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): December 5, 2024

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 December 5, 2024, Protara Therapeutics, Inc. (the "Company" or "Protara") posted an investor presentation (the "Investor Presentation") to the "Investors—Events and Presentations" section of the Company's website at www.protaratx.com. The Investor Presentation will be used in connection with a conference call and webcast today, December 5, 2024, at 8:30 am ET, to review the clinical data to be presented during a poster session at the 25th Annual Meeting of the Society of Urologic Oncology in Dallas, Texas (the "2024 SUO Conference") and provides an update on the ongoing Phase 2 ADVANCED-2 trial program. A copy of the Investor Presentation is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

On December 5, 2024, the Company also issued a press release reporting new interim clinical data on the ongoing Phase 2 ADVANCED-2 trial program (the "Press Release"). 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 Exhibits 99.1 and 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On December 5, 2024, the Company presented interim results from its ongoing Phase 2 ADVANCED-2 clinical trial of TARA-002 in patients with Non-Muscle Invasive Bladder Cancer ("NMIBC") at a poster session at the 2024 SUO Conference. A copy of the poster, which has been published to the "Investors—Events and Presentations" section of the Company's website, is filed as Exhibit 99.3 to this Current Report on Form 8-K and is incorporated herein by reference.

The Company reported data that highlights the potential of TARA-002 in patients with NMIBC in its Phase 2 ADVANCED-2 clinical trial, which is assessing the safety and anti-tumor activity of intravesical TARA-002, the Company's investigational cell-based therapy, in high-risk NMIBC patients with carcinoma in situ ("CIS") (± Ta/T1) who are Bacillus Calmette-Guérin ("BCG")-Unresponsive or BCG-Naïve. The dataset includes 20 patients who were evaluable at three months, 18 patients who were evaluable at six months and three patients who were evaluable at nine months with a data cutoff of November 19, 2024. 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. In the pivotal cohort of the ADVANCED-2 trial in BCG-Unresponsive patients, the CR rate was 100% (4/4) at six-months and 80% (4/5) at any time. In the proof-of-concept cohort of BCG-Naïve patients, the CR rate was 64% (9/14) at six months and 67% (10/15) at any time.

To date, TARA-002 has demonstrated a favorable safety and tolerability profile with no Grade 2 or greater treatment-related adverse events, and no patients discontinued treatment due to adverse events. The majority of adverse events were Grade 1 and transient, and the most common adverse events were in line with typical responses to bacterial immunopotentiation, such as flu-like symptoms. In addition, the most common urinary symptoms reflect urinary tract instrumentation effects, such as bladder spasm, burning sensation, and urinary tract infection. Most bladder irritations resolved shortly after administration or within a few hours to a few days.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Investor Presentation, dated December 5, 2024.
99.2	Press Release, dated December 5, 2024.
99.3	Poster Presentation, dated December 5, 2024.
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: December 5, 2024

Protara Therapeutics, Inc.

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

PROTARA THERAPEUTICS

ADVANCED-2 TRIAL INTERIM RESULTS

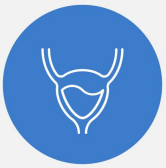
December 2024

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
- Potential to expand clinical program into BCG-naïve, combinations, systemic dosing and intermediate risk

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

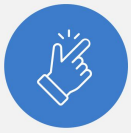
Unique product characteristics anticipated to drive significant adoption

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

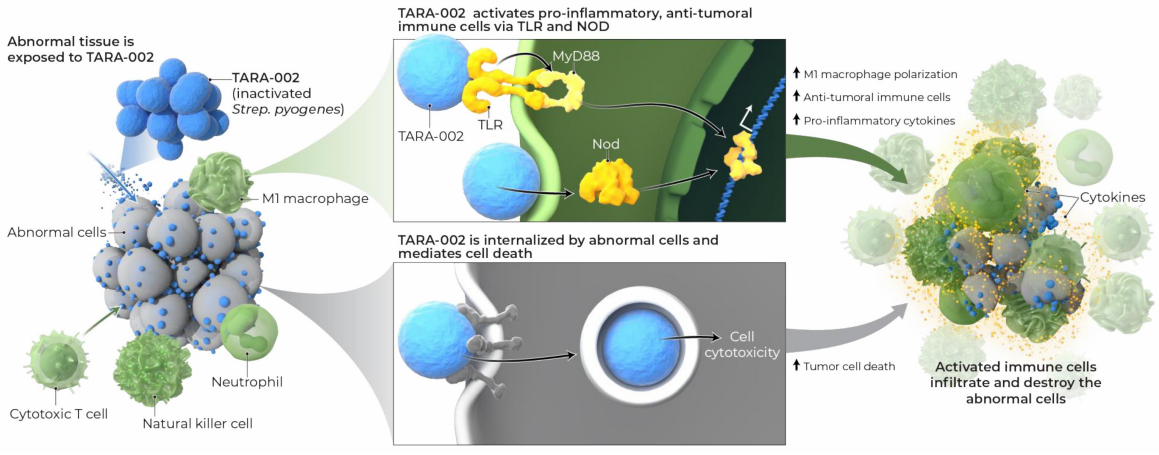
PROTARA THERAPEUTICS

BROAD IMMUNOPOTENTIATION = POTENTIAL FOR DURABLE RESPONSE

Mechanism similar to BCG, unique to other agents in development

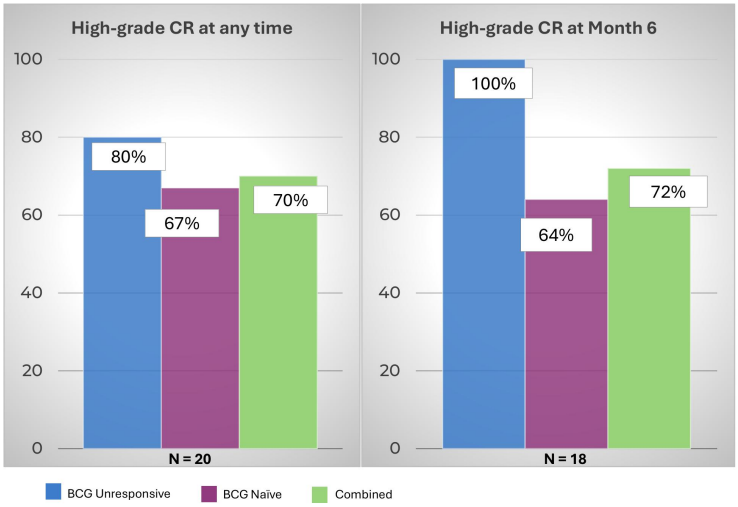
Activates Th1 Immune Cascade [1][2][3]

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

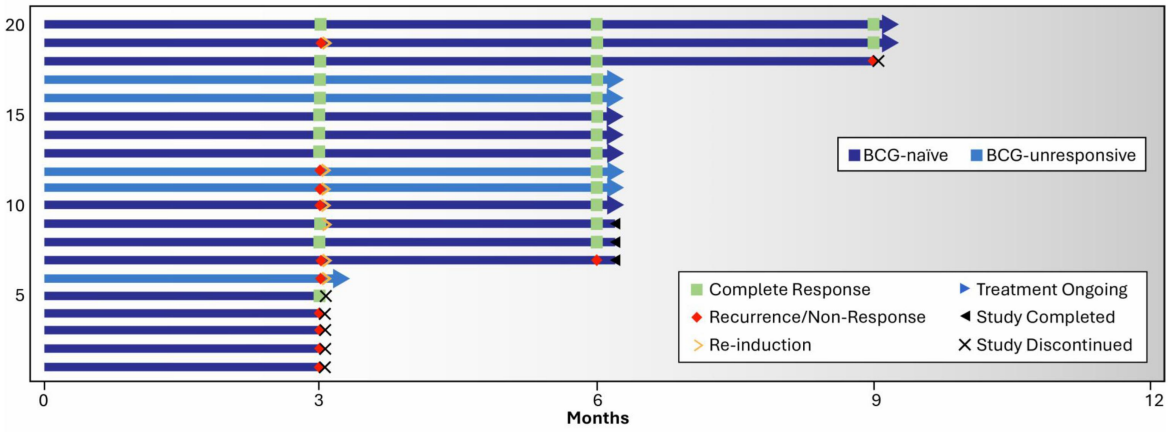


	BCG Un-responsive N = 5 (%)	BCG Naïve N = 15 (%)	Combined N = 20 (%)
High-grade CR at any time	4/5 (80.0)	10/15 (66.7)	14/20 (70.0)
High-grade CR at Timepoint			
Month 6	4/4 (100.0)	9/14 (64.3)	13/18 (72.2)
Month 9	N/A	2/3 (66.7)	2/3 (66.7)
High-grade CR at Month 6 by Baseline Dx			
CIS only	4/4 (100.0)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

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

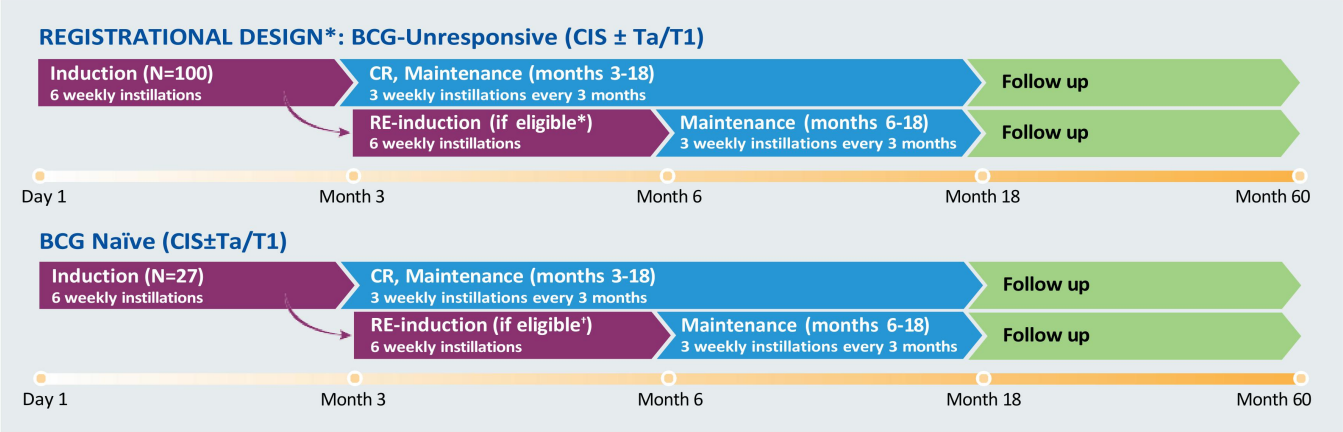
PROTARA THERAPEUTICS

Q&A

APPENDIX

TARA-002 in NMIBC: ADVANCED-2 trial design

Primary endpoint of high-grade complete response (CR) at any time at 6mos; 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

Exhibit 99.2

Protara Announces Positive Results from the Ongoing Phase 2 ADVANCED-2 Trial of TARA-002 in Patients with NMIBC

- *TARA-002 demonstrates 72% six-month landmark complete response rate and 70% complete response rate at any time across BCG exposures*
- *100% six-month landmark complete response rate and 80% complete response rate at any time observed in BCG-Unresponsive patients*
- *64% six-month landmark complete response rate and 67% complete response rate at any time observed in BCG-Naïve patients*
- *80% reinduction salvage rate and compelling durability observed with 100% of patients maintaining a complete response from three months to six months across BCG exposures*
- *Favorable safety and tolerability profile with no Grade 2 or greater treatment-related adverse events*
- *Company to host conference call and webcast today at 8:30 a.m. ET*

NEW YORK, December 5, 2024 (GLOBE NEWSWIRE) -- Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage company developing transformative therapies for the treatment of cancer and rare diseases, today announced results from its ongoing Phase 2 open-label ADVANCED-2 trial. The trial is assessing intravesical TARA-002, the Company's investigational cell-based therapy, in high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) patients with carcinoma in situ or CIS (± Ta/T1) who are Bacillus Calmette-Guérin (BCG)-Unresponsive or BCG-Naïve. 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. These results will be featured today during a poster session at the 25th Annual Meeting of the Society of Urologic Oncology (SUO) in Dallas, Texas.

The dataset includes 20 patients who were evaluable at three months, 18 patients who were evaluable at six months and three patients who were evaluable at nine months with a data cutoff of November 19, 2024. In the pivotal cohort of the ADVANCED-2 trial in BCG-Unresponsive patients, the CR rate was 100% (4/4) at six-months and 80% (4/5) at any time. In the proof-of-concept cohort of BCG-Naïve patients, the CR rate was 64% (9/14) at six months and 67% (10/15) at any time. TARA-002 demonstrated a favorable safety and tolerability profile with no Grade 2 or greater treatment-related adverse events (TRAEs), and no patients discontinued due to adverse events.

"These impressive TARA-002 results demonstrate meaningful activity in a difficult to treat patient population," said Brian Mazzarella, MD, Vice President of Research for Urology America, and ADVANCED-2 study investigator. "The activity of TARA-002 across BCG exposures, coupled with its ease of use and low procedural burden for physicians, make it an exciting potential treatment option for NMIBC patients."

"We are thrilled with these positive six-month data, which reinforce TARA-002's potential in NMIBC, while offering a compelling product profile for physicians and patients," said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. "We believe these encouraging data together with our international site expansion will accelerate patient enrollment, and we look forward to reporting initial data from 12-month evaluable patients in mid-2025."

The majority of adverse events were Grade 1 and transient with no Grade 2 or greater TRAEs as assessed by study investigators. No patients discontinued treatment due to adverse events. The most common adverse events were in line with typical responses to bacterial immunopotentiation, such as flu-like symptoms. The most common urinary symptoms reflect urinary tract instrumentation effects, such as bladder spasm, burning sensation, and urinary tract infection. Most bladder irritations resolved shortly after administration or within a few hours to a few days.

Conference Call and Webcast

Protara will host a conference call and webcast to discuss the data today at 8:30 am ET. The live call can be accessed by registering as a participant here. Upon registration, participants will receive conference call dial-in information. A live webcast of the event can be accessed by visiting the Events and Presentations section of the Company's website: https://ir.protaratx.com. The webcast will be archived for a limited time following the presentation.

About ADVANCED-2

The Phase 2 open-label ADVANCED-2 trial is assessing intravesical TARA-002 in NMIBC patients with carcinoma in situ or CIS (± Ta/T1) who are Bacillus Calmette-Guérin (BCG)-Unresponsive (n≈100) and BCG-Naïve (n=27). The BCG-Unresponsive cohort has been designed to be registrational in alignment with the FDA's 2024 BCG-Unresponsive Non-muscle Invasive Bladder Cancer: Developing Drugs and Biological Products for Treatment Draft Guidance for Industry.

About TARA-002

TARA-002 is an investigational cell therapy in development for the treatment of NMIBC and of LMs, for which it has been granted Rare Pediatric Disease Designation by the U.S. Food and Drug Administration. TARA-002 was developed from the same master cell bank of genetically distinct group A Streptococcus pyogenes as OK-432, a broad immunopotentiator marketed as Picibanil® in Japan and approved in Taiwan by Chugai Pharmaceutical Co., Ltd. Protara has successfully shown manufacturing comparability between TARA-002 and OK-432.

When TARA-002 is administered, it is hypothesized that innate and adaptive immune cells within the cyst or tumor are activated and produce a pro-inflammatory response with release of cytokines such as tumor necrosis factor (TNF)-alpha, interferon (IFN)-gamma, IL-1b, IL-6, IL-12, granulocyte-macrophage colony-stimulating factor (GM-CSF) and natural killer cells. TARA-002 also directly kills tumor cells and triggers a host immune response by inducing immunogenic cell death, which further enhances the antitumor immune response.

About Non-Muscle Invasive Bladder Cancer (NMIBC)

Bladder cancer is the sixth most common cancer in the United States, with NMIBC representing approximately 80% of bladder cancer diagnoses. Approximately 65,000 patients are diagnosed with NMIBC in the United States each year. NMIBC is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle.

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 nutrition 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.

Company Contact:

Justine O'Malley
Protara Therapeutics
Justine.OMalley@protaratx.com
646-817-2836

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ADVANCED-2: Phase 2 Open-label Study to Evaluate Safety and Anti-tumor Activity of Intravesical Instillation of TARA-002 in Adults with High-grade Non-muscle Invasive Bladder Cancer

Brian Mazzarella[1], Gautam Jayram[2], Neal Shore[3], Jacqueline Zummo[4], Wei Sun[4], Khushboo Belani[4], Eppie Brown[4], Brian Desch[4], McKenna Metcalf[4], Andrea DiFiglia[4], Chen Quin Lam[5], Eugene Kramolowsky[6] on behalf of ADVANCED-2 Investigators

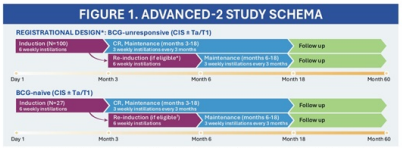
[1]Urology Austin, Austin, TX, United States; [2]Urology Associates P.C., Nashville, TN, United States; [3]Carolina Urologic Research Center, Myrtle Beach, SC, United States; [4]Protara Therapeutics, Inc., New York, NY, United States; [5]Pharmapace Inc., San Diego, CA, United States; [6]Virginia Urology, Richmond, VA, United States

INTRODUCTION

- With the current Bacillus Calmette-Guérin (BCG) shortage and limited effective alternative therapies, there remains a significant unmet need for treatment options for patients with non-muscle invasive bladder cancer (NMIBC).
- TARA-002 is a broad spectrum immune potentiator that elicits a TH1 pro-inflammatory cytokine response.
- TARA-002 is a lyophilized biological preparation for instillation containing cells of *Streptococcus pyogenes* (Group A, type 3) Su strain treated with benzylpenicillin and is being developed for the treatment of high-grade NMIBC.

METHODS

FIGURE 1. ADVANCED-2 STUDY SCHEMA



Abbreviations: BCG = Bacillus Calmette-Guérin; CR = complete response; CIS = carcinoma in situ ; FDA = Food and Drug Administration; HG = high-grade

*Aligned with the FDA's 2024 BCG-Unresponsive NMIBC: Developing Drugs and Biologics for Treatment Guidance for Industry.

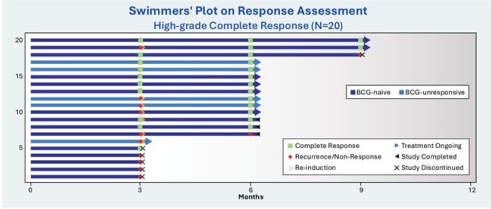
†Residual CIS and/or recurrence of HGTa

- ADVANCED-2 (NCT05951179) is an ongoing, actively enrolling, Phase 2, open-label study to evaluate the safety and efficacy of intravesical instillation of TARA-002 (40 KE) in adults ≥ 18 years with BCG-unresponsive and BCG-naïve (never exposed and those who have not received intravesical BCG for at least 24 months prior to the most recent CIS diagnosis) CIS NMIBC (± Ta/T1) with active disease (**Figure 1**).
- The primary endpoint is high-grade complete response (CR) at any time up to Month 6. Key secondary endpoint is durability of response at Month 12.

Learn more about our study:
NCT05951179
Contact us at **clinicaltrials@protaratx.com** for more information.

RESULTS

FIGURE 2. FIRST RESULTS OF ADVANCED-2: 70% CR AT ANY TIME IN ALL SUBJECTS



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 visit time point were not included.

Central urine cytology is pending for 3 subjects at Month 6 and 1 subject at Month 9.

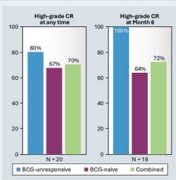
Baseline Characteristics

- All 24 enrolled subjects were white, and the majority were non-Hispanic (96%, 23 of 24) and male (79%, 19 of 24). The median age was 71 years.
- Eastern Cooperative Oncology Group (ECOG) Score was 0 for 75% (18 of 24) of subjects.
- Majority of patients had a baseline diagnosis of CIS only (58%, 14 of 24), and 25% (6 of 24) and 17% (4 of 24) had CIS + Ta and CIS + T1 disease, respectively.

Response Assessment

- The rates of high-grade CR at any time were 70% (14 of 20) overall, 80% (4 of 5) for BCG-unresponsive subjects, and 67% (10 of 15) for BCG-naïve subjects (**Figure 2, Figure 3**).
- The rates of high-grade CR at Month 6 were 72% (13 of 18) overall, 100% (4 of 4) for BCG-unresponsive subjects, and 64% (9 of 14) for BCG-naïve subjects (**Figure 3**).
- 100% (9 of 9) of subjects who were complete responders at Month 3, and continued the study, maintained response through Month 6.
- Of the 5 subjects who did not achieve initial CR and received re-induction, the CR rate at Month 6 was 80% (4 of 5).

FIGURE 3. FIRST RESULTS FROM ADVANCED-2: TARA-002 MONOTHERAPY DEMONSTRATED 72% CR AT 6 MONTHS



	BCG-unresponsive	BCG-naive	Combined
	N = 5	N = 15	N = 20
High-grade CR at any time, n (%)	**4/5 (80.0)**	**10/15 (66.7)**	**14/20 (70.0)**
High-grade CR at Timepoint, n (%)			
Month 6	4/4 (100.0)	9/14 (64.3)	13/18 (72.2)
Month 9	0	2/3 (66.7)	2/3 (66.7)
High-grade CR at any time by Baseline Diagnosis, n (%)			
CIS only	4/5 (80.0)	6/7 (85.7)	10/12 (83.3)
CIS + Ta/T1	0	4/8 (50.0)	4/8 (50.0)
High-grade CR at Month 6 by Baseline Diagnosis, n (%)			
CIS only	4/4 (100.0)	5/6 (83.3)	9/10 (90.0)
CIS + Ta/T1	0	4/8 (50.0)	4/8 (50.0)

Safety

TABLE 1. SUMMARY OF TREATMENT EMERGENT ADVERSE EVENTS IN ALL SUBJECTS

N = 24	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4/5
Subjects with TEAEs, n^ (%)	16 (67)	11 (46)	7 (29)	3 (13)	0
Subjects with Related TEAEs^*, n (%)	6 (25)	6 (25)	0	0	0
Subjects with Serious TEAEs†, n (%)	3 (13)	0	1 (4)	2 (8)	0
Subjects with TEAEs leading to Study Drug Withdrawal, n (%)	0	0	0	0	0

Abbreviations: AE = adverse event; TEAE = treatment emergent AE

^ Subjects may be counted in multiple categories; *TEAEs assessed by the Investigator as study drug related included dysuria, urinary incontinence, fatigue, chills, bladder discomfort, bladder spasm, hematuria and micturition urgency. All were Grade 1; †Non-drug related Serious TEAEs included urinary tract infection (UTI; N = 2) and urosepsis (N = 1).

- Majority of TEAEs were Grade 1 and transient. No subjects experienced drug-related serious AEs (SAEs) or TEAEs leading to withdrawal or death (**Table 1**).
- Common AEs reflect urinary tract instrumentation effects, such as bladder spasm, burning sensation, and UTI.
- AEs were consistent with the known safety profile of an immune-potentiating drug, such as flu-like symptoms.

CONCLUSIONS

- TARA-002 appears to be well tolerated with encouraging efficacy and durability of response in subjects with high-risk NMIBC with CIS.
- Further study is planned to understand the potential of TARA-002 in both the BCG-naïve and BCG-unresponsive population.

Presented at the 2024 Annual Meeting of the Society of Urologic Oncology, December 4-6, 2024; Dallas, Texas

DISCLOSURE: This study is funded by Protara Therapeutics, Inc.