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): November 3, 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 November 3, 2023, Protara Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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 November 3, 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: November 3, 2023

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

Exhibit 99.1

Protara Therapeutics Announces Third Quarter 2023 Financial Results and Business Update

- *Dosing is progressing well in ADVANCED-1EXP trial evaluating TARA-002 in NMIBC patients with CIS; preliminary results expected in 1H24*
- *Company initiated ADVANCED-2 trial evaluating TARA-002 in NMIBC patients with BCG-unresponsive CIS and BCG-naïve CIS*
- *Company initiated Phase 2 trial of TARA-002 in Lymphatic Malformations*
- *Cash, cash equivalents and investments of $74M as of September 30, 2023 expected to fund operations into Q2 of 2025*

NEW YORK, November 3, 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 third quarter ended September 30, 2023 and provided a business update.

“Progress continues across our TARA-002 clinical development programs, with patient dosing now underway in the ADVANCED-2 trial in patients with non-muscle invasive bladder cancer (NMIBC) and the STARBORN-1 trial in pediatric patients with lymphatic malformations (LMs),” said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. “We remain keenly focused on execution across all our ongoing clinical studies and remain on track to report preliminary results from the expansion portion of the ADVANCED-1 trial of TARA-002 in patients with NMIBC in the first half of 2024. With a cash runway into the second quarter of 2025, we believe we are well positioned to achieve key milestones in our TARA-002 development programs.”

Recent Highlights

TARA-002 in NMIBC

- In September 2023, the Company announced dosing of the first patient in ADVANCED-2, a Phase 2 open-label trial evaluating intravesical TARA-002 in up to 102 NMIBC patients with carcinoma in situ (CIS) (± Ta/T1) who are Bacillus Calmette-Guérin (BCG)-naïve (n=27) and BCG-unresponsive (n=75). Trial subjects will receive an induction with or without a reinduction course of six weekly intravesical instillations of TARA-002, followed by a maintenance course of three weekly installations every three months in the BCG-unresponsive cohort.
- As previously announced, patient dosing is underway in the Phase 1b ADVANCED-1EXP study, an open-label expansion trial evaluating intravesical TARA-002 at the 40KE[1] dose in up to 12 CIS patients, including BCG-naïve, BCG-unresponsive, and BCG-inadequately treated patients. The Company remains on track to report preliminary results in the first half of 2024. The primary endpoint of the trial is the complete response rate at three months.

TARA-002 in LMs

- In October 2023, the Company announced dosing of the first patient in STARBORN-1, a Phase 2 clinical trial of TARA-002 in pediatric patients with macrocystic and mixed-cystic LMs. Including an age de-escalation safety lead-in, the trial will enroll approximately 30 patients who will receive up to four injections of TARA-002 spaced approximately six weeks apart. The primary endpoint of the trial is the proportion of participants with macrocystic and mixed cystic LMs who demonstrate clinical success, defined as having either a complete response (90% to 100% reduction from baseline in total LM volume) or substantial response (60% to less than 90% reduction in total LM volume) as measured by axial imaging.

IV Choline Chloride Program

- The Company continues to engage with the U.S. Food and Drug Administration and plans to use both regulatory feedback and results from its prevalence study to inform next steps for the IV Choline Chloride development program.

Third Quarter 2023 Financial Results

- As of September 30, 2023, cash, cash equivalents and investments were $74.0 million. The Company expects its current cash, cash equivalents and investments will be sufficient to fund its planned operations into the second quarter of 2025.

- Research and development expenses for the third quarter of 2023 increased to $6.2 million from $3.5 million during the third quarter of 2022, primarily reflecting an increase in expenses related to non-clinical and clinical trial activities for TARA-002 of $2.2 million as well as $0.4 million of increased employee expenses inclusive of stock-based compensation.

- General and administrative expenses for both the third quarter of 2023 and 2022 were $4.5 million.

- For the third quarter of 2023, Protara reported a net loss of $9.9 million, or $0.87 per share, compared with a net loss of $7.7 million, or $0.68 per share, for the same period in 2022. Net loss for the third quarter of 2023 included approximately $1.4 million of stock-based compensation expenses.

About Non-Muscle Invasive Bladder Cancer

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

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. 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 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, lymphatics; recurrent infection, and cosmetic and other functional disabilities.

About IV Choline Chloride

IV Choline Chloride is an investigational, intravenous (IV) phospholipid substrate replacement therapy initially in development for patients receiving parenteral nutrition (PN). 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. IV Choline Chloride has been granted Orphan Drug Designation by the FDA for the prevention of choline deficiency in PN patients.

About TARA-002 in LMs

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 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.

References

1. Klinische Einheit, or KE, is a German term indicating a specified weight of dried cells in a vial.

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	
	September 30, 2023	**December 31, 2022**
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 33,768	$ 24,127
Marketable debt securities	40,266	60,243
Prepaid expenses and other current assets	3,779	1,776
Total current assets	77,813	86,146
Restricted cash, non-current	745	745
Marketable debt securities, non-current	-	17,886
Property and equipment, net	1,401	1,592
Operating lease right-of-use asset	5,567	6,277
Other assets	2,941	644
Total assets	$ 88,467	$ 113,290
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,504	$ 1,586
Accrued expenses	3,305	3,237
Operating lease liability	966	917
Total current liabilities	6,775	5,740
Operating lease liability, non-current	4,736	5,467
Total liabilities	11,511	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 September 30, 2023 and December 31, 2022, 7,991 and 8,027 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively.	-	-
Common stock, $0.001 par value, authorized 100,000,000 shares: Common stock, 11,364,903 and 11,267,389 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively.	11	11
Additional paid-in capital	267,273	262,724
Accumulated deficit	(190,163)	(159,964)
Accumulated other comprehensive income (loss)	(165)	(688)
Total stockholders' equity	76,956	102,083
Total liabilities and stockholders' equity	$ 88,467	$ 113,290

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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 September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 6,218	$ 3,466	$ 18,608	$ 11,819
General and administrative	4,482	4,508	13,964	15,734
Total operating expenses	10,700	7,974	32,572	27,553
Loss from operations	(10,700)	(7,974)	(32,572)	(27,553)
Other income (expense), net:				
Interest and investment income	840	283	2,373	568
Other income (expense), net	840	283	2,373	568
Net loss	$ (9,860)	$ (7,691)	$ (30,199)	$ (26,985)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.87)	$ (0.68)	$ (2.67)	$ (2.40)
Weighted-average shares outstanding, basic and diluted	11,347,887	11,265,475	11,320,027	11,256,995
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable debt securities	171	(8)	523	(919)
Other comprehensive income (loss)	171	(8)	523	(919)
Comprehensive Loss	$ (9,689)	$ (7,699)	$ (29,676)	$ (27,904)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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