Protara Therapeutics Announces First Quarter 2026 Financial Results and Provides a Business Update

May 13, 2026

The Company intends to submit a Biologics License Application (BLA) for TARA-002 in Lymphatic Malformations (LMs) in 2H 2027

Hosting virtual investor webinar discussing LMs program with key opinion leader (KOL) perspectives on May 19, 2026 at 4:30 pm ET

Interim safety and durability data from STARBORN-1 trial of TARA-002 in LMs to be presented at the International Society for the Study of Vascular Anomalies (ISSVA) World Congress 2026 in May

Company expects to complete enrollment of the BCG-Unresponsive registrational cohort of the ADVANCED-2 trial and initiate the ADVANCED-3 registrational trial in BCG-Naïve patients in 2H 2026

Presenting updated 12-month data from Phase 2 ADVANCED-2 trial of TARA-002 in patients with high-grade, BCG-Naïve non-muscle invasive bladder cancer (NMIBC) at the American Urological Association (AUA) Annual Meeting 2026 in May

Cash, cash equivalents and investments of approximately $177 million as of March 31, 2026, expected to support planned operations into 2028

NEW YORK, May 13, 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 first quarter ended March 31, 2026.

“We’re pleased with the productive discussions we’ve had with the FDA around TARA-002 in LMs,” said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. “We intend to submit a BLA for TARA-002 in LMs based on the results of the pivotal STARBORN-1 trial in the second half of 2027. Later this month, we look forward to presenting updated safety and durability data from the STARBORN-1 trial at the ISSVA World Congress and hosting an investor webinar with KOL perspectives.”

Mr. Shefferman added, “In NMIBC, we continue to establish TARA-002's potential as a differentiated treatment through a robust clinical data set demonstrating excellent safety, promising efficacy and encouraging durability, as well as a convenient and tolerable method of administration, in both Bacillus Calmette-Guérin (BCG)-Unresponsive and BCG-Naive patients. Looking ahead, we remain focused on completing enrollment in the BCG-Unresponsive registrational cohort in the ADVANCED-2 trial and initiating the ADVANCED-3 registrational trial in BCG-Naïve patients, both in the second half of the year. Additionally, our THRIVE-3 program for IV Choline Chloride remains on track, and we expect to announce interim results in the second half of 2026.”

Recent Progress and Highlights

TARA-002 in LMs

- Under Breakthrough Therapy designation, Protara is engaged in an ongoing dialogue with the FDA and has received confirmation that the review of TARA-002 has been moved from the Office of Vaccines Research and Review to the Office of Therapeutic Products, which has significant experience in pediatric rare disease and is the review division for TARA-002 in NMIBC.
- Based on engagement with the FDA, the Company intends to submit a BLA for TARA-002 in LMs based on the results of the pivotal STARBORN-1 trial in the second half of 2027 and will continue to submit safety and efficacy data from the trial on an ongoing basis to support the FDA’s evaluation of the risks and benefits of TARA-002 in LMs.
- Protara plans to host a virtual investor webinar discussing TARA-002 in LMs at 4:30 pm ET on May 19, 2026. The event will provide an overview of TARA-002 in LMs, KOL perspectives on the unmet need and TARA-002’s potential role in the treatment paradigm. The live event and accompanying slides can be accessed visiting the Events and Presentations section of the Company’s website https://ir.protaratx.com. A replay of the webcast will be archived for a limited time following the event.
- The Company will present updated interim safety and durability data from the ongoing Phase 2 STARBORN-1 trial evaluating TARA-002 in macrocystic and mixed cystic LMs in a poster session at the ISSVA World Congress on May 20, 2026 in Philadelphia, Pennsylvania.

TARA-002 in NMIBC

- The Company expects to complete enrollment of the BCG-Unresponsive cohort of the ADVANCED-2 trial in the second half of 2026.

- The Company will present updated 12-month landmark results for TARA-002 in BCG-Naïve NMIBC patients in Cohort A of the ADVANCED-2 trial during a poster presentation at the AUA Annual Meeting on May 15, 2026 in Washington, D.C.
- The Company is planning a proposed registrational trial in BCG-Naïve and potentially BCG-Exposed patients. Protara continues to engage with the FDA on aspects of the analysis plan and intends to initiate the ADVANCED-3 trial in the second 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.

First Quarter 2026 Financial Results

- As of March 31, 2026, unrestricted cash and cash equivalents and marketable debt securities totaled $177.4 million. 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 first quarter of 2026 increased to $13.6 million from $9.1 million for the prior year period. This increase was primarily due to a $2.2 million increase in direct expenses for our product candidates and a $2.2 million increase in indirect expenses not directly attributable to one specific product candidate. The increase in direct expenses was primarily due to higher ongoing costs associated with the ADVANCED-2 trial for NMIBC as well as start-up costs related to the ADVANCED-3 trial for NMIBC.
- General and administrative expenses for the first quarter of 2026 increased to $6.1 million from $5.0 million for the prior year period. The increase was primarily due to personnel-related expenses, including stock-based compensation.
- For the first quarter of 2026, Protara incurred a net loss of $17.8 million, or $0.31 per share, compared with a net loss of $11.9 million, or $0.29 per share, for the same period in 2025. Net loss for the first quarter of 2026 included approximately $1.4 million in stock-based compensation expenses.

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, Orphan Drug, Breakthrough Therapy 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. 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.

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, Orphan Drug, 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 of 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 pivotal 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. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands, except share and per share data)

	As of	
	March 31, 2026	**December 31, 2025**
Assets		
Current assets:		
Cash and cash equivalents	$ 14,737	$ 49,657
Marketable debt securities	121,049	105,897
Prepaid expenses and other current assets	4,211	3,950
Total current assets	139,997	159,504
Restricted cash, non-current	745	745
Marketable debt securities, non-current	41,641	42,336
Property and equipment, net	669	759
Operating lease right-of-use asset	2,891	3,174
Other assets	5,980	2,950
Total assets	$ 191,923	$ 209,468
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,031	$ 3,468
Accrued expenses and other current liabilities	3,627	6,229
Operating lease liability	1,264	1,242
Total current liabilities	8,922	10,939
Operating lease liability, non-current	1,793	2,117
Total liabilities	10,715	13,056
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 March 31, 2026 and December 31, 2025, 4,644 and 5,615 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	-	-
Common stock, $0.001 par value, authorized 100,000,000 shares:		
Common stock, 55,055,582 and 53,587,260 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	55	54
Additional paid-in capital	501,718	498,687
Accumulated deficit	(320,201)	(302,419)
Accumulated other comprehensive income (loss)	(364)	90
Total stockholders' equity	181,208	196,412
Total liabilities and stockholders' equity	$ 191,923	$ 209,468

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

	For the Three Months Ended March 31,	
	2026	**2025**
Operating expenses:		
Research and development	$ 13,562	$ 9,148
General and administrative	6,067	4,976
Total operating expenses	19,629	14,124
Income (Loss) from operations	(19,629)	(14,124)
Other income (expense), net:		
Interest and investment income (expense)	1,847	1,729
Other income (expense)	-	481
Other income (expense), net	1,847	2,210
Net income (loss)	$ (17,782)	$ (11,914)
Other comprehensive income (loss):		
Net unrealized gain (loss) on marketable debt securities	(454)	87
Other comprehensive income (loss)	(454)	87
Comprehensive income (loss)	$ (18,236)	$ (11,827)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (0.31)	$ (0.29)
Weighted-average shares outstanding, basic and diluted	57,538,833	40,707,937

Company Contact:

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

Source: Protara Therapeutics