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 4, 2021

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 4, 2021, Protara Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2021 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 4, 2021, 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 4, 2021

By: /s/ Blaine Davis
Blaine Davis
Chief Financial Officer

Exhibit 99.1

Protara Therapeutics Announces Third Quarter 2021 Financial Results and Business Overview

– TARA-002 Confirmatory Large-Scale GMP Comparability Complete –

– U.S. FDA Cleared the Company's IND Application for TARA-002 in NMIBC; Company Plans to Initiate Phase 1 Clinical Trial by Year-End –

– Strong Cash, Cash Equivalents, and Marketable Debt Securities of $138.4M as of September 30, 2021 –

NEW YORK, November 4, 2021 -- 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, 2021 and provided a business update.

"We have made significant progress advancing our TARA-002 clinical programs in the third quarter, most notably the completion of our confirmatory large-scale GMP comparability work and the clearance of our Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA) for our non-muscle invasive bladder cancer (NMIBC) clinical development program. NMIBC is one of the most recurrent and difficult to treat cancers with limited treatment options, and we look forward to initiating our Phase 1 clinical trial of TARA-002 in adults with high-grade NMIBC by the end of the year," said Jesse Shefferman, Chief Executive Officer of Protara Therapeutics. "We are also working to align with the FDA on the design of a clinical trial of TARA-002 in patients with lymphatic malformations (LMs), a rare pediatric indication for which there are currently no U.S. FDA-approved therapies."

Recent Highlights and Upcoming Milestones

TARA-002 in NMIBC

- In October 2021, Protara announced that the FDA cleared the Company's IND application for TARA-002, an investigational cell-based therapy in development for the treatment of NMIBC. The confirmatory, GMP-scale comparability data for TARA-002 in relation to OK-432, the originator therapy for TARA-002, have been completed and were reviewed by the FDA as part of the clearance of the IND.

- The Company plans to commence a Phase 1 clinical trial by the end of 2021 to assess the safety, tolerability, and preliminary signs of anti-tumor activity of TARA-002 in adults with high-grade NMIBC.

TARA-002 in LMs

- In October 2021, the Company updated its IND submission for TARA-002 for the treatment of LMs with completed confirmatory, GMP-scale comparability data, and plans to engage the FDA on the design, and subsequently initiate a clinical trial in pediatric LM patients.

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

- In September 2021, the Company announced the completion of a retrospective prevalence study designed to enhance understanding of the incidence of IFALD in patients dependent on parenteral nutrition (PN). The study found that approximately 30% of patients who are dependent on PN have cholestasis, despite the use of medical management in these patients.

- The Company plans to use the results from the completed retrospective study and ongoing prospective study to inform next steps for the IV Choline Chloride development program.

Corporate Update

- In October 2021, the Company hired Mary Grendell as its new General Counsel. Ms. Grendell has an extensive track record as a legal executive, most recently serving as Vice President, Deputy General Counsel and Corporate Secretary, at Intercept Pharmaceuticals. Previously, she held positions at Mylan (now part of Viatris) and Amgen following her early legal career at Sullivan & Cromwell and Covington & Burling. Ms. Grendell received her J.D. from the University of Pennsylvania Law School and her B.A. from Yale University.

Third Quarter 2021 Financial Results

- As of September 30, 2021, cash, cash equivalents and marketable debt securities totaled $138.4 million.

- Research and development expenses for the third quarter of 2021 increased to $4.1 million from $2.8 million during the third quarter of 2020. The increased R&D expenses were primarily due to increases in non-clinical, clinical and regulatory expenses associated with TARA-002, headcount and stock-based compensation, and other employee-related expenses.

- General and administrative expenses for the third quarter of 2021 increased to $6.7 million from $5.3 million during the third quarter of 2020. The increase was primarily due to increases in headcount and employee-related expenses, development of commercial capabilities, and costs associated with the new corporate office in New York, NY.

- For the third quarter of 2021, Protara reported a net loss of $10.8 million, or $0.96 per share, compared with a net loss of $8.0 million, or $1.26 per share, for the third quarter of 2020. Net loss for the third quarter of 2021 included approximately $2.7 million of stock-based compensation expenses.

About TARA-002

TARA-002 is an investigational cell therapy in development for the treatment of NMIBC and 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 Taiwan by Chugai Pharmaceutical Co., Ltd. Protara has successfully demonstrated 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-6, IL-8, IL-12, interferon (IFN)-gamma, tumor necrosis factor (TNF)-alpha, and vascular endothelial growth factor (VEGF) are secreted by immune cells to induce a strong local inflammatory reaction and destroy the abnormal cells.

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

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 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 identifying and advancing transformative therapies for people with cancer and rare diseases with limited treatment options. 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 therapy for the treatment of intestinal failure-associated liver disease. 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, including anticipated alignment with the FDA on clinical trial design for TARA-002 in pediatric LM patients; Protara’s financial footing; 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; the impact of the COVID-19 pandemic on Protara’s business and the global economy; 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; 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	As of	
	September 30, 2021 (unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 40,742	$ 168,598
Restricted cash	-	50
Marketable debt securities, current	53,016	-
Prepaid expenses and other current assets	1,937	787
Total current assets	95,695	169,435
Non-current assets:		
Restricted cash, non-current	745	745
Marketable debt securities, non-current	44,652	-
Property and equipment, net	1,729	1,240
Operating lease right-of-use asset	7,413	1,060
Goodwill	29,517	29,517
Other assets, non-current	946	1,160
Total assets	$ 180,697	$ 203,157
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 928	$ 914
Accrued expenses	1,920	1,913
Operating lease liability, current	840	88
Total current liabilities	3,688	2,915
Non-current liabilities:		
Operating lease liability, non-current	6,603	999
Total liabilities	10,291	3,914
Commitments and Contingencies (Note 6)		
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, 2021 and December 31, 2020, 8,027 shares issued and outstanding as of September 30, 2021 and December 31, 2020.	-	-
Common Stock, $0.001 par value, authorized 100,000,000 shares:		
Common Stock, 11,235,731 and 11,211,840 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively.	11	11
Additional Paid in Capital	254,218	245,992
Accumulated Deficit	(83,784)	(46,760)
Accumulated Other Comprehensive Income (Loss)	(39)	-
Total Stockholders' Equity	170,406	199,243
Total Liabilities and Stockholders' Equity	$ 180,697	$ 203,157

PROTARA THERAPEUTICS, INC.
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,	
	2021	2020	2021	2020
Operating expense:				
Research & development	$ 4,093	$ 2,796	$ 17,020	$ 8,330
General & administrative	6,737	5,266	20,182	17,157
Total operating expenses	10,830	8,062	37,202	25,487
Operating loss	(10,830)	(8,062)	(37,202)	(25,487)
Other income, net				
Interest income, net	(53)	(92)	(178)	(317)
Total other income, net	(53)	(92)	(178)	(317)
Net loss	(10,777)	(7,970)	(37,024)	(25,170)
Other comprehensive gain (loss):				
Unrealized gains (losses) on available-for-sale marketable debt securities	62	-	(39)	-
Total other comprehensive gain (loss)	62	-	(39)	-
Comprehensive Loss	$ (10,715)	$ (7,970)	$ (37,063)	$ (25,170)
Weighted Average Shares Outstanding, basic and diluted	11,235,507	6,324,295	11,231,513	5,910,849
Net loss per share, basic and diluted	$ (0.96)	$ (1.26)	$ (3.30)	$ (4.26)

Company Contact:

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