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

November 6, 2026

Expect to complete enrollment of the BCG-Unresponsive registrational cohort of the ADVANCED-2 trial of TARA-002 in NMIBC by year-end 2026

Enrollment in registrational STARBORN-1 trial now expected to complete in early 1Q 2027; expect to initiate a rolling BLA submission for TARA-002 in LMs in 2H 2027

Completed enrollment of THRIVE-3 Phase 2b dosing cohort evaluating IV Choline Chloride in patients dependent on long-term parenteral support; remain on track to report interim results by year-end 2026

Entered into an asset purchase agreement with Novex Innovations for TARA-002 manufacturing-related assets for $8.75 million

Cash, cash equivalents and investments of approximately $143 million as of September 30, 2026, expected to support planned operations into 2028

NEW YORK, Nov. 06, 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 third quarter ended September 30, 2026 and provided a business update.

“Protara continues to deliver across our late-stage portfolio, advancing each of our programs toward its next key clinical and regulatory milestone. This steady progress positions us to close out the year with strong momentum and sets the stage for an impactful 2027,” said Jesse Shefferman, Chief Executive Officer at Protara Therapeutics. “TARA-002 has the potential to be a preferred treatment option for patients with non-muscle invasive bladder cancer (NMIBC), and we are on track to complete enrollment of the BCG-Unresponsive registrational cohort by year-end, a key step toward bringing this therapy to patients. Following quarter end, we also entered into a purchase agreement for TARA-002 manufacturing-related assets from Novex Innovations, LLC, our clinical supply partner since 2019. We are excited to bring this manufacturing capability in-house as we advance our late-stage clinical trials and prepare to launch TARA-002 in lymphatic malformations (LMs) and NMIBC.”

Mr. Shefferman added, “Turning to our rare disease pipeline, we now expect to complete enrollment of the registrational STARBORN-1 trial of TARA-002 in LMs early in the first quarter of 2027. Supported by the program’s Breakthrough Therapy designation, we remain on track to initiate our rolling Biologics License Application (BLA) submission in the second half of 2027. We also completed enrollment of the Phase 2b portion of the THRIVE-3 trial of IV Choline Chloride and look forward to reporting interim results by the end of this year.”

Recent Progress and Highlights

TARA-002 in NMIBC

- The Company expects to complete enrollment of the BCG-Unresponsive cohort of the ADVANCED-2 trial in the fourth quarter of 2026.
- During the third quarter of 2026, the Company announced its intent to redesign the ongoing ADVANCED-3 trial. The redesigned ADVANCED-3 trial is expected to be a multi-cohort, open-label trial evaluating the efficacy and safety of intravesical TARA-002 in BCG-Naïve and BCG-Exposed CIS (± Ta/T1) and high-grade, high-risk (HG-HR) papillary (Ta/T1) patients across BCG exposures. The trial is intended to generate a broad body of clinical evidence across HG-HR NMIBC patients. The Company believes this positions TARA-002 to benefit from the recent approach from the U.S. Food and Drug Administration (FDA) to expand the label of a previously approved product for BCG-Unresponsive CIS NMIBC to include HG-HR BCG-Unresponsive papillary disease based on a single-arm trial.

TARA-002 in LMs

- The Company now expects to complete enrollment in the STARBORN-1 trial early in the first quarter of 2027.
- Based on engagement with the FDA under Breakthrough Therapy designation, the Company expects to initiate a rolling BLA submission for TARA-002 in the second half of 2027.

IV Choline Chloride for Patients on Parenteral Support (PS)

- Protara completed enrollment of the Phase 2b portion of the THRIVE-3 trial evaluating IV Choline Chloride in patients on PS. THRIVE-3 (NCT06910943) is a registrational Phase 2b/3 clinical trial evaluating the efficacy and safety of IV Choline Chloride in adolescent and adult patients with intestinal failure who are dependent on PS and have choline deficiency. The Phase 2b portion of the THRIVE-3 trial is an open-label dose confirmation, which enrolled 24 patients.

- The Company remains on track to report interim results from the Phase 2b portion of THRIVE-3 in the fourth quarter of 2026.

Corporate Update

- On November 4, 2026, Protara entered into an asset purchase agreement with Novex Innovations, LLC for TARA-002 manufacturing-related assets for an aggregate purchase price of $8.75 million. Novex has manufactured TARA-002 for Protara since 2019 under a Manufacturing Services Agreement. The Company completed the acquisition to bring manufacturing in-house and secure dedicated manufacturing capacity ahead of a potential commercial launch. The transaction included an assembled workforce, inventory, intellectual property, contracts, equipment, permits, regulatory documentation and records. The Company also entered into certain ancillary agreements, including a transition services agreement and a lease for a research and manufacturing facility.

Third Quarter 2026 Financial Results

- As of September 30, 2026, unrestricted cash and cash equivalents and marketable debt securities totaled $143.1 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 third quarter of 2026 increased to $16.8 million from $9.6 million for the prior-year period. This increase was primarily due to higher direct costs associated with ongoing clinical trials of $4.4 million, personnel-related expenses of $2.0 million and non-program specific research and development expenses, primarily related to TARA-002 chemistry, manufacturing and controls of $0.8 million.
- General and administrative expenses for the third quarter of 2026 increased to $6.3 million from $5.2 million for the prior-year period. The increase was primarily due to personnel-related expenses of $0.6 million and other general and administrative expenses of $0.6 million.
- For the third quarter of 2026, Protara incurred a net loss of $21.7 million, or $0.35 per share, compared with a net loss of $13.3 million, or $0.31 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% are 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	
	September 30, 2026	**December 31, 2025**
Assets		
Current assets:		
Cash and cash equivalents	$ 25,150	$ 49,657
Marketable debt securities	101,900	105,897
Prepaid expenses and other current assets	2,617	3,950
Total current assets	129,667	159,504
Restricted cash, non-current	745	745
Marketable debt securities, non-current	16,031	42,336
Property and equipment, net	1,581	759
Operating lease right-of-use asset	2,308	3,174
Other assets	6,209	2,950
Total assets	$ 156,541	$ 209,468
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,862	$ 3,468
Accrued expenses and other current liabilities	8,220	6,229
Operating lease liability	1,309	1,242
Total current liabilities	14,391	10,939
Operating lease liability, non-current	1,127	2,117
Total liabilities	15,518	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 September 30, 2026 and December 31, 2025, 0 and 5,615 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	-	-
Common stock, $0.001 par value, 200,000,000 and 100,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively:		
Common stock, 59,967,669 and 53,587,260 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	60	54
Additional paid-in capital	505,070	498,687
Accumulated deficit	(363,557)	(302,419)
Accumulated other comprehensive income (loss)	(550)	90
Total stockholders' equity	141,023	196,412
Total liabilities and stockholders' equity	$ 156,541	$ 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 September 30,		For the Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 16,805	$ 9,591	$ 47,322	$ 29,509
General and administrative	6,349	5,169	18,785	15,961
Total operating expenses	23,154	14,760	66,107	45,470
Income (Loss) from operations	(23,154)	(14,760)	(66,107)	(45,470)
Other income (expense), net:				
Interest and investment income (expense)	1,466	1,502	4,969	4,857
Other income (expense)	-	-	-	481
Other income (expense), net	1,466	1,502	4,969	5,338
Net income (loss)	$ (21,688)	$ (13,258)	$ (61,138)	$ (40,132)
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable debt securities	(187)	66	(640)	141
Other comprehensive income (loss)	(187)	66	(640)	141
Comprehensive income (loss)	$ (21,875)	$ (13,192)	$ (61,778)	$ (39,991)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (0.35)	$ (0.31)	$ (1.01)	$ (0.96)
Weighted-average shares outstanding, basic and diluted	62,850,743	42,272,104	60,484,905	41,756,028

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