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): **November 4, 2025**

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

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

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

Registrant's telephone number, including area code: **(786) 629-1376**

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

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

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

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

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

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

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

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

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

Emerging growth company ☐

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

Item 7.01 Regulation FD Disclosure.

On November 4, 2025, Relmada Therapeutics, Inc. (the "Company") made available an investor presentation to be used during investor meetings. A copy of the investor presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Also on November 4, 2025, the Company issued a press release announcing (i) Food and Drug Administration ("FDA") feedback on its proposed NDV-01 Phase III trials and (ii) nine-month safety and efficacy data. A copy of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K and in Exhibits 99.1 and 99.2 attached hereto will not be treated as "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. This information will not be incorporated by reference into any filing under the Securities Act of 1933 or into another filing under the Exchange Act, unless that filing expressly incorporates this information by reference.

Item 8.01 Other Events.

FDA Feedback on proposed NDV-01 Phase III Trials

The FDA indicated that in the Bacillus Calmette-Guerin (BCG)-unresponsive setting, a single arm trial may be acceptable in a patient population refractory to other therapies, with the details of such a design to be discussed further with the FDA. The FDA also indicated that, a randomized, post-transurethral resection of the bladder tumor ("TURBT") adjuvant study comparing NDV-01 to observation in intermediate risk non-muscle invasive bladder cancer (NMIBC) patients with a time-to-event primary endpoint is generally acceptable, subject to submission of the intended trial design and endpoint definition to the FDA in a meeting package. In addition, the FDA agreed with our proposal to rely on FDA's prior findings of safety for Gemzar and Taxotere and published literature for the nonclinical safety assessment of NDV-01 because this is a proposed 505(b)(2) approval. Based on this feedback, we will be requesting Type B meetings with the FDA for the randomized intermediate-risk NMIBC trial and for the BCG-unresponsive trial. We have protocols in active development for both the single-arm study in BCG-unresponsive NMIBC with carcinoma in situ (CIS) who are refractory to other therapies, which would enroll approximately 100 patients, and the randomized intermediate-risk NMIBC trial, which would enroll approximately 266 patients.

There can be no assurance that the FDA will agree that our new protocols and plans are sufficient to support approval of NDV-01 and we may not be able to proceed with our Phase III clinical trials on our proposed timetable.

Nine-Month Safety and Efficacy Data

We obtained nine-month safety and efficacy data for our Phase II study of NDV-01 in high-risk NMIBC. Among 36 enrolled patients who received at least one dose, no new safety signals were observed with respect to the type, frequency or severity of adverse events. No patients experienced Grade ≥3 treatment-related adverse events, and no patients discontinued treatment due to adverse events. Of the 36 patients, 22 (61%) experienced a treatment-related adverse event. Among treatment-related adverse events, 62% were transient uncomfortable urination (dysuria), 9% were asymptomatic positive urine culture and 7% were hematuria. The below table summarizes the efficacy data from the study.

Complete Response (CR)	**% (n/N)**
Anytime	92% (23/25)
3 months	84% (21/25)
6 months	87% (20/23)*
9 months	85% (17/20)*

* *Includes patients with CR after re-induction. 60% CR rate after re-induction.*

Two patients have reached the 12-month assessment, and both have a CR. No patient has progressed to muscle-invasive disease and no patient has undergone radical cystectomy. 11 patients are awaiting the three-month response assessment.

Preliminary Financial Information as of September 30, 2025

While we have not completed our quarter-end financial close process, we expect to report that we had approximately $13.9 million of cash, cash equivalents and short-term investments as of September 30, 2025. This amount is preliminary, has not been audited and is subject to change upon completion of our financial statement closing procedures, and any changes could be material. Additional information and disclosures would be required for a more complete understanding of our financial position as of September 30, 2025, which are not available as of the date of this prospectus supplement. The unaudited financial data included in this prospectus supplement has been prepared by, and is the responsibility of, management of the Company. Our independent registered public accounting firm, CBIZ CPAs P.C., has not audited, reviewed, compiled or applied agreed-upon procedures with respect to the preliminary financial data set forth above. Accordingly, CBIZ CPAs P.C. does not express an opinion or any other form of assurance with respect thereto. We expect to complete our audited financial statements as of and for the quarter ended September 30, 2025 subsequent to the completion of this offering. Accordingly, undue reliance should not be placed on this preliminary estimate.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Investor Presentation, dated November 4, 2025
99.2	Press Release, dated November 4, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Dated: November 4, 2025

RELMADA THERAPEUTICS, INC.

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

Exhibit 99.1

Relmada THERAPEUTICS

CORPORATE OVERVIEW

Unlocking Life Changing Therapies

November 2025

Disclosures

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by us or on our behalf. This press release contains statements which constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Any statement that is not historical in nature is a forward-looking statement and may be identified by the use of words and phrases such as “if”, “may”, “expects”, “anticipates”, “believes”, “will”, “will likely result”, “will continue”, “plans to”, “potential”, “promising”, and similar expressions.

These statements are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including potential for Phase 2 NDV-01 data to continue to deliver positive results supporting further development, potential for clinical trials to deliver statistically and/or clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure of planned or ongoing preclinical and clinical studies to demonstrate expected results, potential failure to secure FDA agreement on the regulatory path for sepranolone, and NDV-01, or that future sepranolone, or NDV-01 clinical results will be acceptable to the FDA, failure to secure adequate sepranolone, or NDV-01 drug supply, and the other risk factors described under the heading “Risk Factors” set forth in the Company’s reports filed with the SEC from time to time.

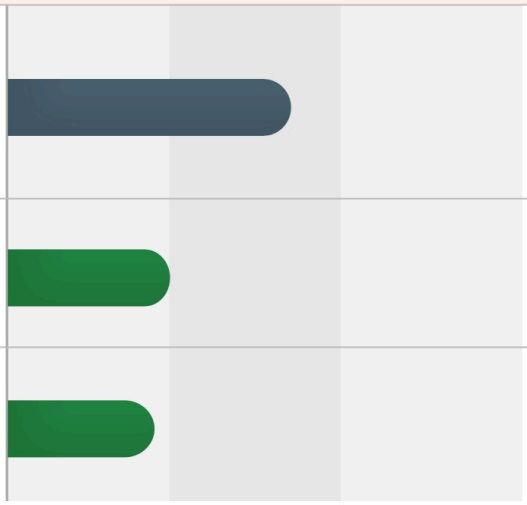
No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Relmada undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned that it is not possible to predict or identify all the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be a complete list.

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.

Innovative pipeline of potential high-value assets

Focused on programs with positive proof-of-concept data

Candidate / indication	Phase 1	Phase 2	Phase 3	Potential populations	Status / potential next steps
NDV-01[1] Non-muscle invasive bladder cancer (NMIBC)				NMIBC US prevalence: 600K patients[3] 68K new US patients with NMIBC[2, 5, 6]	Q1 2026: 12 Month data H2 2025: FDA interaction and product supply scale up H1 2026: Initiate Phase 3 study
Sepranolone Prader-Willi Syndrome (PWS)				WW prevalence: 350K to 400K patients[4]	Q4 2025: Prep for next studies, including manufacturing H1 2026: Initiate Phase 2b study
Sepranolone Other indications				Including TS, Essential Tremor, OCD and other compulsivity-related indications	YE 2025: Identify next opportunity



1. NDV-01: A sustained-release intravesical formulation of gemcitabine/docetaxel (Gem/Doce); **2.** Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); **3.** Markets, Research And. "Non-muscle Invasive Bladder Cancer (NMIBC) Epidemiology Forecasts to 2034." *GlobeNewswire News Room*, 25 Jan. 2024; **4.** Scheimann, Ann O. "Prader-Willi syndrome: Clinical features and diagnosis." *UpToDate*, edited by Mitchell E Geffner et al., 6 Feb. 2023. **5.** Shih, K., Chen, W., Chang, C., Tai, T., Wu, J., Huang, A. C., & Liu, M. (2021). Non-Muscular Invasive Bladder Cancer: Re-envisioning Therapeutic Journey from Traditional to Regenerative Interventions. *Aging and Disease*, *12*(3), 868. https://doi.org/10.14336/ad.2020.1109 **6.** Aldousari, S., & Kassouf, W. (2013). Update on the management of non-muscle invasive bladder cancer. *Canadian Urological Association Journal*, *4*(1), 56. https://pmc.ncbi.nlm.nih.gov/articles/PMC2812001/ **NMIBC:** Non muscle invasive bladder cancer; **WW:** Worldwide; **TS:** Tourette Syndrome; **OCD:** Obsessive-Compulsive Disorder

NDV-01

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

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

Our focus: non-muscle invasive bladder cancer (NMIBC)

High incidence[1]

4.2% of all new cancer cases in the US

High recurrence[2,3]

~30%-61% of high-risk patients recur within one year

High-risk population[4]

74% of patients >65 y/o
73 y/o median age

High cost

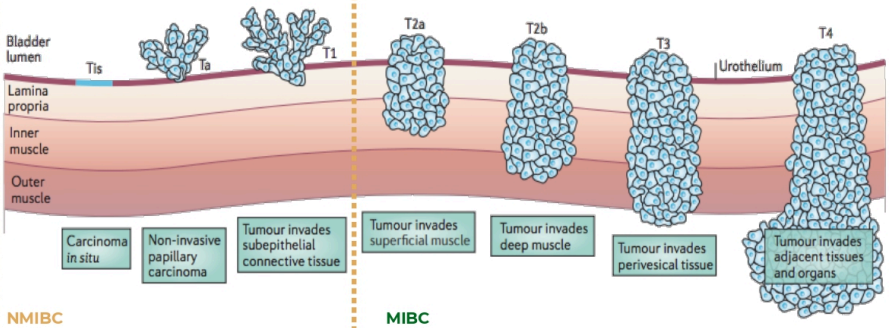
Complex treatment pathways
$6.5B total annual cost (U.S.)[6]

80%
of new cases [7,8]

Non-muscle invasive

20%
of new cases [7,8]

Muscle-invasive



NMIBC

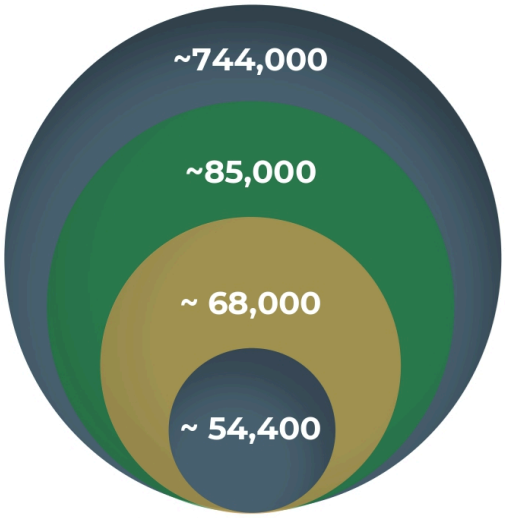
- Papillary tumors: non-invasive projections from the bladder surface
- Carcinoma in situ (CIS): flat, aggressive cancer that is often unresectable

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. SEER Cancer Stat Facts: Bladder Cancer. National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/statfacts/html/urinb.html ; **2.** Białek, Łukasz. "EORTC Bladder Cancer Recurrence and Progression Calculator." Omni Calculator, 1 Aug. 2024, www.omnicalculator.com/health/eortc-bladder-cancer; **3.** Ma J, Roumiguie M, Hayashi T, Kohada Y, Zlotta AR, Lévy S, Matsumoto T, Sano T, Black PC. Long-term Recurrence Rates of Low-risk Non-muscle-invasive Bladder Cancer-How Long Is Cystoscopic Surveillance Necessary? Eur Urol Focus. 2024 Jan;10(1):189-196. ; **4.** CG ONCOLOGY, INC. (2025, April 23). NMIBC | MIBC | Mechanism of Action of CG0070 | CG Oncology. CG Oncology |. https://cgoncology.com/science/#:~:text=4,patients%20with%20newly%20diagnosed%20disease.; **5.** NASS Database Documentation. (n.d.). https://www.hcup-us.ahrq.gov/db/nation/nass/nassdbdocumentation.jsp **6.** Clark O, Sarmento T, Eccleston A, Brinkmann J, Picoli R, Daliparthi V, Voss J, Chandrasekar S, Thompson A, Chang J. Economic Impact of Bladder Cancer in the USA. Pharmacoecon Open. 2024 Nov;8(6):837-845. **7.** Shih, K., Chen, W., Chang, C., Tai, T., Wu, J., Huang, A. C., & Liu, M. (2021). Non-Muscular Invasive Bladder Cancer: Re-envisioning Therapeutic Journey from Traditional to Regenerative Interventions. *Aging and Disease*, *12*(3), 868. https://doi.org/10.14336/ad.2020.1109; **8.** Aldousari, S., & Kassouf, W. (2013). Update on the management of non-muscle invasive bladder cancer. *Canadian Urological Association Journal*, 4(1), 56. https://pmc.ncbi.nlm.nih.gov/articles/PMC2812001/

NMIBC opportunity



US prevalence of Bladder Cancer[1]
(Overall Bladder Cancer)

New bladder cancer cases[2]
71-97% 5-year overall survival, 8% with advanced disease[3]

NMIBC cancer cases (80% of bladder cancers)[4, 6, 8, 9]
50-80% recurrence rate (over five years)[5]

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

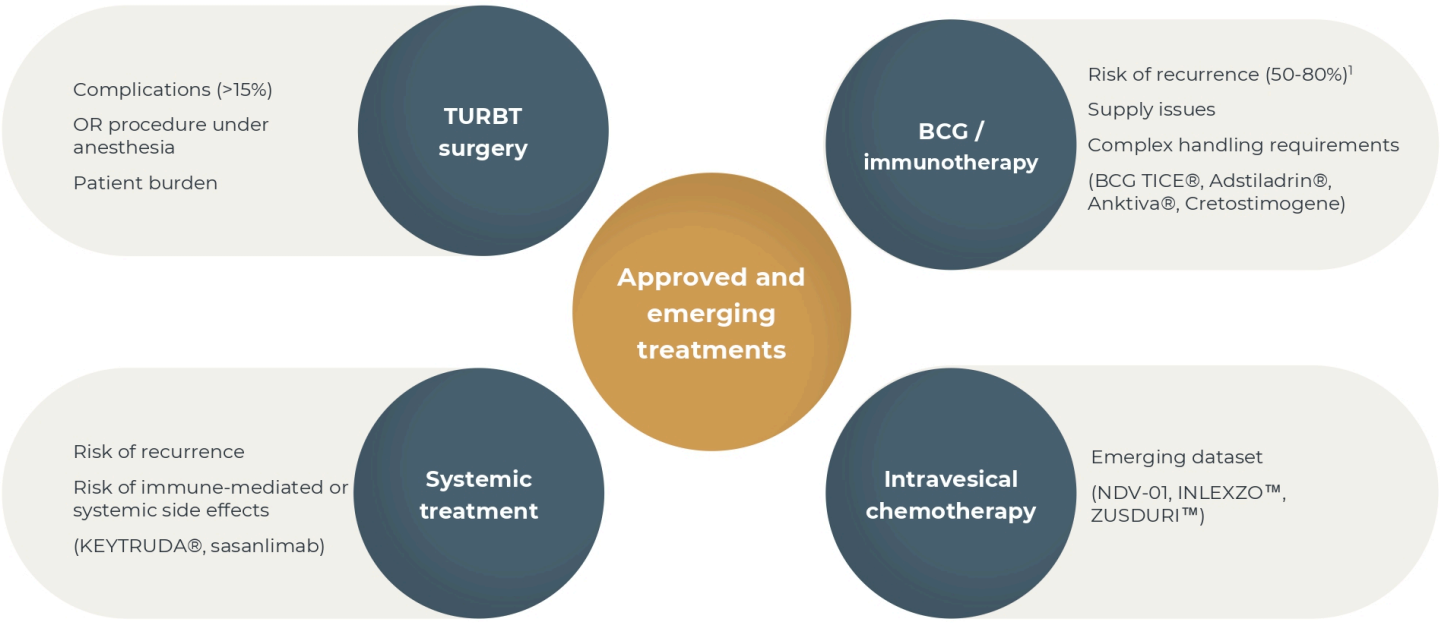
1. https://seer.cancer.gov/statfacts/html/urinb.html; **2.** The American Cancer Society medical and editorial content team. "Key Statistics for Bladder Cancer." American Cancer Society, www.cancer.org/cancer/types/bladder-cancer/about/key-statistics.html; **3.** National Cancer Institute "Bladder Cancer Prognosis and Survival Rates" (https://www.cancer.gov/types/bladder/survival#); **4.** Holzbeierlein et al. ("Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline: 2024 Amendment"); **5.** Białek, Łukasz. "EORTC Bladder Cancer Recurrence and Progression Calculator." Omni Calculator, 1 Aug. 2024, www.omnicalculator.com/health/eortc-bladder-cancer; **6.** Seo, Munseok, and James R. Langabeer II. "Demographic and Survivorship Disparities in Non–muscle-invasive Bladder Cancer in the United States." Journal of Preventive Medicine and Public Health, vol. 51, no. 5, Aug. 2018, pp. 242–47; **7.** Nielsen, Matthew E., et al. "Trends in Stage-specific Incidence Rates for Urothelial Carcinoma of the Bladder in the United States: 1988 to 2006." *Cancer*, vol. 120, no. 1, Oct. 2013, pp. 86–95, doi:10.1002/cncr.28397. **8.** Shih, K., Chen, W., Chang, C., Tai, T., Wu, J., Huang, A. C., & Liu, M. (2021). Non-Muscular Invasive Bladder Cancer: Re-envisioning Therapeutic Journey from Traditional to Regenerative Interventions. *Aging and Disease*, *12*(3) **9.** Aldousari, S., & Kassouf, W. (2013). Update on the management of non-muscle invasive bladder cancer. *Canadian Urological Association Journal*, *4*(1), 56. https://pmc.ncbi.nlm.nih.gov/articles/PMC2812001/ **NMIBC:** Non-Muscle Invasive Bladder; **BCG:** Bacillus Calmette-Guérin

Current NMIBC patient care journey

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

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

Overview of NMIBC treatment landscape



Relmada internal market research, 2025; **1.** Białek, Ł.. (2024, August 1). *EORTC Bladder Cancer Recurrence and Progression Calculator*. Omni Calculator. https://www.omnicalculator.com/health/eortc-bladder-cancer;. **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]: ~ 1 recurrence / year[1]

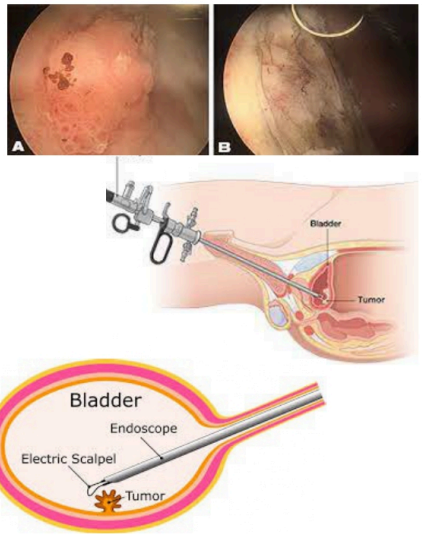
- 5-year risk of initial recurrence: 54.4%. After initial recurrence 60.1% of patients had a second recurrence by 2 years
- After 2nd recurrence, 51.5% of patients had a 3rd recurrence by 3 years[1]

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

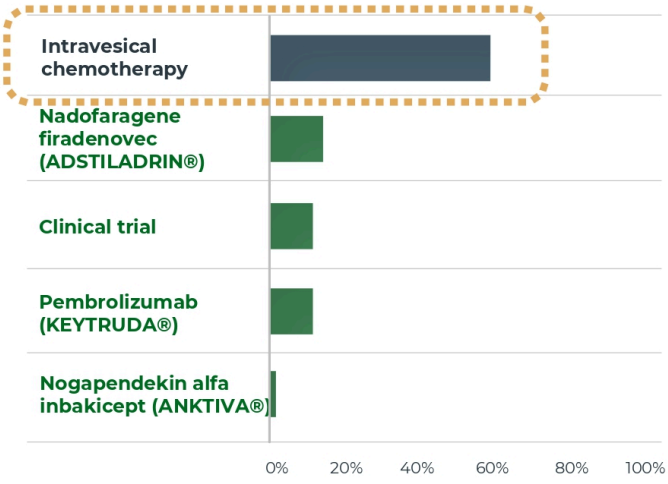
- Complication rate < 15%[2]
- Grade 3/4 complication rate = 9.4%[3]
- Readmission rate = 5%[4]
- Procedural Cost = $7,000-$10,000[5, 7]
- Worsening mental health, physical health and lower urinary tract symptom scores[6]



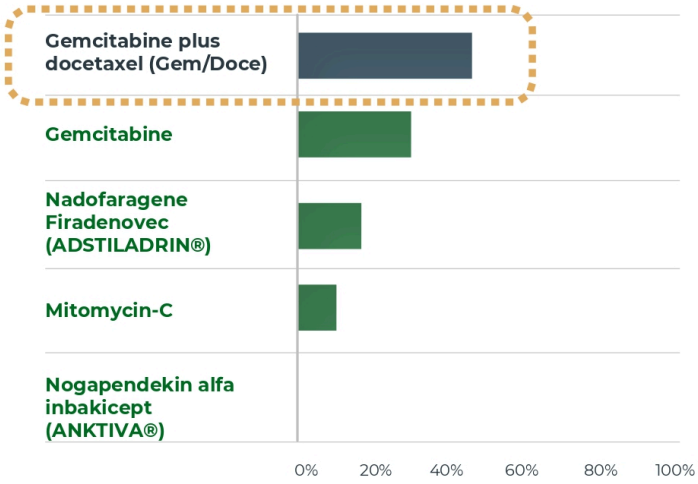
1. Sharma, V., Chamie, K., Schoenberg, M., Lee, V. S., Fero, K., Lec, P., Munneke, J. R., Aaronson, D. S., Kushi, L. H., Quesenberry, C. P., Tang, L., & Kwan, M. L. (2022). Natural history of multiple recurrences in Intermediate-Risk Non-Muscle Invasive Bladder Cancer: Lessons from a prospective cohort. Urology, 173, 134–141. https://doi.org/10.1016/j.urology.2022.12.009 ; **2 .** Pycha A, Lodde M, Lusuardi L, Palermo S, Signorello D, Galantini A, Mian C, Hohenfellner R. Teaching transurethral resection of the bladder: still a challenge? Urology. 2003 Jul;62(1):46-8; **3.** Bansal, A., Sankhwar, S., Goel, A., Kumar, M., Purkait, B., & Aeron, R. (2016). Grading of complications of transurethral resection of bladder tumor using Clavien–Dindo classification system. Indian Journal of Urology, 32(3),232 https://doi.org/10.4103/0970-1591.185104 ; **4.** Jindal, T., Sarwal, A., Jain, P., Koju, R., & Mukherjee, S. (2022). A retrospective analysis of the factors associated with increased risk of readmission within 30 days after primary transurethral resection of bladder tumor. Current Urology, 17(4), 257–261. https://doi.org/10.1097/cu9.0000000000000160 ; **5.** MediGence. (n.d.). Trans Urethral Resection of Bladder Tumor (TURBT) cost worldwide – Compare prices. https://medigence.com/hospitals/urology/trans-urethral-resection-of-bladder-tumor and hospitals/urology/trans-urethral-resection-of-bladder-tumor **6.** Lee LJ, et al. . Humanistic and Economic Burden of Non-Muscle Invasive Bladder Cancer: Results of Two Systematic Literature Reviews. Clinicoecon Outcomes Res. 2020 Nov 23;12:693-709. **7.** Kokkotos, F., Buser, H., An, A., & Ferrara, K. (2022b). Regional trends in the cost of transurethral bladder tumor resection in the outpatient and physician office setting. *Journal of Clinical Oncology*, *40*(6_suppl), 465. https://doi.org/10.1200/jco.2022.40.6_suppl.465

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

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



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



1. Derived from Urology Times: Survey on Treatment Patterns and Preferences in Non–Muscle Invasive Bladder Cancer, June 2025, based on responses from 42 practicing physicians (Saylor, Benjamin P. "Survey: New NMIBC Treatments Face Slow Uptake." *Urology Times*, 17 July 2025, www.urologytimes.com/view/survey-new-nmibc-treatments-face-slow-uptake.), https://indd.adobe.com/view/33cf0914-c989-4e8f-b891-830b0870f177 ; *Publish online*. (n.d.). https://indd.adobe.com/view/33cf0914-c989-4e8f-b891-830b0870f177

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

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

1. Steinberg RL, Thomas LJ, Brooks N, et al. Multi-Institution Evaluation of Sequential Gemcitabine/Docetaxel as Rescue Therapy for NMIBC. J Urol. 2020; **2.** Garneau CA, Marcotte N, Lacombe L, et al. Salvage therapy for BCG failure with intravesical sequential Gem/Doce in patients with recurrent NMIBC. Can Urol Assoc J J Assoc Urol Can. 2024; **3.** Yim K, Melnick K, Mott SL, et al. Sequential intravesical gemcitabine/docetaxel provides a durable remission in recurrent high-risk NMIBC following BCG therapy. Urol Oncol. 2023; **4.** McElree IM, Steinberg RL, Martin AC, et al. Sequential Intravesical gemcitabine/docetaxel for BCG-Naive High-Risk NMIBC. J Urol. 2022; **5.** McElree IM, Orzel J, Stubbee R, et al. Sequential intravesical gemcitabine/docetaxel for treatment-naïve and previously treated intermediate-risk NMIBC. Urol Oncol. 2023; **6.** Tan WS, McElree IM, Davaro F, et al. Sequential Intravesical Gemcitabine/Docetaxel is an Alternative to BCG for the Treatment of Intermediate-risk NMIBC. Eur Urol Oncol. 2023; **7.** Chevuru PT, McElree IM, Mott SL, Steinberg RL, O'Donnell MA, Packiam VT. Long-term follow-up of sequential intravesical gemcitabine and docetaxel salvage therapy for NMIBC. Urol Oncol. 2023; **8.** Narayan VM, Boorjian SA, Alemozaffar M, et al. Efficacy of Intravesical Nadofaragene Firadenovec for Patients With BCG-Unresponsive NMIBC: 5-Year Follow-Up From a Phase 3 Trial. J Urol. 2024. **9**. Steinberg, et. Al (2019). Multi-Institution evaluation of sequential gemcitabine and Docetaxel as rescue therapy for nonmuscle invasive bladder cancer. *The Journal of Urology*, *203*(5), 902–909. https://doi.org/10.1097/ju.0000000000000688 **RFS:** Relapse Free Survival; **BCG:** Bacillus Calmette-Guérin; **NMIBC:** Non-muscle-Invasive Bladder Cancer; **Gem/Doce**: Gemcitabine plus Docetaxel

Conventional Gem/Doce intravesical therapy for NMIBC

4-hour total procedure time

~ 5 minutes for NDV-01

Requires specialized pharmacy preparation

NDV-01 comes ready for use in pre-filled plastic syringes

Complication rates for Conventional Intravesical Therapy

BCG[1,2,6,8,9]

cystitis, urinary frequency < 1/hr (24%-82%), hematuria (23-74%), dysuria (50-70%), bladder contracture, bladder ulcerations, systemic infection

~7–20% of patients are forced to discontinue BCG therapy due to the severity of their lower urinary tract symptoms (LUTS)

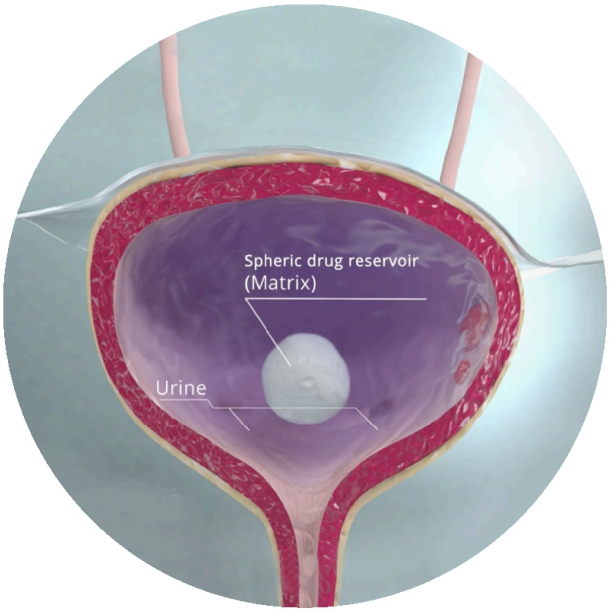
MMC/Gemcitabine[3,4,5,10]

Hematuria (24%), urinary frequency (22%), chemical cystitis (7%)

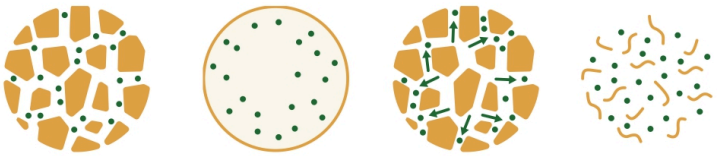
1U.S. Food and Drug Administration & Center For Biologics Evaluation And Research. (2018, February 21). TICE BCG. U.S. Food And Drug Administration. https://www.fda.gov/vaccines-blood-biologics/vaccines/tice-bcg ; **2.** Liu, Y., Lu, J., Huang, Y., & Ma, L. (2019). Clinical spectrum of complications induced by intravesical immunotherapy of bacillus Calmette-Guérin for bladder cancer. Journal of Oncology, 2019, 1–11. https://doi.org/10.1155/2019/6230409 ; **3.** UroGen Pharma. (2025). HIGHLIGHTS OF PRESCRIBING INFORMATION [Press release]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215793s000lbl.pdf ; **4.** Janssen Biotech, Inc. (2025). HIGHLIGHTS OF PRESCRIBING INFORMATION [Press release]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219683s000lbl.pdf ; **5.** Li, R., Li, Y., Song, J., Gao, K., Chen, K., Yang, X., Ding, Y., Ma, X., Wang, Y., Li, W., Wang, Y., Wang, Z., & Dong, Z. (n.d.). Intravesical gemcitabine versus mitomycin for non-muscle invasive bladder cancer: A systematic review and meta-analysis of randomized controlled trial. BMC Urology. https://doi.org/10.1186/s12894-020-00610-9 ; **6.** Bourlotos, G., Baigent, W., Hong, M., Plagakis, S., & Grundy, L. (2024). BCG induced lower urinary tract symptoms during treatment for NMIBC—Mechanisms and management strategies. Frontiers in Neuroscience, 17. https://doi.org/10.3389/fnins.2023.1327053 ; **7.** Koya MP, Simon MA, Soloway MS. Complications of intravesical therapy for urothelial cancer of the bladder. J Urol. 2006 Jun;175(6):2004-10. **8.** Brausi M, Oddens J, Sylvester R, Bono A, van de Beek C, van Andel G, Gontero P, Turkeri L, Marreaud S, Collette S, Oosterlinck W. Side effects of Bacillus Calmette-Guérin (BCG) in the treatment of intermediate- and high-risk Ta, T1 papillary carcinoma of the bladder: results of the EORTC genito-urinary cancers group randomised phase 3 study comparing one-third dose with full dose and 1 year with 3 years of maintenance BCG. Eur Urol. 2014 Jan;65(1):69-76 **9.** Oosterlinck, W., & Decaestecker, K. (2015). Managing the adverse events of intravesical bacillus Calmette–Guérin therapy. *Research and Reports in Urology*, 157. https://doi.org/10.2147/rru.s63448 **10.** Laurent, A. (2025, October 28). *ZUSDURI: Mitomycin hydrogel for bladder chemoablation*. IntuitionLabs. https://intuitionlabs.ai/articles/zusduri-mitomycin-bladder-cancer-treatment

NMIBC: Non-Muscle Invasive Bladder; **BCG:** Bacillus Calmette Guérin; **LUTS:** Lower Urinary Tract Symptoms; **MMC:** Mitomycin-C; **HRQoL:** Health-Related Quality of Life; **Gem/Doce**: Gemcitabine plus Docetaxel

Targeted intravesical therapy



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



Diffusion through pores

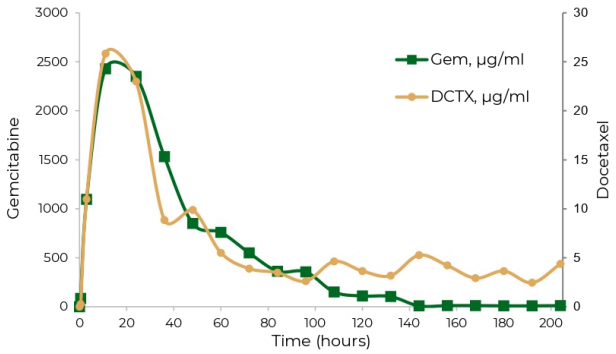
Diffusion through the polymer

Osmotic pumping

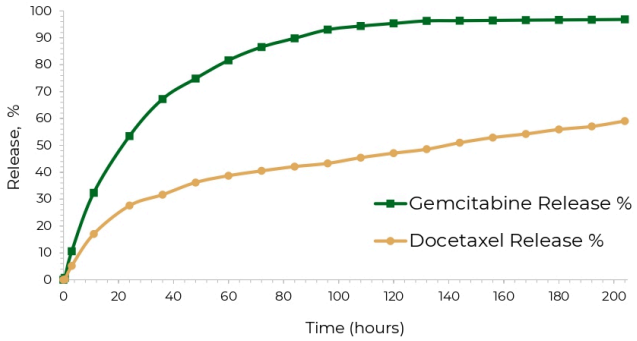
Erosion

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

NDV-01 Gem/Doce concentration over time



NDV-01 cumulative release profile



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

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

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

NDV-01 Competitive advantages

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

Ready for use

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

Sustained release

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

Convenience

Patient is treated **in doctors' office**

Based on an existing effective treatment

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

Safely excreted

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

Relmada internal market research 2025. **NMIBC:** Non-muscle-Invasive Bladder Cancer; **Gem/Doce**: Gemcitabine plus Docetaxel

Study TRCG-011 high-risk NMIBC patients

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

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

ONGOING TRCG-011 STUDY

Study design

Inclusion criteria

- High-risk disease with CIS/Tis, Ta, T 1 tumors[1, 2]
- BCG-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
- CRR at 12 months

Secondary endpoint

- DOR
- EFS

Exploratory

- PK

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

ONGOING TRCG-011 STUDY

Demographic data

Characteristics	N=36	%
Age		
Median (range)	75 (54-93) yr	
Sex		
Male	30	83%
Female	6	17%
BCG doses		
Median BCG doses (range)	6 (0-21)	
BCG-status		
BCG-naive	15	42%
BCG-exposed	4	11%
BCG-unresponsive	17	47%
Stage		
CIS	3	8%
CIS + Ta/T1	7	19%
Ta HG	21	58%
T1 HG	6	17%

ONGOING TRCG-011 STUDY

Efficacy and tolerability

Complete response	n/N	%
Anytime	23/25	92%
3-month	21/25	84%
6-month	20/23	87%*
9-month	17/20	85%*

- No patient had progression to muscle invasive disease
- No patient underwent a radical cystectomy
- Two subjects have reached 12-month assessment, and both have a CR
- 11 patients awaiting 3-month response assessment

*Includes patients with CR after re-induction. 60% CR rate after re-induction; CR = Complete Response

ONGOING TRCG-011 STUDY

Efficacy in BCG-UR Subpopulation

Complete response	n/N	%
Anytime	10/11	91%
3-month	9/11	82%
6-month	7/9	78%
9-month	7/8	88%

- n = 18 patients dosed in BCG-UR subpopulation
- BCG-UR defined by FDA definition[1]

BCG-UR, Bacillus Calmette-Guérin (BCG) - Unresponsive
[1]https://www.fda.gov/media/101468/download.

Durable response over time

92%	84%	87%	85%	Pending completion
Anytime CR rate	*3-month* CR rate	*6-month* CR rate	*9-month* CR rate	

CR: Complete response; BCG-UR, Bacillus Calmette-Guérin (BCG) – Unresponsive; BCG-UR, BCG, Bacillus Calmette-Guérin

ONGOING TRCG-011 STUDY

Treatment-related AE and tolerability

- **No patient had >= Grade 3 TRAE**
- **Of the 36 patients who received >= 1 dose of NDV-01, 22 (61%) had a TRAE**
  - 62% transient uncomfortable urination (dysuria)
  - 9% asymptomatic positive urine culture
  - 7% hematuria
- **No patients discontinued treatment due to AEs**

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

Product / product profile	NDV-01	INLEXZO™[2]	ZUSDURI™[1]
Sponsor	Relmada	Johnson & Johnson	UroGen
Active Agent	Gemcitabine/docetaxel (Gem/Doce)	Gemcitabine	Mitomycin C
NMIBC subtype	High-risk or intermediate-risk	High Risk	Low grade, intermediate risk
Phase	Phase 2	FDA approved	FDA approved
Dosing Format	Sustained-release hydrogel	Indwelling silicone delivery system	Reverse-thermal hydrogel
Presentation	Pre-filled syringe ready for intravesical delivery	Catheter-based insertion; cystoscopic removal	In-office dosing kit requires in-office reconstitution under chilled conditions
Requires device removal?	No	Yes, via cystoscope[1]	No
Yearly costs	NA	$690,000[3]	$120,000[4]

1. UroGen Pharma. (2025). HIGHLIGHTS OF PRESCRIBING INFORMATION [Press release]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215793s000lbl.pdf ; **2.** Janssen Biotech, Inc. (2025). HIGHLIGHTS OF PRESCRIBING INFORMATION [Press release]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219683s000lbl.pdf ; **3.** *CG Oncology Stock maintains buy rating at H.C. Wainwright amid Inlexzo pricing insights.* (2025, October 28). Investing.com. https://www.investing.com/news/analyst-ratings/cg-oncology-stock-maintains-buy-rating-at-hc-wainwright-amid-inlexzo-pricing-insights-93CH-4238680 **4.** Mehan, R., MD, & Liu, N., MD. (2025, July 2). RX Review: Implementing mitomycin for LG-IR-NMIBC in clinical practice. *Urology Times – News &Amp; Insights for Urologists &Amp; Health Professionals.* https://www.urologytimes.com/view/rx-review-implementing-mitomycin-for-lg-ir-nmibc-in-clinical-practice; **NMIBC:** Non-muscle-Invasive Bladder Cancer

FDA Feedback

“Regarding the proposed trial in BCG-unresponsive setting, …The FDA stated that a single arm trial might be acceptable in a more refractory patient population, although details of such a design should be discussed with the FDA.”

“The FDA agreed that a proposal to randomize patients post-TURBT to adjuvant NDV-01 vs observation, evaluating a time-to-event endpoint, is generally acceptable, however, specifics of the intended trial design, including the endpoint definition, should be submitted to the FDA in a meeting package for full review and discussion. ”

“We agree with your proposal to rely on the FDA’s finding of safety, as described in the label of the US-approved listed drugs, Gemzar and Taxotere, and published literature for nonclinical safety assessment of NDV-01. ”

BCG, Bacillus Calmette-Guérin (BCG); TURB-T, Transurethral Resection of Bladder Tumor

Regulatory and Clinical Strategy

- **Single-arm trial in BCG-unresponsive NMIBC with CIS who are refractory to other therapies**
  - Request type B meeting
  - Protocol in development
- **RCT in IR NMIBC – adjuvant therapy after TURBT (NDV-01 vs observation)**
  - Type B meeting requested
  - Protocol is in development to finalize for FDA Briefing Book submission

BCG, Bacillus Calmette-Guérin (BCG); TURB-T, Transurethral Resection of Bladder Tumor; RCT, randomized controlled trial; CIS, carcinoma in situ

Proposed Pivotal Trial in 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

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

Purpose

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

Primary endpoint

- CR at 12 months
- Safety

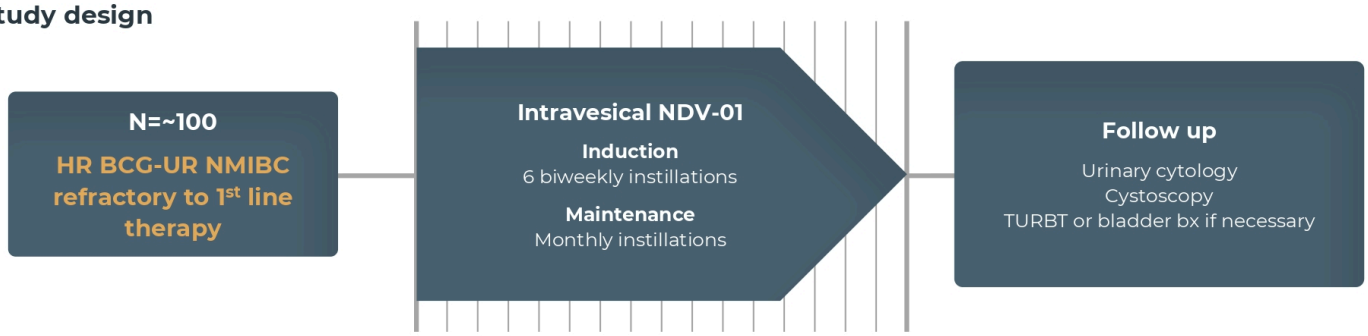
Secondary endpoint

- DOR
- PFS
- RFS amongst responders

Other

- PK

Study design



CR: Complete Response; **DOR:** Duration of Response; **RFS: Recurrence** Free Survival; **PFS:** Progression Free Survival.

Proposed Pivotal Trial in IR NMIBC

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

Inclusion criteria

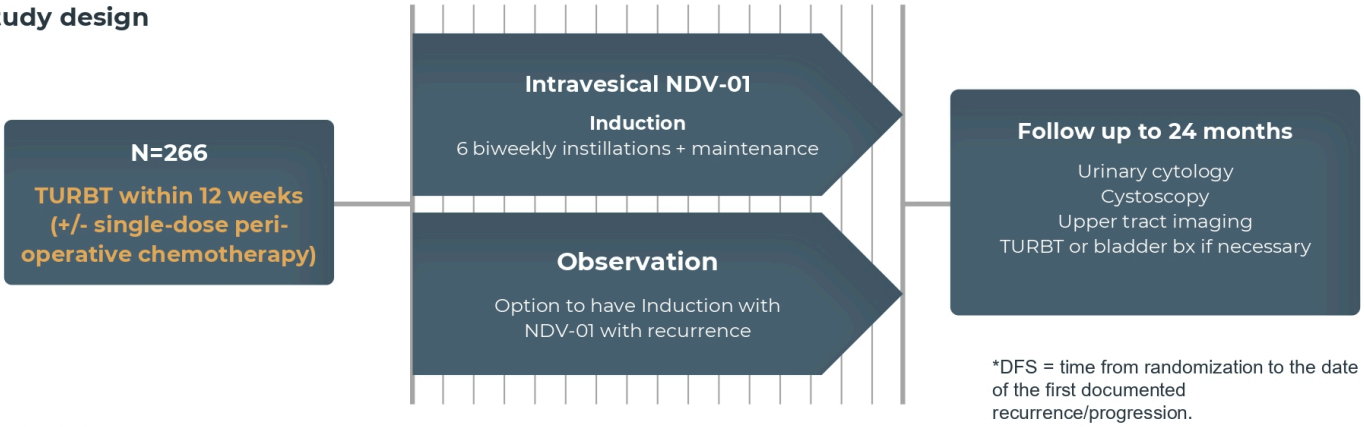
- IR NMIBC

Primary endpoint

- DFS*
- Safety

N=~266

Study design



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

DFS: Disease Free Survival.

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

Q4 2025

FDA engagement
Including planned FDA interactions and manufacturing

Q1 2026

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

H1 2026

Initiate Phase 3 (Registrational) studies
Target population to be confirmed through FDA discussions

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 (γ-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 et al., Neuropsychiatr Dis Treat 2015; Möhler, Neuropharmacology 2012; Belelli & Lambert, Nat Rev Neurosci 2005; Majewska et al., Science 1986; Girdler et al., Biol Psychiatry 2001; Martinez et al., NPP 2016; Bixo et al., Psychoneuroendocrinology 2018; Poromaa et al., Front Neuroendocrinol 2020; **2.** Möhler, H. (2012). The GABA system in anxiety and depression and its therapeutic potential. Neuropharmacology, 62(1), 42–53. https://doi.org/10.1016/j.neuropharm.2011.08.040; **3.** Belelli, D., & Lambert, J.J. (2005). Neurosteroids: Endogenous regulators of the GABAA receptor. Nature Reviews Neuroscience, 6(7), 565–575. https://www.nature.com/articles/nrn1703; **4.** Majewska, M.D. et al. (1986). Steroid hormone metabolites are barbiturate-like modulators of the GABA receptor.Science, 232(4753), 1004–1007. https://doi.org/10.1126/science.2422758. **5.** Girdler, S.S. et al. (2001). Allopregnanolone levels and reactivity to stress in premenstrual dysphoric disorder.Biological Psychiatry, 49(9), 788–797. https://www.biologicalpsychiatryjournal.com/article/S0006-3223(00)01044-1/abstract; **6.** Bixo M, Stiernman L, Bäckström T. Neurosteroids and premenstrual dysphoric disorder. Br J Psychiatry. 2025 Jun 16:1-9 https://www.cambridge.org/core/journals/the-british-journal-of-psychiatry/article/neurosteroids-and-premenstrual-dysphoric-disorder/9F749CEEE76E6DEDD72CF39980CCF77B; **7.** Bixo M. et al., Treatment of premenstrual dysphoric disorder with the GABAA receptor modulating steroid antagonist Sepranolone (UC1010)-A randomized controlled trial. Psychoneuroendocrinology. 2017 Jun;80:46-55. doi: 10.1016/j.psyneuen.2017.02.031. Epub 2017 Mar 1.; https://www.sciencedirect.com/science/article/pii/S0306453016309180?via%3Dihub **8.** Bäckström T, Ekberg K, Hirschberg AL, Bixo M, Epperson CN, Briggs P, Panay N, O'Brien S. A randomized, double-blind study on efficacy and safety of sepranolone in premenstrual dysphoric disorder. Psychoneuroendocrinology. 2021 Nov;133:105426. https://www.sciencedirect.com/science/article/pii/S0306453021003000?via%3Dihub.;

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

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

Q4 2025

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

H1 2026

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

PWS: Prader-Willi syndrome

Corporate summary

Financial overview

$13.9^ million

Cash, cash equivalents & short-term investments

~33.2^ million

Common shares outstanding
(~48.2 million as converted)*

Unlevered balance sheet

No outstanding debt

^ Expected as of September 30, 2025. We have not completed our quarter-end financial close process and this amount is preliminary, has not been audited and is subject to change upon completion of our financial statement closing procedures, and any changes could be material. Additional information and disclosures would be required for a more complete understanding of our financial position as of September 30, 2025, which are not available as of the date hereof.
^ As of September 30, 2025.
*Includes 14.2 million outstanding options and ~0.8 million warrants.

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

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

PWS: Prader-Willi syndrome

Thank you!

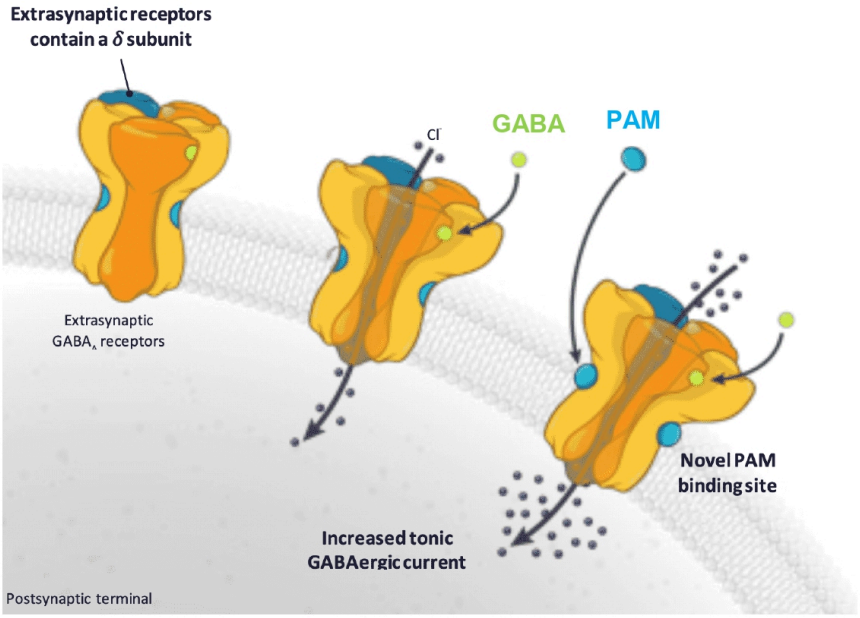
Appendix

NDV-01- Study TRCG-011 - Adverse Events

AE	n (%)	Grade
Dysuria	22 (61%)	1
Positive urine culture	3 (9%)	1
Hematuria	3 (7%)	1/2
Abdominal Pain	2 (6%)	1
Urgency	1 (3%)	1
Frequency	1 (3%)	1
UTI	1 (3%)	1
Cough	1 (3%)	1

AE, adverse event.

Sepranolone has the potential to normalize $GABA_A$ receptor activity



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

Exhibit 99.2

Relmada Announces FDA Feedback Supporting 2 Separate Acceptable Registrational Study Paths for NDV-01 in Non-muscle Invasive Bladder Cancer

Announces NDV-01 9-Month Follow-up Safety and Efficacy Data in NMIBC

FDA feedback supports 2 potential registrational trials – 1) a registrational trial in 2nd line refractory BCG-unresponsive NMIBC, and 2) a randomized controlled trial in intermediate-risk NMIBC.

FDA Feedback also confirms no additional non-clinical studies are required.

9-month follow-up for NDV-01 showed a 92% overall response rate at any time in non-muscle invasive bladder cancer, with good overall safety

CORAL GABLES, FL – November 4, 2025 (GlobeNewswire) – Relmada Therapeutics, Inc. (Nasdaq: RLMD, "Relmada" or the "Company"), a clinical-stage biotechnology company advancing innovative therapies for oncology and central nervous system indications, today announced the receipt of written minutes from a Type B pre-IND meeting with the U.S. Food and Drug Administration (FDA) regarding the planned Phase 3 program for NDV-01 in non-muscle invasive bladder cancer (NMIBC) patients. The Company will be requesting follow-up meetings with FDA to discuss each development path. Relmada secured FDA alignment on certain key elements of the planned Phase 3 pivotal program for NDV-01, expected to begin in H1 2026 and incorporating two independent studies for approval in two separate indications:

- High-grade, 2nd line BCG-unresponsive NMIBC patients
- Intermediate risk NMIBC in the adjuvant setting

Key Outcomes from the FDA Type B pre-IND meeting (specific study design details to be further discussed with the agency):

- **In high-grade, 2nd line BCG-unresponsive setting, the FDA stated that a single arm trial might be acceptable in a more refractory patient population.**
- **In the intermediate risk NMIBC setting, the FDA agreed that a proposal to randomize patients post-TURBT to adjuvant NDV-01 vs observation, evaluating a time-to-event endpoint, is generally acceptable**.
- **Further non-clinical studies are not required**. FDA indicated that no further non-clinical studies are required to support a 505(b)(2) New Drug Application (NDA).

"The positive outcome of our Type B meeting and alignment with the FDA on the Phase 3 pivotal program mark a key milestone for Relmada and NDV-01," said **Raj Pruthi, MD, Chief Medical Officer – Urology**, Relmada Therapeutics. "We believe the FDA's guidance provides a path to advance NDV-01 for patients with NMIBC who currently have limited options. We believe a single-arm registrational study in high-grade, refractory BCG-unresponsive patients offers a rapid route to potential approval, while alignment on a separate second pivotal study in intermediate-risk NMIBC could enable an additional indication and broader clinical adoption."

Sergio Traversa, Chief Executive Officer of Relmada Therapeutics, stated: "We added NDV-01 to our portfolio based on its strong potential to transform the treatment of NMIBC. The outcome of our Type B meeting with the FDA further reinforces our confidence in the path forward and in NDV-01's potential to become a best-in-class, durable, ready and easy-to-use, in-office, bladder-sparing therapy. We look forward to initiating the Phase 3 programs in the first half of 2026."

Also, Relmada announced 9-month follow-up data from the Phase 2 study of NDV-01 in non-muscle invasive bladder cancer.

Highlights of the 9-month follow-up data and updated 3-month and 6-month data from the Phase 2 study of NDV-01:

Clinical Results (Response Data)	
Complete Response	% (n/N)
Anytime	92% (23/25)
3 months	84% (21/25)
6 months	87% (20/23)*
9 months	85% (17/20)*

* Includes patients with CR after re-induction. 60% CR rate after re-induction.

- Two subjects have reached 12-month assessment, and both have a CR
- No patient had progression to muscle invasive disease
- No patient underwent a radical cystectomy
- No new safety signals in terms of type, number, or degree of AEs -- with no patients having a >= Grade 3 TRAE and no patients discontinued treatment due to AEs
- 36 enrolled patients (receiving >= 1 dose), of which 22 (61%) experienced a treatment-related AE. Among treatment-related AEs, 62% were transient uncomfortable urination (dysuria), 9% were asymptomatic positive urine culture and 7% were hematuria.

Efficacy in BCG-Unresponsive Subpopulation:**

Clinical Results (Response Data)	
Complete Response	% (n/N)
Anytime	91% (10/11)
3 months	82% (9/11)
6 months	78% (7/9)
9 months	88% (7/8)

- n = 18 patients dosed in BCG-UR subpopulation
- BCG-UR defined by FDA definition**

BCG-UR, Bacillus Calmette-Guérin (BCG) – Unresponsive

** https://www.fda.gov/media/101468/download.

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 tumor exposure. NDV-01 is ready to use, convenient to administer in-office in less than 10 minutes, and does not require preparation, anesthesia or specialized equipment.

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. NDV-01 has the potential to serve as a frontline or salvage therapy and could be applicable across multiple NMIBC subtypes.

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, 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 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 sepranolone, or that future NDV-01, or sepranolone, clinical results will be acceptable to the FDA, failure to secure adequate NDV-01, or sepranolone, drug supply, and the other risk factors described under the heading "Risk Factors" set forth in the Company's reports filed with the SEC from time to time. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Relmada undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned that it is not possible to predict or identify all the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be a complete list.

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