Protara Therapeutics Announces Fourth Quarter and Full Year 2025 Financial Results and Provides a Business Update

March 10, 2026

Reported interim data from ADVANCED-2 trial in non-muscle invasive bladder cancer (NMIBC); TARA-002 demonstrated 68% complete response rate at six months in BCG-Unresponsive patients

Company expects to complete enrollment of the BCG-Unresponsive registrational cohort of the ADVANCED-2 trial in 2H 2026

On track to initiate the ADVANCED-3 registrational trial in BCG-Naïve patients in 2H 2026

Received Breakthrough Therapy and Fast Track designations for TARA-002 in lymphatic malformations (LMs); regulatory update expected in 1H 2026

Expect to report interim results from THRIVE-3 registrational trial of IV Choline Chloride in patients dependent on long-term parenteral support in 2H 2026

Completed oversubscribed $86 million public offering with participation from new and existing investors

Cash, cash equivalents and investments of approximately $198 million as of December 31, 2025, expected to support planned operations into 2028

NEW YORK, March 10, 2026 (GLOBE NEWSWIRE) -- Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage biotechnology company developing transformative therapies for the treatment of cancer and rare diseases, today provided a business update and announced financial results for the fourth quarter and full year ended December 31, 2025.

“Over the last few months, we reported meaningful clinical and regulatory progress across our portfolio of late-stage programs and are building on this momentum as we advance toward several important milestones in 2026,” said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. “For TARA-002 in non-muscle invasive bladder cancer (NMIBC), the clinical dataset continues to support its potential as a differentiated intravesical therapy with compelling efficacy, a favorable safety profile and a streamlined approach to administration in the clinical setting for both Bacillus Calmette-Guérin (BCG)-Unresponsive and BCG-Naïve patients. We remain on track to complete enrollment in our BCG-Unresponsive registrational cohort in the ADVANCED-2 trial and to initiate the ADVANCED-3 registrational trial in BCG-Naïve patients in the second half of 2026.”

Mr. Shefferman added, “For our rare disease programs, we reported positive interim results for TARA-002 in lymphatic malformations (LMs), followed by the receipt of Breakthrough Therapy and Fast Track designations for TARA-002 in LMs from the U.S. Food and Drug Administration (FDA). We are working with the FDA to bring this promising treatment to patients expeditiously and expect to provide a regulatory update in the first half of 2026. In addition, our THRIVE-3 registrational trial of intravenous (IV) Choline Chloride for patients on parenteral support remains on track, with interim results expected in the second half of 2026. With cash runway into 2028, we are well positioned to continue executing across our pipeline and advance our mission of delivering transformational therapies for patients with cancer and rare diseases.”

Recent Progress and Highlights

TARA-002 in NMIBC

- At the ASCO Genitourinary Cancers Symposium in February 2026, the Company announced updated interim results from the ADVANCED-2 trial in evaluable NMIBC patients with carcinoma in situ or CIS (± Ta/T1) who are BCG-Unresponsive and BCG-Naïve. As of the January 28, 2026 data cutoff:
    - In the BCG-Unresponsive cohort of patients, TARA-002 demonstrated a complete response (CR) rate at any time of 65.7% (23/35) with CR rates of 68.2% (15/22) at six months and 33.3% (5/12) at 12 months. Among responders, the Kaplan-Meier (KM) estimated probability of maintaining a CR for six months was 71.1% (95% CI: 46.7, 95.5). Additionally, among responders, 100% (5 of 5) maintained their CR from nine to 12 months. Re-induction therapy was successful with 61.5% (8 of 13) of re-induced patients converting to a CR at six months.
    - In the BCG-Naïve cohort of patients, TARA-002 demonstrated a CR rate at any time of 72.4% (21/29) with CR rates of 66.7% (18 of 27) at six months and 57.9% (11 of 19) at 12 months. Among responders, the KM estimated probability of maintaining a CR for six months was 73.1% (95% CI: 52.9, 93.4). In addition, among responders, 100% (11 of 11) maintained their CR from nine to 12 months. Re-induction therapy was successful with 66.7% (4 of 6) of re-induced patients converting to a CR at six months.
    - The majority of treatment-related adverse events (TRAEs) were Grade 1 and transient with no Grade 3 or greater TRAEs and no related serious adverse events as assessed by study investigators. No patients discontinued treatment due to TRAEs. The most common TRAEs were dysuria, bladder spasm, fatigue and micturition urgency. Most bladder irritations resolved shortly after administration or within a few hours to a few days.
- The Company has completed enrollment of the BCG-Naïve cohort and expects to complete enrollment of the

BCG-Unresponsive cohort in the second half of 2026.

- The Company remains on track to commence ADVANCED-3, a registrational trial of TARA-002 compared to intravesical chemotherapy in BCG-Naïve patients (who have never been exposed and those who have not received BCG within the last 24 months and are ineligible to receive BCG, have a contraindication to BCG, cannot tolerate BCG, do not have access to BCG or refuse BCG) in the second half of 2026.

TARA-002 in LMs

- In January 2026, the Company announced that the FDA granted TARA-002 Fast Track and Breakthrough Therapy designations for the treatment of pediatric patients with macrocystic and mixed cystic LMs. TARA-002 was previously granted Rare Pediatric Disease designation for the treatment of LMs.
- The Company remains on track to share a regulatory update on the registrational path for TARA-002 in LMs in the first half of 2026.

IV Choline Chloride for Patients on Parenteral Support (PS)

- THRIVE-3, the Company's registrational Phase 3 clinical trial, is ongoing, and the Company expects to report interim results in the second half of 2026.

Corporate Update

Fourth Quarter and Full Year 2025 Financial Results

- As of December 31, 2025, unrestricted cash and cash equivalents and marketable debt securities totaled $197.9 million, including proceeds from the Company's $86.3 million public offering in December 2025. The Company expects its cash and cash equivalents and marketable debt securities will be sufficient to fund its planned operations and milestones into 2028.
- Research and development expenses for the fourth quarter of 2025 increased to $13.1 million from $9.5 million for the prior year period, and for the full year increased to $42.6 million compared to $31.7 million for 2024. The fourth quarter and full year increases were primarily due to the start-up and advancement of clinical trials across our portfolio.
- General and administrative expenses for the fourth quarter of 2025 increased to $6.0 million from $4.8 million for the prior year period, and for the full year increased to $21.9 million compared to $17.5 million for 2024. The fourth quarter and full year increases were primarily due to increases in personnel-related expenses and other general and administrative expenses primarily related to professional and consulting services.
- For the fourth quarter of 2025, Protara incurred a net loss of $17.3 million, or $0.37 per share, compared with a net loss of $12.8 million, or $0.48 per share, for the same period in 2024. Net loss for the year ended December 31, 2025 was $57.4 million, or $1.34 per share, compared with a net loss of $44.6 million, or $2.17 per share, for the year ended December 31, 2024. Net loss for the fourth quarter of 2025 included approximately $1.0 million in stock-based compensation expenses. Net loss for the year ended December 31, 2025 included approximately $3.8 million in stock-based compensation expenses.

About ADVANCED-2

ADVANCED-2 (NCT05951179) is a Phase 2 open-label trial assessing intravesical TARA-002 in non-muscle invasive bladder cancer (NMIBC) patients with carcinoma in situ or CIS (± Ta/T1) who are Bacillus Calmette-Guérin (BCG)-Unresponsive (Cohort B N=75-100) or BCG-Naïve (Cohort A N=31). Trial subjects received an induction course, with or without a reinduction, of six weekly intravesical instillations of TARA-002, followed by a maintenance course of three weekly instillations every three months. The BCG-Unresponsive cohort is designed to be registrational based on the FDA's August 2024 Draft Guidance for Industry on BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biological Products for Treatment.

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, Breakthrough and Fast Track designations by the FDA. TARA-002 is a first-in-class TLR2/NOD2 agonist and novel immunopotentiator derived from inactivated *Streptococcus pyogenes* with a mechanism of action that includes the activation of innate and adaptive immune pathways within the bladder wall. 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 the release of cytokines such as tumor necrosis factor (TNF)-alpha, interferon (IFN)-gamma, IL-6, IL-10 and IL-12. 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.

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 by Chugai Pharmaceutical Co., Ltd. Protara has successfully shown manufacturing comparability between TARA-002 and OK-432.

About Non-Muscle Invasive Bladder Cancer

Bladder cancer is the sixth most common cancer in the United States, with non-muscle invasive bladder cancer (NMIBC) representing approximately 80% of bladder cancer diagnoses, or approximately 65,000 patients in the U.S. 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 Lymphatic Malformations

Lymphatic Malformations (LMs) are rare, congenital malformations of lymphatic vessels resulting in the failure of these structures to connect or drain into the venous system. Protara's focus is on macrocystic and mixed cystic LMs, for which there are no currently approved therapies. They are most frequently present in the head and neck region and are diagnosed in early childhood during the period of active lymphatic growth, with more than 50% detected at birth and 90% diagnosed before the age of three years. The most common morbidities and serious manifestations of the disease include compression of the upper aerodigestive tract, including airway obstruction requiring intubation and possible tracheostomy dependence; intralesional bleeding; impingement on critical structures, including nerves, vessels and lymphatics; recurrent infection; and cosmetic and other functional disabilities. TARA-002 has been granted Rare Pediatric Disease, Breakthrough Therapy and Fast Track designations by the FDA for the treatment of LMs.

About IV Choline Chloride for Patients on Parenteral Support

IV Choline Chloride is an investigational, intravenous phospholipid substrate replacement therapy in development for patients receiving parenteral support (PS). Choline is a known important substrate for phospholipids that are critical for healthy liver function and play an important role in modulating gene expression, cell membrane signaling, brain development and neurotransmission, muscle function and bone health. PS patients are unable to synthesize choline from enteral nutrition sources, and there are currently no available PS formulations containing choline. Approximately 78% of patients dependent on PS are choline-deficient and of those approximately 63% have some degree of liver dysfunction, which can lead to hepatic failure. Every year in the U.S. there are approximately 90,000 people who require PS at home and of those approximately 30,000 are on long-term PS. IV Choline Chloride has the potential to become the first FDA approved IV choline formulation for PS patients. It has been granted Orphan Drug designation by the FDA for the prevention and/or treatment of choline deficiency in patients on long-term parenteral nutrition and has been granted Fast Track designation as a source of choline when oral or enteral nutrition is not possible, insufficient or contraindicated. The U.S. Patent and Trademark Office has issued Protara a U.S. patent claiming a choline composition and a U.S. patent claiming a method for treating choline deficiency with a choline composition, each with a term expiring in 2041.

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, 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 the timing of any particular phases of such trials and the timing of the announcement of any data produced during such trials or phases thereof); statements related to expectations regarding interactions with the U.S. Food and Drug Administration (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.

Protara Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2025	**2024**
Assets		

Current assets:		
Cash and cash equivalents	$ 49,657	$ 162,798
Marketable debt securities	105,897	7,494
Prepaid expenses and other current assets	3,950	1,863
Total current assets	159,504	172,155
Restricted cash, non-current	745	745
Marketable debt securities, non-current	42,336	-
Property and equipment, net	759	1,027
Operating lease right-of-use asset	3,174	4,255
Other assets	2,950	3,272
Total assets	$ 209,468	$ 181,454
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,468	$ 4,429
Accrued expenses and other current liabilities	6,229	5,408
Operating lease liability	1,242	1,124
Total current liabilities	10,939	10,961
Operating lease liability, non-current	2,117	3,359
Total liabilities	13,056	14,320
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.001 par value, authorized 10,000,000 shares:		
Series 1 convertible preferred stock, 8,028 shares authorized at December 31, 2025 and 2024, 5,615 and 7,991 shares issued and outstanding as of December 31, 2025 and 2024, respectively.	-	-
Common stock, $0.001 par value, authorized 100,000,000 shares:		
Common stock, 53,587,260 and 35,044,772 shares issued and outstanding as of December 31, 2025 and 2024, respectively.	54	35
Additional paid-in capital	498,687	412,077
Accumulated deficit	(302,419)	(244,980)
Accumulated other comprehensive income (loss)	90	2
Total stockholders' equity	196,412	167,134
Total liabilities and stockholders' equity	$ 209,468	$ 181,454

PROTARA THERAPEUTICS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	(Unaudited) For the Three Months Ended December 31,		(Audited) For the Years Ended December 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 13,124	$ 9,499	$ 42,633	$ 31,704
General and administrative	5,955	4,813	21,916	17,450
Total operating expenses	19,079	14,312	64,549	49,154
Income (Loss) from operations	(19,079)	(14,312)	(64,549)	(49,154)
Other income (expense), net:				
Interest and investment income (expense)	1,523	1,156	6,380	4,171
Other income (expense)	249	387	730	387
Other income (expense), net	1,772	1,543	7,110	4,558
Net income (loss)	(17,307)	(12,769)	(57,439)	(44,596)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable debt securities	(53)	(27)	88	33
Other comprehensive income (loss):	(53)	(27)	88	33
Comprehensive income (loss)	$ (17,360)	$ (12,796)	$ (57,351)	$ (44,563)

Net income (loss) per share attributable to common stockholders, basic and diluted	$ (0.37)	$ (0.48)	$ (1.34)	$ (2.17)
Weighted-average shares outstanding, basic and diluted	46,041,210	26,432,563	42,836,129	20,592,847

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