to-use, sustained-release intravesical formulation of gemcitabine and docetaxel (Gem/Doce) being developed for the treatment of non-muscle invasive bladder cancer (NMIBC). The formulation is engineered to provide prolonged bladder retention and controlled drug release over approximately 10 days. By forming a soft intravesical matrix, NDV-01 is designed to increase local drug exposure while limiting systemic toxicity. The treatment can be administered conveniently in an office setting in under 5 minutes without the need for anesthesia or specialized equipment. It is encompassed by multiple patent applications that if issued, could provide protection until 2047.

About the NDV-01 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. Patients were evaluated at 3-month intervals using cystoscopy and cytology, with biopsies performed at the treating physician's discretion. Time-to-event endpoints, including complete response (CR) and event free survival (EFS) rates, were analyzed as landmark events and using Kaplan–Meier (KM) analysis. The primary efficacy endpoints are safety and CR rate at 12 months, and secondary efficacy endpoints are duration of response (DOR) and EFS. Treatment-related adverse events (TRAEs) were graded according to CTCAE v5.0 (Common Terminology Criteria for Adverse Events, version 5.0).

About the NDV-01 Phase 3 RESCUE Registrational Pathways:

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. IND filing and program initiation remain on track for mid-2026.

Registration Pathway 1 – An open-label 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.

Registrational Pathway 2 – An open label randomized controlled trial in intermediate-risk NMIBC of adjuvant therapy following TURBT (Transurethral Resection of Bladder Tumor, NDV-01 vs. observation). There are no approved adjuvant treatments for 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).

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 fail to progress, potential for Phase 2 NDV-01 data to fail to continue to deliver positive results supporting further development, potential for clinical trials to fail 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, failure of pending patent applications to result in issued patents, or issued patents being challenged and invalidated by third parties or not providing us with any competitive advantages, 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:

Brian Ritchie
LifeSci Advisors
britchie@lifesciadvisors.com

Media Inquiries:

Corporate Communications
media@relmada.com

Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	As of March 31, 2026 (Unaudited)	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 9,776,400	$ 3,496,540
Short-term investments	224,186,743	89,509,710
Prepaid expenses	1,380,151	977,721
Total current assets	235,343,294	93,983,971
Other assets	19,500	19,500
Total assets	$ 235,362,794	$ 94,003,471
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,731,401	$ 1,568,944
Accrued expenses	7,160,233	4,861,583
Total current liabilities	12,891,634	6,430,527
Stock appreciation rights	3,738,583	1,060,931
Total liabilities	16,630,217	7,491,458
Commitments and Contingencies (See Note 8)		
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, 104,890,223 and 73,333,622 shares issued and outstanding, respectively	104,890	73,333
Additional paid-in capital	935,946,841	784,705,878
Accumulated deficit	(717,319,154)	(698,267,198)
Total stockholders' equity	218,732,577	86,512,013
Total liabilities and stockholders' equity	$ 235,362,794	$ 94,003,471

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

	Three months ended March 31,	
	2026	**2025**
Operating expenses:		
Research and development	$ 8,087,845	$ 11,951,023
General and administrative	11,373,909	6,267,412
Total operating expenses	19,461,754	18,218,435
Loss from operations	(19,461,754)	(18,218,435)
Other income:		
Interest/investment income, net	959,762	440,287
Realized (loss)/gain on short-term investments	(9,867)	62,952
Unrealized (loss)/gain on short-term investments	(540,097)	155,731
Total other income, net	409,798	658,970
Net loss	$ (19,051,956)	$ (17,559,465)
Loss per common share – basic and diluted	$ (0.22)	$ (0.58)
Weighted average number of common shares outstanding – basic and diluted	86,596,873	30,408,890

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

	Three months ended March 31, 2026				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance - December 31, 2025	73,333,622	$ 73,333	$ 784,705,878	$ (698,267,198)	$ 86,512,013
Stock based compensation	-	-	956,186	-	956,186
Proceeds from issuance of common stock, net	29,474,569	29,475	150,352,510	-	150,381,985
ATM Fees	-	-	(65,651)	-	(65,651)
Cashless exercise of pre-funded warrants for common stock	2,082,032	2,082	(2,082)	-	-
Net loss	-	-	-	(19,051,956)	(19,051,956)
Balance – March 31, 2026	104,890,223	$ 104,890	$ 935,946,841	$ (717,319,154)	$ 218,732,577

	Three months ended March 31, 2025				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance - December 31, 2024	30,174,202	$ 30,174	$ 676,373,822	$ (640,882,035)	$ 35,521,961
Stock based compensation	-	-	3,572,769	-	3,572,769
Issuance of restricted common stock	3,017,420	3,017	902,209	-	905,226
Net loss	-	-	-	(17,559,465)	(17,559,465)
Balance – March 31, 2025	33,191,622	$ 33,191	$ 680,848,800	$ (658,441,500)	$ 22,440,491

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

	Three months ended March 31,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (19,051,956)	$ (17,559,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	956,186	3,572,769
Stock appreciation rights compensation	2,677,652	3,038
Issuance of restricted common stock	-	905,226
Realized loss/(gain) on short-term investments	9,867	(62,952)
Unrealized loss/(gain) on short-term investments	540,097	(155,731)
Change in operating assets and liabilities:		
Prepaid expenses	(402,430)	290,051
Accounts payable	1,762,457	(2,865,553)
Accrued expenses	(1,559,361)	(2,194,416)
Net cash used in operating activities	(15,067,488)	(18,067,033)
Cash flows from investing activities		
Purchase of short-term investments	(149,517,480)	(487,916)
Sale of short-term investments	14,290,483	15,847,629
Net cash (used in)/provided by investing activities	(135,226,997)	15,359,713
Cash flows from financing activities		
Proceeds from issuance of common stock	159,999,996	-
Payment of fees for issuance of common stock	(3,360,000)	-
ATM Fees	(65,651)	-
Net cash provided by financing activities	156,574,345	-
Net increase/(decrease) in cash and cash equivalents	6,279,860	(2,707,320)
Cash and cash equivalents at beginning of the period	3,496,540	3,857,026
Cash and cash equivalents at end of the period	$ 9,776,400	$ 1,149,706
Non-cash investing and financing activities:		
Cashless exercise of warrants for common stock	(2,082)	-
Fees for issuance of common stock included in accounts payable	2,400,000	-
Fees for issuance of common stock included in accrued expenses	3,858,011	

Exhibit 99.2

Relmada THERAPEUTICS

CORPORATE OVERVIEW

Unlocking Life Changing Therapies

May 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.

Investment Thesis

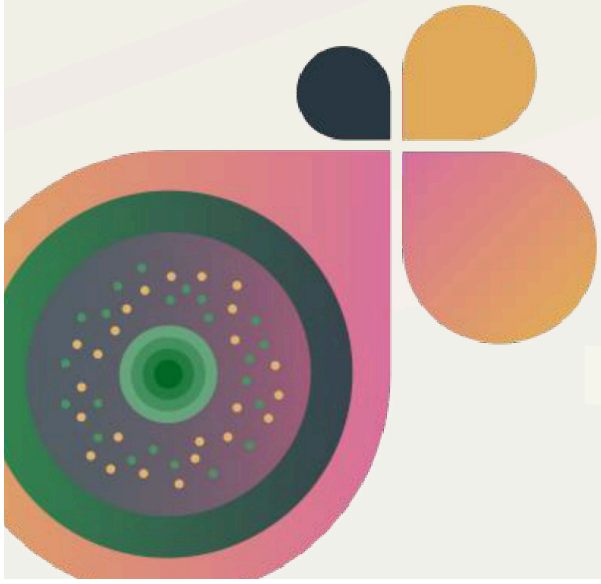
- Innovative pipeline of **potential high-value assets**, led by NDV-01 for non-muscle invasive bladder cancer (NMIBC)
- NDV-01, **a late-stage** sustained-release Gem/Doce with **attractive commercial profile and well-defined regulatory pathway**
- **Improvement vs. conventional Gem/Doce**, positioning 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

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		**Mid-2026**: Initiate Phase 2 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



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

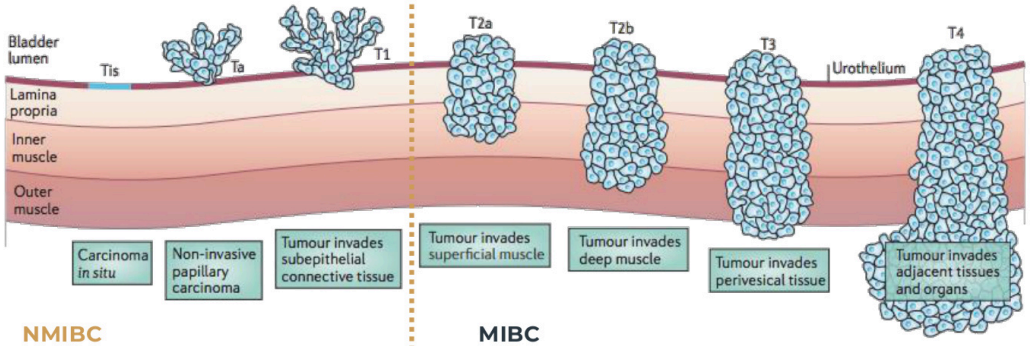
Our Focus: Non-Muscle Invasive Bladder Cancer (NMIBC)

80%
of new cases[1,2]

Non-muscle invasive

20%
of new cases[1,2]

Muscle-invasive



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.

NMIBC Represents Multi-Billion Dollar Market Opportunity

Key Highlights

High incidence[1]

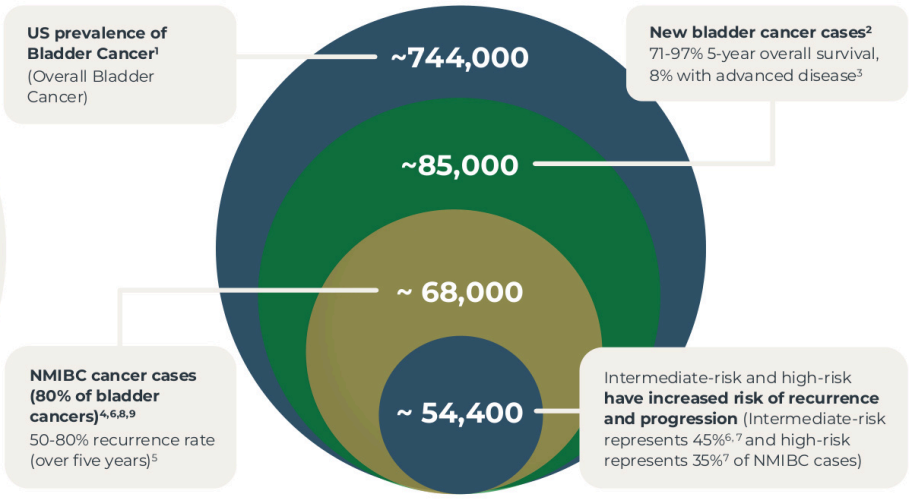
4.2% of all new cancer cases in the US

High recurrence[5]

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

High cost

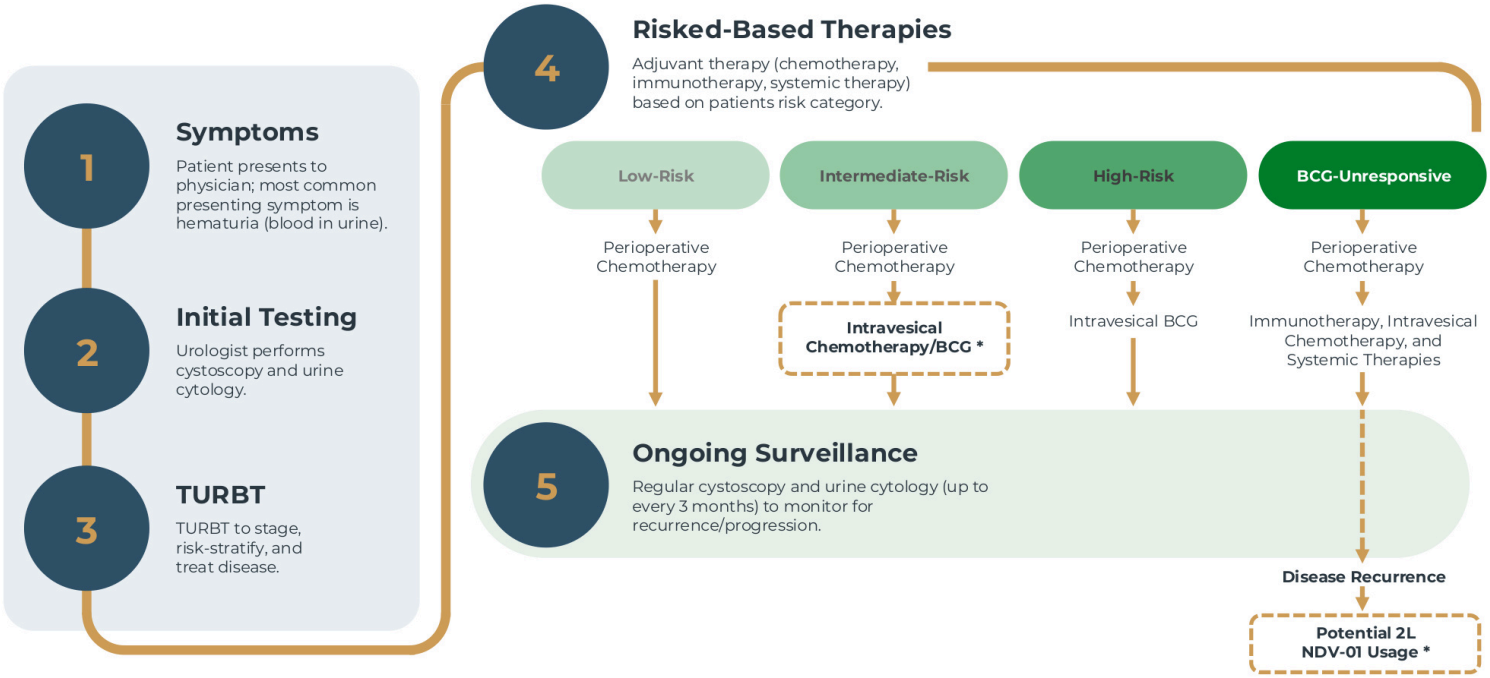
Complex treatment pathways
$6.5B total annual cost (U.S.)[10]



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

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

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

The Burden of Recurrences and TURBT is High

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

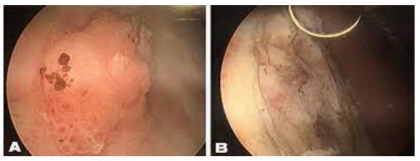
- 5-year risk of initial recurrence: 54.4%. After initial recurrence 60.1% of patients had a second recurrence by 2 years
- After 2nd recurrence, 51.5% of patients had a 3rd recurrence by 3 years

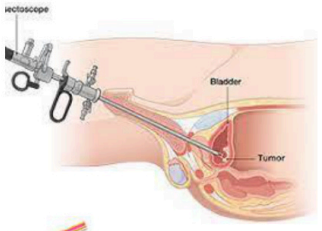
Increased risk of progression with more recurrences[1]

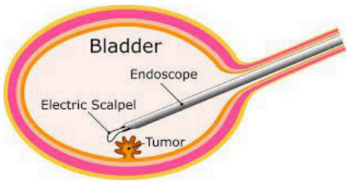
- The 5-year risk of progression: 9.5%, 21.9%, and 37.9% for patients with 1, 2, and 3+ recurrences, respectively

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]



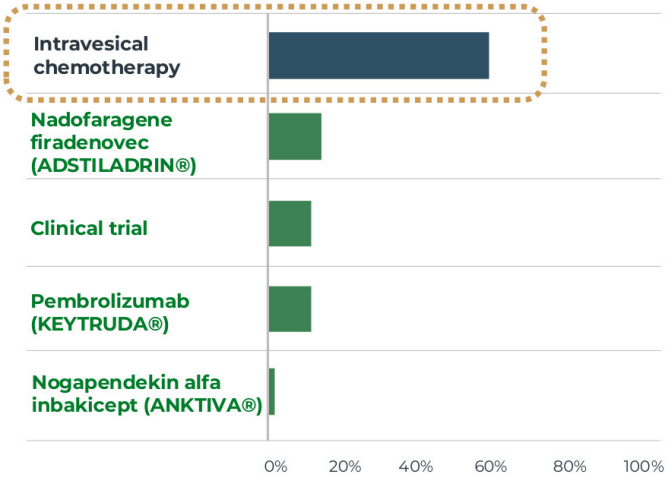




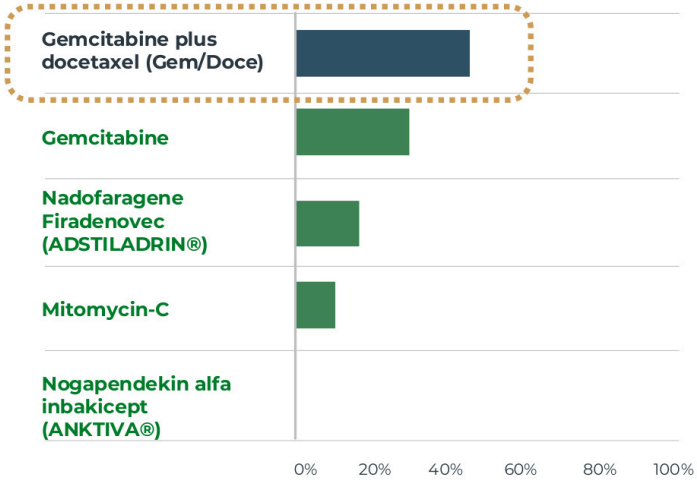
1. Sharma V et al. Urology. 2023. **2 .** Pycha A et al. Urology. 2003. **3.** Bansal A et al. Indian J Urol. 2016. **4.** Jindal T et al. Curr Urol. 2023. **5.** MediGence TURBT cost data. **6.** Lee LJ et al. Clinicoecon Outcomes Res. 2020. **7.** Kokkotos F et al. J Clin Oncol. 2022

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.

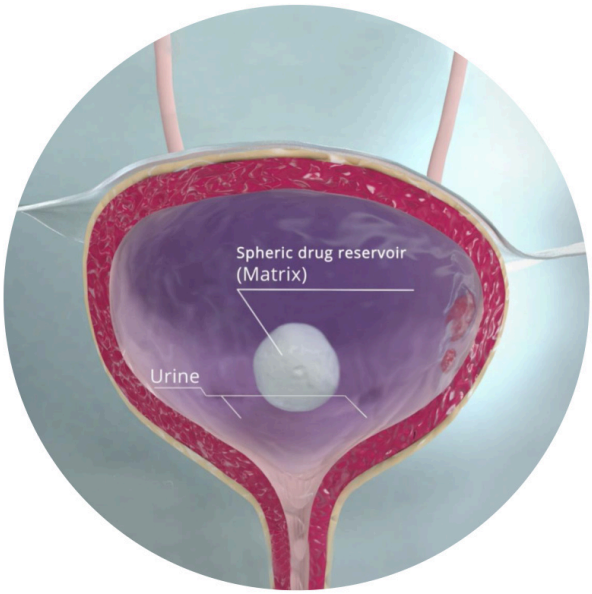
Significant Issues with Conventional Gem/Doce Intravesical Therapy for NMIBC

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

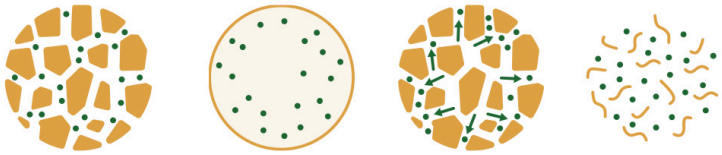
4-hour conventional Gem/Doce workflow

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

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

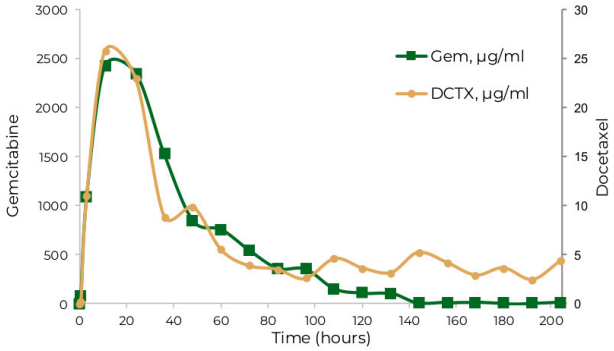
Diffusion through the polymer

Osmotic pumping

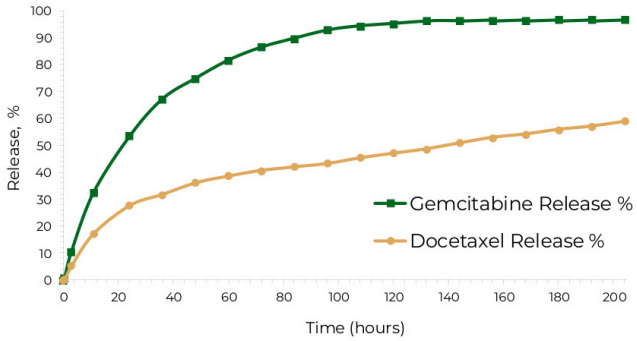
Erosion

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

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

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

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

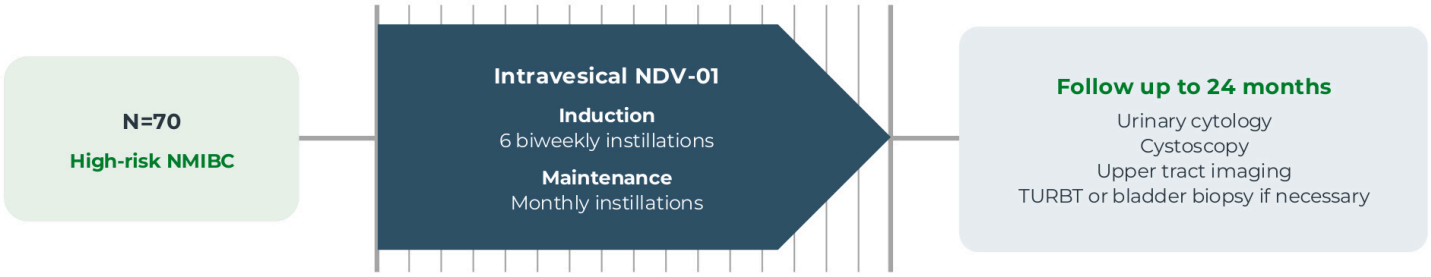
- Safety
- CR Rate at 12 months

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

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

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

ONGOING TRCG-011 STUDY

Efficacy Results

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

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

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)

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	

THE JOURNAL of UROLOGY®

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

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

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

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 1L 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;

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

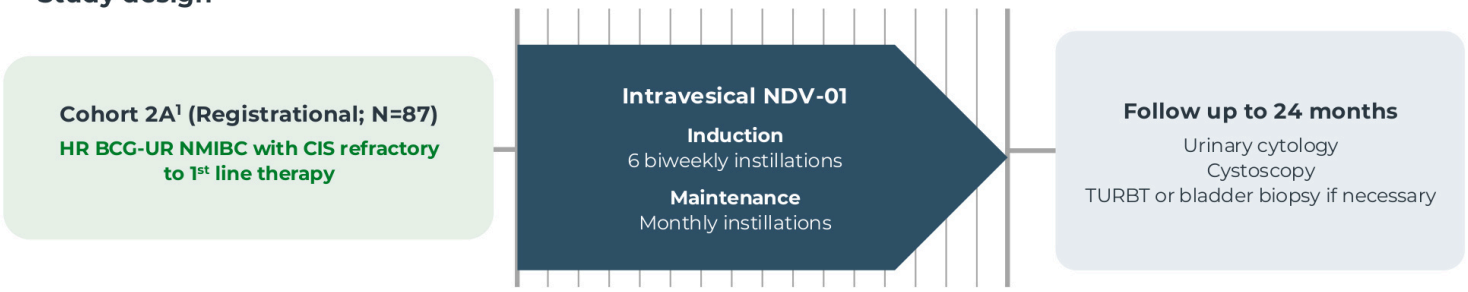
Secondary Endpoint

- 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

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

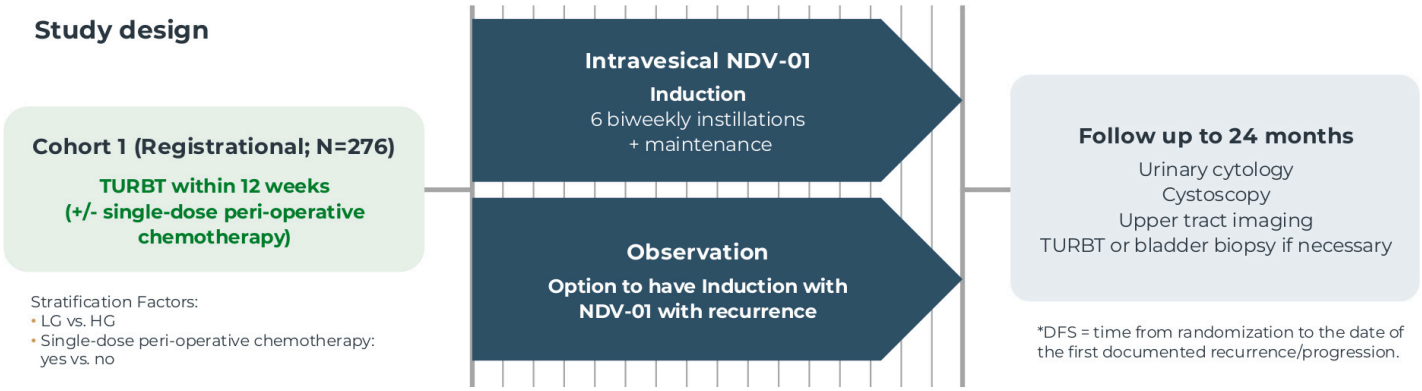
Primary Endpoint

- 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

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

Mid 2026

Initiate Phase 3 RESCUE Trial

Target two independent registrational pathways:

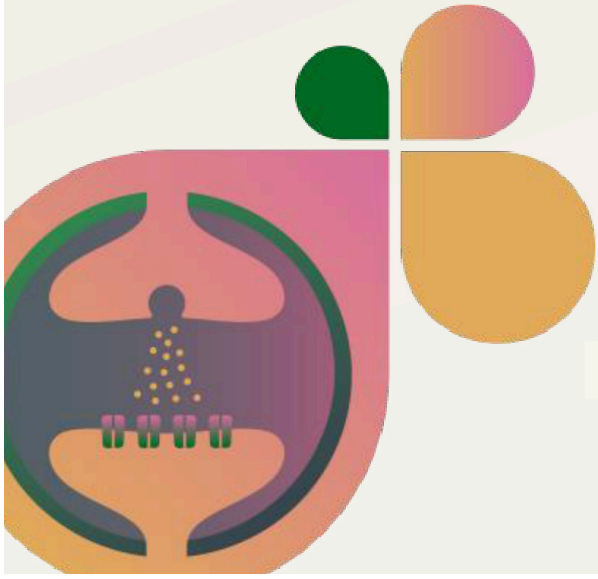
- 2L BCG-Unresponsive NMIBC patients
- Adjuvant Intermediate-Risk NMIBC patients

YE 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



Sepranolone

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

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

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

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 mid-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

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

Corporate Summary

Financial Overview

$234.0 million[1]

Cash, cash equivalents & short-term investments

As of March 31, 2025

$160 million PIPE[2]

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

Provides cash runway through 2029

~104.9 million[3]

Common shares outstanding

~127.9 million as converted – includes ~15.0M outstanding options (weighted average exercise price of $12.51/share) and ~8.0M outstanding warrants

1. As of March 31, 2026 – Includes net proceeds of ~$150M from PIPE on March 9, 2026; **2.** On March 9, 2026; **3.** As of March 31, 2026

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

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

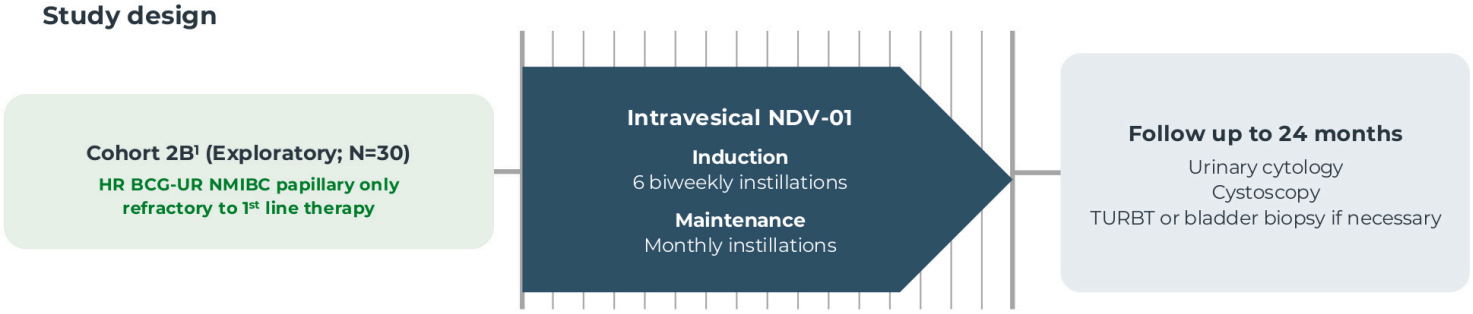
Secondary Endpoint

- DOR
- PFS
- RFS amongst responders

Other

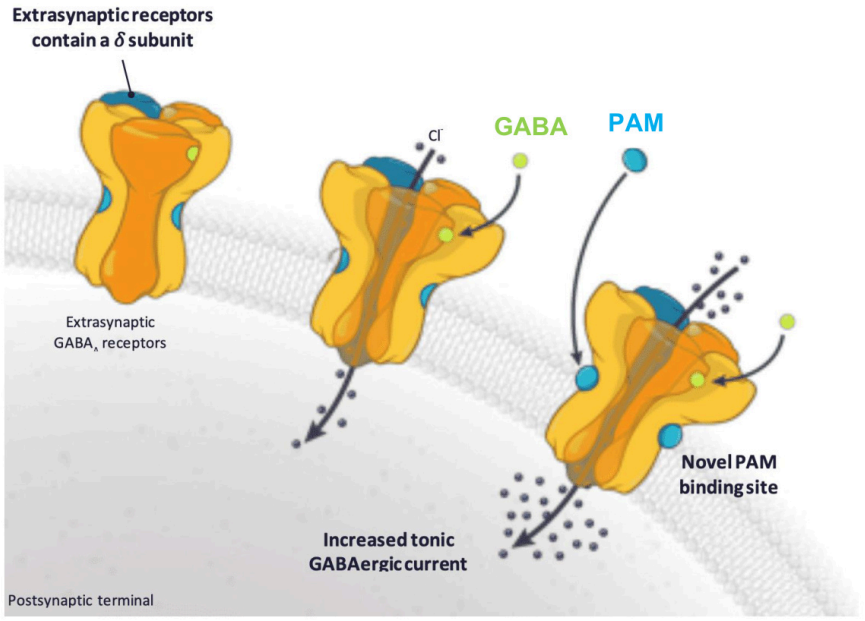
- PK

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

Sepranolone Has the Potential to Normalize $GABA_A$ Receptor Activity



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

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

Charles J. Casamento
Chairman of the Board

John Glasspool
Director

Fabiana Fedeli
Director

Sergio Traversa
Chief Executive Officer

Paul Kelly
Chief Operating Officer

