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): May 4, 2023

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 2.02. Results of Operations and Financial Condition.

On May 4, 2023, Protara Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2023 in the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing regardless of any general incorporation language.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated May 4, 2023, issued by the Registrant.
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.

PROTARA THERAPEUTICS, INC.

Date: May 4, 2023

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

Exhibit 99.1

Protara Therapeutics Announces First Quarter 2023 Financial Results and Business Update

- *Favorable tolerability and anti-tumor activity observed in NMIBC patients treated with TARA-002 in ADVANCED-1 trial*
- *Company plans to initiate ADVANCED-2 trial in BCG-naïve CIS patients and BCG-unresponsive CIS patients in 2H23*
- *Regulatory clearance received from FDA to commence Phase 2 trial of TARA-002 in Lymphatic Malformations; trial expected to initiate in Q423*
- *Continue to expect cash, cash equivalents and investments of $90M as of March 31, 2023 to fund operations into 2025*

NEW YORK, May 4, 2023 – Protara Therapeutics, Inc. (Nasdaq: TARA), a clinical-stage company developing transformative therapies for the treatment of cancer and rare diseases, today announced financial results for the first quarter ended March 31, 2023 and provided a business update.

"We are off to a strong start in 2023, notably with the recent presentation of positive preliminary data from the dose escalation portion of the ADVANCED-1 trial of TARA-002 in patients with high-grade non-muscle invasive bladder cancer (NMIBC) and expect to sustain this productive momentum in the months ahead," said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. "Supported by these exciting preliminary findings, we are keenly focused on continued execution across the NMIBC program, including the recently announced Phase 1b/2 ADVANCED-2 trial of TARA-002 in patients with high-grade carcinoma in situ (CIS), which we expect to commence in the second half of this year. With final regulatory clearance from the U.S. Food and Drug Administration (FDA) on our Phase 2 trial in lymphatic malformations (LMs), we look forward to initiating STARBORN-1 in the near future and progressing our program to bring a much-needed therapy to these pediatric patients who have no approved treatments today. We remain committed to unlocking the full potential of TARA-002 and look forward to sharing our progress throughout the coming quarters."

Recent Highlights

TARA-002 in NMIBC

- In April 2023 at the American Urological Association Annual Meeting, the Company announced positive preliminary results from the Phase 1a dose-escalation component of the ADVANCED-1 clinical trial of TARA-002, its investigational cell-based therapy, for the treatment of patients with high-grade NMIBC. The clinical data indicate that TARA-002 was generally well tolerated and anti-tumor activity was observed, including tumor regression in all three evaluable patients with CIS, including one heavily pre-treated Bacillus Calmette-Guérin (BCG)-unresponsive patient who achieved a complete response.

- The Company plans to initiate ADVANCED-2, a Phase 1b/2 open-label trial evaluating intravesical TARA-002 in up to 102 patients with high-grade CIS. The Phase 1b trial is expected to enroll 27 patients with CIS (± Ta/T1), BCG-Naïve or BCG-experienced, who have not received intravesical BCG for at least 24 months prior to CIS diagnosis. The Phase 2 trial is expected to enroll 75 patients with BCG-unresponsive CIS (± Ta/T1). ADVANCED-2 is expected to initiate in the second half of 2023.

TARA-002 in Lymphatic Malformations (LMs)

- In April 2023, the Company received regulatory clearance from the FDA to commence STARBORN-1, a Phase 2 clinical trial of TARA-002 in pediatric patients with macrocystic and mixed-cystic LMs. Trial start-up activities are well underway in the ten pediatric centers of excellence participating in the trial, and initiation is expected in the fourth quarter of 2023.

IV Choline Chloride in Intestinal Failure Associated Liver Disease (IFALD)

- Protara's prospective study to enhance understanding of the incidence of IFALD in patients dependent on parenteral nutrition is ongoing, with results expected in the third quarter of 2023. The Company continues to engage with the FDA and plans to use both regulatory feedback and results from the prospective study to inform next steps for the IV Choline Chloride development program.

First Quarter 2023 Financial Results

- As of March 31, 2023, cash, cash equivalents and restricted cash were $89.5 million. The Company expects its current cash and cash equivalents will be sufficient to fund its planned operations into 2025.

- Research and development (R&D) expenses for the first quarter of 2023 decreased to $5.1 million from $5.3 million during the first quarter of 2022.

- General and administrative expenses for the first quarter of 2023 decreased to $4.6 million from $5.6 million for the prior year period. This decrease was primarily due to decreases of $0.5 million in employee related expenses (including $0.3 million of stock-based compensation expense), $0.3 million resulting from a reduction in directors and officers liability insurance premiums, as well as $0.2 million related to a reduction in market development activities.

- For the first quarter of 2023, Protara reported a net loss of $9.0 million, or $0.80 per share, compared with a net loss of $10.8 million, or $0.96 per share, for the same period in 2022. Net loss for the first quarter of 2023 included approximately $1.6 million of 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 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 strong immune cascade. Neutrophils, monocytes and lymphocytes infiltrate the abnormal cells and various cytokines, including interleukins IL-2, IL-6, IL-8, IL-10, IL-12, interferon (IFN)-gamma, and tumor necrosis factor (TNF)-alpha are secreted by immune cells to induce a strong inflammatory reaction and destroy the abnormal cells.

About Non-Muscle Invasive Bladder Cancer (NMIBC)

Bladder cancer is the 6th 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 Lymphatic Malformations (LMs)

LMs are rare, congenital malformations of lymphatic vessels resulting in the failure of these structures to connect or drain into the venous system. Most LMs are 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 3 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, lymphatics; recurrent infection, and cosmetic and other functional disabilities.

About IV Choline Chloride and Intestinal Failure-associated Liver Disease (IFALD)

IV Choline Chloride is an investigational, intravenous (IV) phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition (PN) who have IFALD. Choline is a known important substrate for phospholipids that are critical for healthy liver function. Because PN patients cannot sufficiently absorb adequate levels of choline and no available PN formulations contain sufficient amounts of choline to correct this deficiency, PN patients often experience a prolonged progression to hepatic failure and death, with the only known intervention being a dual small bowel/liver transplant. If approved, IV Choline Chloride would be the first approved therapy for IFALD. It has been granted Orphan Drug Designations (ODDs) by the FDA for the treatment of IFALD and the prevention of choline deficiency in PN patients.

About Protara Therapeutics, Inc.

Protara is committed to advancing transformative therapies for people with cancer and rare diseases. Protara's portfolio includes its lead program, TARA-002, an investigational cell-based therapy being developed for the treatment of non-muscle invasive bladder cancer and lymphatic malformations, and IV Choline Chloride, an investigational phospholipid substrate replacement for patients dependent on parenteral nutrition. 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; 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. 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; 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 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
(in thousands, except share and per share data)

	As of	
	March 31, 2023	**December 31, 2022**
Assets	**(unaudited)**	
Current assets:		
Cash and cash equivalents	$ 21,035	$ 24,127
Marketable debt securities	65,575	60,243
Prepaid expenses and other current assets	8,006	1,776
Total current assets	94,616	86,146
Restricted cash, non-current	745	745
Marketable debt securities, non-current	2,893	17,886
Property and equipment, net	1,521	1,592
Operating lease right-of-use asset	6,044	6,277
Other assets	586	644
Total assets	$ 106,405	$ 113,290
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,081	$ 1,586
Accrued expenses	1,396	3,237
Operating lease liability	933	917
Total current liabilities	6,410	5,740
Operating lease liability, non-current	5,227	5,467
Total liabilities	11,637	11,207
Commitments and contingencies (Note 8)		
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, 2023 and December 31, 2022, 8,027 shares issued and outstanding as of March 31, 2023 and December 31, 2022.	-	-
Common stock, $0.001 par value, authorized 100,000,000 shares: Common stock, 11,306,753 and 11,267,389 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively.	11	11
Additional paid-in capital	264,235	262,724
Accumulated deficit	(169,009)	(159,964)
Accumulated other comprehensive income (loss)	(469)	(688)
Total stockholders' equity	94,768	102,083
Total liabilities and stockholders' equity	$ 106,405	$ 113,290

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

	For the Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 5,143	$ 5,269
General and administrative	4,589	5,605
Total operating expenses	9,732	10,874
Loss from operations	(9,732)	(10,874)
Other income (expense), net:		
Interest and investment income	687	119
Other income (expense), net	687	119
Net loss	(9,045)	(10,755)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.80)	$ (0.96)
Weighted-average shares outstanding, basic and diluted	11,303,869	11,250,127
Other comprehensive income (loss):		
Net unrealized (loss) gain on marketable debt securities	219	(731)
Other comprehensive income (loss)	219	(731)
Comprehensive Loss	$ (8,826)	$ (11,486)

Company Contact:

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