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): March 13, 2024

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 March 13, 2024, Protara Therapeutics, Inc. (the "Company") announced its financial results for the quarter and year ended December 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 March 13, 2024, 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: March 13, 2024

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

Exhibit 99.1

Protara Therapeutics Announces Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

- *Preliminary results from ADVANCED-1EXP trial evaluating TARA-002 in NMIBC patients with CIS on track for 1H 2024*
- *Preliminary data from ADVANCED-2 trial evaluating TARA-002 in NMIBC patients with BCG-unresponsive CIS and BCG-naïve CIS expected in 2H 2024*
- *Cash, cash equivalents, and investments of $66M as of December 31, 2023 expected to fund operations into Q2 2025 through several key data milestones*

NEW YORK, March 13, 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 full year and fourth quarter ended December 31, 2023 and provided a business update.

"We expect 2024 to be a milestone-rich year for Protara and believe we are well positioned to continue to execute on advancing our pipeline to deliver meaningful new therapies to patients with cancer and rare diseases," said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. "Notably, we anticipate sharing Phase 1b proof of concept (POC) and preliminary Phase 2 data for our lead TARA-002 indication, non-muscle invasive bladder cancer (NMIBC), later this year, which we believe will continue to support its potential to play an important role in the evolving NMIBC treatment landscape. Progress also continues for our program of TARA-002 in lymphatic malformations (LMs), a highly underserved pediatric population, with dosing in our Phase 2 study now underway."

Recent Progress and Highlights

TARA-002 in NMIBC

- The Company remains on track to report preliminary results from the ongoing Phase 1b ADVANCED-1EXP POC, open-label expansion trial in the first half of 2024. The trial is evaluating intravesical TARA-002 at the 40KE[1] dose in up to 12 carcinoma in situ (CIS) patients, including Bacillus Calmette-Guérin (BCG)-naïve, BCG-unresponsive, and BCG-inadequately treated patients. The primary endpoint will assess the activity levels at the preliminary three-month assessment timepoint, including complete response (CR) rates and immuno-dynamic activity in CIS and CIS +Ta/T1 patients.

- The Company expects to share preliminary results from a pre-planned risk-benefit analysis of the ongoing Phase 2 open-label ADVANCED-2 trial in the second half of 2024. The analysis is expected to include approximately 10 patients who are six-month evaluable. The ongoing ADVANCED-2 trial is assessing intravesical TARA-002 in at least 102 NMIBC patients with CIS (± Ta/T1) who are BCG-naïve (n=27) and BCG-unresponsive (n=75-100). Trial subjects will receive an induction course of six weekly intravesical instillations, and following mandatory biopsy at three months, will either receive a reinduction course of six weekly intravesical instillations of TARA-002, or the first maintenance course of three weekly installations every three months for 24 months.

TARA-002 in LMs

- Dosing continues to progress 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 CR (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 for Patients on Parenteral Nutrition (PN)

- 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.

Fourth Quarter and Full Year 2023 Financial Results

- As of December 31, 2023, cash, cash equivalents, and investments in marketable debt securities totaled $65.6 million. The Company expects its cash, cash equivalents, and investments in marketable debt securities will be sufficient to fund its planned operations and data milestones into the second quarter of 2025.

- Research and development expenses for the fourth quarter of 2023 increased to $6.4 million from $5.0 million for the prior year period, and for the full year increased to $25.0 million compared to $16.8 million for 2022. The fourth quarter and full year increases were primarily due to an increase in expenses related to clinical trials and non-clinical activities for TARA-002.

- General and administrative expenses for the fourth quarter of 2023 decreased to $4.7 million from $5.0 million for the prior year period, and for the full year decreased to $18.6 million compared to $20.7 million for 2022. The fourth quarter and full year decreases were primarily due to a reduction in personnel costs and lower directors and officers liability insurance premiums which were partially offset by an increase in professional costs.

- For the fourth quarter of 2023, Protara incurred a net loss of $10.2 million, or $0.90 per share, compared with a net loss of $39.0 million, or $3.46 per share, for the same period in 2022. Net loss for the year ended December 31, 2023 was $40.4 million, or $3.57 per share, compared with a net loss of $66.0 million, or $5.86 per share, for the year ended December 31, 2022. Net loss in the fourth quarter of 2022 included a non-cash goodwill impairment charge of $29.5 million associated with the accounting for the reverse merger transaction in January 2020. Net loss for the fourth quarter of 2023 included approximately $1.5 million of stock-based compensation expenses. Net loss for the year ended December 31, 2023 included approximately $6.1 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 pro-inflammatory response with release of cytokines such as tumor necrosis factor (TNF)-alpha, interferon (IFN)-gamma IL-6, IL-10, 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.

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 Intravenous (IV) Choline Chloride

IV Choline Chloride is an investigational, IV phospholipid substrate replacement therapy initially in development for patients receiving PN. Choline is a known important substrate for phospholipids that are critical for healthy liver function and also plays an important role in modulating gene expression, cell membrane signaling, brain development and neurotransmission, muscle function, and bone health. PN patients are unable to synthesize choline from enteral nutrition sources, and there are currently no available PN formulations containing choline. Approximately 80 percent of PN-dependent patients are choline-deficient and have some degree of liver damage, which can lead to hepatic failure. IV Choline Chloride has been granted Orphan Drug Designation by the FDA for the prevention of choline deficiency in PN patients. The Company was issued a patent claiming a choline composition 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 (BCG), as well as a Phase 2 trial in pediatric patients with LMs. Additionally, Protara is developing IV Choline Chloride, an investigational phospholipid substrate replacement for patients on parenteral nutrition who are otherwise unable to meet their choline needs via oral or enteral routes. 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; 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.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 39,586	$ 24,127
Marketable debt securities	25,994	60,243
Prepaid expenses and other current assets	3,125	1,776
Total current assets	68,705	86,146
Restricted cash, non-current	745	745
Marketable debt securities, non-current	-	17,886
Property and equipment, net	1,296	1,592
Operating lease right-of-use asset	5,264	6,277
Other assets	2,944	644
Total assets	$ 78,954	$ 113,290
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,434	$ 1,586
Accrued expenses	2,732	3,237
Operating lease liability	983	917
Total current liabilities	6,149	5,740
Operating lease liability, non-current	4,484	5,467
Total liabilities	10,633	11,207
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Preferred stock, $0.001 par value, authorized 10,000,000 shares:		
Series 1 convertible preferred stock, 8,028 shares authorized at December 31, 2023 and 2022, 7,991 and 8,027 shares issued and outstanding as of December 31, 2023 and 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 December 31, 2023 and 2022, respectively.	11	11
Additional paid in capital	268,725	262,724
Accumulated deficit	(200,384)	(159,964)
Accumulated other comprehensive income (loss)	(31)	(688)
Total stockholders' equity	68,321	102,083
Total liabilities and stockholders' equity	$ 78,954	$ 113,290

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

	(Unaudited)		(Audited)	
	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 6,381	$ 4,989	$ 24,989	$ 16,808
General and administrative	4,660	5,003	18,624	20,737
Loss on impairment of goodwill	-	29,517	-	29,517
Total operating expenses	11,041	39,509	43,613	67,062
Loss from operations	(11,041)	(39,509)	(43,613)	(67,062)
Other income (expense), net:				
Interest and investment income	820	543	3,193	1,110
Other income (expense), net	820	543	3,193	1,110
Net loss	$ (10,221)	$ (38,966)	$ (40,420)	$ (65,952)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.90)	$ (3.46)	$ (3.57)	$ (5.86)
Weighted-average shares outstanding, basic and diluted	11,364,903	11,267,389	11,331,338	11,259,615
Other comprehensive income (loss):				
Net unrealized gain (loss) on marketable debt securities	134	(442)	657	(477)
Other comprehensive income (loss)	134	(443)	657	(477)
Comprehensive Loss	$ (10,087)	$ (38,524)	$ (39,763)	$ (66,429)

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