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): January 13, 2025

Protara Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-36694	20-4580525
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

345 Park Avenue South Third Floor New York, NY	10010
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (646) 844-0337

N/A
(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:

☐ 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(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	TARA	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 January 13, 2025, Protara Therapeutics, Inc. (the "Company") posted an updated corporate presentation (the "Presentation") to the "Investors—Events and Presentations" section of the Company's website at www.protaratx.com. A copy of the Presentation is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

On January 13, 2025, the Company also released a press release highlighting recent updates and anticipated 2025 milestones for the Company. A copy of the press release is furnished herewith 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, including Exhibit 99.1 and Exhibit 99.2 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be 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 filing.

Item 8.01 Other Events.

As previously disclosed, on December 11, 2024, the Company completed a public offering of an aggregate of 13,690,000 shares of common stock of the Company, par value $0.001 per share (the "Common Stock") and, for certain purchasers, pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 2,325,372 shares of Common Stock (the "Offering"). The price to the public in the Offering was $6.25 per share of Common Stock and $6.249 per Pre-Funded Warrant, which was the price per share at which the shares of Common Stock were sold to the public in the Offering, minus the $0.001 exercise price per Pre-Funded Warrant. In connection with the Offering, the Company also granted the underwriters the option, for 30 days, to purchase up to an additional 2,402,305 shares of Common Stock at the public offering price, less underwriting discounts and commissions (the "Underwriters' Option").

On January 8, 2025, the underwriters notified the Company of their determination to exercise the Underwriters' Option in part, purchasing an additional 438,738 shares of Common Stock, at the public offering price less underwriting discounts and commissions. Closing for the partial exercise of the Underwriters' Option occurred on January 13, 2025.

The Offering was made pursuant to an effective registration statement on Form S-3 (File No. 333-275290) (the "Registration Statement") previously filed with the Securities and Exchange Commission on November 3, 2023, and declared effective on November 14, 2023, and related prospectus supplement dated December 9, 2024.

The aggregate gross proceeds to the Company from the Offering, including the partial exercise of the Underwriters' Option, are expected to be approximately $102.7 million, before deducting fees to the underwriters and other estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the Offering to fund the clinical development of TARA-002, as well as the development of other clinical programs. The Company may also use the net proceeds from the Offering for working capital and other general corporate purposes.

A copy of the opinion of Sullivan & Cromwell LLP, counsel to the Company, is filed herewith as Exhibit 5.1 to this Current Report on Form 8-K. Exhibits 5.1 and 23.1 (included in Exhibit 5.1) of this Current Report on Form 8-K are hereby incorporated by reference into the Registration Statement.

Forward-Looking Statements

Statements contained in this Form 8-K regarding matters that are not historical facts are "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "designed," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words or expressions referencing future events, conditions or circumstances that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such forward-looking statements include but are not limited to, statements regarding the Company's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the expected use of proceeds from the offering. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that contribute to the uncertain nature of the forward-looking statements include the risks and uncertainties associated with the Company's business and financial condition in general, including the risks and uncertainties described more fully under the caption "Risk Factors" and elsewhere in the Company's filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. The Company undertakes no obligation to update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
5.1	Opinion of Sullivan & Cromwell LLP.
23.1	Consent of Sullivan & Cromwell LLP (included in Exhibit 5.1).
99.1	Corporate Presentation, dated January 13, 2025.
99.2	Press Release, dated January 13, 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.

Date: January 13, 2025

Protara Therapeutics, Inc.

By: /s/ Patrick Fabbio
Patrick Fabbio
Chief Financial Officer

Exhibit 5.1

[Letterhead of Sullivan & Cromwell LLP]

January 13, 2025

Protara Therapeutics, Inc.,
345 Park Avenue South, Third Floor,
New York, New York 10010.

Ladies and Gentlemen:

In connection with the registration under the Securities Act of 1933 (the "Act") of 438,738 shares (the "Securities") of common stock, par value $0.001 per share, of Protara Therapeutics, Inc., a Delaware corporation (the "Company"), we, as your counsel, have examined such corporate records, certificates and other documents, and such questions of law, as we have considered necessary or appropriate for the purposes of this opinion. Upon the basis of such examination, it is our opinion that the Securities have been validly issued and are fully paid and nonassessable.

In rendering the foregoing opinion, we are not passing upon, and assume no responsibility for, any disclosure in any registration statement or any related prospectus or other offering material relating to the offer and sale of the Securities.

The foregoing opinion is limited to the Federal laws of the United States and the General Corporation Law of the State of Delaware, and we are expressing no opinion as to the effect of the laws of any other jurisdiction.

We have relied as to certain factual matters on information obtained from public officials, officers of the Company and other sources believed by us to be responsible.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the reference to us under the heading "Validity of Securities" in the Prospectus Supplement relating to the Securities, dated December 9, 2024. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act.

Very truly yours,

/s/ SULLIVAN & CROMWELL LLP

Exhibit 99.1

PROTARA THERAPEUTICS

CORPORATE PRESENTATION

January 2025

FORWARD LOOKING STATEMENTS

Statements contained in this presentation regarding matters that are not historical facts are "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Protara may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “designed,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words or expressions referencing future events, conditions or circumstances that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such forward-looking statements include but are not limited to, statements regarding Protara’s intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: Protara’s business strategy, including its development plans for its product candidates and plans regarding the timing or outcome of existing or future clinical trials (including reporting initial data from 12-month evaluable patients in mid-2025); statements related to expectations regarding interactions with the FDA, Protara’s financial footing; statements regarding the anticipated safety or efficacy of Protara’s product candidates; and Protara’s outlook for the remainder of the year and future periods. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that contribute to the uncertain nature of the forward-looking statements include: risks that Protara’s financial guidance may not be as expected, as well as risks and uncertainties associated with: Protara’s development programs, including the initiation and completion of non-clinical studies and clinical trials and the timing of required filings with the FDA and other regulatory agencies; general market conditions; changes in the competitive landscape; changes in Protara’s strategic and commercial plans; Protara’s ability to obtain sufficient financing to fund its strategic plans and development and commercialization efforts; having to use cash in ways or on timing other than expected; the impact of market volatility on cash reserves; the loss of key members of management; the impact of general U.S. and foreign, economic, industry, market, regulatory, political or public health conditions; and the risks and uncertainties associated with Protara’s business and financial condition in general, including the risks and uncertainties described more fully under the caption “Risk Factors” and elsewhere in Protara's filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this presentation speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Protara undertakes no obligation to update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise, except as required by law.

Promising NMIBC therapy & de-risked rare disease programs

Oncology

TARA-002 in NMIBC

- Positive interim results from ADVANCED-2 trial in NMIBC
- Unique product characteristics anticipated to drive significant adoption
- Expanding clinical program into BCG-naïve, combinations and systemic priming dosing

Rare Disease

IV Choline for Parenteral Support

- Enrolling pivotal study with PK endpoint
- 30K patient population in the US[1]
- FDA Orphan Drug and Fast Track Designations

TARA-002 in LMs

- Dosing underway in Phase 2 STARBORN-1 trial
- TARA-002 predecessor is standard of care in Japan
- U.S. FDA granted Rare Pediatric Disease Designation – PRV eligible

PROTARA THERAPEUTICS

1. Data on file

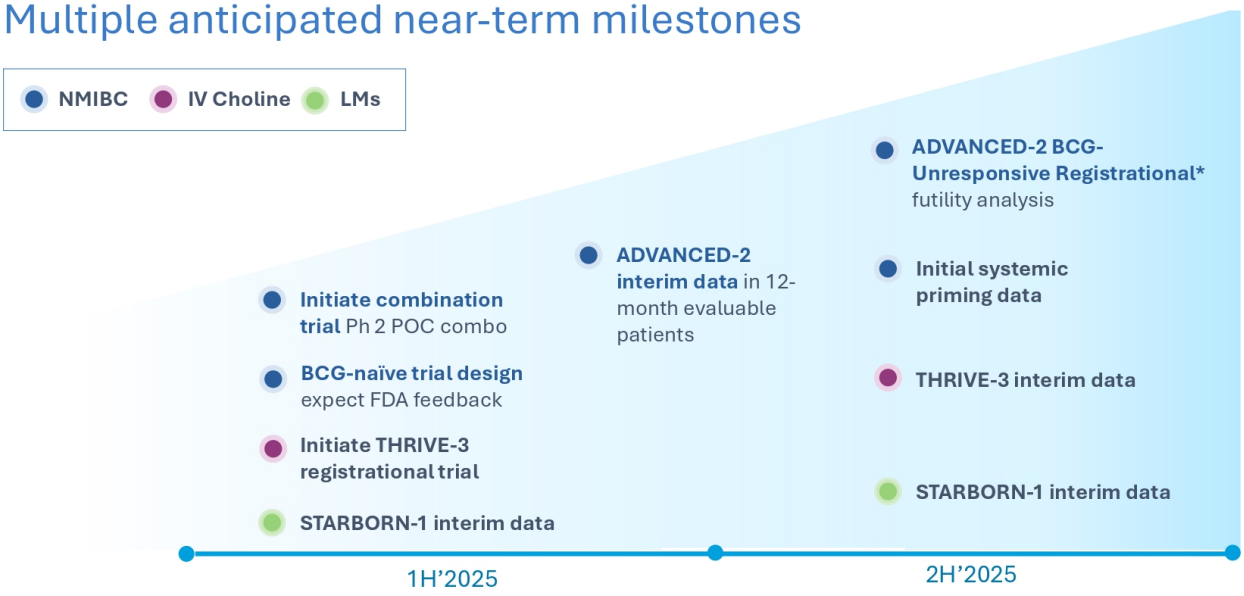
Multiple upcoming opportunities across our pipeline

	Indication	Pre-Clinical	Phase 1	Phase 2	Phase 3	Current Status
ONCOLOGY						
TARA-002	NMIBC: BCG-Unresponsive CIS +/- Ta/T1		**ADVANCED-2** (Cohort B)			*Designed to be registrational*
	NMIBC: BCG-Naïve CIS +/- Ta/T1		**ADVANCED-2** (Cohort A)			*Proof of concept*
TARA-002 Systemic Priming	NMIBC: BCG-Naïve & BCG-Exposed CIS+/- Ta/T1		**ADVANCED-2** (Cohort C)			*Proof of concept*
TARA-002 Combination	NMIBC: BCG-Unresponsive CIS+/- Ta/T1		**ADVANCED-2** (Cohort D)			*Assessing combination potential*
RARE DISEASES						
IV CHOLINE	Choline for parenteral support (PS) patients*		**THRIVE-3**			*PK-based registrational study to initiate in 1H'25*
TARA-002	Lymphatic Malformations (LMs)**		**STARBORN-1**			*Enrolling safety cohorts*

*Granted Orphan Drug Designations by the U.S. FDA
**TARA-002 granted Rare Pediatric Disease designation by the U.S. FDA and orphan drug designation by the European Medicines Agency for the treatment of LMs.
PK=Pharmacokinetic

PROTARA THERAPEUTICS

Multiple anticipated near-term milestones



BALANCE SHEET: $81.5M of cash, cash equivalents and investments as of September 30, 2024. Cash runway into 2027 including $102.7M of gross proceeds from recent public offering

COMMON SHARE EQUIVALENTS (30.3M):** 20.6M Common + 8.0M Preferred + 1.7M Pre-funded warrants on as converted basis as of September 30, 2024 not including 14.1M Common and 2.3M Pre-Funded Warrants issued in recent public offering (46.7M common share equivalents)

PROTARA THERAPEUTICS

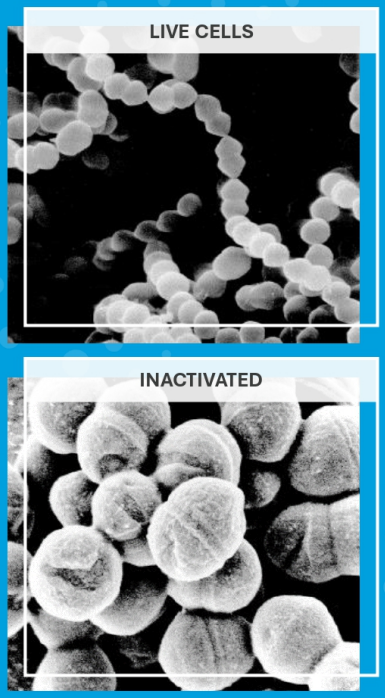
*Designed to be registrational aligned with U.S. FDA guidance on NMIBC clinical trials.
**Does not include 10.8M common warrants issued with the April 2024 private placement exercisable at a $5.25 per share at the earlier or April 10, 2027 or 90 days after public announcement of a minimum 42% six-month CR rate from at least 25 BCG-Unresponsive patients in the ADVANCED-2 clinical trial.

TARA-002

Lyophilized, Inactivated Group A *Streptococcus pyogenes*

TARA-002: Broad Immunopotentiator with significant potential

- TARA-002 is an investigational, genetically distinct strain of *Streptococcus pyogenes* that is inactivated while retaining its immune-stimulating properties
- TARA-002 is manufactured under cGMP conditions from the same Master Cell Bank as originator therapy OK-432,[1] approved for LMs and a number of oncology indications in Japan
- There are close to 2,000 publications for OK-432 in Pubmed
- Protara has worldwide rights, excluding Japan & Taiwan, for TARA-002 / OK-432



1. Marketed in Japan as Picibanil®.

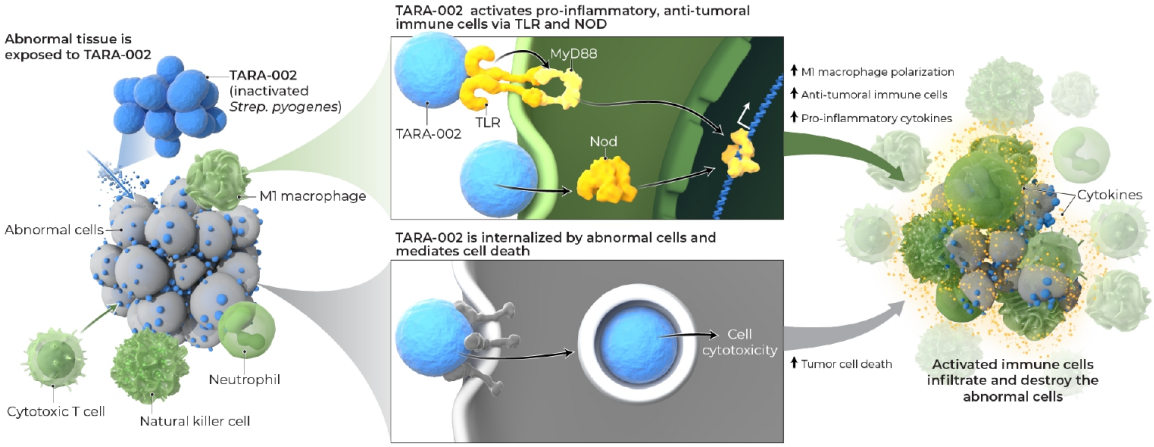
PROTARA THERAPEUTICS

Broad immunopotentiation = potential for durable response

Mechanism similar to BCG, unique to other agents in development

Activates Th1 Immune Cascade [1)(2)(3)]

IL-1b IL-6 IL-12 TNF-α IFN-γ GM-CSF NK-Cells



1. Fujimoto T., et al. J Immunol. 1997: 5619. | 2. Ryoma Y, et al. Anticancer Res. 2004; 3295-3298. | 3. Zhao H, et al. Microbiol. Immunol. 1994; 183-190.

TARA-002

Non-Muscle Invasive Bladder Cancer

Unique product characteristics anticipated to drive significant adoption

Encouraging interim ADAVNCED-2 data

- Compelling response rates in BCG-UN and BCG-naïve
- 100% durability observed from 3-to 6-months and 80% reinduction salvage rate seen across all patients

Favorable safety & tolerability

- To date, no Grade 2 or greater treatment-related adverse events
- To date, majority of adverse events are grade 1 and transient

Anticipated low burden on physicians & patients

- No additional administration procedures or safety protocols required
- Fast administration typically performed by nurse
- Dedicated to ensuring access with minimal burden

PROTARA THERAPEUTICS

Bladder cancer: significant unmet need

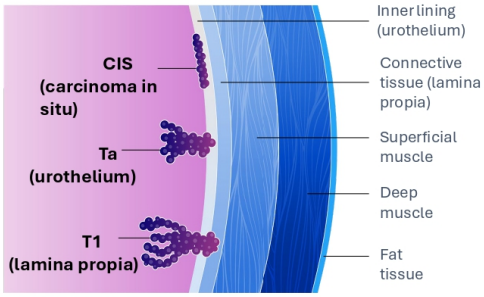
All Bladder Cancers

~80,000
People **diagnosed with bladder cancer** annually in the U.S.[1]

~725,000
People estimated **living with bladder cancer** annually in the US[1]

Average age 73

NMIBC



~75%
Of all bladder cancer diagnoses are **NIMBC**[2]

80%
Estimated to **recur in 3 years**[3]

BCG-UN; Significant unmet need

~40% to 50%
BCG failure rate
radical cystectomy is the SOC after BCG failure[4]

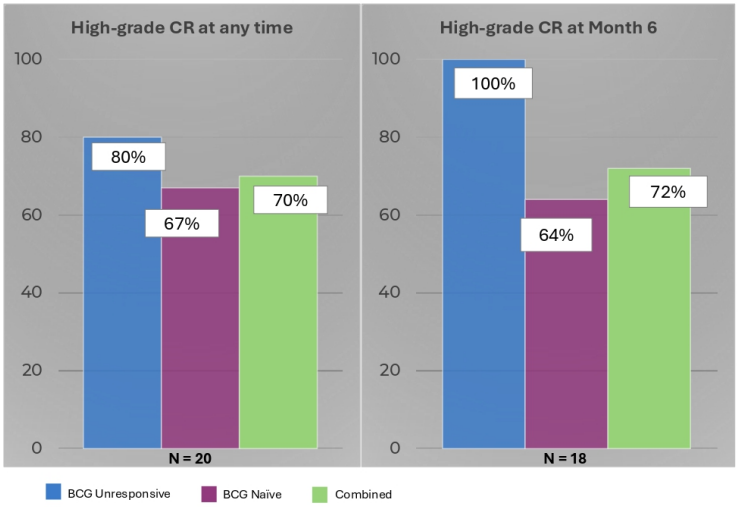
FDA

Currently approved therapies for **BCG-unresponsive NMIBC** were approved on the basis of **single arm trials**

1. National Cancer Institute. SEER Bladder Cancer – Stat Facts. Accessed April 25, 2023. | 2. Anastasiadis et al. Therapeutic Advances in Urology, 2012. | 3. Campbell Walsh 11th edition, 2014, Elsevier. | 4. J Gual Frau et al. Arch Esp Urol. 2016.

PROTARA THERAPEUTICS

TARA-002 demonstrated 72% six-month CRR and 70% CRR at any time across BCG exposures

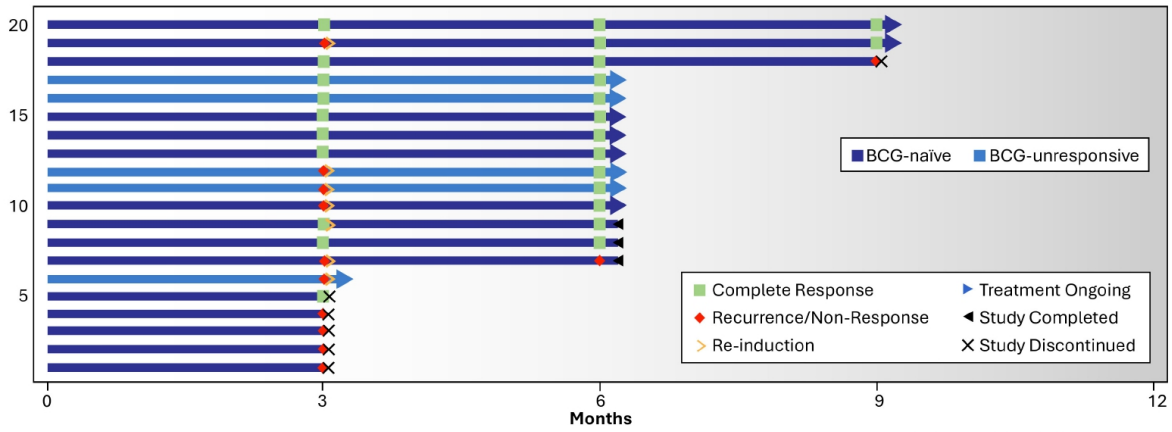


	BCG Un-responsive N = 5 (%)	BCG Naïve N = 15 (%)	Combined N = 20 (%)
High-grade CR at any time	4/5 (80.0)	10/15 (66.7)	14/20 (70.0)
High-grade CR at Timepoint			
Month 6	4/4 (100.0)	9/14 (64.3)	13/18 (72.2)
Month 9	N/A	2/3 (66.7)	2/3 (66.7)
High-grade CR at Month 6 by Baseline Dx			
CIS only	4/4 (100.0)	5/6 (83.3)	9/10 (90.0)
CIS + Ta/T1	N/A	4/8 (50.0)	4/8 (50.0)

Data cut-off date: 19 November 2024

Abbreviations: BCG = Bacillus Calmette-Guérin; CR = complete response; CIS = carcinoma in situ; Dx = diagnosis; NMIBC = non-muscle invasive bladder cancer
Notes: At the time of data cutoff, 20 subjects were evaluated for high-grade CR at Month 3 and later. Eighteen subjects were evaluated for high-grade CR at Month 6 and 3 subjects at Month 9; Evaluable subjects include those who had at least one dose of study drug before the response assessment of time point and were discontinued due to dx progression or treatment failure. Subjects who have not yet completed week 12 visit as of study cut off date are not included;
Central urine cytology is pending for 3 subjects at Month 6 and 1 subject at Month 9.

TARA-002 demonstrated 100% durability from 3 months to 6 months with a reinduction salvage rate of 80%[1]



Data cut-off date: 19 November 2024

Abbreviations: BCG = Bacillus Calmette-Guérin; CR = complete response; CIS = carcinoma in situ

NOTES: At the time of data cutoff, of the 24 subjects enrolled, 20 subjects were evaluated for high-grade CR at Month 3 and later. Eighteen subjects were evaluated for high-grade CR at Month 6 and 3 subjects at Month 9. Evaluable subjects include those who had at least one dose of study drug before the response assessment of time point and were discontinued due to diagnosis of progression or treatment failure. Subjects who have not yet completed the week 12 visit as of study cut of date were not included. Central urine cytology is pending for 3 subjects at Month 6 and 1 subject at Month 9.

1. 100% durability from 3 to 6 months in 9/9 patients; reinduction salvage rate of 80% in 4/5 patients

PROTARA THERAPEUTICS

TARA-002 demonstrated favorable safety and tolerability in interim analysis of ADVANCED-2 trial

AEs reflect urinary tract instrumentation effects and known safety profile of an immune-potentiating drug

N=24	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
Number of Subjects with TEAEs, n^ (%)	16 (67)	11 (46)	7 (29)	3 (13)	0
Number of Subjects with Related TEAEs^, n (%)	6 (25)	6 (25)	0	0	0
Dysuria	3 (13)	3 (13)	0	0	0
Bladder Discomfort	1 (4)	1 (4)	0	0	0
Bladder Spasm	1 (4)	1 (4)	0	0	0
Chills	1 (4)	1 (4)	0	0	0
Fatigue	1 (4)	1 (4)	0	0	0
Hematuria	1 (4)	1 (4)	0	0	0
Micturition Urgency	1 (4)	1 (4)	0	0	0
Urinary Incontinence	1 (4)	1 (4)	0	0	0
Number of Subjects with Serious TEAEs+, n (%)	3 (13)	0	1 (4)	2 (8)	0
Number of Subjects with TEAEs leading to Study Drug Withdrawal, n (%)	0	0	0	0	0

Abbreviations: AE = adverse event; NMIBC = non-muscle invasive bladder cancer; TEAE = treatment emergent AE
^ Subjects may be counted in multiple categories
+ Non-drug related Serious TEAEs included urinary tract infection (UTI; N = 2) and urosepsis (N =1)
Note: the safety population includes any patients who have had at least 1 dose of TARA-002. The 24 patients in safety analysis include 3 patients who have not reached their week 12 assessment, and 1 patient withdrew consent prior to their week 12 assessment

Data cut-off date: 19 November 2024

PROTARA THERAPEUTICS

BCG-Unresponsive: Accelerating trial enrollment

Registrational Trial Enrollment

International expansion
Expansion ongoing across **South America** and **Asia**

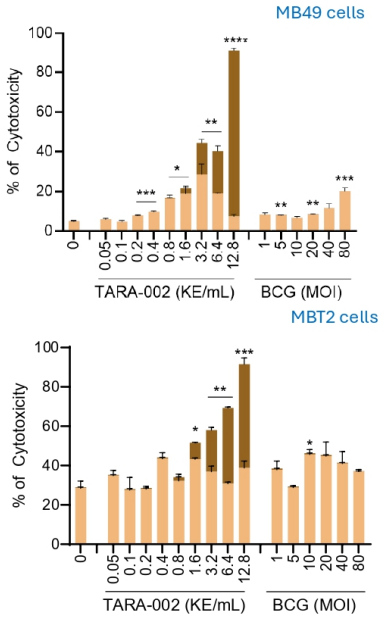
Increased Capacity in U.S.
Other large trials closing

U.S. Sites
Expect to have **25+ sites** in the U.S. by end of Q1'25

Positive TARA-002 data
Positive data expected to drive participation

TARA-002 demonstrates differentiated profile to BCG[1]

1 TARA-002 induces higher cytotoxicity than BCG in bladder cancer cells



2 TARA-002 treatment promotes higher release of pro-inflammatory TH1-type cytokines than BCG in co-culture

Cytokines	BCG	TARA-002
IFN-γ	---	+
TNF-α	+	+++
IL-12p70	=	+
IL-6	+	+
IL-1β	+++	+++
IL-10	=	+
IL-4	+	+
IL-13	=	=
IL-8	**=**	**-**
IL-2	--	--

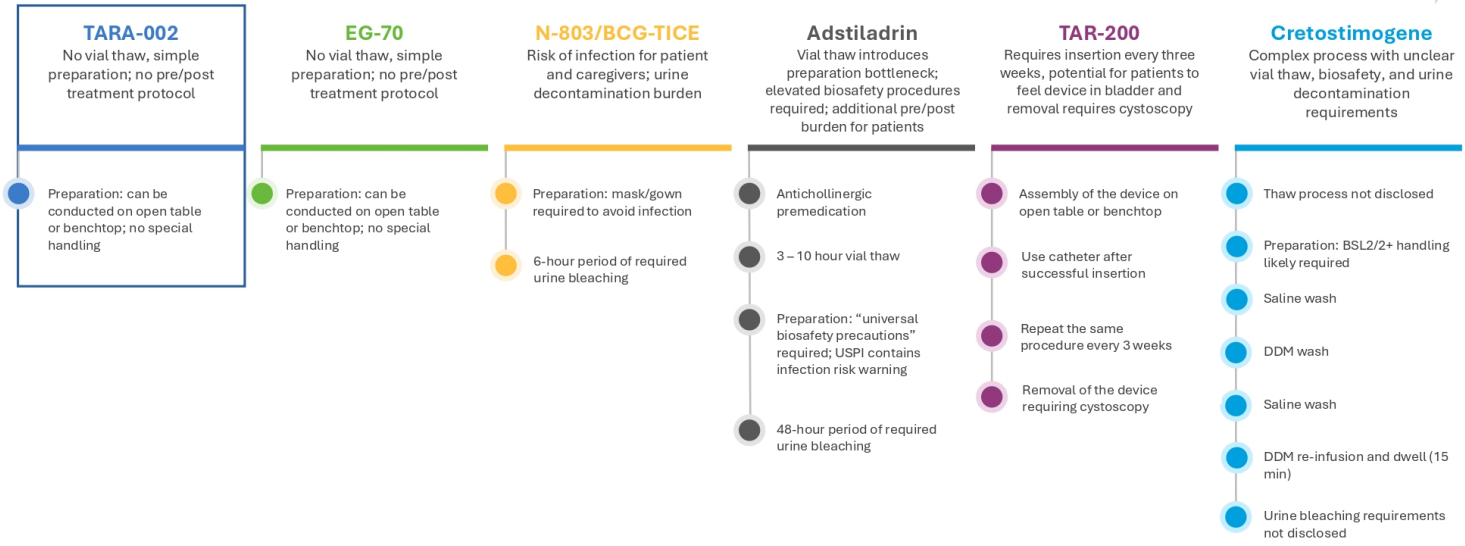
=, no change; +: 2- 5 fold upregulation
+++: ≥ 15-fold upregulation; -: 2- 5 fold upregulation;
--: 5-14-fold upregulation; ---: ≥ 15-fold upregulation

PROTARA THERAPEUTICS

1. Data from company pre-clinical studies

TARA-002 administration among the easiest of approved and experimental NMIBC treatments

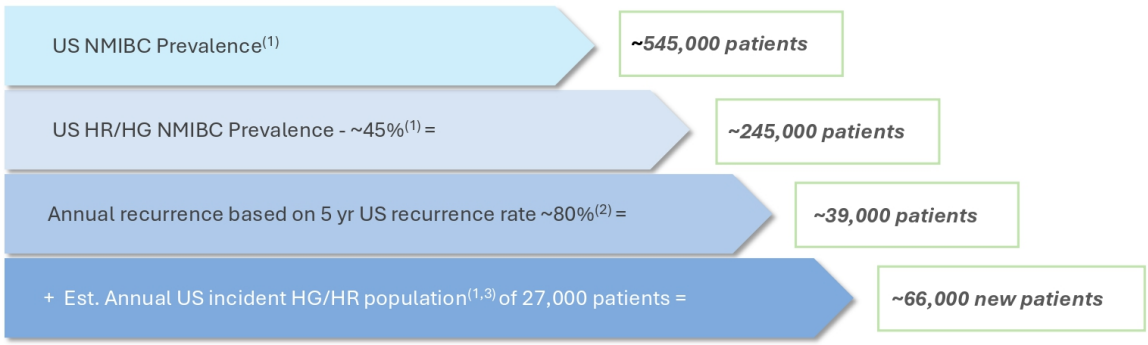
TARA-002 has reduced burden for physicians and patients



Definitions: USPI – U.S. prescribing information; DDM - dodecyl maltoside;
Data derived from product SOPIs and clinical trial publications

High-risk, high grade NMIBC: A significant addressable market in the US

Even in highly competitive scenarios, the market is large enough to sustain multiple entrants



Over 65K HR/HG NMIBC annual patients, at branded therapeutics pricing = ~$5bn-$6bn addressable US market broad enough for a variety of modalities and mechanisms of action (MOAs) to succeed

PROTARA THERAPEUTICS

1. SEER Bladder Cancer Facts, estimated from 2020 figures. 2. Campbell Walsh 11th edition, Elsevier. 3. Yu, et al: j European Urology; Volume 61, Issue 6, June 2012, Pages 1239-1244

TARA-002 HAS A DIFFERENTIATED PROFILE IN NMIBC WITH ENCOURAGING INTERIM DATA

PROMISING CLINICAL DATA
- Positive interim results across BCG exposures

UNIQUE MOA
- Only broad immunopotentiator in the industry pipeline
- Non-clinical data points to encouraging durability
- No overlapping toxicities with other novel therapeutic in NMIBC

POTENTIAL EASE ON PROVIDERS & PATIENTS
- To date, no Grade 2 or greater treatment-related adverse events
- Simple, fast administration via catheter

OPPORTUNITIES TO EXPAND
- First to publish efficacy in BCG-naïve patients; assessing potential next steps
- Only novel agent with the ability to dose systemically – potentially replacing intravesical administration

RELIABLE MANUFACTURING
- Advanced, FDA-inspected, cGMP manufacturing with 20mm vial annual capacity
- Doubling time (2 hrs) vs. BCG (16 hrs) adds to TARA-002's benefit over BCG in the non-refractory setting
- Dedicated to ensuring access with minimal burden

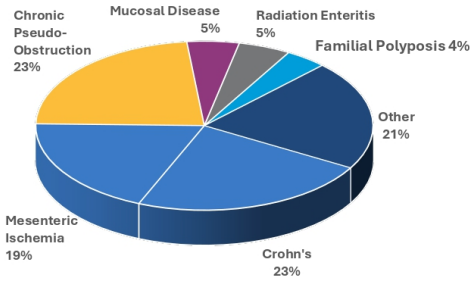
PROTARA THERAPEUTICS

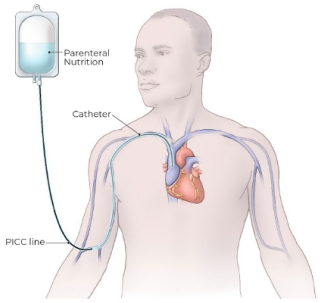
IV CHOLINE CHLORIDE

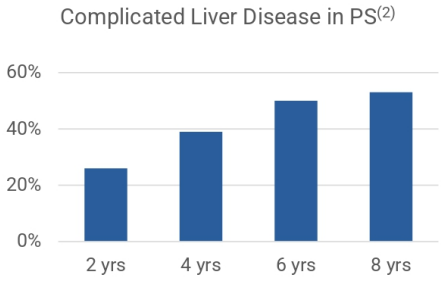
Phospholipid substrate replacement therapy for patients dependent on parenteral support (PS)

Overview of Parenteral Support

Underlying Etiology[1] → **Over time, dependent on PS** → **Liver disease a well-known consequence of PS**







Patients are dependent on PS to meet their nutritional needs; cannot sufficiently create or absorb many important nutrients, **most notably Choline**

Majority of nutrition is delivered via **central line as a sterile injectable drug** – only approved via NDA

No currently available PS formulations contain choline

PROTARA THERAPEUTICS

1. Sasdelli et al. J Clin Nutr.2018;1:8. | 2. Cavicchi et al. Ann Intern Med. 2000;132:525-532
HPN=Home parenteral nutrition; NDA=New Drug Application

Choline deficiency in PS is among the largest rare disease indications

~30,000[1] PS patients in the U.S. and the majority are choline deficient

- 78% of PS-dependent patients are choline-deficient and of those 63% have some degree of liver damage[2]
- Data confirm choline deficiency results in liver, bone, muscle and cognitive impairment[3,4]

Phase 2 study confirmed choline replacement restored normal levels

- Independently conducted Phase 2 data demonstrated significant improvement in serum choline concentrations and a pronounced impact on steatosis[4]
- Choline replacement is included in guidelines and recommendations by key PS professional associations

FDA has cleared the way for "source of choline" label with single study

- FDA granted a targeted indication of "source of choline for PS patients who are, or may become, choline-deficient"
- Single study demonstrating an increase in choline levels required (already demonstrated in Ph 2 trial)
- Both a compound patent and a method of treatment patent in U.S. to 2041

PROTARA THERAPEUTICS

1. Data on file | 2. THRIVE-1: A Multi-Center, Cross-Sectional, Observational Study to Assess the Prevalence of Choline Deficiency in Patients Dependent on Parenteral Nutrition. ESPEN. 2024 | 3. Chawla R, et al. Am J Clin Nutr. 1986 42:577-584. | 3. Zeisel S, et al. Neurology. 1980 30:1226-1229. | 4. Buchman et al. JPEN, 2002 - Protara Therapeutics re-analysis of patient CRFs, data on file.
Definitions: IV, intravenous; PN, parenteral nutrition.

Choline replacement recommended in key PS Guidelines

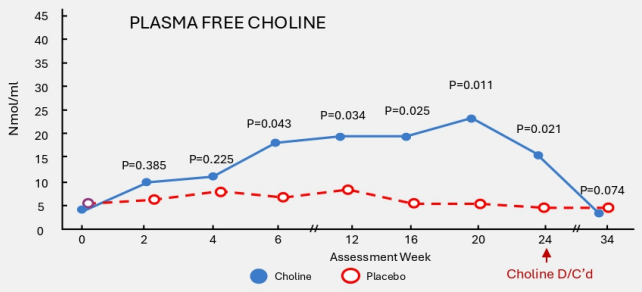
Parenteral Support Professional Societies' Position on Choline

Guidelines / Position Paper	ASPEN 2012 Position Paper (Vanek et al.)[3]:	ESPEN Micronutrient Guideline 2022 (Berger et al.)[4]:
	• Includes recommendations for Multivitamins & Multi-Trace Elements • Recognises the impact of long-term choline deficiency on the development of steatosis and hepatocellular carcinoma • Recommends that a commercially available parenteral choline product, either as an individual product or incorporated into a multivitamin product, should be developed and routinely added to adult parenteral formulas at a dose of 550 mg per day	• (Can/may) monitor choline in patients with abnormal liver function • (Can/may) consider treatment of HPN patients with abnormal liver function or proven deficiency with 550mg-2g/day choline • (Can/may) prescribe a dose of 400-550 mg choline via EN or PN per day has been suggested to support lipid metabolism

Sources: 1. Vanek et al. 2012. 2. Berger et al. 2022 . Links to formal guidelines: ASPEN PN Guidelines & ESPEN Guideline Abbreviations: IV = intravenous; (H)PN = (home) parenteral nutrition; EN = enteral nutrition.

Independent studies demonstrate that treatment with IV Choline rapidly restores choline levels and improves steatosis

PLASMA FREE CHOLINE LEVELS: ALL PATIENTS[1]



Choline supplementation was discontinued at week 24. Data are presented for all subjects up until time of withdrawal from the study.

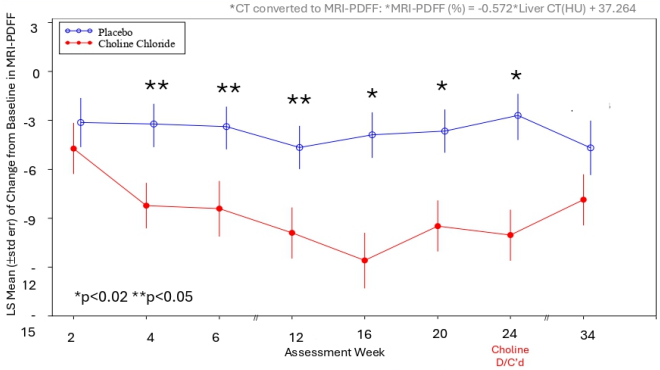
Studies conducted by independent academic institution

1. Buchman et al. JPEN, 2002 - Protara Therapeutics re-analysis of patient CRFs, data on file.

Primary endpoint to replicate in registrational trial

CLINICALLY MEANINGFUL IMPROVEMENT IN STEATOSIS[1]

*CT converted to MRI-PDFF: *MRI-PDFF (%) = -0.572*Liver CT(HU) + 37.264



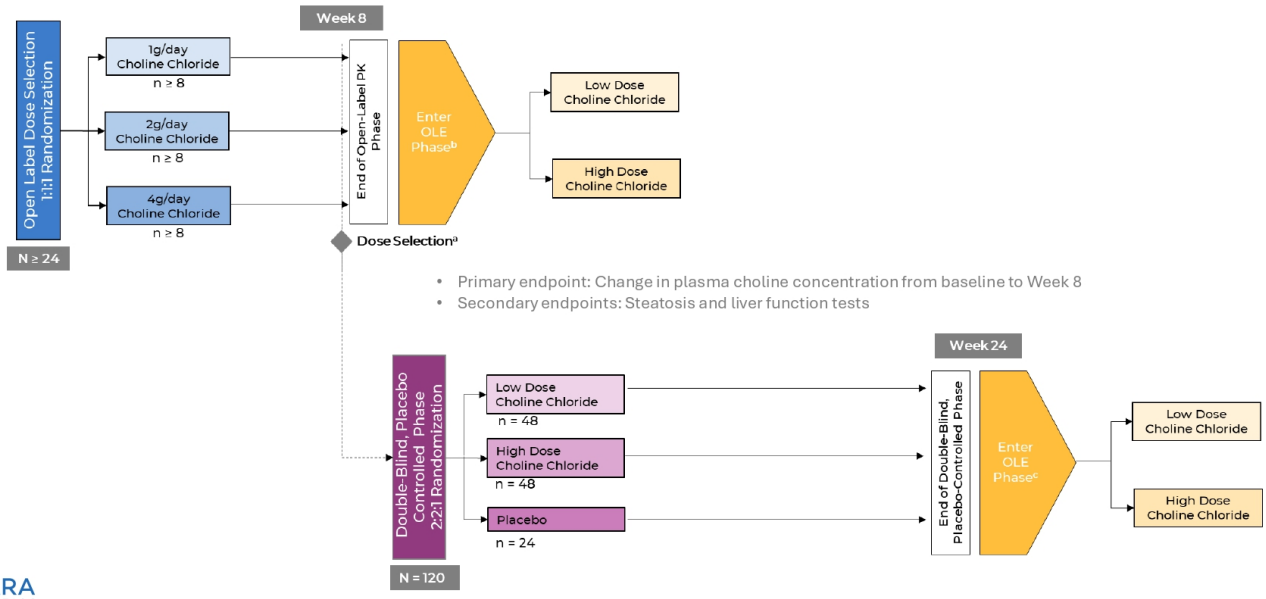
Significant differences in the LS mean change from baseline in MRI-PDFF observed in Choline group vs. placebo at Weeks 4 - 24, demonstrating a clinically meaningful and statistically significant reduction in steatosis (range 31%-54%)

Secondary endpoint to replicate in registrational trial to support clinical benefit

PROTARA THERAPEUTICS

Pivotal trial with PK-based endpoints expected to initiate in 1H'25

THRIVE-3 is a seamless Phase 2b/3 trial with dose confirmation followed by double-blinded, randomized, placebo-controlled trial to assess the safety and efficacy of IV Choline Chloride in adolescents and adults on long-term PS when oral or enteral nutrition is not possible, insufficient, or contraindicated (n=120)



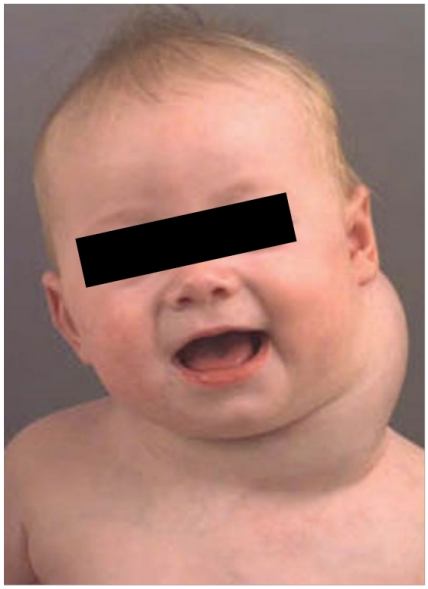
- Primary endpoint: Change in plasma choline concentration from baseline to Week 8
- Secondary endpoints: Steatosis and liver function tests

PROTARA THERAPEUTICS

TARA-002

Lymphatic Malformations (LMs)

TARA-002 in LMs



Lymphatic Malformations

Rare, non-malignant lesions consisting of dilated, lymphatic fluid-filled sacs caused by abnormal development of the lymphatic endothelial system[1]

Epidemiology: incidence of lymphatic malformations is ≈1,400-1,800 LM cases per year[2]

Current treatment options

Current treatment options include surgical excision with high complication (33%) and recurrence (55%) rates[3] as well as off-label use of sclerosants

Potential for Priority Review Voucher upon approval

Granted RPDD in 2021

Ongoing Ph 2 clinical trial

Ph 2 STARBORN-1 trial in pediatric LMs patients is ongoing

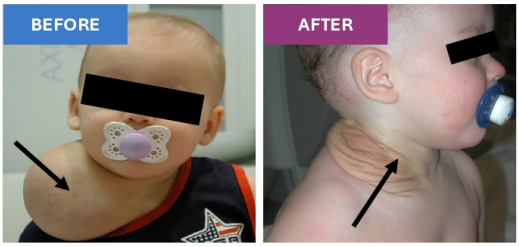
Additional indications

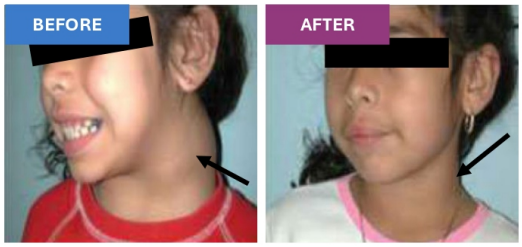
Historical literature and patient experience indicate that TARA-002 could have the potential to treat other maxillofacial cysts

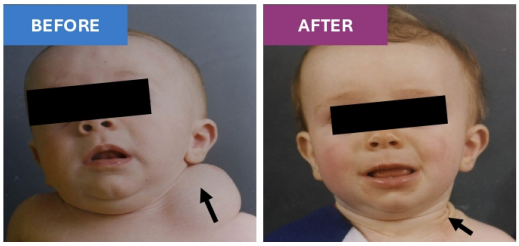
PROTARA THERAPEUTICS

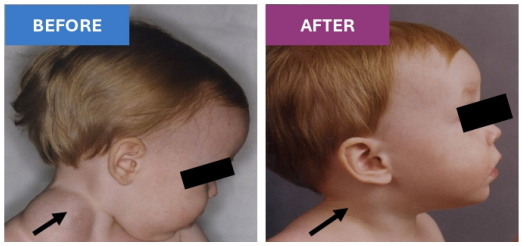
1. Brouillard P, et al. J Clin Invest. 2014;124:898-904. | 2. Internal company estimates | 3. Ha J, et al. Curr Ped Rev. 2014;10:238-248.

Clear evidence of biologic activity observed with OK-432*









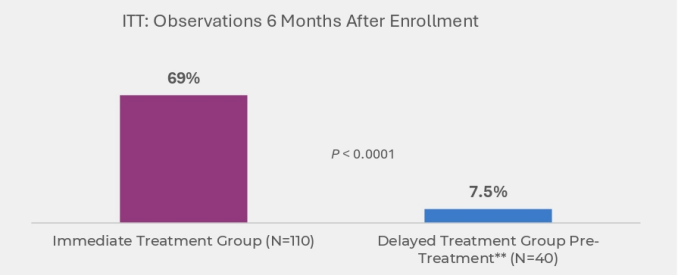
Completed clinical study of OK-432 (TARA-002 predecessor therapy) in U.S. suggests effectiveness with strong support for safety profile

*TARA-002 is developed from the same master cell bank as OK-432

PROTARA THERAPEUTICS

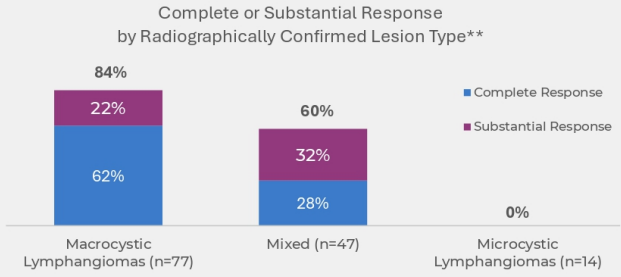
Robust clinical results in large, academic study of OK-432

69% CLINICAL SUCCESS‡ IN IMMEDIATE TREATMENT GROUP 6 MONTHS AFTER ENROLLMENT



- During this same period, 7.5% of patients in the delayed treatment group experienced spontaneous regression of LM
- Treatment: 1-4 injections at 8-week intervals max of 0.2mg/session (2KE)

84%* CLINICAL SUCCESS‡ IN PATIENTS WITH MACROCYSTIC LESION TYPES



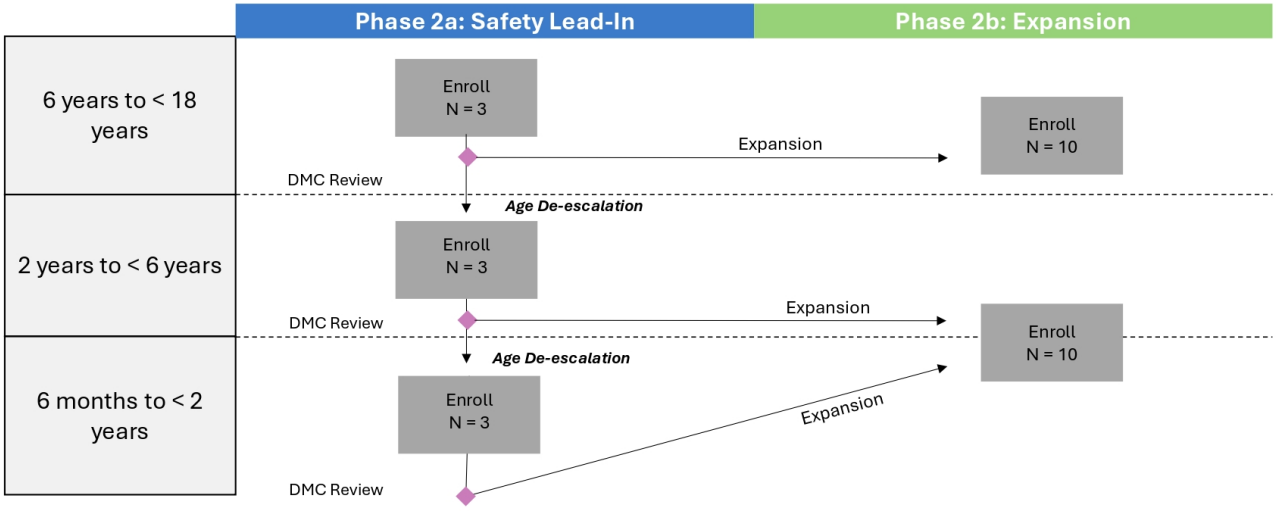
- Patients with radiographically confirmed macrocystic lesions had the greatest chance for clinical success
- In those patients with mixed lesions, clinical success was still achieved

‡ Clinical Success was defined as complete or substantial response.
*Reflects data prior to dosing with OK-432. After dosing, the clinical success rate was 66%, which was not statistically different from the Immediate Treatment Group.
**Results were analyzed by lesion type across all treatment groups
1. Results based on retrospective analysis of source verified data that included the full dataset of subjects enrolled in randomized study between January 1998 and August 2005, including data in the published study (Smith et al. 2009) which included subjects enrolled between January 1998 and November 2004.

PROTARA THERAPEUTICS

TARA-002 in LMs: Phase 2 STARBORN-1 Trial underway

Single Arm Open-Label Safety and Efficacy Study of TARA-002 in Pediatric Patients with Macrocystic and Mixed-cystic LMs (N=29)



PROTARA THERAPEUTICS

APPENDIX

Led by a team of experienced professionals

Jesse Shefferman
Co-founder, Director, Chief Executive Officer

Jacqueline Zummo, PhD, MPH, MBA
Co-founder, Senior Vice President, Chief Scientific Operations Officer

Pat Fabbio
Chief Financial Officer

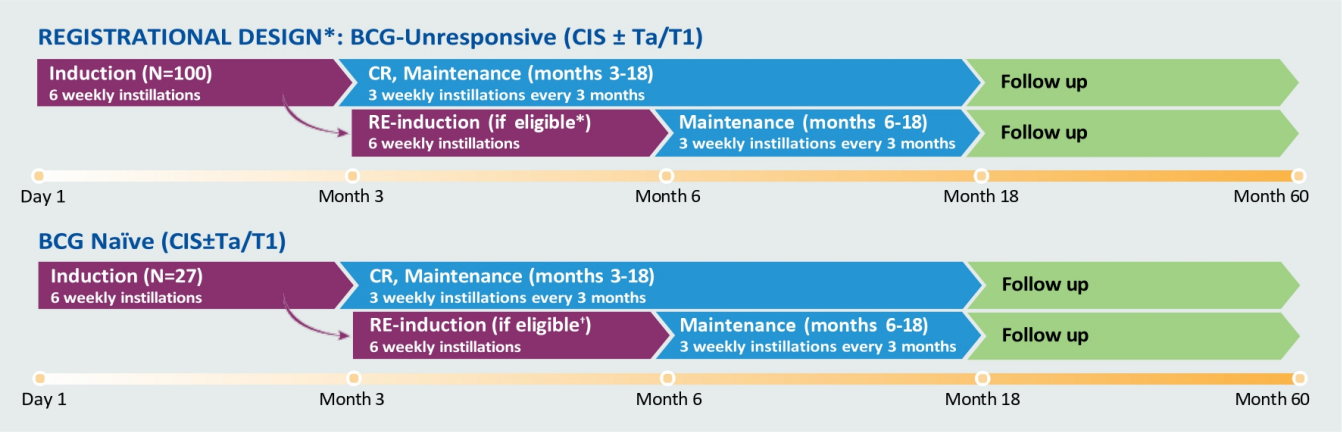
Mary Grendell
General Counsel, Corporate Secretary

Justine O'Malley
Senior Vice President, Investor Relations and Corporate Communications

PROTARA THERAPEUTICS

TARA-002 in NMIBC: ADVANCED-2 clinical trial design

Primary endpoint of high-grade complete response (CR) at any time at 6 months; Key secondary of 12-month DOR



Abbreviations: CR = complete response; CIS = carcinoma in situ
*Aligned with the FDA's 2024 BCG Unresponsive NMIBC: Developing Drugs and Biologics for Treatment Guidance for Industry.
†Residual CIS and/or recurrence of HGTa

ADVANCED-2 demographics and disease characteristics

	N = 24		N = 24
Age (years)		**Prior BCG Status, n (%)**	
Mean (SD)	71 (10.9)	BCG Naïve	17 (71)
Median	71	BCG Exposed	2 (8)
Min, Max	45, 92	BCG Unresponsive	5 (21)
Sex, n (%)		**Prior No. of BCG Doses, n (%)**	
Male	19 (79)	≥ 12 BCG doses	5 (21)
Female	5 (21)	< 12 BCG doses	2 (8)
Race, n (%)		**Prior non-BCG Treatment, n (%)**	
White	24 (100)	Gemcitabine/Docetaxel	2 (8)
Ethnicity, n (%)		Gemcitabine	1 (4)
Hispanic	1 (4)	Mitomycin	3 (12)
Non-Hispanic	23 (96)	Other	2 (8)
ECOG Score, n (%)		**Prior TURBT Status, n (%)**	
0	18 (75)	> 3 TURBTs	5 (21)
1	5 (21)	≤ 3 TURBTs	19 (79)
2	1 (4)		
Baseline Diagnosis, n (%)			
CIS only	14 (58)		
CIS + Ta	6 (25)		
CIS + T1	4 (17)		

PROTARA THERAPEUTICS

Data cut-off date: 19 November 2024

TARA-002: Manufacturing is a potential competitive advantage

- **20M** vial capacity ability to expand capacity **5X**
- Efficient 2 hour doubling time with two-week batch completion
- **47** successful batches to date
- **Completed FDA inspection** without Form 483s

PROTARA THERAPEUTICS

Exhibit 99.2

Protara Highlights Recent Updates and Anticipated 2025 Milestones

Reported positive six-month data from ADVANCED-2 trial of TARA-002 in patients with NMIBC

Completed approximately $100 million public offering, extending runway into 2027

Initial data from 12-month evaluable NMIBC patients in ADVANCED-2 trial expected in mid-2025; Results from a futility analysis of approximately 25 six-month evaluable BCG-Unresponsive patients expected by the end of 2025

Dosing of first patient in THRIVE-3 registrational trial of IV Choline Chloride in patients dependent on parenteral support expected in 1H 2025

Results from additional cohorts of Phase 2 STARBORN-1 trial of TARA-002 in pediatric LMs patients expected by the end of 1H 2025

NEW YORK, January 13, 2025 (GLOBE NEWSWIRE) -- Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage company developing transformative therapies for the treatment of cancer and rare diseases, today highlighted recent updates and anticipated 2025 milestones.

“Following a highly productive 2024 marked by positive data in our NMIBC program and with the funds from a successful financing, we are well positioned to accelerate our development programs and deliver on our mission to provide novel therapies to patients impacted by cancer and rare diseases,” said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. “Looking ahead, we expect several key milestones in 2025, including reporting data on 12-month evaluable patients in our ADVANCED-2 trial of TARA-002 in non-muscle invasive bladder cancer (NMIBC) mid-year. On the heels of our recently reported positive interim data from six-month evaluable patients, we continue to believe that TARA-002 could represent a meaningful and differentiated addition to the NMIBC treatment paradigm with an attractive product profile for both physicians and patients.”

“In addition, we expect to begin the pivotal THRIVE-3 study of intravenous (IV) Choline Chloride in the first half of 2025. We also expect data from our ongoing Phase 2 STARBORN-1 trial of TARA-002 in lymphatic malformations (LMs) by the end of the first half of 2025.”

Recent Company Updates and Planned 2025 Milestones

TARA-002 in NMIBC

- In December 2024, the Company reported positive interim results from its ongoing Phase 2 open-label ADVANCED-2 trial in in NMIBC patients with carcinoma in situ or CIS (± Ta/T1) who are Bacillus Calmette-Guérin (BCG)-Unresponsive and BCG-Naïve at the 25th Annual Meeting of the Society of Urologic Oncology (SUO) in Dallas, Texas. The complete response (CR) rate across BCG exposures was 72% (13/18) at six months and 70% (14/20) at any time, with 100% (9/9) of patients maintaining a CR from three months to six months. In addition, two of three patients maintained a CR at nine months. TARA-002 showed a favorable safety profile, with no Grade 2 or greater treatment-related adverse events and no treatment discontinuations due to adverse events.

- The Company expects to report data on 12-month evaluable patients in the ADVANCED-2 trial in mid-2025 and results from a futility analysis of approximately 25 six-month evaluable BCG-Unresponsive patients are expected by the end of 2025. As previously announced, the BCG-Unresponsive cohort is designed to be registrational in alignment with the 2024 BCG-Unresponsive Non-muscle Invasive Bladder Cancer: Developing Drugs and Biological Products for Treatment Draft Guidance for Industry issued by the U.S. Food and Drug Administration (FDA).

- The Company expects to provide an update on the design of its planned BCG-Naïve registrational trial by the end of the first half of 2025 following regulatory alignment.

- The Company continues to explore the administration of systemic priming dosing prior to initiation of intravesical administration, as well as combination therapy with TARA-002 in NMIBC patients with CIS. Given TARA-002's mechanism of action and safety profile, the Company believes it has strong potential for use in combination therapy and is working to finalize various opportunities for the clinical program.

IV Choline Chloride for Patients on Parenteral Support (PS)

- The Company expects to commence the THRIVE-3 registrational trial of IV Choline Chloride, an investigational phospholipid substrate replacement, in adolescents and adults on long-term PS when oral or enteral nutrition is not possible, insufficient, or contraindicated, in the first half of 2025. IV Choline Chloride was previously granted Fast Track designation by the FDA as a source of choline for this patient population.

- In September 2024, the Company announced results from THRIVE-1, a prospective, observational study, which found that 78% of PS-dependent patients were choline deficient, and 63% of these patients demonstrated liver dysfunction, including steatosis, cholestasis, and hepatobiliary injury.

TARA-002 in LMs

- Protara remains on track to report initial results from additional cohorts in the Phase 2 STARBORN-1 trial of TARA-002 in pediatric patients with macrocystic and mixed cystic LMs by the end of the first half of 2025. The Company previously announced completion of the study's first safety cohort, in which TARA-002 demonstrated encouraging efficacy and was generally well-tolerated.

Financial Guidance

- The Company today provided updated financial guidance. Protara believes its approximately $81.5 million of cash, cash equivalents, and investments in marketable debt securities as of September 30, 2024, together with approximately $100 million gross proceeds from its December 2024 public offering, will be sufficient to fund its planned operations into 2027.

About Protara Therapeutics, Inc.

Protara is a clinical-stage biotechnology company committed to advancing transformative therapies for people with cancer and rare diseases. Protara's portfolio includes its lead candidate, TARA-002, an investigational cell-based therapy in development for the treatment of non-muscle invasive bladder cancer (NMIBC) and lymphatic malformations (LMs). The Company is evaluating TARA-002 in an ongoing Phase 2 trial in NMIBC patients with carcinoma in situ (CIS) who are unresponsive or naïve to treatment with Bacillus Calmette-Guérin (BCG), as well as a Phase 2 trial in pediatric patients with LMs. Additionally, Protara is developing IV Choline Chloride, an investigational phospholipid substrate replacement for patients on parenteral support who are otherwise unable to meet their choline needs via oral or enteral routes. For more information, visit www.protaratx.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Protara may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "designed," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words or expressions referencing future events, conditions or circumstances that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such forward-looking statements include but are not limited to, statements regarding Protara's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: Protara's business strategy, including its development plans for its product candidates and plans regarding the timing or outcome of existing or future clinical trials (including reporting initial data from 12-month evaluable patients in mid-2025); statements related to expectations regarding interactions with the FDA; Protara's financial position; statements regarding the anticipated safety or efficacy of Protara's product candidates; and Protara's outlook for the remainder of the year and future periods. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Factors that contribute to the uncertain nature of the forward-looking statements include: risks that Protara's financial guidance may not be as expected, as well as risks and uncertainties associated with: Protara's development programs, including the initiation and completion of non-clinical studies and clinical trials and the timing of required filings with the FDA and other regulatory agencies; general market conditions; changes in the competitive landscape; changes in Protara's strategic and commercial plans; Protara's ability to obtain sufficient financing to fund its strategic plans and commercialization efforts; having to use cash in ways or on timing other than expected; the impact of market volatility on cash reserves; failure to attract and retain management and key personnel; the impact of general U.S. and foreign, economic, industry, market, regulatory, political or public health conditions; and the risks and uncertainties associated with Protara's business and financial condition in general, including the risks and uncertainties described more fully under the caption "Risk Factors" and elsewhere in Protara's filings and reports with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Protara undertakes no obligation to update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise, except as required by law.

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