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 3, 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 8.01 Other Events.

On March 3, 2021, Protara Therapeutics, Inc. (the "Company") made available an updated Corporate Presentation on the Investor Relations page of the Company's website, which will be used at investor and other meetings. A copy of the Corporate Presentation is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company does not undertake to update this presentation.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Protara Therapeutics, Inc. Corporate Presentation, March 2021.

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.

Dated: March 3, 2021

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

PROTARA THERAPEUTICS

Corporate Presentation

March 2021

Forward Looking Statements

Statements contained in this presentation 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, Protara's manufacturing and development plans for its product candidates and related interactions with the FDA, ex-U.S. development plans, Protara's financial footing, the impact of the COVID-19 pandemic and related governmental responses on Protara's business and clinical programs. 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 sales, revenue, expense and other 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, clinical supply chain, clinical trials, 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. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. 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

Modernizing and Expediting Development of De-Risked Assets

Lead programs: TARA-002 in Non-Muscle Invasive Bladder Cancer (NMIBC) and Lymphatic Malformations (LMs)

- Cell-based immunopotentiator
- FDA confirmed initial comparability to Japanese predecessor OK-432
- NMIBC clinical development plan in place following Pre-Investigational New Drug (PIND) engagement with FDA
- TARA-002/OK-432 is standard of care in Japan for LMs; completed Phase 2 study in U.S. supports treatment effect with support for strong safety profile

Other mid-stage development programs provide diversification and additional growth potential

- IV Choline in intestinal failure associated liver disease (IFALD): Completed End Of Phase 2 dialogue with FDA and aligned on Phase 3 design

Company well funded through anticipated key milestones through early 2023

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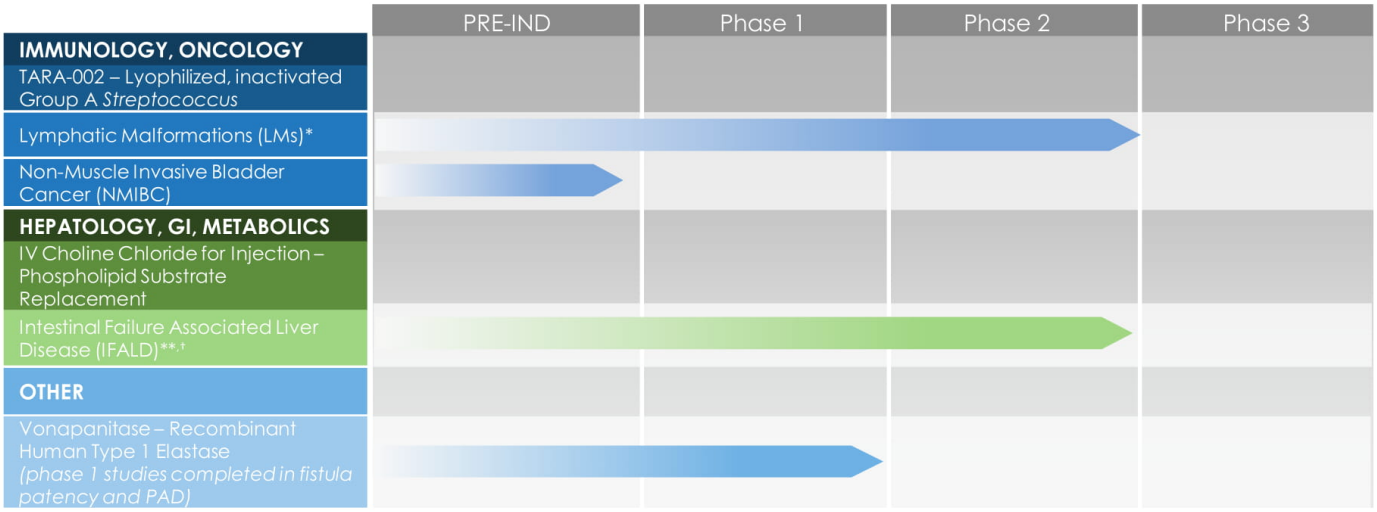
Pipeline Addresses Multiple Indications With High Unmet Need



PROTARA THERAPEUTICS

*TARA-002 Granted Rare Pediatric Disease Designation for the treatment of LMs. OK-432 Granted Orphan Drug Designation by the U.S. FDA for the treatment of LMs, which we believe is applicable under established comparability.
**Granted Orphan Drug and Fast Track Designations by the U.S. FDA
† Phase 1 PK study to be conducted prior to commencing Phase 3

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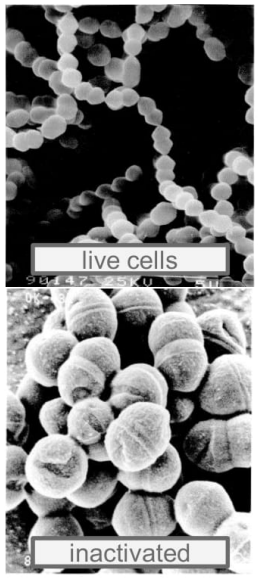
TARA-002

LYOPHILIZED, INACTIVATED GROUP A *STREPTOCOCCUS PYOGENES*

TARA-002: Cell-Based Immunopotentiator with Significant Potential

- TARA-002 is an investigational, genetically distinct strain of *Streptococcus pyogenes* that is inactivated while retaining its immune-stimulating properties
- TARA-002 is manufactured under GMP conditions from the same Master Cell Bank as OK-432[1], once one of the largest selling oncology products in Japan
- FDA has confirmed initial comparability between TARA-002 and OK-432 and path forward to completion of GMP comparability
- Having established initial comparability to OK-432, the extensive data generated by OK-432 will help support TARA-002
- Protara has worldwide rights ex-Japan & Taiwan for TARA-002/OK-432



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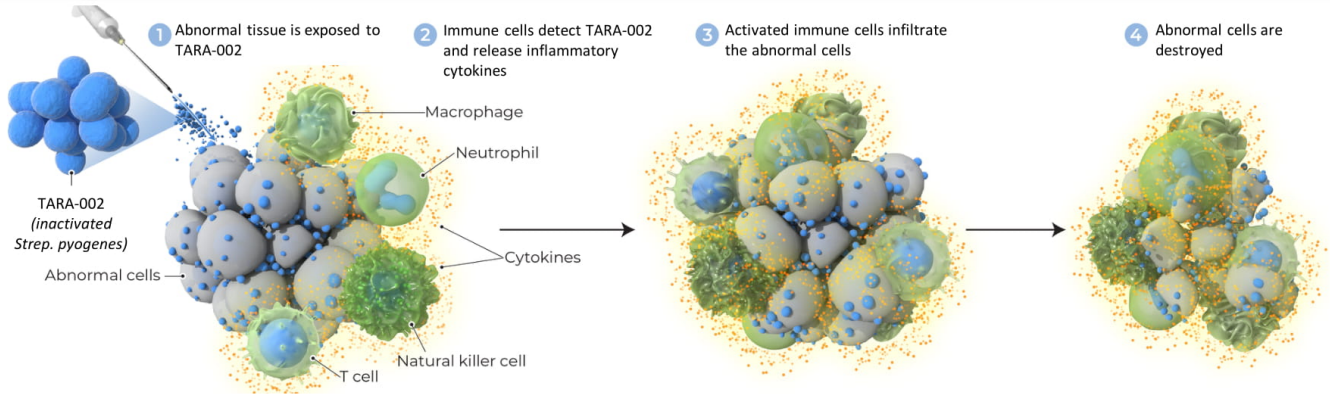
(1) Marketed in Japan and Taiwan as Picibanil®.
Note: Manufacturing modifications reflect manufacturing to U.S. cGMP standards

TARA-002: Mechanism of Anti-Tumor / Anti-Cystic Activity

Th1 Like Anti-Tumor Cytokine Response

Multi-Cytokine Inducer[1][2][3]

IL-2 IL-6 IL-8 IL-10 IL-12 GM-CSF G-CSF TNF-α IFN-γ



PROTARA THERAPEUTICS

(1) Fujimoto T., et al. J Immunol. 1997: 5619.
(2) Ryoma Y, et al. Anticancer Res. 2004; 3295-3298.
(3) Zhao H, et al. Microbiol. Immunol. 1994; 183-190.

OK-432: Human Efficacy Data in Multiple Indications

OK-432 has been approved (ex-US) or studied in multiple indications

APPROVED INDICATIONS IN JAPAN[1]

- **Lymphangiomas (Lymphatic Malformations)**
- Gastric cancer combo with chemo (post-operative)
- Primary lung cancer combo with chemo
- Reduction of ascites in gastrointestinal cancer
- Reduction of pleural effusion in lung cancer
- Unresponsive head, neck & thyroid cancer

OK-432 CLINICAL RESEARCH CONDUCTED IN:

- **Non-Muscle Invasive Bladder Cancer**
- Ovarian cancer
- Malignant mesothelioma
- Pancreatic cancer
- Esophageal cancer
- Oral squamous cell cancer
- Hepatocellular cancer
- Ranula
- Thyroglossal cysts
- Pleurodesis
- Seroma
- Symptomatic lymphocele
- Auricular hematoma

PROTARA THERAPEUTICS

(1) Full Prescribing Information. Chugai Pharmaceuticals. 2016

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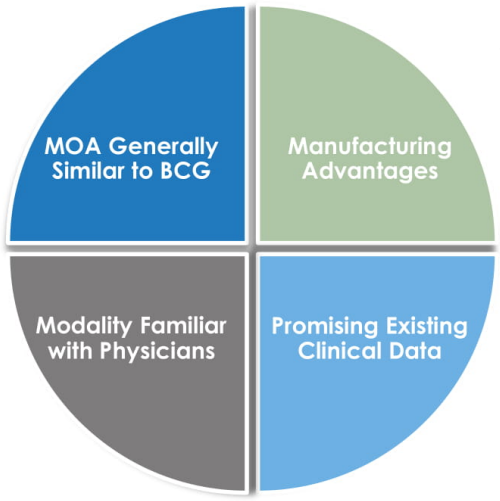
TARA-002

NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)

TARA-002 in NMIBC: Profile Supports Potential in NMIBC

Similar mechanism to BCG, notable patient experience in Asia and manufacturing advantages

- Prompts a predominantly Th1 type cytokine response
- Mechanistically similar to Bacille Calmette-Guérin (BCG)



- State-of-the-art U.S. manufacturing facility
- TARA-002 manufacturing process supported by 40 years of production history of OK-432

- Urologists have been using an attenuated bacteria, BCG, as immunotherapy for decades
- Intravesical administration is preferred clinical approach among urologists[1]

- ~150 NMIBC patients tested with OK-432 demonstrated promising results[2]
- Treatment generally well tolerated

PROTARA THERAPEUTICS

(1) Market Research Conducted by Protara Therapeutics
(2) Study references available by request
Note: OK-432 is not approved for NMIBC

Clinical Evidence of OK-432 Provides Strong Rationale for Development of TARA-002 in NMIBC

Data across multiple investigator-initiated studies in ~150 NMIBC patients treated intravesically shows that OK-432:

- Was generally well-tolerated, with safety and tolerability observed across a range of doses
- Demonstrated treatment effect and lower rates of recurrence vs. control group, including in the randomized, controlled setting

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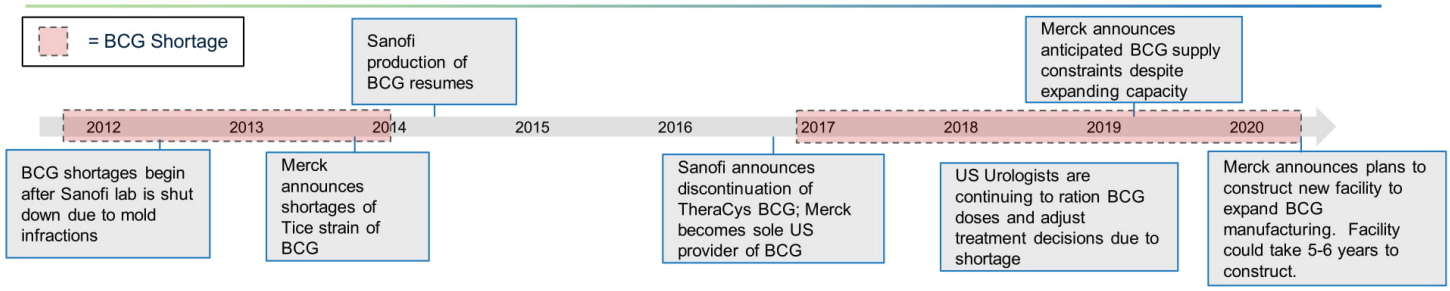
BCG Shortage Causes Significant Impact on Care



Shortage has prompted major urological associations to issue guidance on patient management (1)

"…remain extremely concerned about this shortage and its effects on the care of bladder cancer patients…"

-Joint Statement on BCG Shortage, Feb 2019

American Urological Association | LUGPA Integrated Practices Comprehensive Care | AACU | Urology Care Foundation | SUO | BCAN

Dose rationing and resorting to less desirable treatment options are impacting patient care(2)

*"I see patients **every week** whose **treatment decisions are affected by the BCG shortage**…sometimes I just recommend moving patients more quickly to cystectomy because **we don't have any better options available.**"*

-Academic Hospital Urologist

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(1) AUA/SUO Joint Guideline: Published 2016; Amended 2020
(2) Market Research Conducted by Protara Therapeutics

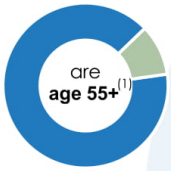
NMIBC Represents the Most Common Form of Bladder Cancer

Bladder Cancer in the US

6th ***most prevalent cancer*** in the U.S.[1]

4x more likely to be diagnosed in **men**[2]

9 in 10 are **age 55+**[1]



High rate of recurrence with 3-year rate estimated at up to **80%**[3]

NMIBC makes up **~80%** of all bladder cancer with **~65,000 diagnosed per year** in the U.S.[4]

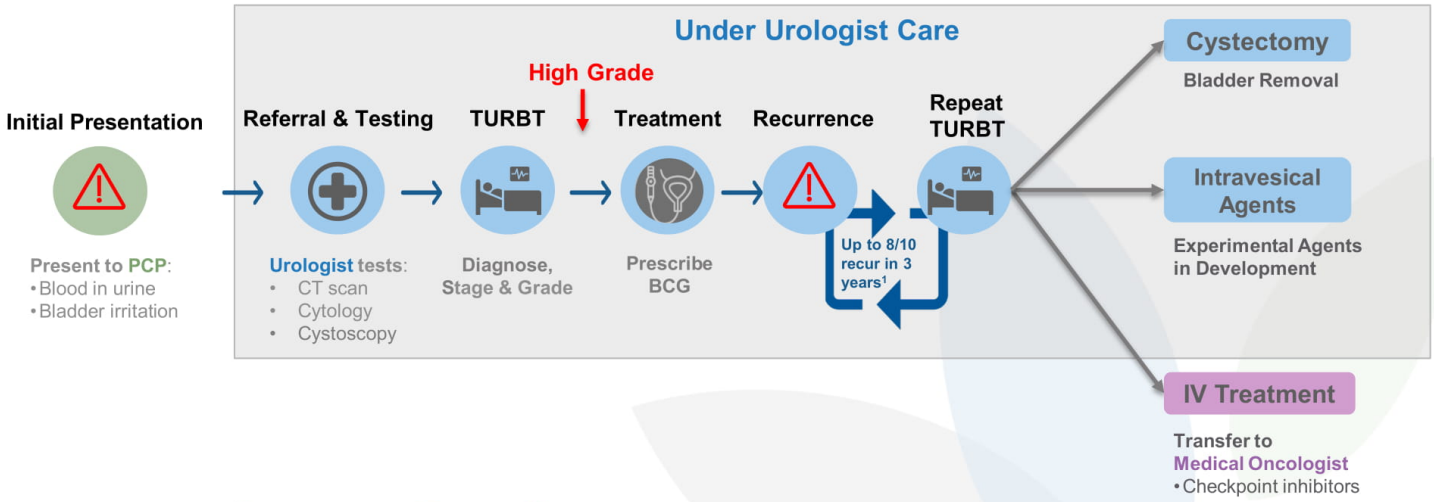
NMIBC patients are treated by a **urologist**

Significant increase in **recurrence, progression** & an escalated number of patients needing **cystectomies**[5]

PROTARA THERAPEUTICS

(1) National Cancer Institute. SEER Bladder Cancer – Stat Facts. Accessed February 5, 2021.
(2) Saginala, K. et al. Med Sci. 2020.
(3) Campbell Walsh 11th edition, Elsevier.
(4) Anastasiadis et al. Therapeutic Advances in Urology, 2012.
(5) Ourfali, S. et. al. European urology focus, 2019.

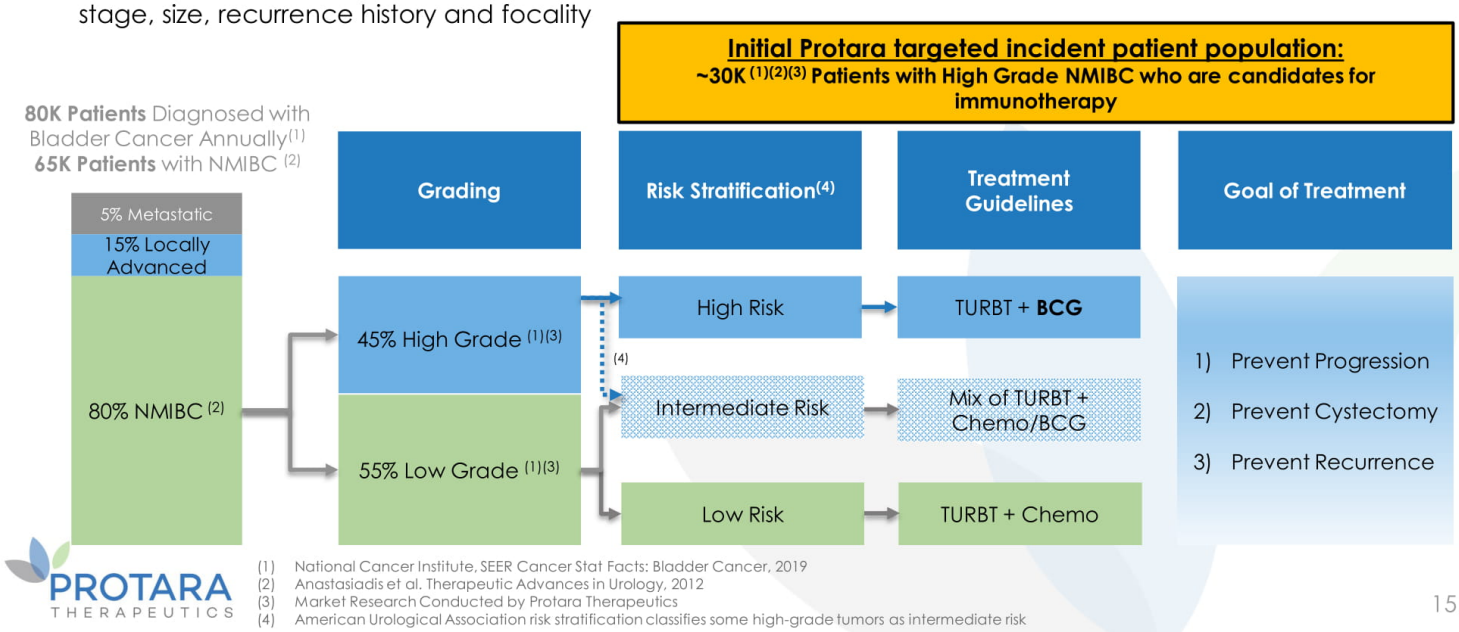
Current Standard of Care Highlights High Unmet Need for Patients



(1) Campbell Walsh 11th edition, Elsevier.

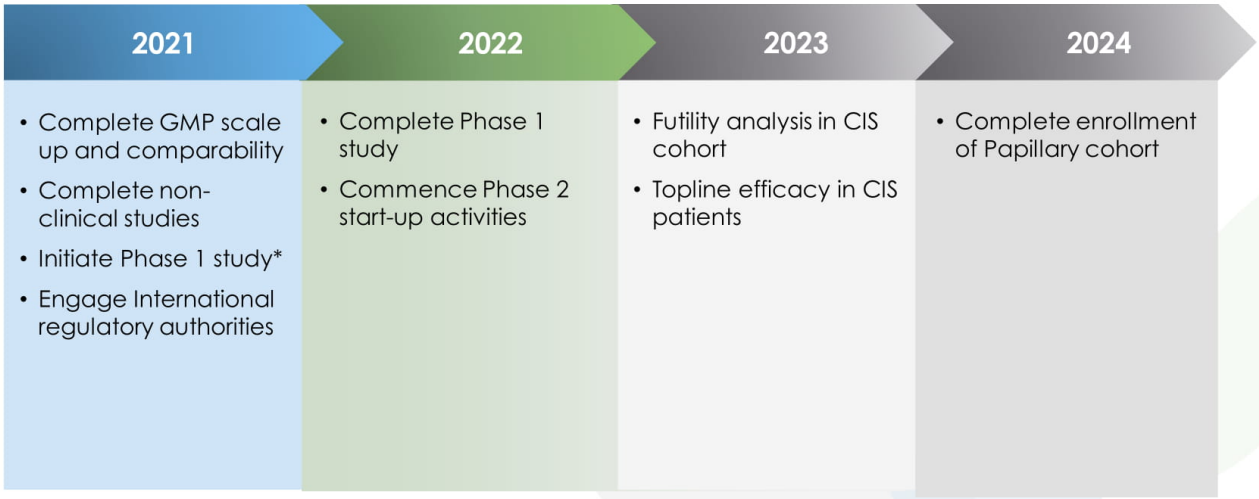
TARA-002 in NMIBC: Overview of U.S. NMIBC & Target Population

NMIBC is categorized and treated based on risk stratification, determined by combination of tumor grade, stage, size, recurrence history and focality



(1) National Cancer Institute, SEER Cancer Stat Facts: Bladder Cancer, 2019
(2) Anastasiadis et al. Therapeutic Advances in Urology, 2012
(3) Market Research Conducted by Protara Therapeutics
(4) American Urological Association risk stratification classifies some high-grade tumors as intermediate risk

TARA-002 in NMIBC: Estimated Development Timeline



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*Subject to acceptance of IND filing

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TARA-002

LYMPHATIC MALFORMATIONS (LMs)

TARA-002 in LMs

Lymphatic Malformations

Rare, non-malignant lesions consisting of dilated, lymphatic fluid-filled sacs caused by abnormal development of the lymphatic endothelial system[1]

Epidemiology

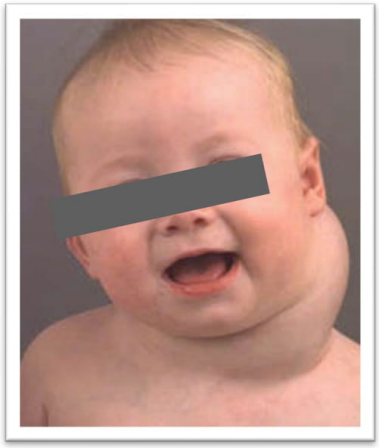
Epidemiology: incidence of lymphatic malformations is ≈1,400-1,800 LM cases per year[2]

Current Treatment Options

Current treatment options include surgical excision with high complication (33%) and recurrence (55%) rates[3] as well as off-label use of sclerosants

FDA Granted Pediatric Rare Disease Designation

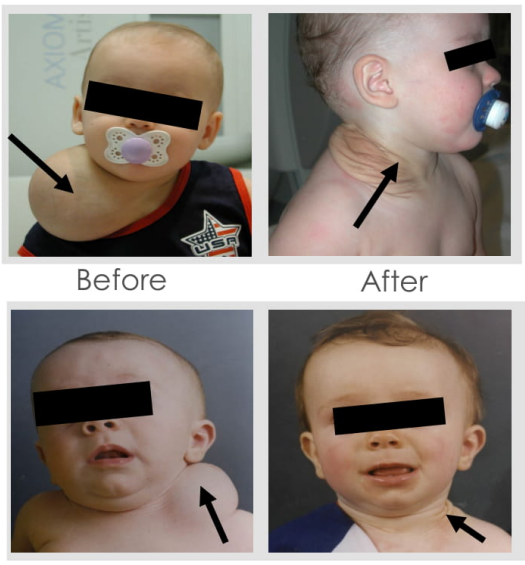
Majority of LMs present at birth (65-75%) or by age 3 (80-90%) during active lymphatic growth period[3]



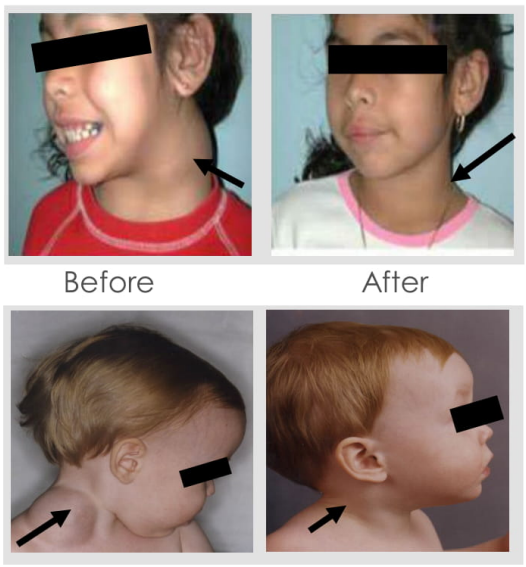
PROTARA THERAPEUTICS

(1) Brouillard P, et al. J Clin Invest. 2014;124:898-904.
(2) Internal company estimates
(3) Ha J, et al. Curr Ped Rev. 2014;10:238-248.

OK-432 in LMs: Clear Evidence of Biologic Activity in Patients



Before After



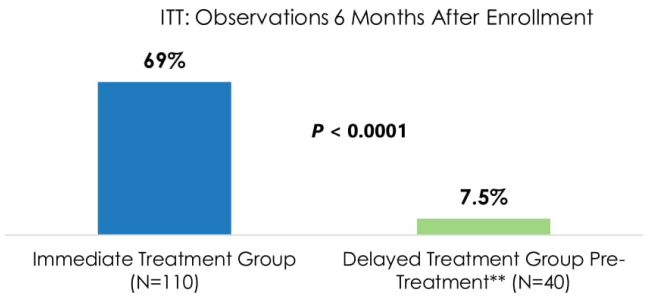
Before After

PROTARA THERAPEUTICS

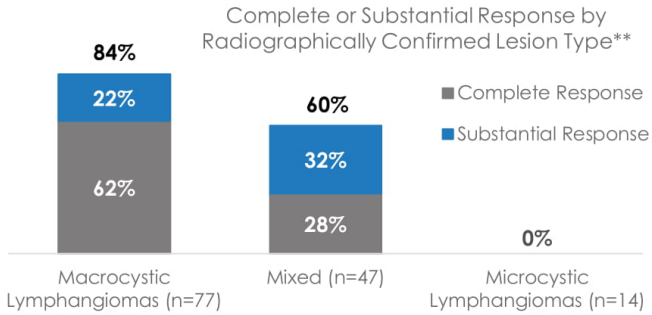
Protara Therapeutics data on file

OK-432 in LMs: Robust Results of Completed Phase 2 Study[1] in U.S.

69% CLINICAL SUCCESS‡ IN IMMEDIATE TREATMENT GROUP 6 MONTHS AFTER ENROLLMENT



84%* CLINICAL SUCCESS‡ IN PATIENTS WITH MACROCYSTIC LESION TYPES



- During this same period, 7.5% of patients in the delayed treatment group experienced spontaneous regression of LM
- Treatment: 1-4 injections at 8-week intervals max of 0.2mg/session (2KE)

- Patients with radiographically confirmed macrocystic lesions had the greatest chance for clinical success
- In those patients with mixed lesions, clinical success was still achieved

‡ Clinical Success was defined as complete or substantial response
*Reflects data prior to dosing with OK-432. After dosing, the clinical success rate was 66%, which was not statistically different from the Immediate Treatment Group
**Results were analyzed by lesion type across all treatment groups
(1) Results based on retrospective analysis of source verified data that included the full dataset of subjects enrolled in the P2 randomized study between January 1998 and August 2005, including data in the published study (Smith et al. 2009) which included subjects enrolled between January 1998 and November 2004.

OK-432 in LMs: Compelling Safety Record

Safety Profile*

- Most common AEs with treatment were local injection site reactions, fever, fatigue, decreased appetite, with resolution within two weeks
- Treatment emergent SAEs **related** to OK-432: reported in 4.1% of patients, with the most severe events being airway obstruction and facial paralysis due to massive swelling post-injection that required tracheostomy and hospitalization. Both of these events were reported as resolved.
- One SAE **related** to OK-432 led to discontinuation: Proptosis of the eye
- One SAE **not related** to OK-432 led to death: Death due to tracheotomy tube obstruction

PROTARA THERAPEUTICS

*Results based on retrospective analysis of source verified data that included the full dataset of subjects enrolled in the P2 randomized study between January 1998 and August 2005, including data in the published study (Smith et al. 2009) which included subjects enrolled between January 1998 and November 2004.

TARA-002 in LMs: Regulatory Update

1. IND update completed and filed with FDA Division of Vaccines and Related Products
2. Vaccines division began review of IND update in late Q4'2020 and requested a CSR summarizing the totality of the Iowa LMs Phase 2 study
3. CSR has been submitted and dialogue with Vaccines Division is ongoing
4. Company continues to prepare for the potential to file a BLA in 2H 2021 or to initiate additional clinical work in LMs as required

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TARA-002 in LMs: Planned Next Steps

If current data set sufficient for BLA/MAA submission

1H'2021
- Apply for Fast-track / Breakthrough Therapy Designation
- **Agree with FDA no study needed**

2H'2021
- Complete GMP comparability
- Engage European regulators
- **Submit BLA**

2022
- Launch in the US
- File marketing applications in the EU
- **US Approval (1H-2022)**

2023
- Launch in the EU and other international geographies

If additional registrational study required

2021
- Apply for Fast-track / Breakthrough Therapy Designation
- **Agree with FDA on design of any additional study**
- Complete GMP comparability (2H-2021)
- Initiate enrollment of study (2H-2021)
- Engage European regulators

2022
- Complete study
- Submit BLA
- **US Approval Q3'2022**

2023
- Launch in the US
- File marketing applications in EU countries

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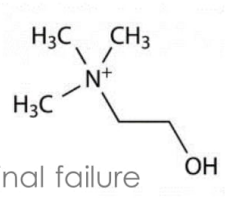
IV CHOLINE CHLORIDE

INTESTINAL FAILURE ASSOCIATED LIVER DISEASE (IFALD)

IV Choline in IFALD: Late-stage Opportunity for an Unmet Medical Need

An Essential Molecule in Several Metabolic Processes

Patients dependent on Parenteral Nutrition (PN) cannot absorb sufficient levels of choline. Data confirms that choline deficient diets results in steatosis and cholestasis[1]



Clinical History Supporting Choline Substrate Replacement in IFALD (intestinal failure associated liver disease) Patients

A Phase 2 study demonstrated the clinical potential of choline substrate replacement therapy by reversing certain hallmark pathologies of IFALD[1]

Strong Market Opportunity with Potential to Expand Addressable Patients

Prevalence of patients on PN 79/million[2]; recent Medicare diagnosis data suggests ≈ 5,000 IFALD patients[3]

Clear Regulatory and Clinical Path Forward

FDA designations (Orphan Drug Designation, Fast Track Designation) combined with encouraging feedback from End of Phase 2 meeting for Phase 1 PK study followed by Phase 3 trial

PROTARA THERAPEUTICS

(1) Buchman A, et al. JPEN. 2001;5:260-268.
(2) Mundi M, et al. ASEPN. 2017;32:799-805.
(3) Internal Protara market research

IV Choline in IFALD: Informative Clinical History

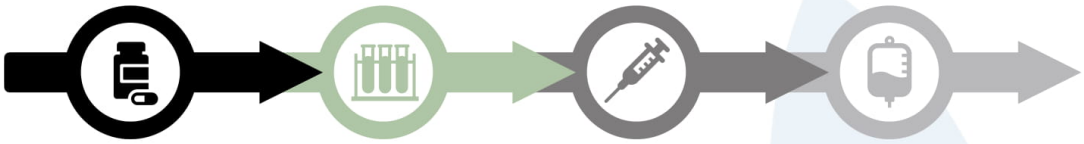
A significant body of supportive evidence across 4 studies

1994 - IV PK Study[2]
n=4 PN patients

1st continuous exposure to IV choline, established safety and 2g dose

2001 - IV Phase 2 RCT[4]
n=15 PN patients

2g dose confirmed, reversal of steatosis, improvement in cholestasis (reduction of ALP*)



1992 - Oral Lecithin Study[1]
n=15 PN patients

Lecithin did not achieve physiologic levels; however did reduce steatosis with moderate ALP* improvement

1995 - IV Pilot Study[3]
n=4 PN patients

IV Choline replacement reversed steatosis, improved other measures of hepatobiliary injury

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1) Buchman A, et al. Gastroenterology. 1992;102:1363-1370.
2) Buchman A, et al. Clin Pharmacol Ther. 1994;55:277-283.
3) Buchman A, et al. Hepatol. 1995;22:1399-1403.
4) Buchman A, et al. JPEN. 2001;5:260-268.

* ALP=Alkaline phosphatase

IV Choline in IFALD: Multi-Center Phase 2a POC Study

Randomized, Controlled Study Design & Objective

IV CHOLINE REPLACEMENT PROOF OF CONCEPT STUDY[1]	
Study Design	Randomized Double-blind Phase 2 Trial
Subjects	15 (9 per protocol)
Age	>16 years old
PN Requirement	Greater than 80% of all nutrient requirements supplied by PN
Randomization	1:1 Usual PN or PN + 2g IV choline/Day
Duration of Treatment	24 Weeks
Visits	Weeks 2,4,6,12,16, 20, 24
Follow up	Week 34
Dose	2g Choline Chloride QD in PN solution

- The IV Choline Chloride replacement proof-of-concept, randomized study did not have pre-specified endpoints
- The primary objective of the study was to determine if IV Choline Chloride substrate replacement would reverse hepatic steatosis and improve liver function in patients receiving long-term parenteral nutrition (PN)

PROTARA THERAPEUTICS

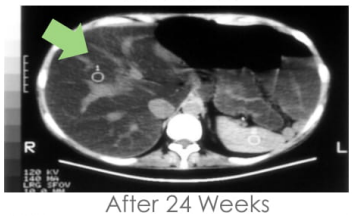
1) Buchman A, et al. JPEN. 2001;5:260-268.

IV Choline in IFALD : Phase 2 Results

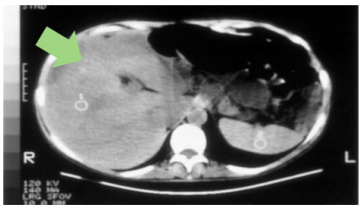
Improvement in Steatosis and Cholestasis

CLINICALLY MEANINGFUL IMPROVEMENT IN STEATOSIS

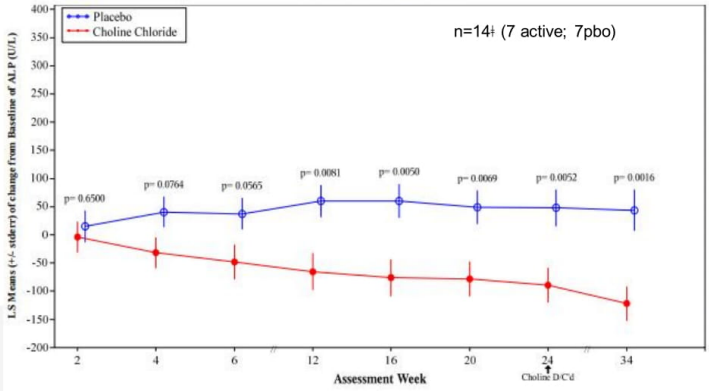
At Baseline



After 24 Weeks



CHOLESTASIS IMPROVEMENT: ALL PATIENTS*(1)



*Mixed model for repeated measurement (MMRM) method used

ǂA placebo subject was excluded from all analyses due to likely IV contrast-induced imaging abnormalities, confirmed by independent radiologist

PROTARA THERAPEUTICS

(1) Protara Therapeutics re-analysis of patient CRF's, data on file

IV Choline in IFALD: Prevalence Study

Prevalence study underway to enhance understanding of the patient population

DESIGN	Retrospective, observational study of patients in both academic & community settings
POPULATION	Patients dependent on PN for 6 or more months
OBJECTIVE	Understand presence/incidence of liver disease in this population to enhance value of development potential
QUESTIONS	How many individuals currently on service have been dependent on PN for 6 or more months? What percentage of these have elevated ALP levels (> 1.5x ULN) as an indicator of liver disease?

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Summary

Building Momentum in 2021

LMs: Near-term Rare Disease Opportunity	• Q1'21: Submitted CSR to FDA (Vaccines Division) to support TARA-002 for LMs with the potential to file our BLA in 2H 2021 • 2H'21: Complete GMP scale up and comparability
NMIBC: Significant Market Potential	• 1H'21: Complete nonclinical studies (tox, MOA, immunogenicity) • 2H'21: File IND • Late 2021: Initiate Phase 1 study*
IV Choline: Late-Stage Pipeline Opportunity	• 2H'21: Complete prevalence study to better characterize epidemiology of IFALD
Financials: Estimated funding through early 2023	• $166M as of September 30, 2020 • 19.2M Common Share Equivalents:11.2M Common + 8.0M Preferred on as-converted basis as of November 10, 2020

*Subject to acceptance of IND filing

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Corporate Presentation

March 2021