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

August 11, 2026

Expect to complete enrollment of the BCG-Unresponsive registrational cohort of the ADVANCED-2 trial in 4Q 2026

The ADVANCED-3 trial is being redesigned as an exploratory trial to expand into and accelerate data in high-grade, high-risk BCG-Naïve and BCG-Exposed CIS (± Ta/T1) patients and papillary (Ta/T1) patients across BCG exposures

Expect to provide an update and complete enrollment of the STARBORN-1 trial in LMs in 4Q 2026; expect to submit a Biologics License Application for TARA-002 in LMs in 2H 2027

On track to report interim results from THRIVE-3 registrational trial of IV Choline Chloride in patients dependent on long-term parenteral support in 4Q 2026

Cash, cash equivalents and investments of approximately $162 million as of June 30, 2026, expected to support planned operations into 2028

NEW YORK, Aug. 11, 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 announced financial results for the second quarter ended June 30, 2026 and provided a business update.

“In the second quarter, we strengthened our late-stage pipeline through continued operational execution, positioning us for multiple important milestones over the coming quarters,” said Jesse Shefferman, Chief Executive Officer at Protara Therapeutics. “We continue to make progress in the ADVANCED-2 trial and expect to complete enrollment in the fourth quarter of 2026. We remain confident that TARA-002 will be a preferred treatment option in the non-muscle invasive bladder cancer (NMIBC) BCG-Unresponsive setting, and we are redesigning ADVANCED-3 to be a multi-cohort, open-label, exploratory trial, which will allow us to study TARA-002 in a broader high-grade, high-risk NMIBC patient population. The redesigned ADVANCED-3 protocol is expected to accelerate and expand the breadth of data available at or around the time of the potential launch of TARA-002 in BCG-Unresponsive carcinoma in situ (CIS) patients.”

Mr. Shefferman added, “We also advanced our rare disease programs during the quarter. We recently presented encouraging interim durability and safety data from the STARBORN-1 pivotal trial of TARA-002 in Lymphatic Malformations (LMs) and, following discussions with the FDA, expect to submit our Biologics License Application (BLA) in the second half of 2027. At the same time, enrollment in the THRIVE-3 registrational trial evaluating IV Choline Chloride continues as planned, with interim results expected in the fourth quarter of this year. As we continue to execute across our portfolio, we believe we are well positioned to deliver a series of important clinical, regulatory and operational catalysts that have the potential to create meaningful value for patients and shareholders.”

Recent Progress and Highlights

TARA-002 in NMIBC

- The Company expects to complete enrollment of the BCG-Unresponsive cohort in the fourth quarter of 2026.
- The Company is redesigning the recently initiated ADVANCED-3 trial to be a multi-cohort, open-label, exploratory trial to evaluate the efficacy and safety of intravesical TARA-002 in high-grade, high-risk BCG-Naïve and BCG-Exposed CIS (± Ta/T1) patients and papillary (Ta/T1) patients across BCG exposures. Importantly, this new design allows Protara to accelerate and expand the breadth of TARA-002 data in a broader high-grade, high-risk NMIBC patient population.

TARA-002 in LMs

- Protara presented updated interim safety and durability data from the ongoing Phase 2 STARBORN-1 trial evaluating TARA-002 in pediatric patients with macrocystic and mixed cystic LMs in a poster session at the International Society for the Study of Vascular Anomalies World Congress in Philadelphia, Pennsylvania. As of an April 10, 2026 data cutoff:
  - TARA-002 demonstrated clinical success in 83% (10/12) of participants that completed treatment and in 100% (10/10) of evaluable patients. All seven participants that reached the 32-week post-treatment assessment remained disease free as of the data cutoff.
  - The majority of AEs were mild to moderate, with no serious AEs reported. The most common AEs were swelling and fatigue, and most were transient and resolved within a few days.
- Based on engagement with the FDA under Breakthrough Therapy designation, 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.

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 fourth quarter of 2026.

Second Quarter 2026 Financial Results

- As of June 30, 2026, unrestricted cash and cash equivalents and marketable debt securities totaled $161.9 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 second quarter of 2026 increased to $17.0 million from $10.8 million for the prior year period. This increase was primarily due to higher direct costs associated with ongoing clinical trials of $3.2 million, increased personnel-related expenses of $1.8 million and increased non-program specific research and development expenses, primarily attributable to chemistry, manufacturing and controls of $1.2 million.
- General and administrative expenses for the second quarter of 2026 increased to $6.4 million from $5.8 million for the prior-year period. The increase was primarily due to an increase in personnel-related expenses of $0.7 million, offset by a decrease in other general and administrative expenses of $0.1 million.
- For the second quarter of 2026, Protara incurred a net loss of $21.7 million, or $0.36 per share, compared with a net loss of $15.0 million, or $0.35 per share, for the prior-year period.

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 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.

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. Patients suffering from high-grade, high-risk NMIBC face high rates of disease recurrence and are potentially subject to full removal of the bladder (cystectomy).

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. More than 50% of LMs are 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 an 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. There are currently no available PS formulations containing choline. 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 ongoing clinical trials 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	
	June 30, 2026	**December 31, 2025**
Assets		
Current assets:		
Cash and cash equivalents	$ 17,076	$ 49,657
Marketable debt securities	125,418	105,897
Prepaid expenses and other current assets	3,658	3,950
Total current assets	146,152	159,504
Restricted cash, non-current	745	745
Marketable debt securities, non-current	19,356	42,336
Property and equipment, net	1,318	759
Operating lease right-of-use asset	2,602	3,174
Other assets	5,920	2,950
Total assets	$ 176,093	$ 209,468
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable	$ 4,663	$ 3,468
Accrued expenses and other current liabilities	7,370	6,229
Operating lease liability	1,286	1,242
Total current liabilities	13,319	10,939
Operating lease liability, non-current	1,463	2,117
Total liabilities	14,782	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 June 30, 2026 and December 31, 2025, 872 and 5,615 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	-	-
Common stock, $0.001 par value, 200,000,000 and 100,000,000 shares authorized at June 30, 2026 and December 31, 2025, respectively:		
Common stock, 59,083,935 and 53,587,260 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	59	54
Additional paid-in capital	503,484	498,687
Accumulated deficit	(341,869)	(302,419)
Accumulated other comprehensive income (loss)	(363)	90
Total stockholders’ equity	161,311	196,412

Total liabilities and stockholders' equity	$ 176,093	$ 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 June 30,		For the Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 16,955	$ 10,770	$ 30,517	$ 19,918
General and administrative	6,369	5,816	12,436	10,792
Total operating expenses	23,324	16,586	42,953	30,710
Income (Loss) from operations	(23,324)	(16,586)	(42,953)	(30,710)
Other income (expense), net:				
Interest and investment income (expense)	1,656	1,626	3,503	3,355
Other income (expense)	-	-	-	481
Other income (expense), net	1,656	1,626	3,503	3,836
Net income (loss)	$ (21,668)	$ (14,960)	$ (39,450)	$ (26,874)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable debt securities	1	(12)	(453)	75
Other comprehensive income (loss)	1	(12)	(453)	75
Comprehensive income (loss)	$ (21,667)	$ (14,972)	$ (39,903)	$ (26,799)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (0.36)	$ (0.35)	$ (0.67)	$ (0.65)
Weighted-average shares outstanding, basic and diluted	61,006,766	42,270,855	59,282,380	41,493,714

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