UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-36694

Protara Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-4580525**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

345 Park Avenue South
3rd Floor
New York, NY
(Address of Principal Executive Offices)

10010
(Zip Code)

(646) 844-0337
(Registrant's telephone number, including area code)

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 Global Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $112.3 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market on June 30, 2025 of $3.03 per share.

As of March 5, 2026, 54,084,378 shares of the registrant's common stock, $0.001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission by April 30, 2026 are incorporated by reference into Part III of this report.

PROTARA THERAPEUTICS, INC.

TABLE OF CONTENTS

FORM 10-K
For the Year Ended December 31, 2025

		Page
PART I		
Item 1.	Business	4
Item 1A.	Risk Factors	37
Item 1B.	Unresolved Staff Comments	72
Item 1C.	Cybersecurity	72
Item 2.	Properties	74
Item 3.	Legal Proceedings	74
Item 4.	Mine Safety Disclosures	74
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	75
Item 6.	Reserved	75
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	75
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	81
Item 8.	Financial Statements and Supplementary Data	82
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	115
Item 9A.	Controls and Procedures	115
Item 9B.	Other Information	115
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	116
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	117
Item 11.	Executive Compensation	117
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	117
Item 13.	Certain Relationships and Related Transactions, and Director Independence	117
Item 14.	Principal Accountant Fees and Services	117
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	118
Item 16.	Form 10-K Summary	121

PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled "*Business,*" "*Risk Factors,*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our other publicly available documents contain forward-looking statements or incorporate by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are subject to the safe harbor created thereby under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements other than statements of historical facts, including statements regarding our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. You can generally identify these forward-looking statements by terminology such as "believes," "expects," "potential," "continues," "may," "will," "should," "seek," "approximately," "predict," "intend," "plans," "estimates," "anticipates" or the negative version of these terms or other comparable terminology. Forward-looking statements inherently involve many risks and uncertainties that could cause actual results to differ from those expressed in forward-looking statements. Forward-looking statements are based on management's current plans and expectations, expressed in good faith and believed to have a reasonable basis. However, we can give no assurance that any expectation or belief will result or will be achieved or accomplished. Investors therefore should not place undue reliance on forward-looking statements.

These forward-looking statements include, but are not limited to, statements about:

- estimates regarding our financial performance, including future revenue, expenses and capital requirements;
- our expected cash position and ability to obtain financing in the future on satisfactory terms or at all;
- expectations regarding our plans to research, develop and commercialize our current and future product candidates, including TARA-002, and Intravenous, or IV, Choline Chloride;
- expectations regarding the safety and efficacy of our product candidates;
- expectations regarding the timing, costs and outcomes of our clinical trials;
- expectations regarding potential market size;
- expectations regarding the timing of the availability of data from our clinical trials;
- expectations regarding the clinical utility, potential benefits and market acceptance of our product candidates;
- expectations regarding our commercialization, marketing and manufacturing capabilities and strategy;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- expectations regarding our ability to identify additional products or product candidates with significant commercial potential;
- developments and projections relating to our competitors and industry;
- our ability to acquire, license and invest in businesses, technologies, product candidates and products;
- our ability to remain listed on the Nasdaq Global Market, or Nasdaq;
- the impact of and changes or developments in government laws and regulations, including any executive orders or tariffs;

- costs and outcomes relating to any disputes, governmental inquiries or investigations, regulatory proceedings, legal proceedings or litigation;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to prevent system failures, data breaches or violations of data protection laws;
- the timing or likelihood of regulatory filings and approvals;
- our ability to protect our intellectual property position; and
- the impact of general U.S., foreign and global economic, industry, market, trade, regulatory, political or public health conditions.

Investors should also carefully read the factors described under Item 1A. "Risk Factors" in this Annual Report on Form 10-K for a description of certain risks that could, among other things, cause our actual results to differ from those expressed in forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above and under Item 1A. "Risk Factors" to be a complete statement of all potential risks and uncertainties.

All forward-looking statements speak only as of the date of this Annual Report and are expressly qualified in their entirety by the risk factors and cautionary statements included in this Annual Report. Except as is required by law, we expressly disclaim any obligation to publicly release any revisions to forward-looking statements to reflect events after the date of this Annual Report.

SUMMARY OF RISKS AFFECTING OUR BUSINESS

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, and other risks and uncertainties that we face, are set forth in Part I, Item 1A. Risk Factors, and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the U.S. Securities and Exchange Commission, or SEC, before making investment decisions regarding our securities.

- We have a limited operating history and have never generated any revenues.
- We expect to incur significant expenses and significant losses for the foreseeable future and may never generate revenue or achieve or maintain profitability.
- We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.
- Our business depends on the successful preclinical and clinical development, regulatory approval and commercialization of our product candidates, including TARA-002 and IV Choline Chloride.
- We have never completed a registrational clinical trial or made a biologics license application, or BLA, or new drug application, or NDA, submission and may be unable to successfully do so for TARA-002 or IV Choline Chloride.
- Disruptions at the U.S. Food and Drug Administration, or FDA, or other comparable foreign regulatory authorities may extend the time necessary for new products to be reviewed and/or approved, which would adversely affect our business. In addition, there is substantial uncertainty regarding new initiatives under the current U.S. Presidential Administration and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed towards other agencies. These initiatives could prevent, limit or delay development and regulatory approval of our product candidates, which would adversely affect our business.
- Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of adoption and use necessary for commercial success.
- Our product candidates, if approved, will face significant competition and their failure to compete effectively may prevent them from achieving significant market penetration.
- We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, which may include sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval; and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, non-clinical, clinical and commercial supplies of any future product candidates.
- We currently have limited marketing capabilities and no sales organization. If we are unable to grow our sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.
- Certain stockholders have the ability to control or significantly influence certain matters submitted to our stockholders for approval.
- We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.
- Pharmaceutical companies are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations, including our clinical trials; harm to our reputation; and other adverse effects on our business or prospects.

Item 1. *Business.*

Overview

We are a New York City based clinical-stage biopharmaceutical company committed to advancing transformative therapies for the treatment of cancer and rare diseases. We were founded on the principle of applying modern scientific, regulatory or manufacturing advancements to established mechanisms in order to create new development opportunities. We prioritize creativity, integrity and tenacity to expedite our goal of bringing life-changing therapies to people with limited treatment options.

Our portfolio includes two development programs utilizing TARA-002, an investigational cell therapy based on the broad immunopotentiator, OK-432, which was originally granted marketing approval by the Japanese Ministry of Health and Welfare as an immunopotentiating cancer therapeutic agent. This cell therapy is currently approved in Japan and Taiwan for lymphatic malformations, or LMs, and multiple oncologic indications. We have secured worldwide rights to the asset excluding Japan and Taiwan and are exploring its use in oncology and rare disease indications. TARA-002 was developed from the same master cell bank of genetically distinct group A Streptococcus pyogenes as OK-432 (marketed as Picibanil® in Japan by Chugai Pharmaceutical Co., Ltd., or Chugai Pharmaceutical). We are currently developing TARA-002 in non-muscle invasive bladder cancer, or NMIBC, and LMs. We are also pursuing IV Choline Chloride, an investigational phospholipid substrate replacement therapy, for patients receiving parenteral support, or PS, which includes both nutrition and fluids.

Neither TARA-002 nor IV Choline Chloride have been approved by the FDA or other comparable regulatory authorities for use for any indications. We have devoted substantial efforts to the development of both TARA-002 and IV Choline Chloride and, to date, have not generated any revenues from product sales. We do not expect to generate revenues in the near-term, and it is possible we may never generate revenues in the future. To finance our current strategic plans, including the conduct of ongoing and future clinical trials and further research and development, we will need to raise additional capital. See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources” for additional information about our liquidity and capital resource needs.

TARA-002 in NMIBC

Our lead oncology program is TARA-002 in NMIBC, which is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle. Bladder cancer is the sixth most common cancer in the U.S., with NMIBC representing approximately 80% of bladder cancer diagnoses. Approximately 65,000 patients are diagnosed with NMIBC in the U.S. each year. Very few new therapeutics have been approved for NMIBC since the 1990s and the current standard of care for NMIBC includes intravesical Bacillus Calmette-Guérin, or BCG.

Following the completion of our ADVANCED-1 and ADVANCED-1EXP trials in October 2024 and September 2024, respectively, to evaluate safety, preliminary efficacy and the dosing of TARA-002, at the 40KE (Klinische Einheit, or KE, is a German term indicating a specified weight of dried cells in vial) dose level, we initiated and are currently conducting our ADVANCED-2 clinical trial. ADVANCED-2 is a Phase 2 open-label clinical trial evaluating intravesical TARA-002 in patients with high-grade carcinoma in situ, or CIS. Cohort A of the Phase 2 trial has completed enrollment and enrolled 31 patients with CIS (± Ta/T1, with Ta defined as non-invasive papillary carcinoma and T1 defined as carcinoma invading the lamina propria) who are either BCG-Naïve or BCG-Exposed and who have not received intravesical BCG for at least 24 months prior to CIS diagnosis. Cohort B of the Phase 2 trial is expected to enroll 75 to 100 patients with BCG-Unresponsive CIS (± Ta/T1) and is designed to be registrational based on the FDA’s August 2024 Draft Guidance for Industry on BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biological Products for Treatment. Trial subjects in ADVANCED-2 receive an induction course, with or without a reinduction, of six weekly intravesical instillations of TARA-002, followed by a maintenance course of three weekly instillations every three months.

In February 2026, we presented updated interim data from our ongoing Phase 2 open-label ADVANCED-2 trial reporting results that continue to support TARA-002’s potential as a mainstay in the NMIBC treatment landscape and demonstrating meaningful and durable activity in BCG-Unresponsive and BCG-Naïve NMIBC patients.

The dataset includes 43 BCG-Unresponsive patients and 31 BCG-Naïve patients who received at least 1 dose of TARA-002; 35 BCG-Unresponsive patients and 29 BCG-Naïve patients completed at least one response assessment and were evaluable for efficacy as of a January 28, 2026 data cutoff. Complete response, or CR, rates at the six months and 12 months landmark time points include all participants who were either evaluable at that time point or had experienced disease progression or treatment failure prior to the scheduled visit.

For the BCG-Unresponsive cohort, the CR rate at any time was 65.7% (23/35). The CR rate was 68.2% (15/22) at six months and 33.3% (5/15) at 12 months. Among responders, the Kaplan-Meier, or KM, estimated probability of maintaining a CR for six months was 71.1% (95% confidence interval, or CI: 46.7, 95.5), and 100% (5/5) maintained their CR from nine to 12 months. Re-induction therapy successfully converted most initial non-responders to responders with durable responses: 61.5% (8/13) of re-induced patients converted to a CR at six months.

For the BCG-Naïve cohort, the CR rate at any time was 72.4% (21/29). The CR rate was 66.7% (18/27) at six months and 57.9% (11/19) at 12 months. Among responders, the KM estimated probability of maintaining a CR for six months was 73.1% (95% CI: 52.9, 93.4), and 100% (11/11) maintained their CR from nine to 12 months. Re-induction therapy successfully converted most initial non-responders to responders with durable responses: 66.7% (4/6) of re-induced patients converted to a CR at six months.

The majority of treatment-related adverse events, or TRAEs, were Grade 1 and transient with no Grade 3 or greater TRAEs and no related serious adverse events, or SAEs, as assessed by study investigators. No patients discontinued treatment due to TRAEs. The most commonly occurring TRAEs were dysuria (14%), bladder spasm (9%), fatigue (7%) and micturition urgency (5%).

We expect to complete enrollment of the BCG-Unresponsive registrational cohort of the ADVANCED-2 trial in the second half of 2026. Enrollment is complete in the BCG-Naïve cohort of the ADVANCED-2 trial with 31 patients. In December 2025, we announced the FDA had provided written feedback supporting a proposed registrational design for a controlled trial in BCG-Naïve patients (who have never been exposed and those who have not received BCG within the last 24 months and are ineligible to receive BCG or contraindicated, cannot tolerate BCG, do not have access to BCG, or refuse BCG). The FDA has agreed that BCG is not required as a comparator and that intravesical chemotherapy is an acceptable comparator to TARA-002 in BCG-Naïve patients. The FDA also is aligned with the primary endpoint of the trial as the CR rate at month 6 with duration of response as a key secondary endpoint. We intend to initiate the ADVANCED-3 trial in the second half of 2026. We have engaged the FDA to determine how to include BCG-Exposed patients in our clinical trials of TARA-002, for whom no FDA-approved treatments are available and who have limited options to access investigational treatment through clinical trials.

In addition to our existing clinical trials in NMIBC, we plan to continue to explore the anti-tumor activity related to the administration of TARA-002 via systemic administration. We continue to believe that combination therapy may play a meaningful role in the NMIBC treatment paradigm and intend to evaluate TARA-002 in combination with other therapies. Given what we have observed to date of TARA-002's mechanism of action and safety profile, we believe it has strong potential as a combination agent, and we continue to evaluate potential combination therapy options for our clinical program. We also continue to conduct non-clinical studies on TARA-002 to better characterize the mechanism of action to help us understand how TARA-002 may perform in potential combinations with other agents used to treat NMIBC, and to help us define other cancer targets for TARA-002, both within urothelial cancer and other types of cancer affecting different parts of the body.

IV Choline Chloride for Patients on PS

We are also pursuing IV Choline Chloride, an investigational phospholipid substrate replacement therapy, for patients receiving PS which includes both nutrition and fluids. 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, neurotransmission, muscle function and bone health. PS patients are unable to synthesize choline from enteral nutrition sources, and there are currently no available PS formulations containing choline. Every year in the U.S. there are approximately 90,000 people who require PS at home and of those approximately 30,000 are on long-term PS. IV Choline Chloride has the potential to become the first FDA-approved IV choline formulation for PS patients.

An IV formulation of choline is recommended for patients on parenteral nutrition, or PN, by the American Society for Parenteral and Enteral Nutrition, or ASPEN, in their Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi — Trace Element Products, as well as by the European Society for Clinical Nutrition and Metabolism, or ESPEN, in their Guideline on Home Parenteral Nutrition. IV Choline Chloride has been granted Orphan Drug Designation, or ODD, by the FDA for the prevention and/or treatment of choline deficiency in patients on long-term PN. The U.S. Patent and Trademark Office, or USPTO, has issued us a U.S. patent claiming a choline composition and a U.S. patent claiming a method for treating choline deficiency with a choline composition, each with a term expiring in 2041.

In April 2024, we announced alignment with the FDA on a registrational path forward for IV Choline Chloride. Previously, we had been pursuing an indication in intestinal failure-associated liver disease, or IFALD, and following feedback from the FDA, are pursuing a broader indication as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated. Feedback from the FDA on our IV Choline Chloride program indicated that a single study with an endpoint of restoring choline levels in PS patients could serve as the basis for a regulatory submission for IV Choline Chloride.

In September 2024, we presented the results of THRIVE-1, a prospective, observational study evaluating the prevalence of choline deficiency and liver injury in patients dependent on PS in the U.S., U.K. and Europe. The study found that 78% of patients who are dependent on PS were choline deficient, and that 63% of choline deficient participants had liver dysfunction, including steatosis, cholestasis and hepatobiliary injury, underscoring the need for IV Choline supplementation in this patient population.

In January 2026, we advanced the development of IV Choline Chloride as a source of choline for adult and adolescent patients on long-term PS and initiated THRIVE-3, a registrational Phase 3 clinical trial. THRIVE-3 is a seamless Phase 2b/3 trial with a dose confirmation portion (n=24) followed by a double-blinded, randomized, placebo-controlled portion to assess the efficacy and safety of IV Choline Chloride over 24 weeks in adolescents and adults on long-term PS when oral or enteral nutrition is not possible, insufficient, or contraindicated (n=100). The primary endpoint of the clinical trial is a pharmacokinetic, or PK, endpoint measuring the change from baseline in plasma choline concentration. We also plan to include a number of secondary endpoints related to liver, bone and memory. The FDA granted IV Choline Chloride Fast Track Designation, or FTD, as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated.

TARA-002 in LMs

We are also pursuing TARA-002 in macrocystic and mixed-cystic LMs, which are rare, non-malignant cysts of the lymphatic vascular system that primarily form in the head and neck region of children before the age of two. In July 2020, the FDA granted Rare Pediatric Disease Designation, or RPDD, for TARA-002 for the treatment of LMs and in May 2022 the European Commission granted Orphan Medicinal Product Designation to TARA-002 for the treatment of LMs. In December 2025, the FDA granted both FDA Breakthrough Therapy Designation, or BTD, and FTD for TARA-002 for the treatment of macrocystic and mixed cystic LMs in pediatric patients. In addition to the clinical experience in Japan, we have secured the rights to a dataset from one of the largest ever conducted Phase 2 trials in LMs, in which OK-432 was administered via a compassionate use program led by the University of Iowa to over 500 pediatric and adult patients. We have an open investigational new drug application, or IND, for TARA-002 in LMs with the Vaccines and Related Products Division of the FDA, or Vaccines Division.

In October 2023, we initiated STARBORN-1, which is a Phase 2 single-arm, open-label, prospective clinical trial to evaluate the safety and efficacy of intracystic injection of TARA-002 for the treatment of macrocystic and mixed-cystic LMs (≥ 50% macrocystic disease) in participants six months to less than 18 years of age in the U.S. Including an age de-escalation safety lead-in, the clinical 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 clinical trial is the proportion of participants with macrocystic LMs and mixed-cystic LMs who demonstrated 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.

In November 2025, we announced interim results from our ongoing Phase 2 STARBORN-1 trial evaluating TARA-002 in pediatric patients with macrocystic and mixed cystic LMs. As of the data cutoff date of November 12, 2025, 12 patients had received at least one dose of TARA-002. Of the eight patients who were evaluable at the eight-week post-treatment assessment, 100% achieved clinical success. 88% of patients achieved clinical success

with just one or two doses of TARA-002. Among macrocystic patients, 83% (5/6) achieved a CR, and the only mixed cystic patient treated also achieved a CR. Two patients who reached the 32-week post-treatment assessment remain disease-free.

The safety profile of TARA-002 in this trial has been favorable, with the majority of adverse events, or AEs, being mild to moderate in severity. No SAEs were reported. The most common AEs were swelling and fatigue, and only one patient discontinued treatment due to a Grade 2 AE of fatigue.

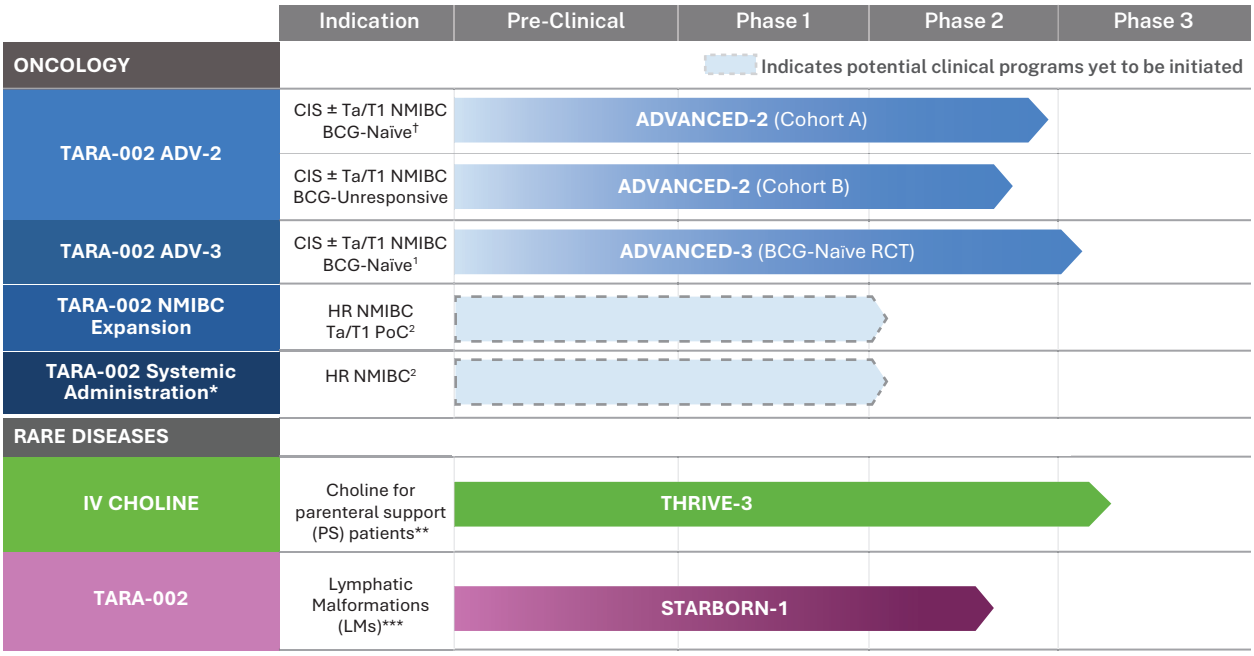
These results underscore the potential of TARA-002 to address an unmet need for pediatric patients with LMs, for whom there are currently no approved therapies. Many patients currently rely on invasive surgical procedures or off-label use of chemotherapies and chemicals, which can be associated with high complication rates and challenging side effects, particularly in pediatric populations.

Other Potential Opportunities

We believe TARA-002 may also have the potential to be used to treat other maxillofacial cysts based on the historical literature from the TARA-002 predecessor, OK-432, as well as recent data from the STARBORN-1 trial in which the one pediatric patient with a ranula achieved a CR after a single 1KE injection of TARA-002. While completing STARBORN-1 in LMs is our priority, we believe there may be an opportunity in the future to explore the potential of TARA-002 to treat different types of maxillofacial cysts.

Our Product Candidate Pipeline

The following chart summarizes the current status of our product candidate pipeline:



* Currently in pre-clinical studies to define dosing.

** IV Choline granted ODD by the FDA for the prevention and/or treatment of choline deficiency in patients on long-term PN and FTD as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated.

*** TARA-002 granted RPDD, as well as BTD and FTD by the FDA and Orphan Medicinal Product Designation by the European Commission for the treatment of LMs.

† Trial also includes BCG-Exposed patients

1 Subject to regulatory clearance

2 Potential expansion opportunity for NMIBC program

Our Corporate Strategy:

We are an oncology and rare disease company focused on applying modern scientific advancements to established mechanisms to deliver efficient de-risked clinical programs. Leveraging the drug development experience of our management team, our goal is to build a leading biopharmaceutical company focused on bringing life-saving therapies to patients with significant unmet needs. Our current key initiatives are listed below:

1. Progress the registrational clinical trial of TARA-002 for the treatment of BCG-Unresponsive NMIBC

Complete enrollment of ADVANCED-2 Cohort B in BCG-Unresponsive NMIBC patients with CIS.

2. Initiate ADVANCED-3 registrational clinical trial of TARA-002 for the treatment of BCG-Naïve NMIBC

Complete the BCG-Naïve cohort of ADVANCED-2 for patients with CIS and initiate the registrational ADVANCED-3 trial evaluating TARA-002 in patients with BCG-Naïve NMIBC.

3. Progress the registrational seamless Phase 2b/3 trial evaluating IV Choline Chloride in patients receiving PS

Progress THRIVE-3, a seamless Phase 2b/3 trial assessing the efficacy and safety of low and high dose IV Choline Chloride in adolescent and adult patients receiving long-term PS when oral or enteral nutrition is not possible, insufficient, or contraindicated.

4. Progress the Phase 2 clinical trial of TARA-002 in patients with macrocystic and mixed-cystic LMs; confirm with FDA the registrational pathway for TARA-002 in LMs

We initiated the STARBORN-1 Phase 2 trial evaluating TARA-002 in pediatric patients with macrocystic and mixed-cystic LMs and expect to complete enrollment of the trial in the second half of 2026. In addition, we expect to meet with the FDA to determine the registrational path forward for TARA-002 in LMs in the first half of 2026.

5. Build our operational capabilities to successfully commercialize our oncology and rare disease programs

As we approach regulatory filings and possible approvals of our oncology and rare disease investigational therapies, we intend to build our commercial infrastructure to successfully launch and commercialize our products in key geographies where we can maximize value. Across the rare disease populations (LMs and patients on PS) as well as bladder cancer, a high volume of patients are concentrated in a small number of centers of excellence. We believe this concentration of treatment centers will potentially enable us to efficiently cover our addressable market with a relatively small commercial footprint. Across our rare disease programs, there is significant unmet need and no available FDA-approved therapies to meet the needs of these patients currently. In NMIBC, there is also a significant unmet need, and we believe TARA-002's important attributes, such as fast, simple administration by a nurse with no cumbersome additional steps or required safety protocols and a favorable tolerability profile, will position the potential therapy favorably with patients and physicians versus other treatment options.

Our Pipeline

TARA-002

TARA-002, our lead program, is an investigational cell therapy developed from the master cell line of the same genetically distinct Streptococcus pyogenes (group A, type 3) Su strain as OK-432, a broad immunopotentiator marketed as Picibanil® in Japan by Chugai Pharmaceutical. We are using the same regulatory starting materials as OK-432 and manufacture TARA-002 using an updated version of the same proprietary processes used to manufacture OK-432. We have designated this product candidate as TARA-002 in order to differentiate the regulatory path in the U.S. and other geographies from that of OK-432 in Japan.

We entered into an agreement with Chugai Pharmaceutical in June 2019, as amended in July 2020, to support our development of TARA-002. The agreement provides us with exclusive access to certain materials and documents relating to OK-432 including the master cell bank of Streptococcus pyogenes used in the manufacturing of OK-432. Additionally, the agreement provides technical support during a certain period. We have utilized the materials, proprietary manufacturing process and technical support provided by Chugai Pharmaceutical to support a

contract development and manufacturing organization, or CDMO, in the production of TARA-002 at a current Good Manufacturing Practices, or cGMP, compliant facility in the U.S. Under the agreement with Chugai Pharmaceutical, we have sole responsibility for the development and commercialization of TARA-002 worldwide, excluding Japan and Taiwan. This agreement is exclusive through June 17, 2030, or following any termination of the agreement by either party.

In Japan, OK-432 is indicated for: the treatment of lymphangiomas (LMs); the prolongation of survival time in patients with gastric cancer (postoperative cases) or primary lung cancer in combination with chemotherapy; and the reduction of cancerous pleural effusion or ascites in patients with lung cancer or gastrointestinal cancer respectively, head and neck cancer (maxillary cancer, laryngeal cancer, pharyngeal cancer, and tongue cancer) and thyroid cancer that are resistant to other drugs.

We are developing TARA-002 for the treatment of NMIBC and LMs initially in the U.S., and plan to also seek approval in other regions in the future and may also explore additional indications where its utility as an immunopotentiator has been hypothesized to be of therapeutic benefit.

TARA-002 in NMIBC

Disease Overview

Bladder cancer is the sixth most common cancer in the U.S., with NMIBC representing approximately 80% of bladder cancer diagnoses. NMIBC is cancer found in the tissue that lines the inner surface of the bladder that has not spread into the bladder muscle. There are three subtypes of NMIBC: Ta, CIS, and T1. Among the types of NMIBC, Ta accounts for most NMIBC cases (70%), whereas T1 and CIS account for 20% and 10%, respectively.

There are approximately 65,000 incidents of NMIBC in the U.S. every year, and based upon currently available data we believe that approximately 45% (approximately 30,000) are made up of high-grade tumor types that are considered higher risk, and therefore candidates for immunotherapies, such as TARA-002. In addition, NMIBC has one of the highest rates of recurrence with the five-year rate estimated at up to 70%.

Treatment

Treatment for NMIBC is typically targeted to reduce unresectable persistence, recurrence after resection and to prevent disease progression to muscle-invasive bladder cancer. The initial treatment for NMIBC includes cystoscopy and complete transurethral resection of the bladder tumor, or TURBT, for papillary Ta or T1, or biopsy for CIS. A single postoperative instillation of intravesical chemotherapy is recommended in patients with low risk of progression, and for patients with intermediate and high-risk disease, a longer course of intravesical therapy is administered. The most efficacious intravesical agent to date has been BCG, a live attenuated form of *Mycobacterium bovis*. BCG has been the subject of multiple supply shortages in the U.S. in the past decade due to the inability to meet demand to treat the large population of patients with NMIBC. There has been a significant increase in bladder cancer recurrence and progression with an escalated number of patients who require cystectomy. As such, with the current BCG shortage and limited effective alternate therapies or dosing strategies, there continues to be a significant unmet need for treatment options for patients with NMIBC.

Clinical Development

Following the completion of our ADVANCED-1 and ADVANCED-1EXP trials in October 2024 and September 2024, respectively, to evaluate safety, preliminary efficacy and the dosing of TARA-002, at the 40KE dose level, we initiated and are currently conducting our ADVANCED-2 clinical trial. ADVANCED-2 is a Phase 2 open-label clinical trial evaluating intravesical TARA-002 in patients with high-grade CIS. Cohort A of the Phase 2 trial has completed enrollment and enrolled 31 patients with CIS (± Ta/T1) who are either BCG-Naïve or BCG-Exposed and who have not received intravesical BCG for at least 24 months prior to CIS diagnosis. Cohort B of the Phase 2 trial is expected to enroll 75 to 100 patients with BCG-Unresponsive CIS (± Ta/T1) and is designed to be registrational based on the FDA's August 2024 Draft Guidance for Industry on BCG-Unresponsive Nonmuscle Invasive Bladder Cancer: Developing Drugs and Biological Products for Treatment. Trial subjects in ADVANCED-2 receive an induction course, with or without a reinduction, of six weekly intravesical instillations of TARA-002, followed by a maintenance course of three weekly instillations every three months.

In April 2025, we presented interim data from our ADVANCED-2 trial with an April 16, 2025 data cutoff. The BCG-Unresponsive dataset included a total of five patients, all of whom were six-and nine-month evaluable, and three of whom were evaluable at 12 months. The CR rate at any time in BCG-Unresponsive patients was 100% (5/5). The CR rate in BCG-Unresponsive patients was 100% (5/5) at six months, 80% (4/5) at nine months, and 67% (2/3) at 12 months.

The BCG-Naïve dataset included a total of 21 patients, including 16 evaluable at six months, eight at nine months, and seven at 12 months. The CR rate at any time in BCG-Naïve patients was 76% (16/21). The CR rate in BCG-Naïve patients was 63% (10/16) at six months, 63% (5/8) at nine months, and 43% (3/7) at 12 months.

The majority of AEs were Grade 1 and transient with no Grade 3 or greater TRAEs, as assessed by study investigators. No patients discontinued treatment due to TRAEs. The most common AEs were in line with typical responses to bacterial immunopotentiation, such as flu-like symptoms. The most common urinary symptoms reflect urinary tract instrumentation effects, such as bladder spasm, burning sensation and urinary tract infection. Most bladder irritations resolved shortly after administration or within a few hours to a few days.

In December 2025, we presented updated interim data from our ADVANCED-2 trial of TARA-002 in BCG-Naïve patients. The dataset included 31 BCG-Naïve patients who received at least one dose of TARA-002; 29 patients completed at least one response assessment and were evaluable for efficacy as of a November 7, 2025 data cutoff. CR rates at the six months and 12 months landmark time points include all participants who were either evaluable at that time point or had experienced disease progression or treatment failure prior to the scheduled visit. The CR rate at any time was 72% (21/29). The CR rate was 69% (18/26) at six months and 50% (7/14) at 12 months. Among initial responders, 88% (14/16) maintained their response through six months and 100% (3/3) through 12 months. Re-induction therapy successfully salvaged most initial nonresponders, resulting in high conversion rates and durable responses: 80% (4/5) of re-induced patients converted to a CR at 6 months, and 100% (4/4) of those responders maintained their CR at 12 months.

The majority of TRAEs were Grade 1 and transient with no Grade 3 or greater TRAEs as assessed by study investigators. No patients discontinued treatment due to TRAEs. The most commonly occurring TRAEs were dysuria (13%), fatigue (13%) and hematuria (6%).

In February 2026, we presented updated interim data from our ADVANCED-2 trial, reporting results that continue to support TARA-002.

The dataset includes 43 BCG-Unresponsive patients and 31 BCG-Naïve patients who received at least one dose of TARA-002; 35 BCG-Unresponsive patients and 29 BCG-Naïve patients completed at least one response assessment and were evaluable for efficacy as of a January 28, 2026 data cutoff. CR rates at the six months and 12 months landmark time points include all participants who were either evaluable at that time point or had experienced disease progression or treatment failure prior to the scheduled visit.

For the BCG-Unresponsive cohort, the CR rate at any time was 65.7% (23/35). The CR rate was 68.2% (15/22) at six months and 33.3% (5/15) at 12 months. Among responders, the KM estimated probability of maintaining a CR for six months was 71.1% (95% CI: 46.7, 95.5), and 100% (5/5) maintained their CR from nine to 12 months. Re-induction therapy successfully converted most initial non-responders to responders with durable responses: 61.5% (8/13) of re-induced patients converted to a CR at six months.

For the BCG-Naïve cohort, the CR rate at any time was 72.4% (21/29). The CR rate was 66.7% (18/27) at six months and 57.9% (11/19) at 12 months. Among responders, the KM estimated probability of maintaining a CR for six months was 73.1% (95% CI: 52.9, 93.4), and 100% (11/11) maintained their CR from nine to 12 months. Re-induction therapy successfully converted most initial non-responders to responders with durable responses: 66.7% (4/6) of re-induced patients converted to a CR at six months.

The majority of TRAEs were Grade 1 and transient with no Grade 3 or greater TRAEs and no related SAEs as assessed by study investigators. No patients discontinued treatment due to TRAEs. The most commonly occurring TRAEs were dysuria (14%), bladder spasm (9%), fatigue (7%) and micturition urgency (5%).

In December 2025, we announced that the FDA has provided written feedback supporting a proposed registrational design for a controlled trial in BCG-Naïve patients (who have never been exposed and those who have not received BCG within the last 24 months and are ineligible to receive BCG or contraindicated, cannot tolerate BCG, do not have access to BCG, or refuse BCG). The FDA has agreed that BCG is not required as a comparator and that intravesical chemotherapy is an acceptable comparator to TARA-002 in BCG-Naïve patients. The FDA also is aligned with the primary endpoint of the trial as the CR rate at month six with duration of response as a key secondary endpoint. We intend to initiate this registrational clinical trial in the second half of 2026. We have engaged the FDA to determine how to include BCG-Exposed patients in our clinical trials of TARA-002, for whom no FDA-approved treatments are available and who have limited options to access investigational treatment through clinical trials.

Non-clinical Development

We continue to conduct non-clinical studies on TARA-002 to better characterize the mechanism of action to help us understand how TARA-002 may perform in potential combinations with other agents used to treat NMIBC. We have completed non-clinical studies comparing TARA-002 to BCG. Mechanistically, TARA-002 and BCG are similar in that they are both intravesically administered broad-spectrum immune potentiators that drive a TH-1 pro-inflammatory response and have a preference to M1 polarization. We found several important differences when we compared the two agents in non-clinical studies that we believe make TARA-002 a potentially compelling new therapy. We found that TARA-002 is a NOD2/TLR 2 agonist (NOD2 is defined as Nucleotide-binding oligomerization domain 2; TLR 2 is defined as toll-like receptor 2) and BCG is a toll-like receptor 4, or TLR4, agonist. When we compared TARA-002 directly to BCG, in a cytotoxicity assay, we found that TARA-002 resulted in significantly stronger tumor cell killing compared to BCG. We also found that TARA-002 resulted in significantly higher upregulation of key pro-inflammatory cytokines and chemokines, including tumor necrosis factor alpha, or TNF-α, and interferon gamma, or interferon-γ. We also observed that TARA-002 meaningfully down-regulated Interleukin-8, or IL-8, which at prolonged elevations is thought to increase risk for tumor recurrence in bladder cancer after BCG therapy.

The approved indications for OK-432 in Japan are based on systemic administration of the drug. There is a significant existing safety database with this route of administration for OK-432 in Japan. In addition, we have completed subcutaneous systemic toxicology studies of TARA-002 and we are considering a proof-of-concept study exploring systemic administration of TARA-002.

Regulatory Interactions

In October 2021, we announced that the Office of Tissues and Advanced Therapies Division, now referred to as the Office of Therapeutic Products, of the FDA's Center for Biologics Evaluation and Research, or CBER, cleared our IND for TARA-002 in NMIBC.

Manufacturing

TARA-002 is manufactured using an equivalent, but modernized, proprietary manufacturing process as is used to produce OK-432 by Chugai Pharmaceutical. We propagated a master cell bank using the same master cell line of the genetically distinct strain of Streptococcus pyogenes (A group, type 3) Su strain as OK-432. The bacteria is rendered inactive during the manufacturing process, consistent with the process used for OK-432. We have contracted a cGMP compliant CDMO to manufacture TARA-002 in the U.S.

IV Choline Chloride for PS Patients

IV Choline Chloride is an IV substrate therapy in development for patients receiving PS.

Choline is a known important substrate for phospholipids, a source of methyl groups needed for many steps in metabolism and plays important roles in modulating gene expression, cell membrane signaling, lipid transport, metabolism, liver health, brain development, neurotransmission, muscle function and bone health. The only way to reliably replenish choline is through exogenous consumption. Patients receiving PS cannot sufficiently absorb adequate levels of choline and available PS components do not contain sufficient amounts of choline to correct this deficit. The use of choline for PS patients is included in key professional medical society recommendations, including

ASPEN. IV Choline Chloride has been granted ODD by the FDA for the prevention and/or treatment of choline deficiency in patients on long-term PN. The FDA granted IV Choline Chloride FTD as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated.

We have entered into a license agreement with Dr. Alan Buchman for exclusive rights to the IND, ODD and other regulatory assets related to IV Choline Chloride, as well as exclusive rights to the data from previously conducted Phase 1 and Phase 2 clinical trials led by Dr. Buchman.

The results of Dr. Buchman's randomized, controlled, Phase 2 clinical trial demonstrated that treatment with IV Choline Chloride resulted in normalization of plasma-free choline concentrations, improvement of hepatic steatosis, and statistically significant improvement in cholestasis in patients dependent on PS.

Disease Overview

PN typically consists of carbohydrate (typically derived from dextrose), fat (lipid emulsion with essential fatty acids), protein (in the form of a balanced free amino acid solution), electrolytes, trace elements, and most vitamins and essential nutrients known to be required by the human body, with the notable exception of choline. PS is a medical treatment, representing PN plus fluids and is used to manage and treat malnourishment and is indicated when there is impaired gastrointestinal function and contraindications to enteral nutrition. ASPEN and the Academy of Nutrition and Dietetics' Dietitians in Nutrition Support both recommend that choline be required in PN products (Vanek et al., 2012); however, there are currently no FDA-approved intravenous choline chloride products. Humans can produce choline endogenously in the liver, but the amount that the body naturally synthesizes is not sufficient to meet human needs, making it an essential nutrient. As a result, humans must obtain choline from their diets. The development of IV Choline Chloride is intended to provide a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Clinical Development

In Dr. Buchman's Phase 2 randomized, double-blind, controlled 24-week clinical trial, patients (n=15) receiving nightly PN for > 85% of their nutritional needs (for at least 12 weeks prior to entry) were randomized to receive via IV infusion (10-12 hours) their usual PN with placebo (n = 8), or PN to which 2g IV Choline Chloride was added (n = 7).

In the IV Choline Chloride group, mean choline levels were within or greater than the estimated normal range (i.e., 6.7 to 26.9 nmol/mL) throughout the 24-week trial and quickly returned to baseline levels when treatment was discontinued.

In September 2024, we presented the results of THRIVE-1, a prospective, observational study evaluating the prevalence of choline deficiency and liver injury in patients dependent on PS in the U.S., U.K. and Europe. The study found that 78% of patients who are dependent on PS were choline deficient, and that 63% of choline deficient participants had liver dysfunction, including steatosis, cholestasis and hepatobiliary injury, underscoring the need for IV Choline supplementation in this patient population.

In January 2026, we advanced the development of IV Choline Chloride as a source of choline for adult and adolescent patients on long-term PS and initiated THRIVE-3. THRIVE-3 is a seamless Phase 2b/3 trial with a dose confirmation portion (n=24) followed by a double-blinded, randomized, placebo-controlled portion to assess the efficacy and safety of IV Choline Chloride over 24 weeks in adolescents and adults on long-term PS when oral or enteral nutrition is not possible, insufficient, or contraindicated (n=100). The primary endpoint of the clinical trial is a PK endpoint measuring the change from baseline in plasma choline concentration. We also plan to include a number of secondary endpoints related to liver, bone and memory.

In addition to the studies performed by Dr. Buchman, we have completed a number of preclinical in vitro and non-clinical pharmacology studies for IV Choline Chloride.

Regulatory Interactions

IV Choline Chloride has been granted ODD by the FDA for the prevention and/or treatment of choline deficiency in patients on long-term PN.

In April 2024, we announced alignment with the FDA on a registrational path forward for IV Choline Chloride.

In October 2024, the FDA granted FTD to IV Choline Chloride as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Manufacturing

Our end-to-end manufacturing of IV Choline Chloride is conducted in the U.S. by a cGMP compliant CDMO.

TARA-002 in LMs

Disease Overview

The International Society for the Study of Vascular Anomalies classifies LMs as either macrocystic, microcystic, or mixed-cystic. Macrocystic and microcystic LMs are differentiated by the size of the fluid-containing portion of the malformation. Macrocystic LMs are characteristically large, fluid-filled cysts with a thin endothelial lining. Macrocystic LMs are composed of cysts greater than 2 cubic centimeters in size and present as a soft, fluid-filled swelling beneath normal or slightly discolored skin. Macrocystic LMs are usually located in the antero-lateral cervical region of the neck; however, it is possible for this type of LM to originate in other areas of the body. In contrast, microcystic LMs have very limited internal space with a thick irregular endothelial lining. Microcystic LMs are comprised of cysts less than 2 cubic centimeters in size and are often composed of micro-lymphatic channels that integrate and infiltrate normal soft tissue. Microcystic LMs can involve both superficial and deep aspects including muscle and bone. Microcystic LMs can thicken or swell causing enlargement of surrounding soft tissue and bones and can be found on any area of the skin or mucous membrane. Mixed-cystic LMs are comprised of varying degrees of both macrocystic and microcystic LMs.

While the exact prevalence of LMs is not known, in the U.S., the condition is thought to be present in approximately one in every 4,000 live births and we believe there are approximately 1,400-1,800 LM cases per year.

Treatment

We are not aware of any approved pharmacotherapies for LMs, except in Japan and Taiwan where OK-432 is approved. In Japan, for example, OK-432 has been the standard of care for LMs for over 25 years.

Treatment of LMs varies depending on the symptoms and complications that present themselves. The standard of care outside Japan for the treatment of LMs is either a partial or complete surgical excision of the cysts. While surgery is the standard approach to the treatment of LMs in the head and neck, the region is a difficult area to operate on because of the large number of important anatomical structures in the area. Major venous and arterial trunks travel through the neck, as do important nerves. Surgery on such malformations frequently results in high rates of recurrence and complications including life-long chronic conditions, such as damage to nerves and other important structures of the head and neck.

Clinical Development

Historical Data on OK-432, predecessor therapy to TARA-002

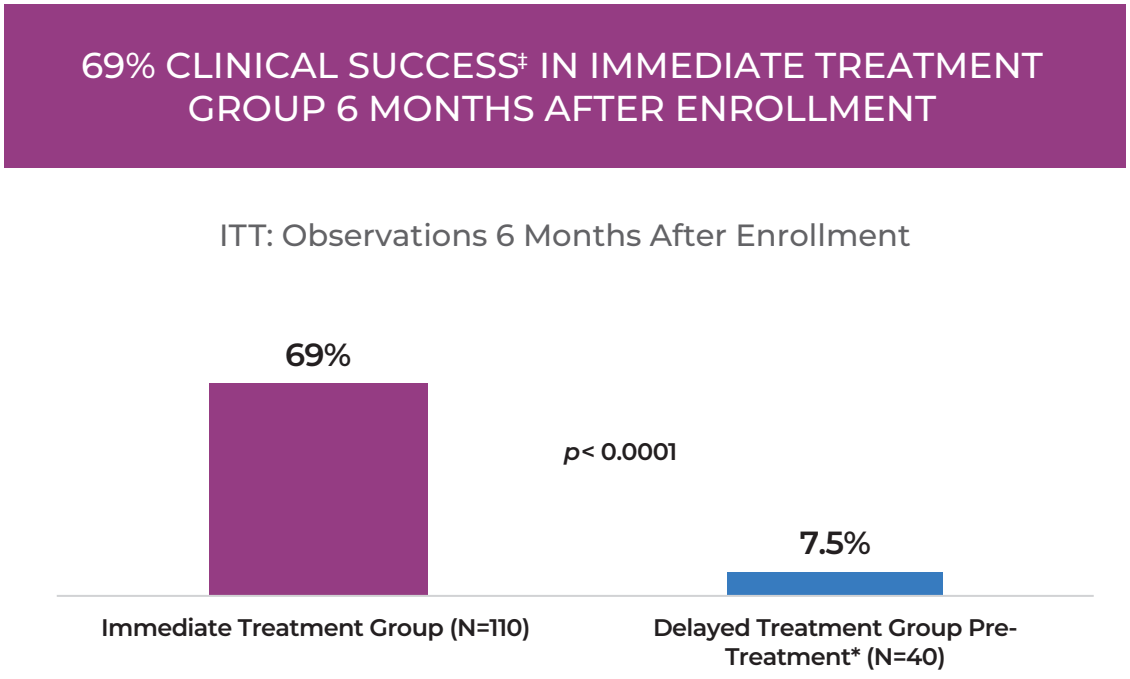
When TARA-002 is administered, it is hypothesized that innate and adaptive immune cells within the cyst or tumor are activated and produce a strong immune cascade. Neutrophils, monocytes, and lymphocytes infiltrate the abnormal cells and various cytokines, including interleukins IL-2, IL-6, IL-10, IL-12, interferon-γ, and TNF-α are secreted by immune cells to induce a strong inflammatory reaction and destroy the abnormal cells. In concert, these immune activities induce a strong local inflammatory reaction in the cyst wall, resulting in fluid drainage, shrinkage and fibrotic adhesion of the cyst.

A randomized, Phase 2 clinical trial led by the University of Iowa studied the use of OK-432 in patients with LMs from 1998 to 2005. Most eligible subjects were between six months and 18 years of age with macrocystic or mixed-cystic LMs (with ≥ 50% macrocystic disease) of the head and/or neck. There were three treatment groups: immediate treatment, or ITG, delayed treatment, or DTG, and open label treatment group. The ITG received treatment with OK-432 upon diagnosis. The DTG received OK-432 treatment following a six-month observation period; the cross-over design was intended to investigate spontaneous resolution. The open-label treatment group included infants younger than six months of age, adults older than 18 years of age, patients with LMs involving sites other than the head and neck (such as the axilla, thorax and extremities), and patients treated on an emergent basis. The open label treatment group were treated immediately with OK-432. Response to therapy was measured by quantitating change in lesion size. Clinical success was defined as a complete (90% to 100%) or substantial (60% to 89%) response to treatment based on radiographically confirmed shrinkage in lesions.

The study results were based on a retrospective analysis of source verified data that included the full dataset of subjects enrolled in the Phase 2 randomized clinical trial between January 1998 and August 2005, including data in the published study (Smith et al. 2009) that included subjects enrolled between January 1998 and November 2004.

Overall, 310 subjects were enrolled with intent to treat: 246 subjects were randomized to the immediate (ITG, N=171) and delayed (DTG, N=75) treatment groups; 64 subjects were nonrandomized and assigned to the open-label group. Analysis of the primary efficacy endpoint (N=150) demonstrated clinical success (complete and/or substantial response) in 69% of patients in the ITG 6 months after enrollment, while 7.5% of patients in the DTG experienced spontaneous regression of a LM during this time interval ($p < 0.0001$). When the results were analyzed by lesion type across all treatment groups, a successful outcome was observed in 84% and 60% of patients with macrocystic and mixed-cystic LMs, respectively. None of the patients with microcystic LMs demonstrated clinical success with OK-432 therapy. The results of the retrospective analysis were consistent with the results observed in the original analysis (Smith et al. 2009).

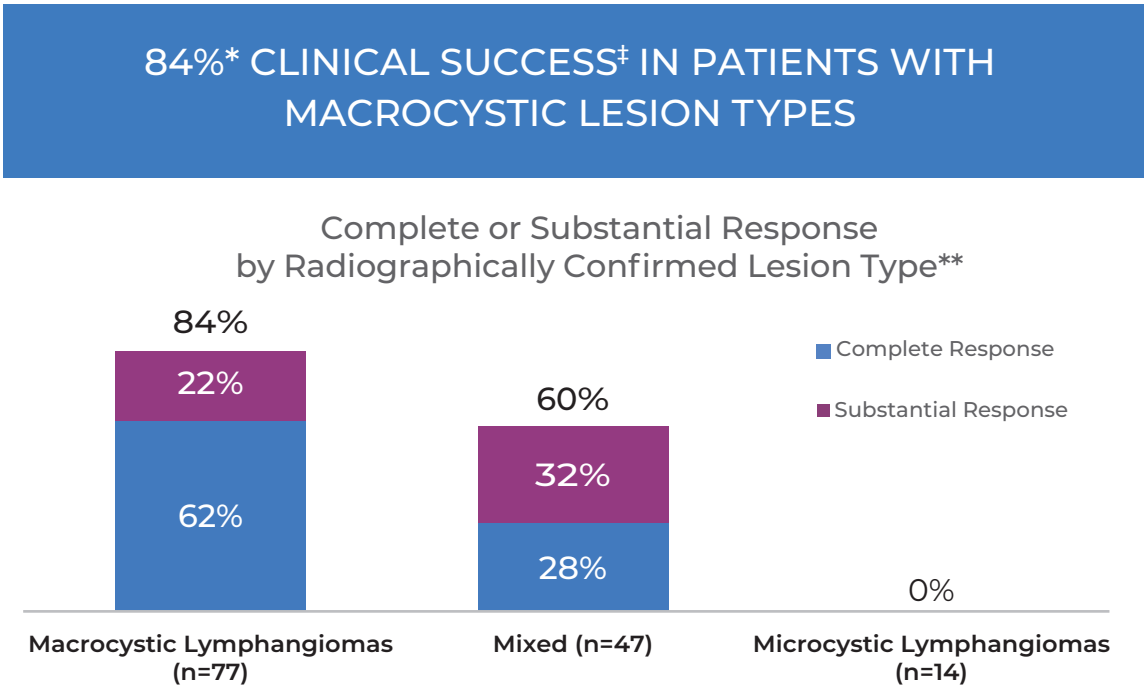
Figure 1: 69% of patients in the ITG had a complete or substantial response to OK-432, meeting the primary endpoint, while 7.5% of patients in the DTG had a complete or substantial response after six months of observation and before treatment.



‡ Clinical Success was defined as complete or substantial response.

* Results were analyzed by lesion type across all treatment groups

Figure 2: patients with radiographically confirmed macrocystic lesions had the greatest likelihood of clinical success and in those patients with mixed lesions, clinical success was also present.



‡ 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 ITG.

** Results were analyzed by lesion type across all treatment groups.

TARA-002 Clinical Development

We have an open IND for LMs with the FDA's Vaccines Division. In October 2023, we initiated the STARBORN-1 trial, a Phase 2 single arm, open-label clinical trial to evaluate the safety and efficacy of TARA-002 in approximately 30 pediatric patients ages six months to less than 18 years old with macrocystic and mixed-cystic LMs. The clinical trial design includes a safety lead-in phase followed by an expansion phase. The primary endpoint of the clinical 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.

In November 2025, we announced interim results from our ongoing Phase 2 open-label STARBORN-1 trial. The interim analysis included a total of 12 patients who enrolled in the trial and received ≥ one dose of TARA-002 as of the November 12, 2025 data cutoff. Of those, eight patients were evaluable at an eight-week post-treatment assessment, two withdrew prior to the eight-week assessment and two remain in dosing. Patients receive up to four injections of TARA-002 spaced approximately six weeks apart. Of the eight patients who were evaluable, the majority (7/8) achieved clinical success with one or two doses. Only one patient, who presented with a 1,739 mL macrocystic LM, required all four doses, and achieved a CR.

Overall, 80% (8/10) of patients that completed treatment achieved clinical success and 100% (8/8) of patients who completed the eight-week response assessment achieved clinical success. 83% (5/6) of macrocystic patients achieved a CR (90% to 100% reduction in total LM volume) and one patient achieved a substantial response (60% to less than 90% reduction in total LM volume). The only mixed cystic patient treated achieved a CR.

Two LMs patients in the interim analysis reached the 32-week post-treatment assessment and remain disease-free. One patient deemed a CR was subsequently diagnosed with a ranula (a different type of maxillofacial cyst from LMs). Two patients withdrew before the eight-week post-treatment assessment, including one patient who was misdiagnosed

and had a rare form of cancer and did not respond to treatment and one patient who dropped out after achieving a notable resolution of their macrocystic LM. The patient received two doses of TARA-002 with 160 mL aspiration at the first dose, which was reduced to a 10 mL aspiration at the second dose.

The majority of AEs were mild to moderate, with no serious AEs reported. The most common AEs were swelling and fatigue. One patient discontinued treatment due to a Grade 2 AE of fatigue.

Historical Safety Profile on OK-432, predecessor therapy to TARA-002

The most common AEs with treatment with OK-432 were local injection site reactions, fever, fatigue and decreased appetite, with resolution within two weeks. Treatment emergent SAEs (treatment emergent SAEs are defined as any SAE occurring or worsening on or after the first dose of study drug and within 35 days after the last dose of study drug) associated with OK-432 treatment were 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.

The safety findings from the sponsor-conducted retrospective analysis are consistent with the original analysis reported in Smith et al. 2009, and with safety data in published studies in approximately 865 patients with LMs after treatment with OK-432.

Historical Preclinical Development on OK-432, predecessor therapy to TARA-002

A comprehensive preclinical development program for OK-432, including in vitro and in vivo pharmacology and toxicology studies, was conducted by Chugai Pharmaceutical to support the filing and approval of an NDA with the Japan Pharmaceuticals and Medical Devices Agency. We believe these studies may help inform the design of a development plan for TARA-002 in LMs. In addition, there is a significant body of literature exploring the use of OK-432 in other maxillofacial cysts demonstrating strong potential for TARA-002 to be explored in the treatment of these cysts as well.

Regulatory Interactions

In July 2020, the FDA granted RPDD for TARA-002 for the treatment of LMs. The FDA grants RPDD for serious diseases that primarily affect children ages 18 years or younger and fewer than 200,000 persons in the U.S. Under the FDA's Rare Pediatric Disease Priority Review Voucher Program, a sponsor who receives an approval of an NDA or BLA for a product for the prevention or treatment of a rare pediatric disease may be eligible for a voucher, which can be redeemed to obtain priority review for any subsequent marketing application or may be sold or transferred prior to such redemption. Under the current provisions in the law, the Rare Pediatric Disease Priority Review Voucher Program will sunset on September 30, 2029, which means that the FDA may only award a Priority Review Voucher, or PRV, for an approved Rare Pediatric Disease product application if the sponsor has received RPDD for the product and the product is subsequently approved by September 30, 2029.

In May 2022, the European Commission granted Orphan Medicinal Product Designation to TARA-002 for the treatment of LMs.

In December 2025, the FDA granted both BTD and FTD for TARA-002 for the treatment of macrocystic and mixed cystic LMs in pediatric patients.

Manufacturing

TARA-002 is manufactured using an equivalent, but modernized, proprietary manufacturing process as is used to produce OK-432 by Chugai Pharmaceutical. We propagated a master cell bank using the same master cell line of the genetically distinct strain of Streptococcus pyogenes (A group, type 3) Su strain as OK-432. The bacteria is rendered inactive during the manufacturing process, consistent with the process used for OK-432. We have contracted a cGMP compliant CDMO to manufacture TARA-002 in the U.S.

Collaborations and License Agreements

Chugai Agreement

On June 17, 2019, we entered into an agreement, or the Chugai Agreement, with Chugai Pharmaceutical, a company organized and existing under the laws of Japan. Chugai Pharmaceutical has developed and commercialized a therapeutic product, OK-432, or Existing Product, in Japan and Taiwan, or the Chugai Territory, and owns and controls certain materials and documents related to the Existing Product, or the Chugai Materials. Pursuant to the Chugai Agreement, Chugai Pharmaceutical has provided us with certain materials and documents relating to the Existing Product and has provided certain technical services to us for our development and commercialization. This pertains to territories other than the Chugai Territory, or the Protara Territory, of a new therapeutic product, or the New Product or TARA-002, comparable to the Existing Product. Under the Chugai Agreement, Chugai Pharmaceutical will exclusively provide the Existing Product and Chugai Materials to us and will not provide the Existing Product or Chugai Materials to any third parties during the Chugai Service Period, other than for medical, compassionate use and/or non-commercial research purposes. Additionally, beginning on the effective date of the Chugai Agreement and ending on the fifth anniversary of such date or upon the termination of the Chugai Agreement, whichever comes earlier, Chugai Pharmaceutical will not provide Chugai Materials or technical support to any third-party for the purpose of development and commercialization in the Protara Territory of a therapeutic product comparable to the Existing Product. We are responsible, at our sole cost and expense, for the development and commercialization of the New Product in the Protara Territory.

On July 14, 2020, we and Chugai Pharmaceutical entered into an amendment of the Chugai Agreement, or the Chugai Pharmaceutical Amendment, with an effective date as of June 30, 2020. The Chugai Amendment extended the date through which Chugai will exclusively provide the Existing Product and materials to us from June 30, 2020 to June 30, 2021, extended the date through which Chugai will not provide materials or technical support to any third-party for the purpose of development and commercialization in a given area from the fifth anniversary to the eleventh anniversary of the original effective date (extended to June 17, 2030), and provides for further such extensions on the occurrence of certain events and milestones. The Chugai Amendment also provides that, in addition to the designated fee payable upon the initial indication approval in the Chugai Agreement described below, we will pay Chugai Pharmaceutical a designated fee in the low, single digit millions for each additional indication approval.

As consideration for Chugai Pharmaceutical's performance under the Chugai Agreement, we agreed to pay Chugai Pharmaceutical a payment in the low, single-digit millions, which will be made in two installments with an initial payment made in July 2020, and the remaining majority of the total amount will be payable upon FDA approval of the New Product.

We granted Chugai Pharmaceutical a right of first refusal on terms to be negotiated between the parties for a license related to the New Product-relevant information, data and documentation and inventions to develop and commercialize the New Product in the Chugai Territory. We will be responsible for manufacturing and supplying, or causing our CDMO to manufacture and supply, the New Product to Chugai Pharmaceutical.

The Chugai Agreement will remain in full force and effect until the first anniversary of the date of FDA approval of the New Product, unless terminated sooner, or the Chugai Term. Following the Chugai Service Period and during the Chugai Term, Chugai Pharmaceutical may terminate the Chugai Agreement, in whole or in part, without cause, by providing us 90 days prior written notice. Following such termination, we would maintain exclusive access to Chugai Materials, subject to the termination clauses outlined below. We may terminate the Chugai Agreement, in whole only, by providing Chugai Pharmaceutical 90 days' prior written notice if: (i) we decide to discontinue the New Product development; (ii) we decide that the FDA's requirements for the New Product are not likely to be met; or (iii) the FDA identifies a safety issue regarding the New Product.

In addition, either party may terminate the Chugai Agreement, in whole or in part, in the event that the other party materially breaches the Chugai Agreement and fails to cure the breach within 30 days of written notice. Either party may terminate the Chugai Agreement in its entirety immediately upon notice to the other party if such other party: (i) is dissolved or liquidated or takes any corporate action for such purpose; (ii) becomes insolvent or is generally unable to pay, or fails to pay, its debts as they become due; (iii) files or has filed against it a petition for voluntary or involuntary bankruptcy or otherwise becomes subject to any proceeding under any domestic or foreign

bankruptcy or insolvency laws; (iv) makes or seeks to make a general assignment for the benefit of creditors; or (v) applies for or has a receiver, trustee, custodian or similar agent appointed by order of any court to take charge of or sell any material portion of its property or business.

In the event that we undergo a change of control, Chugai Pharmaceutical may terminate the Chugai Agreement upon 90 days' written notice to us, absent a written pledge by the new controlling party of its agreement to fulfill and undertake all obligations of ours and to be bound by the Chugai Agreement.

Sponsored Research and License Agreement

On November 28, 2018, we entered into a sponsored research and license agreement, or the Research Agreement, with The University of Iowa, or the University, pursuant to which the University will provide access to certain program data related to Chugai Pharmaceutical's OK-432 and will assist us in conducting certain clinical studies. As consideration for the University's performance under the Research Agreement, we will pay the University $30,000 per year in funding for the project, taking into consideration the time spent by University employees required for the Project. The parties also agree to discuss in good faith potential additional funding required for completion of the project pursuant to the Research Agreement as applicable and necessary. In addition, within 45 days of approval of the TARA-002 BLA by the FDA, we will pay a one-time approval milestone between $0 and $1 million to the University, the amount of which depends on the usefulness of the program data in TARA-002's BLA filing. We will also be responsible for certain tiered royalties on annual net sales of products for the indication, which royalty rates are in the low single digit percentages. These royalty rates are also subject to a reduction in the event that regulatory authorities determine that the program data is not sufficient for regulatory approval on its own and additional pediatric efficacy and safety clinical studies are required. In the event that the annual net sales surpass certain dollar amount thresholds, we will need to make certain additional milestone payments following the close of the calendar quarter in which each milestone is reached, with the payments ranging from $62,500 to $125,000.

We may terminate the Research Agreement upon 30 days' prior written notice to the University. Either party may terminate the project under the Research Agreement and all commitments and obligations with respect thereto upon 30 days' prior written notice to the other party. In the event of any termination of the project under the Research Agreement by the University, (a) the University agrees to complete certain phases of the project and (b) we will continue to provide annual funding until the completion of the second phase of the project. Upon termination of the project by us, the Agreement will terminate and we will reassign to the University the IND for LMs.

Choline License Agreement

On September 27, 2017, we entered into a choline license agreement, or the Choline Agreement, with Alan L. Buchman, M.D., pursuant to which Dr. Buchman granted us an exclusive, worldwide, non-transferable license in and to certain licensed orphan designations, a certain licensed IND, certain existing study data and certain licensed know-how to develop, make, use, sell, offer for sale and import the licensed product during the term of the Choline Agreement. We are solely responsible for all fees and expenses under the Choline Agreement, including all due diligence obligations, regulatory authority fees, attorney fees and consulting fees. During the term of the Choline Agreement, Dr. Buchman may not work with any third parties on any product competing with the licensed product. In consideration for the rights and licenses granted under the Choline Agreement, we made an initial upfront payment of $50,000 to Dr. Buchman.

Certain milestone and royalty payments may also be payable to Dr. Buchman. Pursuant to the Choline Agreement, we paid Dr. Buchman $50,000 in October 2019 because we had not received at least $5 million in working capital from any source or in any manner as of October 15, 2019. We then paid Dr. Buchman a $550,000 milestone in January 2020 following our receipt of at least $5 million in working capital.

Regardless of whether development or commercialization is undertaken by us under the Choline Agreement, commencing in November 2022 and during the term of the Choline Agreement, we will pay Dr. Buchman a minimum annual royalty that ranges from $25,000 to $75,000.

We have an obligation to pay Dr. Buchman sales royalties based on aggregate net sales of IV Choline Chloride in each calendar quarter, with the tiered royalty rates ranging from 5.0% to 10.5% of net sales. In the event of development or commercialization activity by any sublicensees, we also agreed to pay Dr. Buchman a royalty in the mid-single

digit percentage of (i) net cash receipts, after payment of taxes, received by us from sublicensees for their sales of licensed products and (ii) any other consideration received by us from such sublicensees; in each case, including a fair monetary value for any transaction that is not a bona fide arms-length transaction or that is for consideration other than monetary. Further, in the event of a sale or transfer of a PRV, regarding the license product, regardless of whether any development or commercialization activity is undertaken by us or our sublicensees, we agreed to pay Dr. Buchman a milestone payment representing the mid-single digit percentage of (i) net cash receipts, after payment of taxes and (ii) any other consideration; in each case, received by us, our affiliates, or our sublicensees, including a fair monetary value for any transaction that is not a bona fide arms-length transaction or that is for consideration other than monetary.

We will also pay Dr. Buchman up to $775,000 in additional payments upon the achievement of various regulatory approval milestones.

The Choline Agreement will remain in full force and effect until the last sale of the licensed product under the Choline Agreement. After we received the FDA's written minutes from the initial FDA meeting concerning the development of the first licensed product for one or more of the licensed indications, we paid an additional payment of $100,000 to Dr. Buchman and elected to not terminate the Choline Agreement at that time. The Choline Agreement may be terminated by Dr. Buchman if, following regulatory approval of a licensed product, we have not made our first sale of a licensed product within such country within a specified time period. We may terminate the Choline Agreement for convenience upon 90 days' prior written notice to Dr. Buchman. Dr. Buchman may terminate the Choline Agreement for non-payment of any payment due that has not been cured. Either party may terminate the Choline Agreement if the other party is in material breach and has not cured such breach within 60 days' notice. In addition, Dr. Buchman may terminate the Choline Agreement upon 60 days' prior written notice if: (a) we cease or threaten to cease to carry on our business; (b) a petition or resolution for the making of an administration order or for the bankruptcy, winding-up or dissolution of us is presented or passed; (c) we file a voluntary petition in bankruptcy or insolvency; (d) a receiver or administrator takes possession of our assets; or (e) any similar procedure is commenced against us in the U.S.

License Agreement

On December 22, 2017, we entered into a license agreement, or the License Agreement, with The Feinstein Institute for Medical Research, a not-for-profit corporation organized and existing under the laws of New York, or the Institute. The Institute owns, by assignment, a U.S. patent related to the treatment of fatty liver disease in humans. Pursuant to the License Agreement, the Institute granted us an exclusive, worldwide license, with the right to grant sublicenses to non-affiliate third parties, to develop, make, have made, use, sell, offer for sale and import certain products for use in the field of fatty liver disease in humans receiving total PN, by administering, as monotherapy, a pharmaceutical composition comprising intravenous choline, wherein the fatty liver disease is selected from IFALD, non-alcoholic fatty liver, non-alcoholic steatohepatitis, or NASH, NASH-associated liver fibrosis, or non-alcoholic cirrhosis. Notwithstanding the exclusive rights granted to us, the Institute will retain the right to make, use and practice such patents in its own laboratories solely for non-commercial scientific purposes and for continued non-commercial research.

As consideration for the license grant, we agreed to pay the Institute tiered royalties of between 1.0% and 1.5% of all net sales. In addition, we agreed to pay the Institute a low double digit percentage of net proceeds resulting from agreements entered into within two years from the effective date of the License Agreement and a mid-single digit percentage of net proceeds resulting from agreements entered into thereafter. We also agreed to make certain license maintenance payments of $15,000 beginning on the second anniversary of the effective date of the License Agreement and continuing upon every anniversary thereafter until the first commercial sale of a licensed product. Beginning on the first anniversary of the effective date of the License Agreement after the first commercial sale of a licensed product and every anniversary of the effective date of the License Agreement thereafter, we will pay the Institute $30,000 as a license maintenance fee. Such license maintenance fees are non-refundable but are creditable against future royalty payments due to the Institute during the 12-month period following each such anniversary.

We agreed to make certain one-time milestone payments in the aggregate amount of $375,000 upon the achievement of certain regulatory approval milestones, of which $100,000 was paid on January 28, 2020 upon us having consummated certain private placements of securities.

Unless terminated earlier, the License Agreement will expire upon the expiration of the last to expire patent under the License Agreement. We may terminate the License Agreement by giving the Institute 60 days' prior notice. Either party may terminate the License Agreement in the event of a default or breach by the other party that has not been cured within 60 days of such notice. If we (i) make an assignment for the benefit of creditors or if proceedings for a voluntary bankruptcy are instituted on our behalf; (ii) are declared bankrupt or insolvent or (iii) are convicted of a felony relating to the manufacture, use or sale of the licensed products or a felony relating to moral turpitude, the Institute may terminate the License Agreement.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the U.S. and internationally for our product candidates, novel biological discoveries, epitopes, new therapeutic approaches and potential indications, and other inventions that are important to our business. Throughout the development of our product candidates, we will seek to identify additional means of obtaining patent protection that would potentially enhance commercial success. We also rely upon trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

The patent positions of biotechnology companies like us are generally uncertain and involve complex legal, scientific and factual questions. We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed rights under proprietary technologies of third parties to develop, manufacture and commercialize specific aspects of our products and services. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that it may require to develop or commercialize our future technology may have a material adverse impact on it. If third parties prepare and file patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention. For a more comprehensive discussion of the risks related to our intellectual property, please see "*Risk Factors — Risks Related to Our Intellectual Property.*"

TARA-002:

TARA-002 is a genetically distinct Su strain of Streptococcus pyogenes (group A, type 3). TARA-002 is produced through a proprietary manufacturing process, during which the bacteria is inactivated. We believe a significant barrier to entry exists, as we believe only Chugai Pharmaceutical and we have the specific strain and possess the know-how to manufacture the product. We anticipate that, if approved by the FDA, TARA-002 will be protected by 12 years of biologic exclusivity. In addition, the USPTO has issued to us U.S. Patent No. 12,551,514 claiming a method of treating NMIBC with a combination of non-viable cells of streptococcus pyogenes and an immune checkpoint inhibitor, with a term expiring in 2044.

IV Choline Chloride:

With respect to IV Choline Chloride, we have acquired an exclusive, worldwide license to U.S. Patent 8,865,641 B2 from the Feinstein Institute for Medical Research providing protection in the U.S. until 2035. The patent applies to a method of treating a fatty liver disease in a subject. In particular, the method comprises administering to the subject an effective amount of a cholinergic pathway stimulating agent, wherein the fatty liver disease is selected from non-alcoholic fatty liver, alcoholic fatty liver, or NASH, alcoholic steatohepatitis, or ASH, NASH-associated liver fibrosis, ASH-associated liver fibrosis, non-alcoholic cirrhosis and alcoholic cirrhosis. In addition, in 2022, the USPTO issued to us Patent No. US 11,311,503 claiming a sterile aqueous choline salt composition with a term expiring in 2041. We expect to list such patent in the FDA's Orange Book List of Approved Drug Products with

Therapeutic Equivalence Evaluations if IV Choline Chloride is approved by the FDA. Further, in 2024, the USPTO issued to us Patent No. US 12,083,081 claiming a method of treating choline deficiency with a choline composition, also with a term expiring in 2041.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we may file, the patent term is 20 years from the earliest date of filing a non-provisional patent application related to the patent. A U.S. patent also may be accorded a patent term adjustment under certain circumstances to compensate for delays in obtaining the patent from the USPTO. In some instances, such a patent term adjustment may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, in the U.S., the term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering certain of those products, when applicable.

We also rely on trade secrets relating to product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, including through breaches of such agreements with our employees and consultants. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific partners, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

Manufacturing

We rely on CDMOs to produce our drug candidates in accordance with cGMP as well as regulations for use in clinical trials and for commercial product. The manufacturing of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

The CDMOs that we partner with have the capability to produce clinical supply required for clinical trials, as well as support commercial scale-up activities for both TARA-002 and IV Choline Chloride.

TARA-002 is manufactured using an equivalent, but modernized, proprietary manufacturing process as is used to produce OK-432 by Chugai Pharmaceutical, starting with a master cell line propagated by us but utilizing the same genetically distinct strain of Streptococcus pyogenes (A group, type 3) Su strain, which is inactivated during the manufacturing process, as OK-432.

Both TARA-002 and IV Choline Chloride are or will be manufactured in the U.S. The starting materials for TARA-002 were provided to us pursuant to an agreement with Chugai Pharmaceutical. The regulatory starting materials for IV Choline Chloride are available commercially.

Sales and Marketing

We plan to become a fully-integrated commercial biopharmaceutical company in the U.S. pursuing our mission of supporting and improving the lives of patients suffering from cancer and rare diseases.

If approved by the FDA, we plan to commercialize all of our current product candidates in the U.S. first and then either alone or with partners in other geographies, if approved by the regulatory authorities in those other locations. As we advance TARA-002 and IV Choline Chloride through our respective clinical development programs, we plan to grow our commercial organization in support of anticipated product launches.

Competition

The process for commercialization of new drugs is very competitive, and we could potentially face worldwide competition from other pharmaceutical companies, biotechnology companies and ultimately generic or biosimilar products. Our potential competitors may develop or market therapies that are available sooner, more clinically effective, safer or less expensive than any therapeutic products we develop. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing.

With respect to our lead product candidate, TARA-002, for the treatment of NMIBC and LMs, the active ingredient in TARA-002 is a genetically distinct strain of Streptococcus pyogenes (group A, type 3) Su strain, which is inactivated during the manufacturing process. TARA-002 is produced through a proprietary manufacturing process. We anticipate that, if approved by the FDA, TARA-002 will be protected by 12 years of biologic exclusivity. In addition, based on the prevalence of the disease, TARA-002 is likely to have seven years of concurrent ODD exclusivity for the treatment of LMs. Further, the USPTO issued to us Patent No. 12,551,514 claiming a method of treating NMIBC with a combination of non-viable cells of streptococcus pyogenes and an immune checkpoint inhibitor, with a term expiring in 2044.

There are no approved pharmacotherapies currently available for the treatment of LMs in the U.S., and the current treatment options include a high-risk surgical procedure and off-label use of sclerosants, including doxycycline, bleomycin, ethanol and sodium tetradecyl sulfate. There are a number of drug development companies and academic researchers exploring oral and topical formulations of various agents for the treatment of LMs including macrolides, phosphodiesterase inhibitors, and calcineurin/mTOR inhibitors. These are in early development.

TARA-002, if approved for the treatment of NMIBC, would be subject to competition from existing treatment methods of surgery, chemotherapy and immunomodulatory therapy. For example, the current standard of care for NMIBC includes intravesical BCG TICE (manufactured by Merck & Co., Inc.). Other products approved for the treatment of NMIBC include Merck & Co., Inc.'s Keytruda, Endo International plc's Valstar, Ferring B.V.'s Adstiladrin, ImmunityBio, Inc.'s VesAnktiva in combination with BCG and Janssen's Inlexzo. Additional product candidates in development include but may not be limited to Japanese BCG Laboratory's BCG Tokyo, Pfizer Inc.'s Sasanlimab in combination with BCG, CG Oncology Inc.'s CG0070, enGene Inc.'s, EG-70, Pfizer Inc.'s PADCEV, Janssen's TAR-200 plus Cetrelimab, Urogen Pharma Ltd.'s Jelmyto, Theralase Technologies Inc.'s Ruvidar, and Auro BioSciences, Inc.'s Aura-0011. Additional pharmaceutical and biotechnology companies with product candidates in development for the treatment of NMIBC include but may not be limited to Verity, AstraZeneca PLC, Bristol-Myers Squibb Company, Roche Group, Asieris Pharmaceuticals, BeiGene, Ltd, NanOlogy, LLC, Linton Pharm Co., Ltd., Lindis Biotech GmbH, Taizhou Hanzhong biomedical co. Ltd., Shionogi & Co. Ltd., Rapamycin Holdings, Inc., Vaxiion Therapeutics Inc., Incyte Corporation, LiPac Oncology, Inc., Anika Therapeutics Inc., Surge Pharmaceuticals Pvt. Ltd., and Istari Oncology, Inc.

There are currently no available PS formulations containing choline. IV Choline Chloride is the only sterile injectable form of choline chloride that can be combined with PS. Further, the USPTO, issued to us Patent No. US 11,311,503 claiming a sterile aqueous choline salt composition, and Patent No. US 12,083,081 claiming a method of treating choline deficiency with a choline composition, each with a term expiring in 2041.

Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacturing, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, and biologics additionally under the Public Health Service Act, or PHSA, as well as their respective implementing regulations. Drugs are approved via NDAs while biologics are approved via BLAs. The application process and requirements for approval of BLAs are very similar to those for NDAs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to file NDAs or BLAs and/or to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

The process required by the FDA before biopharmaceutical product candidates may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or cGLP, regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the clinical trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of a drug product candidate and the safety, purity and potency of a biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of an NDA or BLA, including a substantial application user fee unless a waiver applies, after completion of all pivotal clinical trials that includes substantial evidence of safety, purity and potency or efficacy from results of non-clinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP, and of selected clinical investigation sites to assess compliance with current Good Clinical Practices, or cGCP;
- FDA review and approval, or licensure, of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the U.S.; and
- Compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, to conduct post-approval studies.

Preclinical and Clinical Development

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal testing, the submission to the FDA of an IND, which is a request for authorization from the FDA to administer an investigational product candidate to humans, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including cGLP regulations, an international standard meant to ensure the presence of a standard quality system under which laboratory work and non-clinical studies are conducted, recorded and archived.

The IND includes results of animal and in vitro studies assessing the toxicology, PKs, pharmacology and pharmacodynamic characteristics of the product candidate; chemistry, manufacturing, and controls information; the general investigational plan; the proposed protocol(s) for clinical trials; and any available human data or literature to support the use of the investigational product. Long-term preclinical tests, such as tests of reproductive toxicity

and carcinogenicity in animals, may continue after the IND is submitted. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, an international standard designed to protect the rights and health of human subjects participating in research, which includes the requirement that all research participants provide their informed consent for their participation in any clinical trial, and to define the roles, qualifications and responsibilities of clinical trial sponsors, administrators and monitors. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the clinical trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a clinical trial may move forward at designated check points based on access to certain data from the clinical trial and may recommend that the clinical trial be stopped if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These clinical trials are designed to test the safety, dosage tolerance, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of a drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances, including (1) where the study is a large multicenter clinical trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second clinical trial would be practically or ethically impossible or (2) when in conjunction with confirmatory evidence. In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These post-approval trials may be made a condition to approval of the NDA or BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for

testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In addition, the sponsor of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

Application Submission, Review and Approval

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, non-clinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications in the U.S. The NDA or BLA must include all relevant data available from all preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of an NDA or BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be filed based on the FDA's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. For new molecular entities, the FDA's goal is to review standard applications within ten months after it files the application, or, if the application qualifies for priority review, six months after the FDA files the application. In both standard and priority reviews, the review process may be extended by FDA requests for additional information or clarification. The FDA reviews the application to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee — typically a panel that includes clinicians, statisticians and other experts — to provide insight on application review questions. The FDA is not bound by the recommendation of the advisory committee, but generally follows such recommendation. Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The FDA will issue an approval letter or a Complete Response letter, or CRL, upon completion of review of an NDA or BLA. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the NDA or BLA. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product. If, or when, deficiencies outlined in a CRL have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

As a condition of NDA or BLA approval, the FDA may impose limitations on the indicated uses for which such product may be marketed. For example, the FDA may impose a REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre-and post-marketing requirements is not maintained or if problems occur

after the product reaches the marketplace. The FDA may require one or more post-approval trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing trials.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. The government published a regulation and policy to expand and enhance the requirements related to registering and reporting the results of clinical trials, which may result in greater enforcement of these requirements in the future.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant ODD to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug or biologic for this type of disease or condition will be recovered from sales in the U.S. for that drug or biologic. ODD must be requested before submitting an NDA or BLA. After the FDA grants ODD, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. ODD does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the FDA application fee.

A designated orphan product may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Rare Pediatric Disease Priority Review Voucher Program

The FDA incentivizes the development of drugs and biologics for diseases that meet the definition of a "rare pediatric disease" defined to mean a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the U.S. or affects 200,000 or more in the U.S. and for which there is no reasonable expectation that the cost of developing and making in the U.S. a drug for such disease or condition will be received from sales in the U.S. of such drug. The sponsor of a product candidate granted RPDD may be eligible for a voucher that can be used to obtain a priority review for a subsequent NDA or BLA after the date of approval of the designated Rare Pediatric Disease drug product, referred to as a PRV. To receive a Rare Pediatric Disease PRV, a sponsor must notify the FDA, upon submission of the NDA or BLA, of its intent to request a voucher. If the FDA determines that the NDA or BLA is a Rare Pediatric Disease product application, and if the NDA or BLA is granted priority review by the FDA and subsequently approved, the FDA will award the sponsor of the application a PRV upon approval of the NDA or BLA. The FDA may revoke a Rare Pediatric Disease PRV if the product for which it was awarded is not marketed in the U.S. within 365 days of the product's approval. The sponsor submitting the PRV must notify the FDA of is intent to submit the voucher with the NDA or BLA at least 90 days prior to submission of the NDA or BLA and must pay a priority review user fee in addition to any other required user fee. The FDA must take action on an NDA or BLA

under priority review within six months of the FDA's filing of the NDA or BLA. A RPDD does not guarantee that an applicant will receive a priority review or a PRV upon approval of its NDA or BLA. If a PRV is received, under the Rare Pediatric Disease PRV Program, it may be sold or transferred an unlimited number of times prior to its redemption.

The Rare Pediatric Disease PRV Program has always had a scheduled sunset date established in the law. Under the current provisions in the law, the Rare Pediatric Disease PRV Program will sunset on September 30, 2029, which means that the FDA may only award a PRV for an approved Rare Pediatric Disease product application if the sponsor has received RPDD for the product by and the product is subsequently approved by September 30, 2029.

Fast Track Designation

Under the FDA's Fast Track program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the submission of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for FTD within 60 days of receipt of the sponsor's request. FTD is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product can reach the market expeditiously. If a product receives FTD, the sponsor may engage in more frequent interactions with the FDA, and the FDA may conduct a rolling review, meaning the FDA will review sections of the NDA or BLA before the full application is complete. This rolling review is available if, in agreement with the FDA, the applicant provides a schedule for the submission of the remaining information. However, the FDA does not start the review clock for the application until the last section of the NDA or BLA is submitted. FTD may be withdrawn by the FDA at any time if the FDA believes that the designation is no longer supported by emerging data in the development process.

Breakthrough Therapy Designation

Additionally, a drug candidate may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints. The FDA expects that such evidence generally would be derived from early phase clinical trials such as Phase 1 or Phase 2 clinical trials. For purposes of BTD, preliminary clinical evidence refers to evidence that is sufficient to indicate that the drug may demonstrate substantial improvement in effectiveness or safety over available therapies. The FDA must determine if the product candidate qualifies for BTD within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner. BTD may be withdrawn by the FDA at any time if they believe that the designation is no longer supported by emerging data in the development process.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Biopharmaceutical manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon sponsors and their third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon sponsor and third-party manufacturers. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, mandated modification of promotional materials or issuance of corrective information, issuance by the FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biopharmaceuticals. A company can make only those claims relating to safety and efficacy, purity and potency of a biopharmaceutical that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the U.S.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. As with drugs, after approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

The Hatch-Waxman Amendments

Orange Book listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly

known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify certain statements to the FDA with respect to any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. Certain changes to a drug, such as the addition of a new indication to the package insert, can be the subject of a three-year exclusivity period if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to the approval of the application. The FDA cannot approve an ANDA for a generic drug that includes the change during the exclusivity period.

Patent term extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval up to a maximum of five years). The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of product approval. Only one patent applicable to an approved drug is eligible for extension and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended, and the application for the extension must be submitted prior to the expiration of the patent. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, numerous biosimilars and several interchangeable biosimilars have been licensed under the BPCIA and approved in Europe. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars and interchangeable biosimilars.

Biosimilarity, which requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, must be shown through analytical studies, animal studies, and a clinical trial or trials unless the Secretary of the U.S. Department of Health and Human Services, or HHS, waives a required element. A biosimilar product may be deemed interchangeable with a previously approved product if it is biosimilar to the reference product and the product demonstrates that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that its reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which its reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA and litigated in the courts.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs, BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. Alternatively, for an original NDA for a new active ingredient, the application could instead be required to include reports on a molecularly targeted pediatric cancer investigation, if the drug is intended for the treatment of an adult cancer and directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. The FDA may grant full or partial waivers, or deferrals, for submission of data. With certain exceptions, the PREA does not apply to any drug for an indication for which ODD has been granted. This exemption does not apply to an original NDA for a new active ingredient for an indication for which ODD has been granted if the NDA is subject to the molecularly targeted pediatric cancer investigation requirement.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity — patent or nonpatent — for a drug and BLA holders a six-month extension of market exclusivity for biologics if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug or biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications.

Other U.S. Healthcare Laws and Compliance Requirements

In the U.S., a pharmaceutical company's operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the HHS (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, clinical research, sales, marketing and scientific/educational grant programs will need to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. A pharmaceutical company's practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the Anti-Kickback Statute are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment and exclusion from government healthcare programs. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or the FCA.

The federal false claims, including the FCA, and civil monetary penalty laws, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Accordingly, HIPAA imposes criminal and civil liability for, among other things, executing a scheme or making materially false statements in connection with the delivery of or payment for health care benefits, items or services. Like the Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state healthcare programs, or, in several states, apply regardless of the payor.

Pharmaceutical companies may be subject to data privacy and security regulations by both the federal government and the states in which they conduct business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, including subcontractors, or agents of covered entities that receive or obtain protected health information, or PHI, in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws, for example, Washington's My Health My Data Act and the California Consumer Privacy Act of 2018, or CCPA, as amended by the California Privacy Rights Act, or CPRA, govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

The National Security Division of the DOJ issued a new rule referred to as the Data Security Program, or DSP, to implement Executive Order 14117 aimed at preventing access to "bulk U.S. sensitive personal data" and "government-related data" by "countries of concern" (including China, Russia, Iran, North Korea, Cuba, and Venezuela) and "covered persons" (as all such terms are defined in the DSP). Effective as of April 8, 2025, the DSP imposes stringent obligations on companies within its scope and prohibits or restricts "covered data transactions" that grant countries of concern or covered persons access to bulk U.S. sensitive personal data or any amount of government-related data.

Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, average manufacturer price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to a pharmaceutical company's products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, or to

entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, pharmaceutical companies must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states and/or localities have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of a pharmaceutical company's activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If a pharmaceutical company's operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to it, it may be subject to penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, or refusal to allow it to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if it becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of its operations, any of which could adversely affect its ability to operate its business and the results of its operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the U.S. and in foreign markets, sales of any products for which a pharmaceutical company receives regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the U.S., third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and commercial payors are critical to new product acceptance.

A pharmaceutical company's ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which regulatory approval is obtained.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require pharmaceutical companies to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of a product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of biopharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Current and Future Healthcare Reform

In the U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives that directly and indirectly affect manufacturers' ability to successfully commercialize approved products and seek government coverage and reimbursement.

Legislative changes have been proposed and adopted since the ACA was enacted. For example, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap has, in some cases, required pharmaceutical manufacturers to pay more in rebates than they have received on the sale of products. In addition, in 2024, CMS issued a final rule that decreased Medicare reimbursement for physician services by 2.8%, effective January 1, 2025. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels.

Several healthcare reform proposals culminated in the enactment of the Inflation Reduction Act, or the IRA, in August of 2022, which, among other things, eliminated, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket costs and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket limit, and 20% once the out-of-pocket limit has been reached. The IRA also requires HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drugs that have been approved for at least seven years (11 years for single-source biologics) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the negotiated maximum fair price for each product has been announced.

In addition, CMS selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs, which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs under Medicare Part B. For 2029 and subsequent years, 20 Part B or Part D drugs will be selected. A drug or biological product that has an ODD for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA also extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, but those subsidies expired at the end of 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. The outcome of these lawsuits is uncertain, and some IRA drug discount provisions have not been challenged in litigation. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of pharmaceutical products.

The current federal administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, which include the FDA and CMS, and related agencies. These actions include, for example, directives to reduce agency workforce, which include the FDA and CMS, and related agencies. In addition, on May 12, 2025, President Trump issued an Executive Order that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers most favored nation, or MFN, price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the Executive Order requires HHS to propose a rulemaking to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, or CMMI, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the U.S., if they are also sold in comparably developed countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs competed with drugs whose prices were reduced as a result of MFN pricing initiatives. Further, as part of the Make America Healthy Again, or MAHA, Commission's recent Strategy Report, the federal administration is working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. These federal administrative actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks.

At the state level, legislatures are increasingly enacting legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, the FDA released a final rule in 2020 providing guidance for states to build and submit importation proposals for drugs from Canada. The FDA authorized the first such plan in Florida in 2024, but the implementation of Florida's plan has been extended.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions including maintaining books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Data Privacy and Security Regulations

Numerous state, federal and foreign laws, regulations and standards govern the collection, transfer, sharing, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the U.S., numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

See "*Risk Factors — General Risk Factors — Pharmaceutical companies are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations, including our clinical trials; harm to our reputation; and other adverse effects on our business or prospects"* for additional information about these privacy and security laws, regulations, and other obligations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect a pharmaceutical company's business. These and other laws govern the use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by operations.

If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Other Regulations

Pharmaceutical companies are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. Pharmaceutical companies may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of December 31, 2025, we had 51 employees, 46 of whom were full-time employees and five of whom were temporary employees. As of December 31, 2025, 29 of our employees were engaged in research and development activities and 22 of our employees were engaged in administrative support, business development, finance, human resources, information systems, legal, or market development. As of December 31, 2025, all of our employees were located in the U.S. None of our U.S. employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees.

Corporate Information

On January 9, 2020, Protara Therapeutics, Inc. (formerly ArTara Therapeutics, Inc., formerly Proteon Therapeutics, Inc., or the Company or Protara), and privately-held ArTara Subsidiary, Inc., or Private ArTara, completed the merger and reorganization, or the Merger, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated September 23, 2019, or the Merger Agreement, by and among the Company, Private ArTara and REM 1 Acquisition, Inc., a wholly owned subsidiary of the Company, or Merger Sub, whereby Merger Sub merged with and into Private ArTara, with Private ArTara surviving as a wholly owned subsidiary of the Company. The Merger was structured as a reverse merger and Private ArTara was determined to be the accounting acquirer based on the terms of the Merger and other factors.

We were originally incorporated in Delaware in March 2006, and at that time, acquired Proteon Therapeutics, LLC, the predecessor of Protara, which was formed in June 2001.

Our principal executive offices are located at 345 Park Avenue South, 3rd Floor, New York, New York 10010, our telephone number is (646) 844-0337 and our website address is *www.protaratx.com*. The contents of our website are not incorporated into this Annual Report on Form 10-K and our reference to the URL for our website is intended to be an inactive textual reference only. The information contained on, or that can be accessed through, our website is not a part of this document.

Unless the context requires otherwise, references in this Annual Report on Form 10-K to "Protara", "TARA", "we", "us", the "Company" and "our" refer to Protara Therapeutics, Inc. and our subsidiaries.

Available Information

Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act, will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors.

You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report on Form 10-K and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.

Risks Related to Our Financial Condition

We have a limited operating history and have never generated any revenues.

We are a clinical stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. Our operations have been limited to organizing and staffing the Company, business planning, raising capital, developing our pipeline assets (TARA-002 and IV Choline Chloride), identifying product candidates, and other research and development. We have no products approved for commercial sale and have not generated any revenue from commercial product sales. Although our employees have made regulatory submissions and conducted successful clinical trials in the past across many therapeutic areas while employed at other companies, we have not yet demonstrated an ability to successfully complete registrational clinical trials and have never completed the development or commercialization of any product candidate, nor have we ever generated any revenue from product sales or otherwise. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

We expect to incur significant expenses and significant losses for the foreseeable future and may never generate revenue or achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues, and cannot estimate with precision the extent of our future losses. We expect to incur increasing levels of operating losses for the foreseeable future as we execute on our plans to continue research and development activities, including the ongoing and planned clinical development of our product candidates, potentially acquire new products and/or product candidates, seek regulatory approvals of and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, and incur the additional costs of operating as a public company. We expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

To become and remain profitable, we must develop or acquire and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval, manufacturing, marketing and selling any product candidate for which we obtain marketing approval, and satisfying post-marketing requirements, if any. We may never succeed in these activities and, even if we succeed in obtaining approval for and commercializing one or more products, we may never generate revenues that are significant enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Furthermore, because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand the business or continue operations. A decline in our value could also cause you to lose all or part of your investment.

We will need to raise additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

We will require substantial additional funds to conduct the costly and time-consuming preclinical studies and clinical trials necessary to pursue regulatory approval of each current and future product candidate and to continue the development of TARA-002 and IV Choline Chloride, including in new indications or uses. Our future capital requirements will depend upon a number of factors, including: the number and timing of current and future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; and the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests and divert our management's focus on achieving our business objectives. As a result of economic conditions, general global economic uncertainty, U.S. and foreign political conditions, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. Further, in recent years, rising inflation, in part, caused a disruption in the capital markets and an increase in interest rates. Despite recent declines in interest rates, further inflation and/or the continuation of elevated interest rates may lead to a recession or market correction that could impact our access to capital, increase the cost of capital, and could in the future negatively affect our liquidity. A recession or market correction, inflation and/or increases in interest rates could materially affect our business and the value of our common stock.

If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interests of our common stockholders will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income or taxes may be limited.

Under current federal tax law, net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such net operating losses arising in tax years beginning after December 31, 2020 is limited to 80% of taxable income. Not all states and localities fully conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" which is generally defined as a greater than

50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes to offset such income, which could potentially result in increased future cash tax liability to us and adversely affect our future cash flows.

The April 2024 Common Warrants are speculative in nature.

The April 2024 Common Warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, the April 2024 Common Warrants are exercisable upon issuance at an exercise price of $5.25 per share and may be exercised at any time on or prior to the earlier of (i) April 10, 2027 and (ii) the date that is 90 days after the public announcement that the Company has demonstrated a six-month CR rate of minimum 42% from at least 25 BCG-Unresponsive patients in the ADVANCED-2 (Cohort B) clinical trial. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the April 2024 Common Warrants and consequently, whether it will ever be profitable for holders of the April 2024 Common Warrants to exercise the warrants.

The exercise of some or all of the April 2024 Common Warrants will dilute the ownership interests of existing stockholders and increase the number of shares of common stock eligible for resale in the public market. Any sales in the public market of the shares of common stock issuable upon such exercise of the April 2024 Common Warrants, or the anticipation of such exercises and sales, could adversely affect the prevailing market prices of our common stock. Additionally, the existence of the April 2024 Common Warrants may encourage short selling by market participants because the exercise of the April 2024 Common Warrants could be used to satisfy short positions, or because the anticipated exercise of the April 2024 Common Warrants for shares of common stock could depress the price of our common stock.

Further, if the outstanding April 2024 Common Warrants are exercised in full, we would be entitled to receive the cash exercise price of $5.25 per warrant. We would be able to use these additional proceeds to fund our operations. To the extent the market price of our common stock does not equal or exceed the exercise price of the April 2024 Common Warrants before they expire, we would not be entitled to these proceeds, and we may be required to pursue additional financing alternatives.

Risks Related to Drug/Biologics Development and Commercialization

Our business depends on the successful preclinical and clinical development, regulatory approval and commercialization of our product candidates, including TARA-002 and IV Choline Chloride.

The success of our business, including our ability to finance our operations and generate revenue in the future, primarily depends on the successful development, regulatory approval and commercialization of our product candidates, including of TARA-002 and IV Choline Chloride. The clinical and commercial success of our product candidates, including TARA-002 and IV Choline Chloride, depend on a number of factors, including the following:

- the timely and successful completion of planned and ongoing non-clinical studies and clinical trials, including our ongoing Phase 2 clinical trial of TARA-002 in NMIBC, our ongoing Phase 2 clinical trial of TARA-002 in LMs and our ongoing Phase 2b/3 clinical trial of IV Choline Chloride, which may be significantly slower or costlier than we currently anticipate and/or produce results that do not achieve the endpoints of the trials;
- effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;

- positive results from our current and future clinical programs that support a finding of safety and effectiveness and an acceptable benefit-risk profile of our product candidates in the intended populations;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional studies beyond those planned to support the approval and commercialization of our product candidates;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with their contractual obligations and with all regulatory requirements applicable to our product candidates;
- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates, to remain in good standing with regulatory agencies and to develop, validate and maintain commercially viable manufacturing processes that are compliant with cGMP;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates;
- commercial launch of our product candidates, if approved, whether alone or in collaboration with others;
- a continued acceptable safety, tolerability and efficacy profile during clinical development and following approval of our product candidates; and
- acceptance of the benefits and use of our product candidates, including method of administration, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- establishment and maintenance of healthcare coverage and adequate reimbursement and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and
- the existence of a regulatory environment conducive to the successful development of our product candidates, including in the event of a potential or actual government shutdown affecting Federal agencies, or in the event of any changes and/or additional regulations relating to the FDA as a result of the current U.S. Presidential Administration, which could impact the FDA's staffing, resources and ability to timely review and process regulatory submissions, prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or that could impose additional regulatory obligations on us.

If any one of these factors is not present, many of which are beyond our control, we could experience significant delays or an inability to obtain regulatory approval of our product candidates, including TARA-002 or IV Choline Chloride.

Our clinical trials may take longer to enroll than anticipated due to competing clinical trials or otherwise or may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during their development, which could increase our costs or necessitate the abandonment or limitation of the development of the product candidate.

We have never completed a registrational clinical trial or made a BLA or NDA submission and may be unable to successfully do so for TARA-002 or IV Choline Chloride.

The conduct of a clinical trial is a long, expensive, complicated and highly regulated process. Although our employees have conducted successful clinical trials and made regulatory submissions in the past across many therapeutic areas while employed at other companies, we, as a company, have not completed any registrational clinical trials, or submitted a BLA or NDA and as a result may require more time and incur greater costs than we anticipate. Failure to commence or complete, or delays in registrational clinical trials or planned regulatory submissions would prevent us from, or delay us, in obtaining potential regulatory approval of and commercializing TARA-002 or IV Choline Chloride, which would adversely impact our financial performance.

Disruptions at the FDA or other comparable foreign regulatory authorities may extend the time necessary for new products to be reviewed and/or approved, which would adversely affect our business. In addition, there is substantial uncertainty regarding new initiatives under the current U.S. Presidential Administration and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed towards other agencies. These initiatives could prevent, limit or delay development and regulatory approval of our product candidates, which would adversely affect our business.

Disruptions at the FDA or other comparable foreign regulatory authorities may extend the time necessary for new products to be reviewed and/or approved, which would adversely affect our business. For example, starting in January 2025, the current U.S. Presidential Administration has reduced the number of federal employees, including at the FDA, by establishing voluntary termination programs, by position eliminations and by involuntary terminations. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similar consequences may also occur as a result of a significant shutdown of the federal government. For example, over the last several years, and most recently in late 2025, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if geopolitical or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, or if the volume of applications to the FDA for new product candidates increases materially, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. If the FDA is constrained in its ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

In addition, FDA-regulated industries, such as ours, face substantial uncertainty in regard to the regulatory environment we face as we proceed with research and development efforts following the inauguration of the current U.S. Presidential Administration in January 2025. Some of these efforts have manifested to date as efforts to reduce the size of the federal government, including large-scale reductions in force at the FDA. The loss of key personnel at the FDA, including those in leadership positions, is likely to impact operations at the FDA, which could result in, among other things, delays or limitations on our ability to obtain guidance from the FDA on our product candidates in development, longer review times, and delays in obtaining the requisite regulatory approvals of our product candidates. Moreover, the current U.S. Presidential Administration has paused payments by, reduced the budget of, and terminated grants provided by the National Institutes of Health, or NIH, as related to its funding for medical research, which has decreased, and may continue to decrease, the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. Some of these actions have been challenged in court and there remains general uncertainty regarding future activities. The current U.S. Presidential Administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic products. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the current U.S. Presidential Administration, there could be a material adverse effect on us and our business.

Even if a product candidate obtains regulatory approval, it may fail to achieve the broad degree of adoption and use necessary for commercial success.

The commercial success of both TARA-002 and IV Choline Chloride, if approved, will depend significantly on the broad adoption and use of them by physicians and patients for approved indications, and neither may be commercially successful even though the product is shown to be safe and effective. The degree and rate of physician and patient adoption of a product, if approved, and successful commercialization will depend on a number of factors, including but not limited to:

- the efficacy, durability and safety of such product as demonstrated in clinical trials;
- patient demand for approved products that treat the indication for which a product is approved;
- the willingness of the target population to try new therapies;

- the safety and effectiveness and potential and perceived advantages of the product compared to other available therapies;
- the availability of coverage and adequate reimbursement from third-party payors such as private health insurers, managed care plans, and other healthcare payors and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- the cost of treatment in relation to alternative treatments and willingness to pay on the part of patients;
- the clinical indications for which the product candidate is approved by the FDA or ex-U.S. regulatory authorities;
- in the case of TARA-002 for LMs, overcoming physician or patient biases toward alternative treatments for LMs;
- insurers' willingness to see the applicable indication as a disease worth treating;
- proper administration;
- the prevalence and severity of any side effects;
- patient satisfaction with the results, administration and overall treatment experience;
- the ability to successfully commercialize the product in the U.S. and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- our ability and our partners' ability to establish and enforce intellectual property rights in and to our product candidates;
- limitations or contraindications, warnings, precautions or approved indications for use different than those sought by us that are contained in the final FDA-approved labeling for the applicable product;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, and distribution efforts;
- adverse publicity about a product or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals; and
- potential product liability claims or other product-related litigation.

If either TARA-002 or IV Choline Chloride is approved for use but fails to achieve the broad degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Further, even if regulatory approvals are obtained, we may never be able to successfully commercialize TARA-002 or IV Choline Chloride, or the FDA or comparable foreign regulatory authorities may require labeling changes or impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of TARA-002 or IV Choline Chloride to continue our business.

Preclinical and clinical development involves lengthy and expensive processes with uncertain outcomes. We may incur additional expenses or experience delays in completing, or ultimately be unable to complete, the development of our current product candidates or any future product candidates.

All of our current product candidates are in clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive non-clinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of non-clinical studies and early clinical trials or early cohorts of our clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials or later cohorts of our clinical trials. Moreover, a clinical trial can fail at any stage of testing. Differences in clinical trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Additionally, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier clinical trials. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support clinical development of our current or any of our future product candidates.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including: the size and nature of the patient population; the number and location of clinical sites we enroll; the proximity of patients to clinical sites; the eligibility and exclusion criteria for the clinical trial; the design of the clinical trial; the inability to obtain and maintain patient consents; the risk that enrolled participants will drop out before completion; and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. These factors could increase our costs or necessitate the abandonment or limitation of the development of our product candidates.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such clinical trials are being conducted, or the FDA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the independent data monitoring committee for such clinical trial. A suspension or termination may be imposed due to a number of factors, including: failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; unforeseen safety issues or adverse side effects; failure to demonstrate a benefit from using a product or treatment; failure to establish or achieve clinically meaningful clinical trial endpoints; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development expenses will increase if we experience delays in clinical testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

We rely, and expect to continue to rely, on third-party CROs and other third parties to conduct and oversee our clinical trials. If these third parties do not meet our requirements or otherwise conduct the clinical trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates.

We rely, and expect to continue to rely, on third-party CROs to conduct and oversee our TARA-002 and IV Choline Chloride clinical trials and studies and other aspects of product development. We also rely on various medical institutions, clinical investigators and contract laboratories to conduct our clinical trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and cGCP, requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and record-keeping for drug and biologic products. These CROs and other third parties have and will continue to play a significant role in the conduct of these clinical trials and the subsequent collection and analysis of data from the clinical trials. We will rely heavily on these parties for the execution of our clinical trials, preclinical and non-clinical studies and will control only certain aspects of their activities. We and our CROs and other third-party contractors will be required to comply with cGCP and cGLP, requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce these cGCP and cGLP requirements through periodic inspections of clinical trial sponsors, principal investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable cGCP and cGLP requirements, or reveal non-compliance from an audit or inspection, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials or preclinical studies comply with applicable cGCP and cGLP requirements. In addition, our clinical trials generally must be conducted with product candidate produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites fail to comply with their contractual commitments or terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

Interim, topline and preliminary data from our clinical trials may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose further preliminary, interim or topline data from our preclinical, non-clinical studies and clinical trials, which is based on a preliminary analysis of then-available data. For example, in 2026, we released interim data from our clinical trials and expect to continue to release interim data from such trials in advance of releasing final, fully-evaluated data. The results and related findings and conclusions of any interim or preliminary data, including from our 2026 data release, as well as any future releases of any interim or preliminary data are subject to change as patient enrollment and treatment continues and more patient data become available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary, interim, or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. Accordingly, preliminary, interim, and topline data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure.

The clinical development of our product candidates has included and may continue to include clinical trial sites outside the U.S., and the FDA and applicable foreign regulatory authorities may not accept data from such sites.

The clinical development of our product candidates has included and may continue to include clinical trial sites outside the U.S. and we may in the future choose to conduct one or more of our full clinical trials outside of the U.S. For example, our ongoing Phase 2 ADVANCED-2 clinical trial of TARA-002 in NMIBC is being conducted in the U.S., and in a number of other countries. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the U.S. or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authorities may be subject to certain conditions or exclusions. Where data from foreign clinical trials or clinical trial sites are intended to serve as the basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from clinical trials conducted outside of the U.S. or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan.

TARA-002 is an immunopotentiator, and one indication that we are pursuing is the treatment of LMs. There are no FDA-approved therapies for the treatment of LMs and it is difficult to predict the timing and costs of clinical development for TARA-002 for LMs.

To date, there are no FDA-approved therapies for the treatment of LMs. The regulatory approval process for novel product candidates such as TARA-002 can be more expensive and take longer than for other, better known or extensively studied therapeutic approaches or diseases. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring TARA-002 to market in LMs could decrease our ability to generate sufficient revenue to maintain our business.

Certain disorders we seek to treat have low incidence and prevalence, and it may be difficult to identify patients with these disorders, which may lead to delays in enrollment for our clinical trials or slower commercial revenue if approved.

Our current product candidates are targeting certain disorders that have low incidence and prevalence. For example, we estimate the incidence of LMs in the U.S. is approximately 1,400-1,800 cases per year. This could be a significant obstacle to the timely recruitment and enrollment of a sufficient number of eligible patients into our clinical trial. Further, we expect to rely in part on our relationships with patient advocacy groups to assist in identifying eligible patients, and any deterioration of those relationships could impede our ability to successfully enroll patients. Patient enrollment may be affected by other factors including:

- the severity of the disease under investigation;
- design of the study protocol;
- the eligibility criteria for the clinical trial;
- the perceived risks, benefits and convenience of administration of the product candidate being studied;
- our efforts to facilitate timely enrollment in clinical trials;

- the availability of other clinical trials being conducted for the same indication;
- the patient referral practices of physicians; and
- the proximity and availability of clinical trial sites to prospective patients.

Our inability to enroll a sufficient number of patients with these diseases for our planned clinical trials, including LMs, would result in significant delays and could require us to not initiate or abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Additionally, our projections of the number of people who have these disorders, including LMs, are based on estimates, including third-party analyses commissioned by us. The total addressable market opportunity for our product candidates will ultimately depend upon, among other things, the final approved product labeling for each of our product candidates, if our product candidates are approved for sale in our target indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients globally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Our products may potentially be dosed on a one-time basis, which means that certain patients who enroll in our clinical trials may have complete resolution of their LM and never require additional treatment on a commercial basis.

Our product candidates may cause undesirable or unforeseen side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Undesirable or unforeseen side effects from our product candidates, including TARA-002 or IV Choline Chloride could arise either during clinical development or, if approved, after the product has been marketed. Undesirable side effects could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials and could result in a more restrictive or narrower label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Any side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, in connection with a product after obtaining U.S. or foreign regulatory approval, a number of potentially negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings in the labeling;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these occurrences could prevent us or our potential partners from achieving or maintaining market acceptance of the product and could substantially increase the costs of commercializing such product.

A Fast Track Designation by the FDA may not lead to a faster development or regulatory review or approval process.

The FDA has granted FTD to IV Choline Chloride as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated and TARA-002 for the treatment of pediatric patients with macrocystic and mixed cystic LMs. We may seek FTD for other potential indications for IV Choline Chloride or TARA-002 or for our other product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FTD. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we receive FTD, we may not experience a faster development process, review or approval, including for IV Choline Chloride as a source of choline when oral or enteral nutrition is not possible, insufficient, or contraindicated or TARA-002 for pediatric patients with macrocystic and mixed cystic LMs or any other indication. The FDA may withdraw FTD if it believes that the designation is no longer supported by data from our clinical development program.

An Orphan Drug Designation by the FDA or European Commission does not increase the likelihood that our product candidates will receive marketing exclusivity.

We have obtained ODD from the FDA for TARA-002 for the treatment of LMs and for IV Choline Chloride for the prevention and/or treatment of choline deficiency in patients on long-term PN. We have also obtained Orphan Medicinal Product Designation from the European Commission for TARA-002 for the treatment of LMs. We may seek ODD for future product candidates or other indications, and we may be unsuccessful in those efforts. Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs and provide them with marketing exclusivity upon approval. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the U.S., ODD entitles a party to financial incentives such as tax advantages and user-fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs for rare diseases, regardless of whether the drugs are designated for the orphan use. In addition, if a product that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances.

Although we have obtained ODD for TARA-002 for the treatment of LMs and IV Choline Chloride for the prevention and/or treatment of choline deficiency in patients on long-term PN, and even if we obtain ODD for additional product candidates or other indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. If a competitor with a product that is determined by the FDA to be the same as one of our product candidates obtains marketing approval before us for the same indication we are pursuing and obtains orphan drug exclusivity, our product candidate may not be approved until the period of exclusivity ends unless we are able to demonstrate that our product candidate is clinically superior. Even after obtaining approval, we may be limited in our ability to market our product. In addition, exclusive marketing rights in the U.S. may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different principal molecular structural features can be approved for the same condition. Even after a product is approved with orphan drug exclusivity, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. ODD neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

A Breakthrough Therapy Designation by the FDA may not lead to a faster development or regulatory review or approval process.

The FDA has granted BTD for TARA-002 for the treatment of pediatric patients with macrocystic and mixed cystic LMs. We may seek BTD for TARA-002 for other indications or for our other product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the clinical trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the marketing application.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that a product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a BTD for a drug may not necessarily result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if the product candidate qualifies as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review.

Although the FDA has granted Rare Pediatric Disease Designation for TARA-002 for the treatment of LMs, a BLA for TARA-002, if approved, may not meet the eligibility criteria for a PRV.

RPDD has been granted by the FDA for TARA-002 for the treatment of LMs. In 2012, Congress authorized the FDA to award PRVs to sponsors of certain rare pediatric disease product applications. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a PRV may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application. The FDA may also revoke any PRV if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

For the purposes of this program, a "rare pediatric disease" is a (a) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents; and (b) rare disease or conditions within the meaning of the Orphan Drug Act. Under current law, after September 30, 2029, the FDA may not award any RPDD PRVs, although the FDA's authority to do so could be extended by Congress in the future.

If TARA-002 is approved, it may not be approved by September 30, 2029, and, therefore, we may not be in a position to obtain a PRV prior to expiration of the program, unless Congress further reauthorizes the program. Additionally, designation of a drug for a rare pediatric disease does not guarantee that an NDA or BLA will meet the eligibility criteria for a rare pediatric disease PRV at the time the application is approved, including the requirement that the NDA or BLA was granted priority review. Finally, a RPDD does not lead to faster development or regulatory review of the product or increase the likelihood that it will receive marketing approval. We may or may not realize any benefit from receiving a designation.

Any adverse developments that occur in patients undergoing treatment with OK-432/Picibanil or in patients participating in clinical trials conducted by third parties may affect our ability to obtain regulatory approval or commercialize TARA-002.

Chugai Pharmaceutical, over which we have no control, has the rights to commercialize TARA-002 and the originator therapy to TARA-002, OK-432, which is currently marketed under the name Picibanil, in Japan for various indications. In addition, clinical trials using Picibanil are currently ongoing in various countries around the world. If SAEs occur with patients using Picibanil or during any clinical trials of Picibanil conducted by third parties, the FDA

may delay, limit or deny approval of TARA-002 or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive FDA approval for TARA-002 and a new and serious safety issue is identified in connection with use of Picibanil or in clinical trials of Picibanil conducted by third parties, the FDA may withdraw the approval of the product or otherwise restrict our ability to market and sell TARA-002. In addition, treating physicians may be less willing to administer TARA-002 due to concerns over such AEs, which would limit our ability to commercialize TARA-002.

We may choose to delay or discontinue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate the potential return on investment for those product candidates.

At any time, we may decide to delay or discontinue the development of any of our product candidates for a variety of reasons, including the appearance of new technologies that make our product candidates obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements.

If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

Other Risks Related to Our Business

Our product candidates, if approved, will face significant competition and their failure to compete effectively may prevent them from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, uncertain and complex patent terms, and a strong emphasis on developing newer, fast-to-market proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing, including TARA-002 and IV Choline Chloride. We will face competition from a number of sources, such as pharmaceutical companies, biotechnology companies, generic drug companies, consumer products companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, regulatory expertise, clinical trial expertise, intellectual property portfolios, international reach, experience in obtaining patents and regulatory approvals for product candidates and other resources than we have. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts.

With respect to our lead product candidate, TARA-002, for the treatment of NMIBC and LMs, the active ingredient in TARA-002 is a genetically distinct strain of Streptococcus pyogenes (group A, type 3) Su strain, which is inactivated during the manufacturing process. TARA-002 is produced through a proprietary manufacturing process. We anticipate that, if approved by the FDA, TARA-002 will be protected by 12 years of biologic exclusivity. In addition, based on the prevalence of the disease, TARA-002 is likely to have seven years of concurrent ODD exclusivity for the treatment of LMs. Further, the USPTO issued to us Patent No. 12,551,514 claiming a method of treating non-muscle invasive bladder cancer with a combination of non-viable cells of streptococcus pyogenes and an immune checkpoint inhibitor, with a term expiring in 2044.

There are no approved pharmacotherapies currently available for the treatment of LMs and the current treatment options include a high-risk surgical procedure and off-label use of sclerosants, including doxycycline, bleomycin, ethanol and sodium tetradecyl sulfate. There are a number of drug development companies and academic researchers exploring oral and topical formulations of various agents for the treatment of LMs including macrolides, phosphodiesterase inhibitors, and calcineurin/mTOR inhibitors. These are in early development.

TARA-002, if approved for the treatment of NMIBC, would be subject to competition from existing treatment methods of surgery, chemotherapy and immunomodulatory therapy. For example, the current standard of care for NMIBC includes intravesical BCG TICE (manufactured by Merck & Co., Inc.). Other products approved for the treatment of NMIBC include Merck & Co., Inc.'s Keytruda, Endo International plc's Valstar, Ferring B.V.'s Adstiladrin, ImmunityBio, Inc.'s VesAnktiva in combination with BCG and Janssen's Inlexzo. Additional product candidates in development include but may not be limited to Japanese BCG Laboratory's BCG Tokyo, Pfizer Inc.'s Sasanlimab in combination with BCG, CG Oncology Inc.'s CG0070, enGene Inc.'s, EG-70, Pfizer Inc.'s PADCEV, Janssen's TAR-200 plus Cetrelimab, Urogen

Pharma Ltd.'s Jelmyto, Theralase Technologies Inc.'s Ruvidar, and Auro BioSciences, Inc.'s Aura-0011. Additional pharmaceutical and biotechnology companies with product candidates in development for the treatment of NMIBC include but may not be limited to Verity, AstraZeneca PLC, Bristol-Myers Squibb Company, Roche Group, Asieris Pharmaceuticals, BeiGene, Ltd, NanOlogy, LLC, Linton Pharm Co., Ltd., Lindis Biotech GmbH, Taizhou Hanzhong biomedical co. Ltd., Shionogi & Co. Ltd., Rapamycin Holdings, Inc., Vaxiion Therapeutics Inc., Incyte Corporation, LiPac Oncology, Inc., Anika Therapeutics Inc., Surge Pharmaceuticals Pvt. Ltd., and Istari Oncology, Inc.

There are no treatments currently available for patients on PS who are choline-deficient. IV Choline Chloride is the only sterile injectable form of choline chloride that can be combined with PN. Further, the USPTO, issued to us Patent No. US 11,311,503 claiming a sterile aqueous choline salt composition, and Patent No. US 12,083,081 claiming a method of treating choline deficiency with a choline composition, each with a term expiring in 2041.

We currently have limited marketing capabilities and no sales organization. If we are unable to grow our sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.

We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the U.S., Canada, the European Union, Latin America and other jurisdictions we may seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products, and business development activities involving external alliances, from prior employment at other companies, we, as a company, have no prior experience in the marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and pricing/reimbursement/access capabilities would impact adversely the commercialization of these products.

TARA-002 and any future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that its reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which its reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider our product candidates eligible for reference product exclusivity, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We have only received the exclusive rights to the materials required to commercialize TARA-002 in territories other than Japan and Taiwan until June 17, 2030, or an earlier date if Chugai Pharmaceutical terminates the agreement with us for any number of reasons, following which such rights become non-exclusive.

Pursuant to an agreement with Chugai Pharmaceutical dated June 17, 2019, as amended on July 14, 2020 (effective as of June 30, 2020), Chugai Pharmaceutical agreed to provide us with exclusive access to the starting material necessary to manufacture TARA-002 as well as technical support necessary for us to develop and commercialize

TARA-002 anywhere in the world other than Japan and Taiwan. However, this agreement does not prevent Chugai Pharmaceutical from providing such materials and support to any third-party for medical, compassionate use and/or non-commercial research purposes and this agreement is exclusive only through June 17, 2030 or, the earlier termination of the agreement by either party. Once our rights to the materials and technology necessary to manufacture, develop and commercialize TARA-002 are not exclusive, third parties, including those with greater expertise and greater resources, could obtain such materials and technology and develop a competing therapy, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

Even if we obtain regulatory approval to begin commercializing any of our products, we would remain subject to ongoing regulatory review, which could subsequently result in a suspension or termination of sale of these products, limitations on the approved indication or additional warnings, or, if we fail to comply with regulatory requirements, other penalties.

Even after we achieve U.S. regulatory approval for a product candidate, if any, we will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance and AE reporting, storage, advertising, promotion and recordkeeping for our product candidates. In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the manufacturing, processing, distribution or storage facility where, or processes by which, the product is made, a regulatory agency may impose restrictions on that product or us, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of any approved product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of product candidates;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

We face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability or similar causes of action as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding that we comply with applicable laws on promotional activity. Our products and product candidates are designed to affect important bodily functions and processes. Any

side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or potentially even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others, and under some circumstances even government agencies. If we cannot successfully defend ourselves against product liability or similar claims, we will incur substantial liabilities, reputational harm and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire clinical trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- significant delay in product launch;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

We have obtained product liability insurance coverage for our clinical trials. Large judgments have been awarded in class action or individual lawsuits against other pharmaceutical companies based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, restrictive and narrow, and, in the future, we may not be able to maintain adequate insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability or other similar legal actions. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all and for all geographies in which we wish to launch. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could decrease our cash and harm our business, financial condition, operating results and future prospects.

Our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with whom we may collaborate may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, anti-kickback and Medicare/Medicaid rules, or laws that require the true, complete and accurate reporting of financial information or data, books and records. If any such or similar actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of

significant civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, debarments, contractual damages, imprisonment, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of our operations, any of which could adversely affect our ability to operate our business and our operating results.

We may be subject to risks related to off-label use of our product candidates, if approved.

The FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA-approved uses, consistent with the product's approved labeling. Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, the DOJ, the Office of Inspector General of the HHS, state attorneys general, members of Congress and the public. For example, the FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Although physicians may prescribe products for off-label uses as the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-label uses of products for which marketing clearance has not been issued. Companies may only share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling. Violations, including promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil, criminal and/or administrative sanctions by the FDA. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. will be heavily scrutinized by relevant foreign regulatory authorities.

In the U.S., engaging in impermissible promotion of our product candidates for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to significant civil, criminal and/or administrative penalties and fines and agreements, such as a corporate integrity agreement, that materially restrict the manner in which we promote or distribute our product candidates. If we do not lawfully promote our products once they have received regulatory approval, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could have a material adverse effect on our business, financial condition and operating results and even result in having an independent compliance monitor assigned to audit our ongoing operations for a lengthy period of time.

If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for TARA-002 or IV Choline Chloride following regulatory approval, their commercial success may be hindered severely.

If TARA-002 or IV Choline Chloride only becomes available by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse most or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and private third-party payors is often critical to new product acceptance. Coverage decisions may depend on clinical and economic standards that disfavor new drug products when more established or lower-cost therapeutic alternatives are already available or subsequently become available, or may be affected by the budgets and demands on the various entities responsible for providing health insurance to patients who will use TARA-002 or IV Choline Chloride. Even if we obtain coverage for our products, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use a product unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost.

In addition, the market for our products will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies and there may be time limitations on when a new drug may even apply for formulary inclusion. Also, third-party payors may refuse to include products in their formularies or otherwise restrict patient access to such products when a less costly biosimilar or generic equivalent or other treatment alternative is available in the discretion of the formulary.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the U.S., although private third-party payors tend to follow Medicare practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as from state to state. Consequently, the coverage determination process is often a time-consuming and costly process that must be played out across many jurisdictions and different entities and that will require us to provide scientific, clinical and health economics support for the use of our products compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what time frame.

Further, we believe that future coverage and reimbursement likely will be subject to increased restrictions both in the U.S. and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the U.S. or international markets, which could harm our business, financial condition, operating results and prospects. Further, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare reform measures could hinder or prevent the commercial success of our product candidates.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any future product candidates we may develop, or affect pricing and third-party payment for our product candidates, which could negatively affect our business, financial condition and prospects. In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in 2010, the ACA was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Additionally, there has been increasing legislative and enforcement interest in the U.S. with respect to drug pricing practices since the ACA was enacted. For example, in November 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule was delayed until January 1, 2032 by the IRA. In addition, under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs has been eliminated. Elimination of this cap has, in some cases, required pharmaceutical manufacturers to pay more in rebates than they have received on the sale of products. In 2024, CMS issued a final rule that decreased Medicare reimbursement for physician services by 2.8%, effective January 1, 2025. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Additionally, several healthcare reform initiatives culminated in the enactment of the IRA in 2022, which, among other things, eliminated, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee maximum out-of-pocket costs and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket limit, and 20% once the out-of-pocket limit has been reached. The IRA also extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, but those subsidies expired at the end of 2025. The IRA also allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in 2024, and the

negotiated maximum fair price for each product has been announced. These negotiations resulted in significant price reductions for the products from their 2023 list prices, ranging from 38 to 79 percent, with an average price reduction of 59.4 percent. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs under Medicare Part B. For 2029 and subsequent years, 20 Part B or Part D drugs will be selected. A drug or biological product that has an ODD for only one rare disease or condition are excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation, and in 2024, CMS finalized regulations for the Medicare Part B and Part D inflation rebates. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties.

These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Although full economic effect of the IRA on our business and the pharmaceutical industry in general is unknown at this time, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. Similarly, the adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also reduce our profitability. We expect pricing pressures will continue globally.

The current federal administration is pursuing policies to reduce regulations and expenditures across government including at HHS, which include the FDA and CMS, and related agencies. These actions included, for example, directives to reduce agency workforce which include the FDA and CMS, and related agencies. In addition, on May 12, 2025, President Trump issued an Executive Order that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers MFN price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the Executive Order requires HHS to propose a rulemaking to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under CMMI, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the U.S., if they are also sold in comparably developed countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs competed with drugs whose prices were reduced as a result of MFN pricing initiatives.

At the state level, legislatures are increasingly enacting legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, the FDA released a final rule in 2020 providing guidance for states to build and submit importation proposals for drugs from Canada. The FDA authorized the first such plan in Florida in 2024, but the implementation of Florida's plan has been extended. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the U.S. or Canada. Other states have also submitted proposals that are pending review by the FDA.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

We are subject to strict healthcare laws, regulation and enforcement, and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse, privacy, transparency, and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct business. The healthcare laws and regulations that may affect our

ability to operate include but are not limited to: the federal Anti-Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; HIPAA, as amended by HITECH; the Prescription Drug Marketing Act (for sampling of drug product among other things); the federal physician sunshine requirements under the ACA; the FCPA as it applies to activities outside of the U.S.; the federal Right-to-Try legislation; and similar state laws of such federal laws, which may be broader in scope.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil FCA.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business and result in reputational damage. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, including punitive damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, imprisonment, additional oversight and reporting obligations, or the curtailment or restructuring of our operations, and injunctions, any of which could adversely affect our ability to operate our business and financial results.

We may in-license and acquire product candidates and may engage in other strategic transactions, which could impact our liquidity, increase our expenses and present significant distractions to our management.

Part of our strategy is to in-license and acquire product candidates and we may engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near-and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we complete could harm our business, financial condition, operating results and prospects.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

We may in-license, acquire, develop and market additional products and product candidates. Because our internal research and development capabilities are limited, we may be dependent on pharmaceutical and biotechnology companies, academic or government scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly on our ability to identify and select promising pharmaceutical and biologic product candidates and products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the

possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

We expect to rely on agreements with third parties for the successful development and commercialization of our product candidates.

We expect to rely upon the efforts of third parties for the successful development and commercialization of our current and future product candidates. The clinical and commercial success of our product candidates may depend upon maintaining successful relationships with third-party partners which are subject to a number of significant risks, including the following:

- our partners' ability to execute their responsibilities in a timely, cost-efficient and compliant manner;
- reduced control over delivery and manufacturing schedules;
- price increases and product reliability;
- manufacturing deviations from internal or regulatory specifications;
- quality incidents;
- the failure of partners to perform their obligations for technical, market or other reasons;
- misappropriation of our current or future product candidates; and
- other risks in potentially meeting our current and future anticipated commercialization schedule for product candidates or satisfying the requirements of our end-users.

We cannot assure you that we will be able to establish or maintain third-party relationships in order to successfully develop and commercialize our product candidates.

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, which may include sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval; and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, non-clinical, clinical and commercial supplies of any future product candidates.

We do not currently have the infrastructure or capability to supply, store, manufacture or distribute preclinical, non-clinical, clinical or commercial quantities of drug substances or products. Additionally, we have not entered into a long-term commercial supply agreement to provide us with such drug substances or products. As a result, our ability to develop our product candidates is dependent, and our ability to supply our products commercially will depend, in part, on our ability to obtain active pharmaceutical ingredient, or API, and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical, non-clinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, we may be unable to continue to develop or commercialize our products and product candidates.

We do not have direct control over whether our contract suppliers and manufacturers will maintain current pricing terms, be willing to continue supplying us with API and finished products or maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMP for production of both API and finished products. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidate successfully, and we may be held liable for injuries sustained as a result.

In order to conduct larger or late-stage clinical trials for our product candidates and supply sufficient commercial quantities of any of our products, if approved, our contract manufacturers and suppliers will need to produce our API and other substances and materials used in our product candidates in larger quantities, more cost-effectively and, in

certain cases, at higher yields than they currently achieve. If our third-party contractors are unable to scale up the manufacturing of any of our product candidates successfully in sufficient quality and quantity and at commercially reasonable prices, or are shut down or put on clinical hold by government regulators, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to transfer the processes successfully on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the U.S. This may give rise to difficulties in importing our products or product candidates or their components into the U.S. or other countries.

Furthermore, as we depend on third-party suppliers and manufacturers, some of which may be located outside of the U.S., any future additional or new tariffs or other changes in trade measures adopted by the U.S. government could adversely impact the Company's business, financial condition, and results of operations, particularly where supply chain delays adversely impact availability of materials, components or manufacturing of our product candidates. Any decision by the U.S. government to adopt such actions, such as an increase in customs duties or tariffs, the renegotiation of U.S. trade agreements or any other action that could have a negative impact on international trade, including corresponding actions taken by other countries in response to U.S. governmental actions, could adversely impact our supply chain, manufacturing and availability of our product candidates.

The manufacturing of biologics is complex and our third-party manufacturers may encounter difficulties in production. If our CDMO encounters such difficulties, the ability to provide supply of TARA-002 for clinical trials, our ability to obtain marketing approval, or our ability to obtain commercial supply of TARA-002, if approved, could be delayed or stopped.

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We are completely dependent on CDMOs to fulfill our clinical and commercial supply of TARA-002. The process of manufacturing biologics is complex, highly regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely harm our business. Moreover, if the FDA determines that our manufacturer is not in compliance with FDA laws and regulations, including those governing cGMP, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMP, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for TARA-002 or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Scaling up a biologic manufacturing process is a difficult and uncertain task,

and any CDMO we contract may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely meet product demand.

Our CDMOs and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time-consuming or costly.

Our CDMOs and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. The operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive biopharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

From time to time, the U.S. has experienced a decrease in unemployment rates and an increasingly competitive labor market, which has at times resulted in difficulties in hiring or retaining sufficient qualified personnel to maintain and grow our business. We are uncertain as to the employment environment in the future, or how that environment will impact our workforce, including our ability to attract and retain qualified management and other key personnel.

We or the third parties upon which we depend may be adversely affected by natural disasters and other catastrophic events and by man-made problems such as terrorism and war that could disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our office is located in New York, New York. If a disaster, power outage, computer hacking, or other event occurred that prevented us from using all or a significant portion of an office, that damaged critical infrastructure, such as enterprise financial systems, IT systems, manufacturing resource planning or enterprise quality systems, or

that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, we have expanded our clinical development of TARA-002 in NMBIC to clinical trial sites outside the U.S. and may continue expanding to other geographies. If political or civil conditions require it, our sites may need to delay or suspend clinical trial activities. In addition, enrollment and retention of patients at such sites could be disrupted by geopolitical events, including civil or political unrest, such as the current ongoing conflict between Russia and Ukraine. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the research, development, regulatory approval, manufacture, distribution or commercialization of TARA-002 or IV Choline Chloride, our business, financial condition, operating results and prospects would suffer.

The effects of epidemics and pandemics and their corresponding macroeconomic impacts could materially and adversely impact our business, including our clinical development plans and non-clinical research.

As a result of the COVID-19 pandemic and the associated health and safety measures that were imposed, we had and, in the event of a resurgence of the pandemic or the onset of another public health crisis, may again experience, disruptions that could severely impact our business, including but not limited to delays or difficulties in clinical trial site operations and in the enrollment, scheduling and retention of patients in our clinical trials; interruption of key manufacturing, research and clinical development and other activities; and delays or difficulties conducting and completing non-clinical studies.

In addition, macroeconomic factors, including supply chain disruptions, rising inflation and resulting increases in interest rates, which were, in part, tied to the impacts of the COVID-19 pandemic, had an impact on our operations, and any future pandemic or public health crisis may have the same effects. Similarly, if banks and financial institutions enter receivership or become insolvent in the future due to financial conditions affecting the banking system and financial markets, there could be an adverse effect on our ability to access our cash and cash equivalents and investments, including transferring funds, making payments or receiving funds, any of which could have a material adverse effect on our business and financial condition.

If we are not able to respond to and manage the impact of such events effectively, our business will be harmed.

Risks Related to Our Common Stock

We expect our stock price to be highly volatile.

The market price of our shares could be subject to significant fluctuations. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile, even subject to large daily price swings. For example, the closing price of our common stock from the period January 1, 2025 to December 31, 2025 has ranged from a low of $2.78 to a high of $7.56. Some of the factors that may cause the market price of our shares to fluctuate include, but are not limited to:

- the results of current and any future clinical trials of TARA-002 or IV Choline Chloride and any clinical trial failure, including any failure resulting from difficulties or delays in identifying patients, enrolling patients, retaining patients, meeting specific clinical trial endpoints or completing and timely reporting the results of any clinical trial;
- our ability to obtain regulatory approvals for TARA-002, IV Choline Chloride or future product candidates, and delays of, or failures to obtain such approvals;
- the failure of TARA-002 or IV Choline Chloride or future product candidates, if approved, to achieve commercial success;
- potential side effects associated with TARA-002 or IV Choline Chloride or future product candidates;
- issues in manufacturing, or the inability to obtain adequate supply of, TARA-002, IV Choline Chloride or future product candidates;
- the entry into, or termination of, or breach by partners of key agreements, including key commercial partner agreements;

- the initiation of, material developments in, or conclusion of, any litigation or other actions to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- announcements of any dilutive equity financings;
- inability to obtain additional funding;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts;
- the loss of key employees;
- changes in laws or regulations application to TARA-002 or IV Choline Chloride or future product candidates; and
- sales of our common stock by us, our insiders or our other stockholders.

Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our shares.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. In addition, such securities litigation often has ensued after a reverse merger or other merger and acquisition activity. Such litigation if brought could impact negatively our business.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

As a public company, we have incurred, and will continue to incur, significant legal, accounting and other expenses, including costs associated with public company reporting and other SEC requirements. We have also incurred, and will continue to incur, costs associated with corporate governance requirements, including requirements under the Exchange Act, the Sarbanes-Oxley Act and other applicable legislation, as well as rules implemented by the SEC and Nasdaq.

We expect the rules and regulations applicable to public companies will continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. Our executive officers and other personnel will need to continue to devote substantial time to managing operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it expensive for us to operate our business.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We must perform system and process evaluations and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. While we remain a smaller reporting company and non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. When we cease to be a smaller reporting company and no longer qualify as a non-accelerated filer, we would incur substantial professional fees and internal costs to expand our accounting and finance functions. We may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities or by Nasdaq.

We are able to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in our common stock being less attractive to investors.

We qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, we are able to take advantage of reduced disclosure requirements, such as certain simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Comparatively reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for our investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive due to our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues were below $100 million and we have a public float of less than $700 million.

We do not anticipate paying any dividends in the foreseeable future.

The current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of your shares of our stock will be your sole source of gain, if any, for the foreseeable future.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

We will not receive a significant amount, or potentially any, additional funds upon the exercise of our April 2024 Pre-Funded Warrants and December 2024 Pre-Funded Warrants; however, any exercise would increase the number of shares eligible for future resale in the public market and result in substantial dilution to our stockholders.

In April 2024 and December 2024, we issued the April 2024 Pre-Funded Warrants and December 2024 Pre-Funded Warrants to purchase a total of 1,700,000 and 2,325,372 shares of our common stock, respectively, 3,400,272 of which are outstanding as of the date of this report. Each April 2024 Pre-Funded Warrant and December 2024 Pre-Funded Warrant is exercisable for $0.001 per share of common stock underlying such Pre-Funded Warrant. Accordingly, we will not receive a significant amount of additional funds upon the exercise of the April 2024 Pre-Funded Warrants and December 2024 Pre-Funded Warrants. To the extent such Pre-Funded Warrants are exercised, additional shares of common stock will be issued for nominal consideration, which will result in dilution to the then existing holders of our common stock and will increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of the common stock, causing our stock price to decline.

The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock and this could adversely impact the consideration our other stockholders would receive.

In April 2024 and December 2024, we issued the April 2024 Pre-Funded Warrants, December 2024 Pre-Funded Warrants and April 2024 Common Warrants. Each April 2024 Common Warrant is exercisable solely by means of a cash exercise, except that the April 2024 Common Warrant is exercisable via cashless exercise if at the time of exercise, a registration statement registering the issuance of the shares of common stock underlying the common stock warrants under the Securities Act is not then effective. The April 2024 Common Warrants include certain rights upon "fundamental transactions" as described in the April 2024 Common Warrants. Additionally, each holder of warrants will not be entitled to exercise any portion of any April 2024 Pre-Funded Warrant, December 2024 Pre-Funded Warrant or April 2024 Common Warrant, which, upon giving effect to such exercise, would cause (A) for the holders of the April 2024 Pre-Funded Warrants and April 2024 Common Warrants, (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 9.99%, or for certain holders, 4.99%, of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise and (B) for the holders of the December 2024 Pre-Funded Warrants, the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise. However, for the April 2024 Pre-Funded Warrants, December 2024 Pre-Funded Warrants and April 2024 Common Warrants, any holder may increase or decrease such percentage to any other percentage (not in excess of 19.99%) upon prior notice from the holder to us.

Although these warrants are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, entrench our management and our board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us and the holders of these warrants concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline significantly.

We have registered the issuance and/or resale of shares issuable upon exercise of these warrants under an effective registration statement. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public market upon issuance. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur.

Given the amount and terms of these warrants, we may find it more difficult to raise additional equity capital on favorable terms or at all while these warrants are outstanding.

Risk Related to Our Ownership Structure and Governance

Certain stockholders have the ability to control or significantly influence certain matters submitted to our stockholders for approval.

Certain stockholders have consent rights over certain significant matters of our business. These include decisions to effect a merger or other similar transaction, changes to our principal business, and the sale or other transfer of TARA-002 or other assets with an aggregate value of more than $2,500,000. As a result, these stockholders have significant influence over certain matters that require approval by our stockholders.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of our business more difficult and may prevent attempts by our stockholders to replace or remove management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits stockholders owning in excess of 15% of the outstanding voting stock from merging or combining with us. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for certain disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Risks Related to Intellectual Property Rights

We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our product candidates will depend, in part, on our ability to obtain and maintain patent protection in both the U.S. and other countries, to preserve our trade secrets and to prevent third parties from infringing on our proprietary rights. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents around the world.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that are desirable. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to our patents that would not constitute infringement. Any of these outcomes could impair our ability to enforce the exclusivity of our patents effectively, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic and over-the-counter pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will issue from any pending or future patent or other similar applications owned by or licensed to us. Even if patents or other intellectual property rights have issued or will issue, we cannot

guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target.

Competitors in the field of immunology and oncology therapeutics have created a substantial amount of prior art, including scientific publications, posters, presentations, patents and patent applications and other public disclosures including on the Internet. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop or threaten our ability to commercialize or finance our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the U.S., and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending and especially enforcing such rights in foreign jurisdictions. International and U.S. free trade agreements like the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPs Agreement, administered by the World Trade Organization provide global protection of certain intellectual property rights, but in a number of markets we may be unable to patent our products or to enforce the patents that we receive for our products. Further, many developing countries, and some developed countries, do not provide effective data package protection even though it is specified in the TRIPs Agreement. If we encounter such difficulties in protecting, or are otherwise precluded from effectively protecting, our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or will be enforced by courts, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets and unpatented know-how will not otherwise become known, inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use and if we and our agents or representatives inadvertently disclose trade secrets and/or unpatented know-how, we may not be allowed to retrieve this and maintain the exclusivity we previously enjoyed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the U.S., especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. and even in launching an identical version of our product notwithstanding we have a valid patent in that country. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, or produce copy products, and, further, may export otherwise infringing products to territories where we have patent protection but enforcement on infringing activities is inadequate or where we have no patents. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could

result in substantial costs and divert our efforts and attention from other aspects of our business, could put our global patents at risk of being invalidated or interpreted narrowly and our global patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate or infringement actions brought against us, and the damages or other remedies awarded, if any, may not be commercially meaningful when we are the plaintiff. When we are the defendant we may be required to post large bonds to stay in the market while we defend ourselves from an infringement action.

In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patent holder's patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. In these situations, the royalty the court requires to be paid by the license holder receiving the compulsory license is not calculated at fair market value and can be inconsequential, thereby adversely affecting the patent holder's business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third-party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the Unites States. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. For example, in Brazil, pharmaceutical patents require initial approval of the Brazilian health agency (ANVISA). Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and/or timely pay a prosecution fee. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to enter the market, which could materially adversely affect our business, financial condition, operating results and prospects.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

We have entered into in-license arrangements with respect to certain of our product candidates. These license agreements impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot assure that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S.-and foreign-issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields across many countries, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies notwithstanding patents we may possess. Because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, because patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to our technology. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or the like. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, or, in the case of in-licensed technology, the licensor may have to participate, in the U.S., in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act or other countries' laws similar to the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug, and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court would decide that we are infringing the third-party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court would order us to pay the other party significant damages for having violated the other party's patents.

Because we rely on certain third-party licensors and partners and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third-party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could adversely affect our business, financial condition or operating results.

We may be subject to claims that our officers, directors, employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates,

many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

General Risk Factors

Pharmaceutical companies are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations, including our clinical trials; harm to our reputation; and other adverse effects on our business or prospects.

In the ordinary course of business, we collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, Process (or Processing of), personal data and other sensitive and confidential information, including information we collect about patients in connection with clinical trials, sensitive third-party data or, as necessary to operate our business, for legal and marketing purposes, and for other business-related purposes.

Accordingly, we are, or may become, subject to numerous federal, state, local and international data privacy and security laws, regulations, guidance and industry standards as well as external and internal privacy and security policies, contracts and other obligations that apply to the Processing of personal data by us and on our behalf, collectively, Data Protection Requirements. The number and scope of Data Protection Requirements are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other. If we fail, or are perceived to have failed, to address or comply with Data Protection Requirements, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions against us that could include investigations, fines, penalties, audits and inspections, additional reporting requirements and/or oversight, temporary or permanent bans on all or some Processing of personal data, orders to destroy or not use personal data. Further, individuals or other relevant stakeholders could bring a variety of claims against us for our actual or perceived failure to comply with the Data Protection Requirements. Any of these events could have a material adverse effect on our reputation, business, or financial condition, and could lead to a loss of actual or prospective customers, collaborators or partners; interrupt or stop clinical trials; result in an inability to Process personal data or to operate in certain jurisdictions; limit our ability to develop or commercialize our products; or require us to revise or restructure our operations, or each, a material adverse impact.

We are, or may become, subject to U.S. privacy laws. For example, in the U.S., there are a broad variety of data protection laws and regulations that may apply to our activities such as state data breach notification laws, state personal data privacy laws (for example, the CCPA), state health information privacy laws, and federal and state consumer protection laws.

A number of U.S. states have enacted data privacy laws. In particular, the CCPA, together with the CPRA, requires covered businesses that process personal data of California residents to disclose their data collection, use and sharing practices. Further, the CCPA provides California residents with new data privacy rights (including the ability to opt out of the sale of personal data), imposes new operational requirements for covered businesses, provides for civil penalties for violations (up to $7,500 per violation), as well as a private right of action for certain data breaches (that is expected to increase data breach class action litigation and result in significant exposure to costly legal judgements and settlements). The CPRA, among other things, gives California residents the ability to limit use of certain sensitive personal data, establishes restrictions on the retention of personal data, expands the types of data breaches subject to the CCPA's private right of action, and establishes a new California Privacy Protection Agency to implement and enforce the new law. Although there are limited exemptions for clinical trial data under the CCPA and the CPRA, the CCPA and the CPRA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. The federal government is also considering comprehensive privacy legislation.

The DSP preventing access to bulk U.S. sensitive personal data by certain countries or persons is new, complex and only recently enforceable, and as such, there is a risk that our interpretation of its applicability, scope, and requirements is incorrect, incomplete, or misapplied. Compliance with the DSP may now, or in the future, require us to invest heavily in data security and compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Finally, non-compliance with the DSP could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

Outside the U.S., an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, Japan's Act on the Protection of Personal Information, or APPI, China's Personal Information Protection Law, or PIPL, and Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018) impose strict requirements for processing personal data. Under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data.

European data protection laws (including the EU GDPR and UK GDRP) are wide-ranging in scope and impose numerous, significant and complex compliance burdens in relation to the Processing of personal data, such as: limiting permitted Processing of personal data to only that which is necessary for specified, explicit and legitimate purposes; requiring the establishment of a legal basis for Processing personal data; broadening the definition of personal data; creating obligations for controllers and processors to appoint data protection officers in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; establishing limitations on the collection and retention of personal data through "data minimization" and "storage limitation" principles; honoring data subject rights; formalizing a heightened standard to obtain data subject consent; establishing obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data; introducing the obligation to provide notice of certain significant personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or EU in certain circumstances. In particular, the Processing of "special categor[ies] [of] personal data" (such as personal data related to health and genetic information), which could be relevant to our operations in the context of our clinical trials, imposes heightened compliance burdens under European data protection laws and is a topic of active interest among relevant regulators.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, that the European Commission does not consider to provide an adequate level of data privacy and security, such as the U.S. The European Commission released a set of "Standard Contractual Clauses," or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists a possibility that the validity of SCCs will be challenged in European courts. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data.

In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries that they do not consider to provide an adequate level of personal data protection, such as the U.S., and certain countries outside Europe (e.g., Brazil) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business.

While we use SCCs for transfers of personal data from the EEA, UK and Switzerland to recipients in non-adequate countries, in the event we are unable to implement a valid compliance mechanism for cross-border data transfers (e.g., SCCs are invalidated), we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. Inability to import personal data to the U.S. may significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties subject to European and other data protection laws or requiring us to increase our personal data processing capabilities in Europe and/or elsewhere at significant expense.

These laws exemplify the vulnerability of our business to the evolving regulatory environment related to personal data and may require us to modify our Processing practices at substantial costs and expenses in an effort to comply. Given the breadth and evolving nature of Data Protection Requirements, preparing for and complying with these requirements is rigorous, time-intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that Process personal data on our behalf.

We may publish privacy policies and other documentation regarding our Processing of personal data and/or other confidential, proprietary or sensitive information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees, third-party collaborators, service providers, contractors or consultants fail to comply with our policies and documentation. Such failures can subject us to potential regulatory action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, subjects about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business or have other material adverse impacts.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; loss of revenue or profits; interruptions to our operations such as our clinical trials; harm to our reputation; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we may collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, Process, proprietary, confidential and sensitive information, including personal data (including, key-coded data, health information and other special categories of personal data), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties, or collectively, Sensitive Information.

We may use third-party service providers and subprocessors to help us operate critical business systems to Process Sensitive Information on our behalf in a variety of contexts, including without limitation, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. We may share or receive Sensitive Information with or from third parties.

If we, our service providers, partners or other relevant third parties have experienced, or in the future experience, any security incident(s) that result in, any data loss; deletion or destruction; unauthorized access to; loss, unauthorized acquisition, disclosure, or exposure of, Sensitive Information, or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, or collectively, a Security Incident, it may materially adversely affect our business, financial condition, operating results and prospects, including the diversion of funds to address the breach, and interruptions, delays, or outages in our operations and development programs. In the first quarter of 2020, our email server was compromised in a cyber-attack. We quickly isolated the incident and have, since, implemented additional risk prevention measures.

Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase. These threats are becoming increasingly difficult to detect especially as more advanced artificial intelligence and machine learning become available and increasingly used. These threats come from a variety of sources, including

traditional computer "hackers", threat actors, employee error, theft or misuse, sophisticated nation-states, and nation-state supported actors. We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through phishing attacks); software bugs; malicious code (such as viruses and worms); denial-of-service attacks (such as credential stuffing); malware (including as a result of advanced persistent threat intrusions); supply-chain attacks, server malfunctions, software and hardware failures; loss of data or other information technology assets; adware; natural disasters; terrorism; war; telecommunication and electrical failures; ransomware attacks; and other similar threats.

Ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data, loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our systems and networks or the systems and networks of third parties that support us and our services. We may also be the subject of server malfunction, software or hardware failures, loss of data or other computer assets, and other similar issues. A significant portion of our workforce and third-party partners work remotely from time to time, and reliance on remote working technologies and the prevalent use of mobile devices that access confidential and personal data information increase the risk of Security Incidents, which could lead to the loss confidential information, personal data, trade secrets or other intellectual property.

We may be required to expend additional, significant resources, fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against Security Incidents and to mitigate, detect, and remediate actual and potential vulnerabilities. Certain data privacy and security obligations may require us to implement specific security measures or use industry-standard or reasonable measures to protect our information technology systems and Sensitive Information. Even if we were to take and have taken security measures designed to protect against Security Incidents, there can be no assurance that such security measures or those of our service providers, partners and other third parties will be effective in protecting against all Security Incidents and material adverse impacts that may arise from such Security Incidents. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a Security Incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

If we (or a third-party upon whom we rely) experience a Security Incident or are perceived to have experienced a Security Incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. In addition, our actual or prospective customers, collaborators, partners and/or clinical trial participants may stop using our product candidates or working with us. This discontinuance, or failure to meet the expectations of such third parties, could result in material harm to our operations, financial performance or reputation and affect our ability to grow and operate our business.

Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of Sensitive Information, including preventing us from conducting clinical trials, tests or research and development activities and prevent us from managing the administrative aspects of our business.

Applicable Data Protection Requirements (as defined below) may require us to notify relevant stakeholders of Security Incidents, including affected individuals, partners, collaborators, customers, regulators, law enforcement agencies, credit reporting agencies and others. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could materially adversely affect our business, financial condition, operating results and prospects.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that any limitations or exclusions of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages if we fail to comply with Data Protection Requirements related to information security or Security Incidents.

We cannot be sure that our insurance coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse impacts arising out of our Processing operations, privacy and security practices, or Security Incidents we may experience. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large excess or deductible or co-insurance requirements), could materially adversely affect our business, financial condition, operating results and prospects.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk Management & Strategy

We maintain a cyber risk management program designed to identify, assess, manage, mitigate and respond to cybersecurity threats. This program, in conjunction with our enterprise risk management and data privacy programs, address cybersecurity risks to the corporate information technology, or IT, environment including systems, hardware, software, data, people and processes.

The underlying processes and controls of our cyber risk management program incorporate recognized best practices and standards for cybersecurity and IT, including the National Institute of Standards and Technology, or NIST, Cybersecurity Framework, or CSF, and processes and controls supporting data protection requirements under applicable law. The NIST CSF offers a thorough set of guidelines and best practices to help establish a strong cybersecurity posture. Utilizing the NIST CSF enables us to systemically identify, assess and manage cybersecurity risks most relevant and impactful to our business operations. It is important to note that using the NIST CSF as a guide does not imply our cybersecurity program meets any specific technical standards or requirements.

Our cybersecurity risk management strategy includes the following approach:

Annually, we engage third-party specialists to perform an assessment of the Company's cyber risk management program against the NIST CSF. The annual risk assessment identifies, quantifies and categorizes significant cyber risks. In addition, we, in conjunction with the third-party cyber risk management specialists, develop a risk mitigation plan to address such cyber risks, and where necessary, remediate potential vulnerabilities identified through the annual assessment process.

In addition, we maintain policies over areas such as protecting and handling confidential information, processing of personal data, access on/off boarding, user management, acceptable use and IT change control management to help govern the processes put in place by management designed to protect our IT assets, data and services from threats and vulnerabilities. We employ additional key practices within the cyber risk management program including, but not limited to maintenance of an IT assets inventory, periodic network scans, identity access management controls including restricted access to privileged accounts, backup and recovery, security information and event management, or SIEM, tools and physical security measures at our facilities. We also utilize information protection/detection systems, or IPS/IDS, including maintenance of firewalls and anti-malware tools, network and data traffic monitoring with automated alerting, ongoing cybersecurity user awareness training, industry-standard encryption protocols, formalized change management processes and critical data backups to reduce cybersecurity risk.

Cybersecurity partners, including assessors, consultants, advisors and other third-party service providers, are a key part of our cybersecurity risk management strategy and infrastructure. We partner with industry recognized cybersecurity providers leveraging third-party technology and expertise and engage with these partners to monitor and maintain the performance and effectiveness of IT assets, data and services. The cybersecurity partners provide services including, but not limited to systems inventory monitoring, configuration management, periodic network scanning, user management, mobile device monitoring, capacity monitoring, network protection and monitoring, IPS/IDS management, remote access monitoring and management, user activity monitoring, data backups management, infrastructure maintenance, SIEM monitoring, incident response, cybersecurity strategy, and cyber risk advisory, assessment and remediation.

We have implemented third-party risk management processes to manage the risks associated with reliance on vendors, critical service providers and other third parties that may lead to a service disruption or an adverse cybersecurity incident. This includes processes for performing third-party risk ratings and data classification mapping of current and ongoing vendors. The program promotes good cybersecurity practices with our third-party vendors and helps to ensure their adherence to our cybersecurity standards.

In evaluating the risks identified as a result of the annual cybersecurity assessment process, our cybersecurity partners assist us in assessing the likelihood, severity, and impact of relevant risks, including the impact on employees, stakeholders, and vendors. These risks are prioritized and monitored by our cybersecurity partners and management team.

Our cybersecurity program includes an incident response plan that includes all relevant and critical members of management and third-party service providers alike. The team is responsible for assessing and managing cybersecurity incident response processes, response times, and communication plans in the event corrective actions and mitigation procedures are required to isolate and eradicate an incident.

Governance & Oversight

Our IT governance & oversight team led by our chief financial officer in conjunction with our director of IT and our third-party IT and cybersecurity service providers is responsible for oversight and administration of our cyber risk management program, and for informing senior management and other relevant stakeholders regarding the prevention, detection, mitigation and remediation of cybersecurity incidents. Our team has experience selecting, deploying and overseeing cybersecurity technologies, initiatives, and processes directly or via selection of strategic third-party partners. We also rely on threat intelligence and other information obtained from governmental, public, or private sources, including external consultants engaged by us for strategic cyber risk management, advisory and decision making.

The Audit Committee of the Board of Directors, or the Audit Committee, oversees our cybersecurity risk exposures and the steps taken by management to monitor and mitigate cybersecurity risks. The cybersecurity stakeholders, including member(s) of management assigned with cybersecurity oversight responsibility and/or third-party consultants providing cyber risk advisory services, brief the Audit Committee on cyber threats and vulnerabilities identified through the risk management process, the effectiveness of our cyber risk management program, the emerging threat landscape and new cyber risks on at least an annual basis. This includes updates on our processes to prevent, detect and mitigate cybersecurity incidents. In addition, the Audit Committee is responsible for reporting information about such risks to the Board of Directors and material cybersecurity risks and/or events are reviewed by the Board of Directors, at least annually, as part of our corporate risk oversight processes.

We face risks from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. We acknowledge that the risk of cyber incidents is prevalent in the current threat landscape and that a future cyber incident may occur in the normal course of our business. However, prior cybersecurity incidents have not been material and are not reasonably likely to have had a material adverse effect on our business, financial condition, results of operations, or cash flows. We proactively seek to detect and investigate unauthorized attempts and attacks against our IT assets, data, and services, and to prevent their occurrence and recurrence where practicable through changes or updates to internal policies, processes, and operations; however, potential vulnerabilities to known or unknown threats will still remain. See *Item 1A. "Risk Factors"* for more information on Company cybersecurity risks.

Item 2. Properties.

As of December 31, 2025, we leased approximately 10,000 square feet of space for our headquarters in New York, New York under an agreement that expires in May 2028. We leased approximately an additional 10,000 square feet for our development laboratory, a manufacturing facility and an additional manufacturing space, all located in North America under an agreement that expires in June 2029. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is traded on the Nasdaq under the symbol "***TARA***".

Holders of Our Common Stock

As of March 5, 2026, there were 54,084,378 shares of common stock outstanding held by approximately 19 stockholders of record. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs and plans for expansion.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K regarding information about securities authorized for issuance under our equity compensation plans.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this document, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a New York City based clinical-stage biopharmaceutical company committed to advancing transformative therapies for the treatment of cancer and rare diseases. We were founded on the principle of applying modern scientific, regulatory or manufacturing advancements to established mechanisms in order to create new development opportunities. We prioritize creativity, integrity and tenacity to expedite our goal of bringing life-changing therapies to people with limited treatment options.

Our portfolio includes two development programs utilizing TARA-002, an investigational cell therapy based on the broad immunopotentiator, OK-432, which was originally granted marketing approval by the Japanese Ministry of Health and Welfare as an immunopotentiating cancer therapeutic agent. This cell therapy is currently approved in

Japan and Taiwan for LMs and multiple oncologic indications. We have secured worldwide rights to the asset excluding Japan and Taiwan and are exploring its use in oncology and rare disease indications. TARA-002 was developed from the same master cell bank of genetically distinct group A Streptococcus pyogenes as OK-432 (marketed as Picibanil® in Japan by Chugai Pharmaceutical). We are currently developing TARA-002 in NMIBC and in LMs.

We are also pursuing IV Choline Chloride, an investigational phospholipid substrate replacement therapy, for patients receiving PS which includes both nutrition and fluids. 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, neurotransmission, muscle function and bone health. PS patients are unable to synthesize choline from enteral nutrition sources, and there are currently no available PS formulations containing choline. See *"Item 1. Business"* for additional information regarding our various clinical trial programs.

We have devoted substantial efforts to the development of our programs and do not have any approved products and, to date, have not generated any revenues from product sales. Neither TARA-002 nor IV Choline Chloride have been approved by the FDA or other comparable regulatory authorities for use for any indications. We do not expect to generate revenues in the near-term, and it is possible we may never generate revenues in the future. To finance our current strategic plans, including the conduct of ongoing and future clinical trials and further research and development costs, we will need to raise additional capital. See *"Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources"* for additional information about our liquidity and capital resource needs.

Since inception, we have incurred significant operating losses. As of December 31, 2025, we had an accumulated deficit of approximately $302.4 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next few years as we continue our development of, and seek marketing approvals for, our product candidates, prepare for and begin the commercialization of any approved products and add infrastructure and personnel to support our product development efforts and operations as a public company in the U.S.

As a clinical-stage company, our expenses and results of operations are likely to fluctuate significantly from quarter-to-quarter and year-to-year. We believe that our period-to-period comparisons of our results of operations should not be relied upon as indicative of our future performance.

As of December 31, 2025, we had approximately $197.9 million in unrestricted cash and cash equivalents, and marketable debt securities.

Financial Overview

Research and Development

Research and development expenses consist primarily of costs incurred for the development of our current and potential future product candidates, which include personnel-related expenses, including salaries, benefits, travel and stock-based compensation expense, external expenses incurred under agreements with CROs or CDMOs, the cost of acquiring, developing and manufacturing clinical trial materials, clinical and non-clinical related costs and costs associated with regulatory operations and facilities, which includes depreciation and other expenses such as rent, maintenance and other supplies.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, including salaries, benefits, travel expenses and stock-based compensation, for executive management and other administrative personnel. General and administrative expenses also include professional fees for legal, investor relations, consulting, auditing and accounting services, business and market development activities, as well as costs related to human resources, information technology and facilities. In addition, these expenses include costs associated with operating as a public company, such as expenses related to our Nasdaq listing and SEC compliance and director and officer liability insurance premiums.

Other Income (Expense), net

Other income (expense), net consists of interest and investment income (expense) and other income (expense). Interest and investment income (expense) consists of interest and dividend income on our cash and cash equivalents and marketable debt securities and amortization of premiums and/or accretion of discounts. Other income (expense) may also include non-operating items, such as refundable tax credits and other miscellaneous income not related to our core operating activities.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of consolidated financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances. Actual results may differ materially from those estimates or assumptions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements and related notes appearing elsewhere in this Annual Report on this Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Our critical accounting policy is the accounting for research and development prepaid and accrued expenses.

Research and Development Prepaid and Accrued Expenses

We record accruals for estimated costs of research, preclinical, non-clinical, clinical and manufacturing development within accrued expenses which are significant components of research and development expenses. A substantial portion of our ongoing research and development activities are conducted by third-party service providers. We accrue costs incurred under these third-party arrangements based on estimates of actual work completed in accordance with the respective agreements. We determine the estimated costs to accrue through discussions with internal personnel and our external service providers as to the percentage of completion of the services and the agreed-upon fees to be paid for such services. Payments made to third parties under these arrangements in advance of performance of the related services are recorded as prepaid expenses until the services are rendered.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations (in thousands):

	For the Years Ended December 31,		Period-to-Period Change
	2025	2024	
Operating expenses:			
Research and development	$ 42,633	$ 31,704	$ 10,929
General and administrative	21,916	17,450	4,466
Total operating expenses	64,549	49,154	15,395
Income (Loss) from operations	(64,549)	(49,154)	(15,395)
Other income (expense), net:			
Interest and investment income (expense)	6,380	4,171	2,209
Other income (expense)	730	387	343
Other income (expense), net	7,110	4,558	2,552
Net income (loss)	$ (57,439)	$ (44,596)	$ (12,843)

Research and development expenses

The following table summarizes our research and development expenses (in thousands):

	For the Years Ended December 31,		Period-to-Period Change
	2025	2024	
Direct expenses by product candidate:			
TARA-002 in NMIBC	$ 18,377	$ 12,306	$ 6,071
TARA-002 in LMs	2,606	2,558	48
IV Choline Chloride	8,501	4,555	3,946
Total direct expenses by product candidate	29,484	19,419	10,065
Indirect research and development expenses	13,149	12,285	864
Total	$ 42,633	$ 31,704	$ 10,929

Research and development expenses were $42.6 million for the year ended December 31, 2025, which represented an increase of approximately $10.9 million as compared to the year ended December 31, 2024. This increase was primarily due to a $10.1 million increase in direct expenses for our product candidates and a $0.9 million increase in indirect expenses. The increase in direct expenses was primarily due to site expansion and enrollment efforts for the ADVANCED-2 trial for NMIBC, start-up costs related to the ADVANCED-3 trial for NMIBC, as well as start-up and enrollment costs related to the THRIVE-3 trial for IV Choline Chloride. The increase in indirect expenses was primarily due to a $2.0 million increase in personnel-related expenses offset by a decrease of $1.1 million in research and development expenses not directly attributable to one specific product candidate.

General and administrative expenses

The following table summarizes our general and administrative expenses (in thousands):

	For the Years Ended December 31,		Period-to-Period Change
	2025	2024	
Personnel-related expenses, including stock-based compensation	$ 11,207	$ 8,867	$ 2,340
Other general and administrative expenses	10,709	8,583	2,126
Total	$ 21,916	$ 17,450	$ 4,466

General and administrative expenses were $21.9 million for the year ended December 31, 2025, which represented an increase of approximately $4.5 million as compared to the year ended December 31, 2024. This increase was primarily due to an increase of $2.3 million in personnel-related expenses, as well as an increase of $2.1 million in other general and administrative expenses primarily related to professional and consulting services.

Other income (expense), net

Other income (expense), net was $7.1 million for the year ended December 31, 2025, which represented an increase of approximately $2.6 million as compared to the year ended December 31, 2024. The $2.2 million increase in interest and investment income (expense) is due primarily to investment returns on a higher invested balance. The $0.3 million increase in other income (expense) is due to an increase in refundable tax credits received in the year ended December 31, 2025.

Liquidity and Capital Resources

Overview

As of December 31, 2025 and 2024, our unrestricted cash and cash equivalents, and marketable debt securities were $197.9 million and $170.3 million, respectively. We have not generated revenues since our inception and have incurred net losses of approximately $57.4 million and $44.6 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had working capital of approximately $148.6 million and stockholder's equity of approximately $196.4 million. During the year ended December 31, 2025, cash flows used in operating

activities were approximately $56.4 million, consisting primarily of a net loss of approximately $57.4 million, which includes non-cash activities of approximately $4.0 million, inclusive of $3.8 million in stock-based compensation expense, as well as cash used for changes in operating assets and liabilities of $2.9 million. Since inception, we have met our liquidity requirements principally through the sale of our common stock, preferred stock and pre-funded warrants in private placements of securities and public offerings of securities. In addition, we may receive proceeds upon the exercise of the common warrants issued in the April 2024 private placement described below.

Liquidity

On November 3, 2023, we filed a shelf registration statement on Form S-3, or the Shelf Registration Statement, which became effective in November 2023. The Shelf Registration Statement permits the offering, issuance and sale by us of up to a maximum aggregate offering price of $300.0 million of common stock, preferred stock, debt securities and warrants in one or more offerings and in any combination. In December 2024, we sold and issued approximately $102.8 million in gross proceeds of common stock and pre-funded warrants in a public offering, or the December 2024 Public Offering, under the Shelf Registration Statement. The net proceeds were approximately $95.9 million. In December 2025, we sold and issued approximately $86.3 million in gross proceeds of common stock in a public offering, or the December 2025 Public Offering, under the Shelf Registration Statement. The net proceeds were approximately $80.4 million.

In April 2024, the Company entered into a private placement transaction, or the April 2024 Private Placement, whereby the Company sold and issued common stock, warrants and in, in some circumstances, pre-funded warrants to certain purchasers. At the close of the April 2024 Private Placement, the Company received approximately $45.0 million in gross proceeds. The net proceeds were approximately $42.0 million. Additionally, as part of the April 2024 Private Placement, purchasers were offered common warrants. Common warrants exercised as of December 31, 2025 have resulted in $3.8 million in proceeds and, if exercised, proceeds from the remaining common warrants as of December 31, 2025 could result in an additional $53.1 million.

We are in the business of developing biopharmaceuticals and have no current or near-term revenues. We have incurred substantial clinical and other costs in our drug development efforts. We will need to raise additional capital in order to fully realize management's plans.

We believe that our current financial resources are sufficient to satisfy our estimated liquidity needs for at least 12 months from the date of issuance of our consolidated financial statements included elsewhere in this Annual Report on this Form 10-K.

As a result of volatility in the capital markets, economic conditions, general global economic uncertainty, political change, global pandemics and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development activities. Despite recent moderation, the sustained elevated interest rates in recent years have had, and may continue to have, a negative effect on market prices for common stock of public companies, especially those in the biotech industry and those that have no current or near-term revenue. Further, a recession or market correction, supply chain disruptions and/or inflation could materially affect our business and the value of our common stock.

Cash Flows

The following table summarizes our sources and uses of cash (in thousands):

	For the Years Ended December 31,		Period -to-Period Change
	2025	2024	
Net cash provided by (used in) operating activities	$ (56,365)	$ (35,808)	$ (20,557)
Net cash provided by (used in) investing activities	(139,491)	19,155	(158,646)
Net cash provided by (used in) financing activities	82,715	139,865	(57,150)
Net increase (decrease) in cash and cash equivalents, and restricted cash	$ (113,141)	$ 123,212	(236,353)

Comparison of the Years Ended December 31, 2025 and 2024

Net cash provided by (used in) operating activities was approximately $(56.4) million for the year ended December 31, 2025 compared to approximately $(35.8) million for the year ended December 31, 2024. The increase of approximately $20.6 million in cash used in operating activities was primarily driven by an increase in net loss of $12.8 million, an increase in cash used for operating assets and liabilities, primarily related to changes in prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities, resulting from the timing of payments to our service providers of $6.9 million, and by a decrease in non-cash items, consisting principally of accretion of discount on marketable debt securities and stock-based compensation expense of $0.8 million.

Net cash provided by (used in) investing activities was approximately $(139.5) million for the year ended December 31, 2025 compared to approximately $19.2 million for the year ended December 31, 2024. The increase in cash used of $158.7 million resulted primarily from an increase in purchases of marketable debt securities of $175.2 million offset slightly by an increase in proceeds from marketable debt securities matured and redeemed of $16.6 million.

Net cash provided by (used in) financing activities was $82.7 million for the year ended December 31, 2025 compared to $139.9 million for the year ended December 31, 2024. The decrease of approximately $57.2 million resulted primarily from less capital being raised from public and private offerings in the year ended December 31, 2025 as compared to the year ended December 31, 2024 of $53.1 million. During the year ended December 31, 2025, cash provided by financing activities related to public offerings was $82.9 million as compared to December 31, 2024 where cash provided by financing activities related to private and public offerings was $136.0 million. Additionally, during the year ended December 31, 2024 cash provided by financing activities related to the exercise of common warrants was $3.8 million.

Contractual and Other Obligations

Operating lease obligations

Our operating lease obligations primarily consist of lease payments on our corporate headquarters in New York, New York, as well as lease payments for our development laboratory, a manufacturing facility and an additional manufacturing space, all located in North America which are described in further detail in Note 9 of our consolidated financial statements included in this Annual Report on Form 10-K. Future contractual payments on operating lease obligations due within one year of December 31, 2025 are $1.4 million, and future contractual payments on operating lease obligations due greater than one year from December 31, 2025 are $2.2 million.

Other obligations

From time to time, we enter into certain types of contracts that contingently require us to indemnify parties against third-party claims, supply agreements, and agreements with directors and officers. The terms of such obligations vary by contract and in most instances a maximum dollar amount is not explicitly stated therein. Generally, amounts under these contracts cannot be reasonably estimated until a specific claim is asserted, thus no liabilities have been recorded for these obligations on our consolidated balance sheet for the periods presented.

We enter into contracts in the normal course of business with CROs and clinical sites for the conduct of clinical trials, non-clinical research studies, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts generally provide for termination on notice, and therefore are cancelable contracts.

Certain of these agreements require us to pay milestones to such third parties upon achievement of certain development, regulatory or commercial milestones as further described in Note 10 of our consolidated financial statements included in this Annual Report on Form 10-K. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and commercial milestones, which may not be achieved.

We also have obligations to make future payments to third parties that become due and payable on the achievement of certain milestones, including future payments to third parties with whom we have entered into research, development and commercialization agreements. We have not included these commitments on our consolidated balance sheet for the periods presented because the achievement and timing of these milestones is not fixed and determinable.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

No disclosure required.

Item 8. Financial Statements and Supplementary Data.

Protara Therapeutics, Inc.

Index to Consolidated Financial Statements

	Page No.
Protara Therapeutics, Inc. for the Years Ended December 31, 2025 and 2024	
Report of Independent Registered Public Accounting Firm (PCAOB ID:42)	83
Consolidated Balance Sheets as of December 31, 2025 and 2024	85
Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2025 and 2024	86
Consolidated Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2025 and 2024	87
Consolidated Statements of Cash Flows for the Years Ended December 31, 2025 and 2024	89
Notes to Consolidated Financial Statements	90

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Protara Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Protara Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

	Clinical trial prepaid and accrued expenses
Description of the Matter	As discussed in Note 2 to the consolidated financial statements, depending on the timing of payments to service providers, the Company records clinical trial prepaid or accrued expenses based on management's estimates of the work performed under the service agreements, milestones achieved and experience with similar contracts. Auditing the Company's accounting for clinical trial prepaid and accrued expenses is challenging due to the fact that information necessary to estimate the clinical trial prepaid and accrued expenses is accumulated from multiple sources. The determination of the clinical trial prepaid and accrued expenses when the Company has either not been invoiced or has not received information regarding actual costs incurred requires evaluation of the extent of completion of the services.

	Clinical trial prepaid and accrued expenses
How We Addressed the Matter in Our Audit	To test the clinical trial prepaid and accrued expenses, our audit procedures included, among others, i) confirming the completeness of the terms and conditions of certain significant service agreements directly with the vendor; ii) testing the completeness and accuracy of the Company's clinical trial prepaid and accrued expense models through verification of significant inputs, such as costs incurred and invoices paid, to the terms and conditions of the underlying agreements; iii) meeting with clinical operations personnel outside of the accounting department to discuss the basis for assumptions used in estimating cost of services provided but not yet invoiced; and iv) performing a hindsight analysis of invoices received subsequent to the balance sheet date and comparing to the Company's estimates.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021
New York, New York
March 10, 2026

Protara Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 49,657	$ 162,798
Marketable debt securities	105,897	7,494
Prepaid expenses and other current assets	3,950	1,863
Total current assets	159,504	172,155
Restricted cash, non-current	745	745
Marketable debt securities, non-current	42,336	—
Property and equipment, net	759	1,027
Operating lease right-of-use asset	3,174	4,255
Other assets	2,950	3,272
Total assets	$ 209,468	$ 181,454
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,468	$ 4,429
Accrued expenses and other current liabilities	6,229	5,408
Operating lease liability	1,242	1,124
Total current liabilities	10,939	10,961
Operating lease liability, non-current	2,117	3,359
Total liabilities	13,056	14,320
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, 2025 and 2024, 5,615 and 7,991 shares issued and outstanding as of December 31, 2025 and 2024, respectively	—	—
Common stock, $0.001 par value, authorized 100,000,000 shares:		
Common stock, 53,587,260 and 35,044,772 shares issued and outstanding as of December 31, 2025 and 2024, respectively	54	35
Additional paid-in capital	498,687	412,077
Accumulated deficit	(302,419)	(244,980)
Accumulated other comprehensive income (loss)	90	2
Total stockholders' equity	196,412	167,134
Total liabilities and stockholders' equity	$ 209,468	$ 181,454

See accompanying notes to consolidated financial statements.

Protara Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Years Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 42,633	$ 31,704
General and administrative	21,916	17,450
Total operating expenses	64,549	49,154
Income (Loss) from operations	(64,549)	(49,154)
Other income (expense), net:		
Interest and investment income (expense)	6,380	4,171
Other income (expense)	730	387
Other income (expense), net	7,110	4,558
Net income (loss)	(57,439)	(44,596)
Other comprehensive income (loss):		
Net unrealized gain (loss) on marketable debt securities	88	33
Other comprehensive income (loss)	88	33
Comprehensive income (loss)	$ (57,351)	$ (44,563)
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (1.34)	$ (2.17)
Weighted-average shares outstanding, basic and diluted	42,836,129	20,592,847

See accompanying notes to consolidated financial statements.

Protara Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(in thousands, except share and per share data)

	Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	7,991	$ —	11,364,903	$ 11	$ 268,725	$ (200,384)	$ (31)	$ 68,321
Issuance of common stock upon settlement of restricted stock units	—	—	73,909	—	(83)	—	—	(83)
Issuance of common stock upon exercise of stock options	—	—	47,580	—	135	—	—	135
Stock-based compensation – restricted stock units	—	—	—	—	480	—	—	480
Stock-based compensation – stock options	—	—	—	—	3,645	—	—	3,645
Issuance of common stock from April 2024 Private Placement, net of offering costs of $3,034	—	—	9,143,380	10	41,954	—	—	41,964
Issuance of common stock from December 2024 Public Offering, net of offering costs of $6,665	—	—	13,690,000	13	93,415	—	—	93,428
Issuance of common stock from exercise of common warrants	—	—	725,000	1	3,806	—	—	3,807
Unrealized gain (loss) on marketable debt securities	—	—	—	—	—	—	33	33
Net income (loss)	—	—	—	—	—	(44,596)	—	(44,596)
Balance at December 31, 2024	7,991	$ —	35,044,772	$ 35	$ 412,077	$ (244,980)	$ 2	$ 167,134

Protara Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity — (Continued)
(in thousands, except share and per share data)

	Series 1 Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Issuance of common stock upon settlement of restricted stock units	—	—	94,167	—	(185)	—	—	(185)
Issuance of common stock upon exercise of stock options	—	—	8,239	—	21	—	—	21
Stock-based compensation – restricted stock units	—	—	—	—	685	—	—	685
Stock-based compensation – stock options	—	—	—	—	3,141	—	—	3,141
Issuance of common stock upon conversion of Series 1 Preferred Stock	(2,376)	—	2,376,244	2	(2)	—	—	—
Issuance of common stock upon exercise of pre-funded warrants	—	—	625,100	1	—	—	—	1
Issuance of common stock from December 2024 Public Offering, net of offering costs of $214	—	—	438,738	1	2,527	—	—	2,528
Issuance of common stock from December 2025 Public Offering, net of offering costs of $5,812	—	—	15,000,000	15	80,423	—	—	80,438
Unrealized gain (loss) on marketable debt securities	—	—	—	—	—	—	88	88
Net income (loss)	—	—	—	—	—	(57,439)	—	(57,439)
Balance at December 31, 2025	**5,615**	**$ —**	**53,587,260**	**$ 54**	**$ 498,687**	**$ (302,419)**	**$ 90**	**$ 196,412**

See accompanying notes to consolidated financial statements.

Protara Therapeutics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net income (loss)	$ (57,439)	$ (44,596)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	3,826	4,125
Operating lease right-of-use asset	1,081	1,009
Depreciation	362	332
Realized loss (gain) on redemption of marketable debt securities	(9)	—
Amortization of premium (Accretion of discount) on marketable debt securities	(1,245)	(685)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,087)	1,262
Other assets	322	(328)
Accounts payable	(873)	1,381
Accrued expenses and other current liabilities	821	2,676
Operating lease liabilities	(1,124)	(984)
Net cash provided by (used in) operating activities	(56,365)	(35,808)
Cash flows from investing activities:		
Purchase of marketable debt securities	(204,631)	(29,382)
Proceeds from maturity and redemption of marketable debt securities	65,234	48,600
Purchase of property and equipment	(94)	(63)
Net cash provided by (used in) investing activities	(139,491)	19,155
Cash flows from financing activities:		
Proceeds from December 2024 Public Offering, net of offering costs of $6,051	—	94,042
Proceeds from private placement, net of offering costs of $3,034	—	41,964
Proceeds from exercise of Underwriters' Option in December 2024 Public Offering, net of offering costs of $214	2,528	—
Offering costs paid in connection with the December 2024 Public Offering	(614)	—
Proceeds from exercise of April 2024 Common Warrants	—	3,807
Proceeds from exercise of December 2024 Pre-Funded Warrants	1	—
Proceeds from December 2025 Public Offering, net of offering costs of $5,286	80,964	
Proceeds from exercise of stock options	21	135
Taxes paid related to net share settlement of restricted stock units	(185)	(83)
Net cash provided by (used in) financing activities	82,715	139,865
Net increase (decrease) in cash and cash equivalents and restricted cash	(113,141)	123,212
Cash and cash equivalents and restricted cash – beginning of year	163,543	40,331
Cash and cash equivalents and restricted cash – end of year	$ 50,402	$ 163,543
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	$ —	$ —
Income taxes	$ —	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Proceeds from public offering – offering costs incurred but not paid	$ 526	$ 614

See accompanying notes to consolidated financial statements.

1. Organization and Nature of the Business

Overview

Protara Therapeutics, Inc., and its consolidated subsidiaries, or Protara or the Company, is a clinical-stage biopharmaceutical company committed to advancing transformative therapies for the treatment of cancer and rare diseases. Protara's portfolio includes two development programs utilizing TARA-002, an investigational cell therapy in development for the treatment of non-muscle invasive bladder cancer, or NMIBC, and lymphatic malformations, or LMs. Additionally, the Company's portfolio includes Intravenous, or IV, Choline Chloride, an investigational phospholipid substrate replacement therapy in development for patients receiving parenteral support, or PS.

Liquidity and Capital Resources

The Company is in the business of developing biopharmaceuticals and has no current or near-term revenues. The Company has incurred substantial clinical and other costs in its drug development efforts. The Company will need to raise additional capital in order to fully realize management's plans.

The Company believes that its current financial resources are sufficient to satisfy the Company's estimated liquidity needs for at least 12 months from the date of issuance of these consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in the accompanying consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Significant items subject to such estimates include but are not limited to research and development accruals as well as contingencies.

On an ongoing basis, the Company's management evaluates its estimates based on historical and anticipated results, trends, and various other assumptions believed to be reasonable. Actual results could differ from those estimates. The results of any changes in accounting estimates are reflected in the financial statements of the period in which the change becomes evident.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid instruments with an original maturity of three months or less when acquired to be cash equivalents. Cash and cash equivalents may be held in depository, money market accounts and/or U.S. Treasury securities, and are reported at fair value.

The Company's restricted cash balances consist of cash deposits to collateralize letter of credit obligations.

(amounts in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (cont.)

The following table provides a reconciliation of cash and cash equivalents, and restricted cash in the consolidated balance sheets to the total amount shown in the consolidated statements of cash flows:

	As of December 31,	
	2025	**2024**
Cash and cash equivalents	$ 49,657	$ 162,798
Restricted cash, non-current	745	745
Total	$ 50,402	$ 163,543

Fair Value Measurements

Accounting Standards Codification, or ASC, 820 provides the framework for measuring fair value and establishes a fair value hierarchy that prioritizes the inputs used in pricing the asset or liability. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements).

Fair value is defined as the exchange price, or an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, the three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

- Level 1 Quoted prices in active markets for identical assets or liabilities.
- Level 2 Quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly.
- Level 3 Significant unobservable inputs that cannot be corroborated by market data.

The carrying amounts of cash and cash equivalents, prepaid expenses and accounts payable approximate their fair values due to the short-term nature of these instruments.

Marketable Debt Securities

The Company classifies investments in marketable debt securities with remaining maturities when purchased of greater than three months as current. Investments with a remaining maturity date greater than one year are classified as non-current. The Company classifies all marketable debt securities as available-for-sale. The cost of securities sold is based on the specific identification method. Interest earned on securities that are classified as available-for-sale are included in interest and investment income (expense).

The Company records investments at fair value with unrealized gains and losses recorded as a component of other comprehensive income (loss) in the consolidated statements of operations and comprehensive loss until realized. Realized gains and losses are reflected in interest and investment income (expense) in the consolidated statements of operations and comprehensive loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Fair value is determined based on quoted market rates when observable or utilizing data points that are observable, such as quoted prices, interest rates and yield curves. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary. The Company has the ability to hold such securities with an unrealized loss until its forecasted recovery. The Company determined that there was no material change in the credit risk of these investments.

2. Summary of Significant Accounting Policies (cont.)

The Company periodically evaluates the need for an allowance for credit losses. This evaluation includes consideration of several qualitative and quantitative factors, including whether it plans to sell the security, whether it is more likely than not it will be required to sell any marketable debt securities before recovery of its amortized cost basis, and if the entity has the ability and intent to hold the security to maturity, and the portion of any unrealized loss that is the result of a credit loss. Factors considered in making these evaluations include quoted market prices, recent financial results, operating trends, and implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, expected cash flows from securities, other publicly available information that may affect the value of the marketable debt security, duration and severity of decline in value and the Company's strategy and intentions for holding the marketable debt security.

Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents, restricted cash and investments in marketable debt securities.

The Company invests its excess cash primarily in money market funds and high quality investment grade marketable debt securities of governments and/or corporations. The Company has adopted an investment policy that includes guidelines relative to credit quality, diversification and maturities to preserve principal and liquidity.

Property and Equipment, net

Property and equipment, including leasehold improvements, are recorded at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful life of the asset. Depreciation begins at the time the asset is placed in service. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or estimated useful life of the asset. Repairs and maintenance costs are expensed as incurred, whereas major improvements are capitalized as additions to property and equipment.

The estimated useful lives for significant property and equipment categories are as follows:

Asset Classification	Estimated Useful Life
Computer equipment	3-5 years
Furniture, fixtures and other	5 years
Laboratory equipment	7 years
Leasehold improvements	Shorter of the lease term or useful life of asset

Leases

The Company enters into contracts in the normal course of business and assesses whether any such contracts contain a lease. The Company determines if an arrangement is a lease at inception if it conveys the right to control the identified asset for a period of time in exchange for consideration. Under ASC 842, lease expense is recognized as a single lease cost on a straight-line basis over the lease term. The lease term consist of non-cancelable periods and may include options to extend or terminate the lease term, when it is reasonably certain such options will be exercised.

Leases classified as operating leases are included in operating lease right-of-use, or ROU, assets, current operating lease liabilities and noncurrent operating lease liabilities in our consolidated balance sheets. Finance leases are included in property and equipment and finance lease obligations, in our consolidated balance sheets. ROU assets represent the right to use an underlying asset for the lease term. Lease liabilities represent the present value of future lease payments, discounted using an incremental borrowing rate, which is a management estimate based on the information available at the commencement date of a lease arrangement. ROU assets and lease liabilities are recognized at the lease commencement date.

2. Summary of Significant Accounting Policies (cont.)

The Company has elected to account for the lease and non-lease components for leases as a single component for classes of all underlying assets and allocate all the contract consideration to the lease component only. Lease cost for operating leases is recognized on a straight-line basis over the lease term and is included in operating expenses on the consolidated statements of operations and comprehensive loss. Variable lease payments are included in lease operating expenses.

The Company recognizes costs associated with lease arrangements having an initial term of 12 months or less, or short-term leases, on a straight-line basis over the lease term; such short-term leases are not recorded on the balance sheet.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset or asset group may not be recoverable or that the useful life is shorter than originally estimated. When such events occur, the Company compares the carrying amounts of the asset or asset group to the undiscounted expected future cash flows. If this comparison indicates that the asset or asset group is impaired, the amount of impairment is measured as the difference between the carrying value and fair value of the asset or asset group. If the useful life is shorter than originally estimated, the Company will amortize the remaining carrying value over the new shorter useful life. To date, no such impairment loss has been recognized.

Segment Information

In accordance with ASC 280, operating segments are defined as components of an enterprise for which separate discrete information is available for evaluation by the chief operating decision maker, or CODM, or decision-making group in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating and reporting segment. See Note 16, Segment Information for further information.

Research and Development

Research and development expenses consist primarily of third-party costs incurred to develop drug candidates, personnel-related expenses, including salaries, benefits, travel and stock-based compensation expense, depreciation and other allocated overhead costs, which include rent and maintenance of facilities and other supplies. Research and development costs are expensed as incurred.

Before a drug candidate receives regulatory approval, the Company records upfront and milestone payments made to third parties under licensing arrangements as expense provided that there is no alternative future use of the rights in other research and development projects.

Nonrefundable advance payments to vendors for goods or services that will be used or received in future research and development activities are deferred and recognized as expense in the period in which the related goods are delivered or services are performed. Where milestone payments are due to third parties under research and development collaboration arrangements or other contractual agreements, the milestone payment obligations are expensed when the milestone conditions are met and the amount of payment is reasonably estimable.

Once a drug candidate receives regulatory approval, the Company records any milestone payments in identifiable intangible assets, less accumulated amortization and, unless the asset is determined to have an indefinite life, the Company amortizes the payments on a straight-line basis over the remaining agreement term or the expected product life cycle, whichever is shorter.

Certain third-party costs are included as a component of research and development expense. These expenses include fees paid to contract research organizations, or CROs, and other clinical trial costs, contractual services costs and costs for supply of its drug candidates. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses

2. Summary of Significant Accounting Policies (cont.)

are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts in conjunction with known variable factors such as enrolled patients and site activity. The Company monitors each of these factors and adjusts estimates accordingly.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Interest and Investment Income (Expense)

Interest and investment income (expense) consist primarily of interest income, accretion income earned and amortization expense incurred and realized gains or losses related to our marketable debt securities, interest income related to cash and cash equivalents and restricted cash and dividend income related to money market funds.

Stock-Based Compensation

The Company's stock-based compensation programs provide for stock awards including stock options, restricted stock units, or RSUs, and an employee stock purchase program, or ESPP. The Company accounts for stock-based compensation using the fair value method.

The Company measures all stock options and other stock-based awards granted to employees, directors, and consultants based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. The Company recognizes forfeitures at the time forfeitures occur.

The fair value of each option is estimated on the date of grant using the Black-Scholes option-pricing model. Expected volatility for the Company's common stock is determined based on a weighting of its own historical volatility and the historical volatility of a peer-group of similar public companies. The expected term of options granted to employees is calculated using the simplified method, which represents the average of the contractual term of the option and the weighted-average vesting period of the option. The simplified method is used as the Company does not have sufficient appropriate exercise data on which to base its own estimate. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The risk-free interest rate is based upon the U.S. Treasury yield curve commensurate with the expected term at the time of grant or remeasurement.

The stock-based compensation expense associated with purchase rights under the ESPP is measured at fair-value using a Black-Scholes option-pricing model at commencement of each offering period and recognized over that offering period. The Black-Scholes option pricing assumptions are similar to those used for stock options with the exception of the expected term of purchase rights for the ESPP which is based on the duration of an offering period.

The fair values of RSUs are based on the fair market value of the Company's common stock on the date of the grant.

RSUs were historically granted to directors pursuant to the Company's equity plan. Settlement for these RSUs is deferred until the earliest to occur of: (i) the director's termination of service, (ii) death, (iii) disability or (iv) a change in control of the Company. In the event of a change in control of the Company, the RSUs will vest in full.

The fair value of all stock-based awards is recognized as stock-based compensation expense on a straight-line basis over the vesting period, which is typically three years for RSUs and one or four years for stock options.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same way the payroll costs or service payments are classified for the related stock-based award recipients.

2. Summary of Significant Accounting Policies (cont.)

Income Taxes

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. The measurement of net deferred tax assets is reduced by the amount of any tax benefit that, based on available evidence, is not expected to be realized, and a corresponding valuation allowance is established. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations.

Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon settlement. A liability for unrecognized tax benefits is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. The Company's policy is to record interest and penalties on uncertain tax positions as a component of income tax expense in the consolidated statements of operations and comprehensive loss.

Net Income (Loss) Per Share Attributable to Common Stockholders

Basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares of common stock outstanding during the period includes any contingently issuable shares for which there is no circumstance under which those shares would not be issued and shares issuable upon the exercise of warrants to purchase common stock for no or nominal consideration.

Diluted net income (loss) per share is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period plus the common equivalent shares for the period including any dilutive effect from unvested RSUs, outstanding stock options, potential shares issuable under the ESPP, and potential shares issuable upon conversion of preferred stock or exercise of outstanding warrants to purchase common stock.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480 and ASC 815. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. Finally, the Company determines if the warrants meet the definition of a derivative based on their contractual terms. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and at each balance sheet date thereafter. Changes in the estimated fair value of liability-classified warrants are recognized as a non-cash gain or loss on the consolidated statements of operations and comprehensive loss. The Company also evaluates if changes in contractual terms or other considerations would result in the reclassification of outstanding warrants from liabilities to stockholders' equity (or vice versa).

(amounts in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (cont.)

The fair market value of the warrants may be estimated using a Black-Scholes option-pricing model or potentially more complex valuation models depending on the nature of the contractual terms.

Recently Adopted Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, 2023-09 — *Improvements to Income Tax Disclosures*, which enhances the transparency and decision usefulness of income tax disclosures. The Company adopted ASU 2023-09 for the year ended December 31, 2025 retrospectively to all periods presented in the consolidated financial statements. The adoption of this ASU had no material impact on the Company's consolidated financial position, results of operations, or cash flows. Additional required disclosure has been included within Note 13.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03 — *Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures*, which enhances the disclosures for various types of expenses. The standard is effective for public companies for annual periods beginning after December 15, 2026. Early adoption is available. The Company is still evaluating the full extent of the potential impact of the adoption of ASU 2024-03.

In December 2025, the FASB issued ASU 2025-11 — *Interim Reporting (Topic 270) — Narrow-Scope Improvements*, which improves the guidance in *Interim Reporting (Topic 270)* by improving the navigability of the required interim disclosures and clarifying when that guidance is applicable. The standard is effective for public companies for annual periods beginning after December 15, 2027. Early adoption is available. The Company is still evaluating the full extent of the potential impact of the adoption of ASU 2025-11.

Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were available to be issued. Other than as described in Note 11, the Company did not identify any subsequent events that would have required adjustment or disclosure in the financial statements.

3. Fair Value of Financial Instruments

The tables below present information about the Company's financial instruments that are measured and carried at fair value on a recurring basis as of December 31, 2025 and 2024 and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value, as described under Note 2, Summary of Significant Accounting Policies.

	As of December 31, 2025			
	Level 1	**Level 2**	**Level 3**	**Total**
Cash and cash equivalents:				
Money market funds[(a)]	$ 45,355	$ —	$ —	$ 45,355
Corporate bonds[(a)]	—	3,704	—	3,704
Restricted cash, non-current:				
Money market funds[(b)]	745	—	—	745
Marketable debt securities:				
Corporate bonds[(c)]	—	125,682	—	125,682
U.S. Treasury securities[(c)]	22,551	—	—	22,551
Total	$ 68,651	$ 129,386	$ —	$ 198,037

(amounts in thousands, except share and per share data)

3. Fair Value of Financial Instruments (cont.)

	As of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents:				
Money market funds[(a)]	$ 162,297	$ —	$ —	$ 162,297
Restricted cash, non-current:				
Money market funds[(b)]	745	—	—	745
Marketable debt securities:				
U.S. Treasury securities[(c)]	7,494	—	—	7,494
Total	$ 170,536	$ —	$ —	$ 170,536

(a) Money market funds and corporate bonds with original maturities of 90 days or less are included within cash and cash equivalents in the consolidated balance sheets.

(b) Restricted money market funds are included within restricted cash, non-current in the consolidated balance sheets.

(c) U.S. Treasury securities and corporate bonds with original maturities greater than 90 days are included within marketable debt securities in the consolidated balance sheets and classified as current or non-current based upon whether the maturity of the financial asset is less than or greater than 12 months.

Money market funds and U.S. Treasury securities are classified as Level 1 within the fair value hierarchy, because they are valued using quoted prices in active markets. Corporate and agency bonds classified as Level 2 within the fair value hierarchy are valued on the basis of prices from an orderly transaction between market participants provided by reputable dealers or pricing services. Prices of these securities are obtained through independent, third-party pricing services and include market quotations that may include both observable and unobservable inputs. In determining the value of a particular investment, pricing services may use certain information with respect to transactions in such investments, quotations from dealers, pricing matrices and market transactions in comparable investments and various relationships between investments. There were no transfers of financial instruments among Level 1, Level 2, and Level 3 during the period presented.

4. Marketable Debt Securities

Marketable debt securities, all of which were classified as available-for-sale, consist of the following:

	As of December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Corporate bonds – presented in marketable debt securities	$ 83,291	$ 77	$ (22)	$ 83,346
Corporate bonds – presented in marketable debt securities, non-current	42,359	11	(34)	42,336
U.S. Treasury securities – presented in marketable debt securities	22,493	58	—	22,551
Total	$ 148,143	$ 146	$ (56)	$ 148,233

	As of December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury securities – presented in marketable debt securities	$ 7,492	$ 2	$ —	$ 7,494
Total	$ 7,492	$ 2	$ —	$ 7,494

The Company has recorded the securities at fair value in its consolidated balance sheets and unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss). For the years ended December 31, 2025 and 2024 realized gains were $9 and $0, respectively. Gains are included in interest and investment income (expense) within the consolidated statements of operations and comprehensive loss.

(amounts in thousands, except share and per share data)

4. Marketable Debt Securities (cont.)

The remaining maturities of all debt securities held at December 31, 2025 were less than five years. There were no sales of securities in the periods presented.

Credit Losses

Securities with an amortized cost basis in excess of estimated fair value are assessed to determine what amount of the excess, if any, is caused by expected credit losses.

As of December 31, 2025, marketable debt securities in a loss position consist of the following:

	As of December 31, 2025					
	In Continuous Loss Position Less Than 12 Months		In Continuous Loss Position Greater Than 12 Months		Total	
	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses
Corporate bonds – presented in marketable debt securities	$ 24,034	$ (22)	$ —	$ —	$ 24,034	$ (22)
Corporate bonds – presented in marketable debt securities, non-current	29,824	(34)	—	—	29,824	(34)
Total	$ 53,858	$ (56)	$ —	$ —	$ 53,858	$ (56)

As of December 31, 2024, no securities were held in a loss position. As of December 31, 2025 and 2024, it was determined that there were no expected credit losses.

Interest and Investment Income (Expense)

Interest and investment income (expense) consist of the following:

	For the Year Ended December 31,	
	2025	2024
Interest income	$ 5,023	$ 3,326
Accretion of discount (Amortization of premium), net	1,308	809
Dividend income	40	36
Realized gain (loss)	9	—
Total	$ 6,380	$ 4,171

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	As of December 31,	
	2025	2024
Prepaid research and development	$ 1,926	$ 853
Accrued interest on marketable debt securities	1,257	—
Prepaid insurance	355	622
Prepaid software	115	116
Prepaid retention bonuses	—	80
Other prepaid expenses	232	190
Other current assets	65	2
Total	$ 3,950	$ 1,863

(amounts in thousands, except share and per share data)

6. Property and Equipment, net

Property and equipment, net consist of the following:

	As of December 31,	
	2025	2024
Computer equipment	$ 316	$ 235
Furniture, fixtures and other	379	352
Laboratory equipment	978	913
Leasehold improvements	553	553
Property and equipment not yet placed into service	1	80
Total property and equipment	2,227	2,133
Less: Accumulated depreciation	(1,468)	(1,106)
Total	$ 759	$ 1,027

Depreciation expense was $362 and $332 for the years ended December 31, 2025 and 2024, respectively. During the year ended December 31, 2025, $218 and $144 was included in research and development expense and general and administrative expense, respectively, within the consolidated statements of operations and comprehensive loss. During the year ended December 31, 2024, $202 and $130 was included in research and development expense and general and administrative expense, respectively, within the consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024, substantially 100% of the Company's total property and equipment, net was attributable to the U.S.

7. Other Assets

Other assets consist of the following:

	As of December 31,	
	2025	2024
Prepaid research and development, non-current	$ 2,930	$ 3,245
Other non-current assets	20	27
Total	$ 2,950	$ 3,272

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
	2025	2024
Employee costs	$ 3,267	$ 2,533
Research and development	2,683	2,740
Other expenses	279	135
Total	$ 6,229	$ 5,408

(amounts in thousands, except share and per share data)

9. Leases

Operating leases

In December 2020, the Company entered into an agreement to lease approximately 10,000 square feet of office space in New York, New York, or the Office Lease, which commenced in April 2021. The Office Lease has a term of approximately seven years and contains provisions for a free-rent period, annual rent increases and an allowance for tenant improvements. The Company has an option to extend the term by five years, however, the Company determined at the lease commencement date that it was not reasonably certain to exercise the renewal option and such renewal was excluded from the operating lease ROU asset and operating lease liability recorded for this lease.

The Company is responsible for real estate taxes, maintenance and other operating expenses applicable to the leased premises which are recognized as variable lease expense in the period when incurred. In conjunction with the Office Lease, the Company established a letter of credit of approximately $745 secured by cash balances included in restricted cash, non-current, within the consolidated balance sheets.

In June 2021, the Company amended the existing lease agreement with its contract development and manufacturing organization, or CDMO, establishing a term of eight-years from the amendment date.

Leases classified as operating leases are included in operating lease ROU assets, operating lease liabilities and operating lease liabilities, non-current in the Company's consolidated balance sheets. The Office Lease and the CDMO leased spaces are included in operating lease ROU assets and operating lease liabilities within the consolidated balance sheets. The Office Lease and the CDMO leased spaces are located within the U.S. Cash paid for operating lease liabilities was $1,395 and $1,327 during the years ended December 31, 2025 and 2024, respectively.

Lease expense consist of the following:

	For the Year Ended December 31,	
Lease expense	**2025**	**2024**
Operating lease expense	$ 1,353	$ 1,353
Total	$ 1,353	$ 1,353

Variable lease expense was $124 and $99 for the years ended December 31, 2025 and 2024, respectively.

The weighted average discount rate and weighted-average remaining lease term for operating leases were:

	As of December 31,	
	2025	**2024**
Weighted-average discount rate	7.0%	7.0%
Weighted-average remaining lease term – operating lease (in months)	31	43

As of December 31, 2025, the expected annual minimum lease payments of the Company's operating lease liabilities were as follows:

For the year ending December 31:	**Operating Lease Payments**
2026	$ 1,429
2027	1,429
2028	718
2029	87
Thereafter	—
Total future operating lease payments	3,663
Less: imputed interest	(304)
Present value of future minimum lease payments	$ 3,359

10. Commitments and Contingencies

Employment Agreements

Executive Employment Agreements

The Company's executive officers have entered into at-will employment agreements.

Collaborations and License Agreements

Choline License Agreement

On September 27, 2017, the Company entered into a license agreement, or the Choline License Agreement, with Alan L. Buchman, or Dr. Buchman. Pursuant to the Choline License Agreement, the Company received from Dr. Buchman the license rights in and to the "Licensed Orphan Designations", the "Licensed IND", "Existing Study Data" and the "Licensed Know-How" for one or more of the licensed indications.

Certain milestone and royalty payments may also be payable to Dr. Buchman. Regardless of whether development or commercialization is undertaken by the Company under the Choline License Agreement, during the term of the Choline License Agreement, the Company shall pay Dr. Buchman a minimum annual royalty that ranges from $25 to $75. The Company will also pay Dr. Buchman up to $775 in additional milestone payments upon the achievement of various regulatory approval milestones. Further, the Company has an obligation to pay Dr. Buchman sales royalties based on aggregate net sales of IV Choline Chloride in each calendar quarter, with tiered royalty rates ranging from 5.0% to 10.5% of net sales. In the event of development or commercialization activity by any sublicensees, the Company also agreed to pay Dr. Buchman a royalty in the mid-single digit percentage of: (i) net cash receipts, after payment of taxes, received by the Company from sublicensees for their sales of licensed products and (ii) any other consideration received by the Company from such sublicensees; in each case, including a fair monetary value for any transaction that is not a bona fide arms-length transaction or that is for consideration other than monetary. Further, in the event of a sale or transfer of a priority review voucher regarding the license product, regardless of whether any development or commercialization activity is undertaken by the Company or the Company's sublicensees, the Company agreed to pay Dr. Buchman a milestone payment representing the mid-single digit percentage of: (i) net cash receipts, after payment of taxes and (ii) any other consideration; in each case, received by the Company, the Company's affiliates, or the Company's sublicensees, including a fair monetary value for any transaction that is not a bona fide arms-length transaction or that is for consideration other than monetary.

During the years ended December 31, 2025 and 2024, the Company recorded research and development expense of $75 and $52, respectively, in connection with the Choline License Agreement.

License Agreement

On December 22, 2017, the Company entered into an agreement, or the Feinstein Agreement, with The Feinstein Institute for Medical Research, or the Feinstein Institute, a not-for-profit corporation with 50 research labs and 2,500 clinical research studies. Pursuant to the Feinstein Agreement, the Company acquired an exclusive license relating to treatment of fatty liver diseases in humans for which Choline may be an effective therapeutic. In consideration for the rights and license granted, the Feinstein Institute would receive a royalty of one percent (1%) of the first one hundred million dollars ($100,000) of net sales of IV Choline Chloride and a royalty of one and one-half percent (1.5%) of all net sales thereafter. In addition, the Company would pay the Feinstein Institute twelve and one-half percent (12.5%) of net proceeds resulting from agreements entered within two years from the effective date, and seven and one-half percent (7.5%) of net proceeds resulting from agreements entered into thereafter. Pursuant to the Feinstein Agreement additional payments would be due to the Feinstein Institute for license maintenance payments and for meeting milestone events. Pursuant to the Feinstein Agreement, upon the achievement of certain future NDA milestones, the Company would be obligated to remit an aggregate of $275.

10. Commitments and Contingencies (cont.)

During each of the years ended December 31, 2025 and 2024, the Company recorded research and development expense of $15 in connection with the Feinstein Agreement.

Sponsored Research and License Agreement

On November 28, 2018, the Company entered into a sponsored research and license agreement, or the Iowa Agreement, with the University of Iowa. Pursuant to the Iowa Agreement, the University of Iowa, which is engaged in clinical research to improve the diagnosis and treatment of lymphangioma using a pharmaceutical product (OK-432), would assist the Company in collecting case reports, forms, source data, and safety data available to the University of Iowa in support of the development of the Company's proprietary Streptococcus Pyogenes investigational product, TARA-002 for the LMs indication. During the term of the services, the Company would generally pay the University of Iowa thirty thousand dollars ($30) per year to fund the project, plus additional amounts upon the realization of certain milestones. More specifically, upon an approval of TARA-002 by the Food and Drug Administration, or the FDA, the Company would pay up to $1,750 to the University of Iowa for meeting these milestones. Furthermore, the Company would pay the University of Iowa royalties of up to 1.75% for net sales ranging from $0 - $25,000, 2.25% for net sales ranging from $25,000 to $50,000, and 2.50% for net sales in excess of $50,000. Pursuant to the Iowa Agreement, the University of Iowa would be entitled to additional payments for the Company achieving annual net sales of product according to the milestones. For annual net sales of product up to $25,000: $62; for annual net sales of product of up to $50,000: $62; and for annual net sales of product of up to $100,000: $125.

There were no research and development expenses recognized, pursuant to the Iowa Agreement, during the years ended December 31, 2025 and 2024.

Chugai Agreement

On June 17, 2019, the Company entered into an agreement, or the Chugai Pharmaceutical Agreement, with Chugai Pharmaceutical Co., LTD, or Chugai Pharmaceutical, a drug manufacturing firm with offices and operations in Japan. Pursuant to the Chugai Pharmaceutical Agreement, Chugai Pharmaceutical would help the Company in its goals to develop and commercialize a therapeutic product, or the New Product, which is comparable to the Chugai Pharmaceutical existing therapeutic product, or the Existing Product. In addition, the Company would be entitled to the use of Chugai Pharmaceutical materials and technical support as necessary. On July 14, 2020, the Company and Chugai Pharmaceutical entered into an amendment, or the Chugai Amendment, to the Chugai Pharmaceutical Agreement, with an effective date of June 30, 2020. The Chugai Amendment extended the date through which Chugai Pharmaceutical will exclusively provide the Existing Product and materials to the Company from June 30, 2020 to June 30, 2021, extended the date through which Chugai Pharmaceutical will not provide materials or technical support to any third-party for the purpose of development and commercialization in a given area from the fifth anniversary to the eleventh anniversary of the original effective date, and provides for further such extensions on the occurrence of certain events and milestones. The amendment further provides that, in addition to the designated fee provided upon the initial indication approval in the Chugai Pharmaceutical Agreement, the Company will pay Chugai Pharmaceutical a designated fee for each additional indication approval. The Company is obligated to Chugai Pharmaceutical for certain payments upon the completion of agreed upon milestones. As consideration for Chugai Pharmaceutical's performance under the Chugai Pharmaceutical Agreement, the Company agreed to pay Chugai Pharmaceutical a payment in the low, single-digit millions related to such initial indication approval, which payment will be made in two installments with an initial payment in July 2020, and the remaining majority of the payment payable upon FDA approval of the New Product.

There were no research and development expenses recognized, pursuant to the Chugai Pharmaceutical Agreement, during the years ended December 31, 2025 and 2024.

10. Commitments and Contingencies (cont.)

Contingencies

From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities. Management is of the opinion that the ultimate outcome of these matters would not have a material adverse impact on the financial position of the Company or the results of its operations.

In the normal course of business, the Company enters into contracts in which it makes representations and warranties regarding the performance of its services and that its services will not infringe on third-party intellectual rights. There have been no significant events related to such representations and warranties in which the Company believes the outcome could result in losses or penalties in the future.

11. Stockholders' Equity

Common Stock

As of December 31, 2025, the Company had 100,000,000 shares of common stock authorized for issuance, $0.001 par value per share, of which 53,587,260 and 35,044,772 shares were issued and outstanding as of December 31, 2025 and 2024, respectively.

The holders of the Company's common stock are entitled to one vote per share.

Preferred Stock

As of December 31, 2025 and 2024, the Company had 10,000,000 shares of preferred stock authorized for issuance, $0.001 par value per share, of which 8,028 shares of Series 1 Convertible Preferred Stock are authorized for issuance. As of December 31, 2025 and 2024, 5,615 and 7,991 shares were issued and outstanding, respectively.

Description of Series 1 Convertible Preferred Stock

Each share of Series 1 Convertible Preferred Stock is convertible into approximately 1,000 shares of the Company's common stock, at a conversion price initially equal to approximately $7.01 per common share, subject to adjustment for any stock splits, stock dividends and similar events, at any time at the option of the holder, provided that any conversion of Series 1 Convertible Preferred Stock by a holder into shares of the Company's common stock would be prohibited if, as a result of such conversion, the holder, together with its affiliates and any other person or entity whose beneficial ownership of the Company's common stock would be aggregated with such holder's for purposes of Section 13(d) of the Exchange Act would beneficially own more than 9.99% of the total number of shares of the Company's common stock issued and outstanding after giving effect to such conversion. Upon written notice to the Company, the holder may from time to time increase or decrease such limitation to any other percentage not in excess of 19.99% specified in such notice. In addition, upon the occurrence of certain transactions that involve the merger or consolidation of the Company, an exchange or tender offer, a sale of all or substantially all of the assets of the Company or a reclassification of its common stock, each share of Series 1 Convertible Preferred Stock will be convertible into the kind and amount of securities, cash and/or other property that the holder of a number of shares of common stock issuable upon conversion of one share of Series 1 Convertible Preferred Stock would receive in connection with such transaction.

The terms of the Series 1 Convertible Preferred Stock provide that, in the event of a fundamental transaction (as such term is described in the certificate of designation of preferences, rights and limitations of series 1 convertible non-voting preferred stock), each share of Series 1 Convertible Preferred Stock outstanding will thereafter be convertible into the kind and amount of securities, cash and/or other property which a holder of the number of shares of common stock of the Company issuable upon conversion of one share of Series 1 Convertible Preferred Stock immediately prior to such fundamental transaction would have been entitled to receive pursuant to such fundamental transaction, provided that, if the value of the aggregate of such securities, cash and/or other property which the holder

11. Stockholders' Equity (cont.)

of one share of Series 1 Convertible Preferred Stock would be entitled to upon conversion thereof would be less than the stated value, then each outstanding share of Series 1 Convertible Preferred Stock will instead be convertible into such kind of securities, cash and/or other property with an aggregate value equal to the stated value.

Each share of Series 1 Convertible Preferred Stock is entitled to a preference of $10.00 per share upon liquidation of the Company, and thereafter will share ratably in any distributions or payments on an as-converted basis with the holders of common stock.

The holders of Series 1 Convertible Preferred Stock are not entitled to vote.

During the year ended December 31, 2025, 2,376 shares of Series 1 Convertible Preferred Stock were converted into 2,376,244 shares of common stock.

April 2024 Private Placement

On April 5, 2024, the Company entered into a subscription agreement with certain purchasers, or the Purchasers, pursuant to which the Company agreed to sell and issue to the Purchasers, in a private placement, or the April 2024 Private Placement, an aggregate of 9,143,380 shares of the Company's common stock, or the April 2024 Shares, and, for certain purchasers, pre-funded warrants, or the April 2024 Pre-Funded Warrants, to purchase an aggregate of 1,700,000 shares of the Company's common stock. In each case, the April 2024 Shares or April 2024 Pre-Funded Warrants were issued with warrants, or the April 2024 Common Warrants, to purchase an aggregate of up to 10,843,380 shares of the Company's common stock. Each April 2024 Share, along with its attached April 2024 Common Warrant, had a purchase price of $4.15, and each April 2024 Pre-Funded Warrant, along with its attached April 2024 Common Warrant, had a purchase price of $4.149. The closing date of the April 2024 Private Placement was April 10, 2024. The April 2024 Private Placement resulted in gross proceeds of approximately $44,998 and net proceeds of approximately $41,964, reflecting approximately $3,034 of placement agent's fees, legal costs and other expenses connected with the transaction.

The April 2024 Pre-Funded Warrants are exercisable at any time, at an exercise price of $0.001 per share. The April 2024 Common Warrants are exercisable on or prior to the earlier of: (i) April 10, 2027 or (ii) 90 days after the public announcement that the Company has demonstrated a six-month complete response rate of minimum 42% from at least 25 Bacillus Calmette-Guérin, or BCG,-Unresponsive patients in the ADVANCED-2 (Cohort B) clinical trial, at an exercise price of $5.25 per share.

The April 2024 Pre-Funded Warrants and the April 2024 Common Warrants are exercisable so long as the aggregate number of shares of the Company's common stock beneficially owned by the holder (together with its affiliates) would not exceed 9.99%, or for certain holders, 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of such April 2024 Pre-Funded Warrant or April 2024 Common Warrant, as applicable. Such percentage may be increased or decreased to any number not in excess of 19.99% at the holder's election upon notice to the Company, any such increase shall not take effect until the sixty-first day after notice to the Company.

Both the April 2024 Pre-Funded Warrants and the April 2024 Common Warrants contain standard adjustments to the exercise price, inclusive of stock splits, stock dividends and pro rata distributions and contain customary terms regarding the treatment of such April 2024 Pre-Funded Warrants or April 2024 Common Warrants in the event of a fundamental transaction, which include but are not limited to a merger or consolidation involving the Company, a sale of all or substantially all of the assets of the Company or a business combination resulting in any person acquiring more than 50% of the outstanding shares of common stock of the Company.

The Company concluded that the April 2024 Pre-Funded Warrants and April 2024 Common Warrants met the requirements to be classified in stockholders' equity.

11. Stockholders' Equity (cont.)

The fair market value of the April 2024 Pre-Funded Warrants was estimated as the difference between the share price of our stock on the agreement date and the exercise price of the April 2024 Pre-Funded Warrant.

The fair market value of the April 2024 Common Warrants at their issuance was estimated using the Black-Scholes option-pricing model. The assumed dividend yield was based upon the Company's expectation of not paying dividends in the foreseeable future. Expected volatility for the Company's common stock was determined based on the historical volatility of the Company over the full term of the warrant. The risk-free interest rate was based upon the U.S. Treasury yield curve commensurate with the expected term at the time of grant. The expected term of the April 2024 Common Warrants was calculated utilizing the three-year expiration date, taking into consideration the possibility of an accelerated expiration date pursuant to the terms of the April 2024 Common Warrants.

The estimated fair market values of the April 2024 Shares, April 2024 Pre-Funded Warrants and April 2024 Common Warrants have been recorded in additional paid-in capital.

Through December 31, 2025, 725,000 April 2024 Common Warrants have been exercised, and none have expired. As of December 31, 2025, 10,118,380 April 2024 Common Warrants were outstanding.

Subsequent to December 31, 2025, 370,000 April 2024 Common Warrants were exercised.

Through December 31, 2025, no April 2024 Pre-Funded Warrants have been exercised. As of December 31, 2025, 1,700,000 April 2024 Pre-Funded Warrants were outstanding.

December 2024 Public Offering

On December 9, 2024, the Company entered into an underwriting agreement, or the 2024 Underwriting Agreement, with TD Securities (USA) LLC, Cantor Fitzgerald & Co. and LifeSci Capital LLC, as representatives, or the 2024 Representatives, of the several underwriters named therein, or collectively, the 2024 Underwriters, pursuant to which the Company agreed to sell and issue to the 2024 Underwriters an aggregate of 13,690,000 shares, or the December 2024 Shares, of common stock of the Company, par value $0.001 per share and, for certain purchasers, pre-funded warrants, or the December 2024 Pre-Funded Warrants, to purchase an aggregate of 2,325,372 shares of common stock, or collectively the December 2024 Public Offering. The price to the public in the December 2024 Public Offering was $6.25 per December 2024 Share and $6.249 per December 2024 Pre-Funded Warrant, which is the price per share at which the December 2024 Shares were sold to the public in the December 2024 Public Offering, minus the $0.001 exercise price per December 2024 Pre-Funded Warrant. In addition, under the terms of the 2024 Underwriting Agreement the Company granted the 2024 Underwriters the option, for 30 days, to purchase up to an additional 2,402,305 shares of common stock at the public offering price, less underwriting discounts and commissions, or the 2024 Underwriters' Option.

The December 2024 Public Offering closed on December 11, 2024, resulting in gross proceeds of approximately $100.1 million and net proceeds of approximately $93.4 million, reflecting approximately $6.7 million of underwriters' fees, legal costs and other expenses connected with the transaction.

The December 2024 Pre-Funded Warrants are exercisable at any time, at an exercise price of $0.001 per share. The December 2024 Pre-Funded Warrants contain standard adjustments to the exercise price, including for stock splits, stock dividends and pro rata distributions and contain customary terms regarding the treatment of such December 2024 Pre-Funded Warrants in the event of a fundamental transaction, which include but are not limited to a merger or consolidation involving the Company, a sale of all or substantially all of the assets of the Company or a business combination resulting in any person acquiring more than 50% of the outstanding shares of common stock of the Company. Additionally, the December 2024 Pre-Funded Warrants include restrictions on exercise in the event the Purchaser's beneficial ownership of the Company's common stock would exceed 4.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise.

The Company concluded that the December 2024 Pre-Funded Warrants met the requirements to be classified in stockholders' equity.

11. Stockholders' Equity (cont.)

The fair market value of the December 2024 Pre-Funded Warrants has been determined as the spread between the price paid by the 2024 Underwriters and the share price of the Company's common stock on the agreement date. The estimated fair values of the December 2024 Shares and December 2024 Pre-Funded Warrants have been recorded in additional paid-in capital.

On January 8, 2025, the 2024 Underwriters notified the Company of their determination to exercise the 2024 Underwriters' Option in part, and purchased an additional 438,738 shares of common stock, at the public offering price less underwriting discounts and commissions. Closing for the partial exercise of the 2024 Underwriters' Option occurred on January 13, 2025. The transaction costs were charged to additional paid-in capital in the period the 2024 Underwriters' Option was exercised.

The exercise of the 2024 Underwriters' Option resulted in gross proceeds of approximately $2.7 million and net proceeds of approximately $2.5 million, reflecting approximately $0.2 million of underwriters' fees, legal costs and other expenses connected with the transaction.

Through December 31, 2025, 625,100 December 2024 Pre-Funded Warrants have been exercised. As of December 31, 2025, 1,700,272 December 2024 Pre-Funded Warrants were outstanding.

December 2025 Public Offering

On December 4, 2025, the Company entered into an underwriting agreement, or the 2025 Underwriting Agreement, with J.P. Morgan Securities LLC, TD Securities (USA) LLC and Piper Sandler & Co., as representatives, or the 2025 Representatives, of the several underwriters named therein, or collectively, the 2025 Underwriters, pursuant to which the Company agreed to sell and issue to the 2025 Underwriters an aggregate of 13,043,479 shares, or the December 2025 Shares, of common stock of the Company, par value $0.001 per share, or collectively the December 2025 Public Offering. The price to the public in the December 2025 Public Offering was $5.75 per December 2025 Share. In addition, under the terms of the 2025 Underwriting Agreement the Company granted the 2025 Underwriters the option, for 30 days, to purchase up to an additional 1,956,521 shares of common stock at the public offering price, less underwriting discounts and commissions, or the 2025 Underwriters' Option.

The December 2025 Public Offering closed on December 8, 2025, resulting in gross proceeds of approximately $75.0 million and net proceeds of approximately $69.9 million, reflecting approximately $5.1 million of underwriters' fees, legal costs and other expenses connected with the transaction.

On December 11, 2025, the 2025 Underwriters notified the Company of their determination to exercise the 2025 Underwriters' Option in full, and purchased an additional 1,956,521 shares of common stock, at the public offering price less underwriting discounts and commissions. Closing for the full exercise of the 2025 Underwriters' Option occurred on December 15, 2025. The exercise of the 2025 Underwriters' Option resulted in gross proceeds of approximately $11.3 million and net proceeds of approximately $10.5 million, reflecting approximately $0.8 million of underwriters' fees, legal costs and other expenses connected with the transaction.

12. Stock-Based Compensation

2014 Equity Incentive Plan

On October 3, 2014, the stockholders approved the 2014 Equity Incentive Plan. On June 20, 2017, the Company's Board of Directors amended the 2014 Equity Incentive Plan, or the Amended and Restated 2014 Plan. On July 31, 2017, the stockholders approved this amendment. On January 1, 2020, Protara Therapeutics, Inc. amended its Amended and Restated 2014 Plan to increase the number of shares of stock available for issuance under the Amended and Restated 2014 Plan to 1,048,300 shares and made conforming changes and updates pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended.

12. Stock-Based Compensation (cont.)

The Amended and Restated 2014 Plan, as amended, provides for the grant of incentive and non-statutory stock options, stock appreciation rights, restricted stock and stock unit awards, performance units, stock grants and qualified performance-based awards. The Amended and Restated 2014 Plan, as amended, provided that the number of shares reserved and available for issuance would automatically increase each January 1, by four percent of the Company's common stock on the immediately preceding December 31, adjusted for the number of shares of the Company's common stock issuable upon conversion of any security that the Company may issue that is convertible into or exchangeable for the Company's common stock, or such lesser number of shares as determined by the Company's Board of Directors. Terms of the stock awards, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the Amended and Restated 2014 Plan, as amended. Certain awards provide for accelerated vesting if there is a change in control as defined in the Amended and Restated 2014 Plan, as amended.

On January 1, 2024, pursuant to the annual evergreen feature of the Amended and Restated 2014 Plan, as amended, the number of shares authorized under the Amended and Restated 2014 Plan, as amended, was increased by 911,380 shares to 4,474,683 shares. Following the approval of the Company's 2024 Equity Incentive Plan, or 2024 EIP, by the stockholders of the Company on June 7, 2024, no additional awards will be made under the Amended and Restated 2014 Plan, as amended.

As of December 31, 2025, there were 3,537,989 shares of common stock subject to outstanding awards under the Amended and Restated 2014 Plan, as amended.

2017 Equity Incentive Plan

On August 10, 2017, ArTara Subsidiary, Inc. (a predecessor of the Company), or Private ArTara, along with its Board of Directors and its stockholders approved the ArTara Therapeutics, Inc. 2017 Equity Incentive Plan to enable Private ArTara and its affiliates to recruit and retain highly qualified personnel and to incentivize personnel for productivity and growth.

The total number of shares authorized under the 2017 Equity Incentive Plan was 2,000,000 for the issuance of stock options, stock appreciation rights, restricted stock and RSUs to among others, members of the Board of Directors, employees, consultants and service providers to the Company and its affiliates. As of January 9, 2020, in connection with the Merger, no additional awards will be made under the 2017 Equity Incentive Plan.

As of December 31, 2025, there were 134,328 shares of common stock subject to outstanding awards under the 2017 Equity Incentive Plan.

2020 Inducement Plan

On March 26, 2020, the Compensation Committee of the Board of Directors, or the Compensation Committee, approved the 2020 Inducement Plan in order to award non-statutory stock options, restricted stock awards, restricted stock unit awards and other stock-based awards to persons not previously an employee or director of the Company, or following a bona fide period of non-employment, as an inducement material to such persons entering into employment with the Company. The Compensation Committee also adopted a form of stock option grant notice and stock option agreement and forms of restricted stock unit grant notice and restricted stock unit agreement for use with the 2020 Inducement Plan.

The 2020 Inducement Plan provided for a total of 600,000 shares for the issuance of the Company's common stock. On March 3, 2025, the Compensation Committee approved a Certificate of First Amendment to the 2020 Inducement Plan, or the Amended 2020 Inducement Plan, to increase the number of shares provided for under the Amended 2020 Inducement Plan by 600,000 shares to 1,200,000 shares.

(amounts in thousands, except share and per share data)

12. Stock-Based Compensation (cont.)

As of December 31, 2025, there were 1,182,800 shares of common stock subject to outstanding awards and 17,200 shares of common stock available for future issuance under the Amended 2020 Inducement Plan.

2024 Equity Incentive Plan

On June 7, 2024, the stockholders approved the 2024 EIP. The 2024 EIP provided for the grant of 1,500,000 shares of common stock for stock options, stock appreciation rights, restricted stock, RSUs, performance units, performance shares and other stock and cash awards. On June 11, 2025, the stockholders approved an amendment to the 2024 EIP, or the Amended 2024 EIP, increasing the number of shares available for grant under the Amended 2024 EIP by 2,800,000 shares to 4,300,000 shares.

Terms of the stock awards, including vesting requirements, are determined by the Board of Directors, or the Compensation Committee thereof, subject to the provisions of the Amended 2024 EIP.

As of December 31, 2025, there were 1,699,419 shares of common stock subject to outstanding awards and 2,600,581 shares of common stock available for future issuance under the Amended 2024 EIP.

2024 Employee Stock Purchase Plan

On June 7, 2024, the stockholders of the Company approved the 2024 Employee Stock Purchase Plan, or 2024 ESPP. The number of shares authorized under the 2024 ESPP is 1,000,000.

As of December 31, 2025, the number of shares available for issuance under the 2024 ESPP was 1,000,000. During the years ended December 31, 2025 and 2024, no shares were issued under the 2024 ESPP.

Restricted Stock Units

The following table summarizes restricted stock unit activity:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Non-vested as of December 31, 2024	295,914	$ 2.69
Granted	428,081	4.13
Forfeited	(22,439)	3.98
Vested	(130,411)	3.32
Non-vested as of December 31, 2025	571,145	$ 3.57

The fair value of RSUs is amortized on a straight-line basis over the requisite service period of the respective awards. As of December 31, 2025, the unamortized value of RSUs was $1,369 and the weighted average remaining amortization period was 1.82 years. As of December 31, 2025 and 2024, 289,500 RSUs have vested that have not yet been settled into shares of the Company's common stock.

During the year ended December 31, 2025, the Company issued 94,167 shares of the Company's common stock from the net settlement of 130,411 RSUs. The Company paid $185 in connection with the net share settlement of these RSUs.

(amounts in thousands, except share and per share data)

12. Stock-Based Compensation (cont.)

Stock Options

The Company determined the fair value of stock options granted utilizing the Black-Scholes valuation model and based upon the assumptions as provided below:

	For the Year Ended December 31,	
	2025	**2024**
Exercise price	$2.80 – $6.74	$1.91 – $5.18
Dividend yield	0.00%	0.00%
Expected volatility	77.85% – 82.77%	95.56% – 99.20%
Risk-free interest rate	3.77% – 4.48%	3.69% – 4.49%
Expected term (in years)	5.50 – 6.08	5.27 – 6.08

The following table summarizes stock option activities for the year ended December 31, 2025:

	Number of Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (years)**	**Aggregate Intrinsic Value[1]**
Outstanding as of December 31, 2024	3,855,478	$ 7.30	7.66	$ 6,736
Granted	1,902,863	4.18		
Exercised	(8,239)	2.62		
Forfeited	(50,472)	3.29		
Expired	(5,739)	5.02		
Outstanding as of December 31, 2025	5,693,891	$ 6.30	7.51	$ 8,982
Vested or expected to vest as of December 31, 2025	5,693,891	$ 6.30	7.51	$ 8,982
Exercisable as of December 31, 2025	2,904,405	$ 8.90	6.32	$ 4,072

(1) Aggregate intrinsic value represents the difference between the exercise price of the option and the closing market price of our common stock on December 31, 2025. The intrinsic value of options exercised during the years ended December 31, 2025 and 2024 were $7 and $23, respectively.

The weighted average grant date fair value per share of the options granted during the years ended December 31, 2025 and 2024 was $3.01 and $1.62, respectively. As of December 31, 2025, there was approximately $5,881 of unrecognized stock-based compensation for unvested stock option grants which is expected to be recognized over a weighted average period of 2.44 years. The total unrecognized stock-based compensation cost will be adjusted for actual forfeitures as they occur.

Summary of Stock-Based Compensation Expense

The following tables summarize total stock-based compensation expense recognized:

	For the Year Ended December 31,	
	2025	**2024**
Stock Options	$ 3,141	$ 3,645
RSUs	685	480
Total	$ 3,826	$ 4,125

(amounts in thousands, except share and per share data)

12. Stock-Based Compensation (cont.)

Stock-based compensation expense was reflected within the consolidated statements of operations and comprehensive loss as:

	For the Year Ended December 31,	
	2025	2024
General and administrative	$ 2,893	$ 3,060
Research and development	933	1,065
Total	$ 3,826	$ 4,125

13. Income Taxes

For financial reporting purposes, income (loss) before taxes includes the following components:

	For the Year Ended December 31,	
	2025	2024
United States	$ (57,309)	$ (44,538)
Foreign	(42)	(25)
Total income (loss) before taxes	$ (57,351)	$ (44,563)

Federal and State income tax expense (benefit) is as follows:

	For the Year Ended December 31,	
	2025	2024
Current		
Federal	$ —	$ —
State	—	—
Foreign	—	—
Total current	—	—
Deferred		
Federal	(13,649)	(11,192)
State	2,608	(8,583)
Foreign	—	—
Total deferred	(11,041)	(19,775)
Change in valuation allowance	11,041	19,775
Total income tax expense (benefit)	$ —	$ —

Deferred income taxes, if applicable, are provided for the differences between the basis of assets and liabilities for financial reporting and income tax purposes.

(amounts in thousands, except share and per share data)

13. Income Taxes (cont.)

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets are as follows:

	As of December 31,	
	2025	**2024**
Deferred tax assets:		
Net operating loss carry forwards	$ 44,907	$ 37,195
Capitalized research and development	21,164	18,336
Stock option expense	4,960	6,342
Research and development tax credits	9,107	6,931
Operating lease liability	887	1,471
RSU expense	2,617	3,173
Other	842	817
Total deferred tax assets	84,484	74,265
Valuation allowance	(83,550)	(72,509)
Deferred tax assets, net of valuation allowance	934	1,756
Deferred tax liabilities:		
Operating ROU asset	(838)	(1,396)
Other	(96)	(360)
Total deferred tax liabilities	(934)	(1,756)
Deferred tax assets, net of valuation allowance and deferred tax liabilities	$ —	$ —

A reconciliation of the provision for income taxes with the amounts computed by applying the statutory federal income tax to income before provision for income taxes is as follows:

	For the Year Ended December 31,			
	2025		**2024**	
U.S. federal statutory rate	$ (12,044)	(21.00)%	$ (9,338)	(21.00)%
State and local income taxes, net of the federal benefit[(a)]	350	0.61%	531	1.19%
Foreign tax effects	5	0.01%	4	0.01%
Tax credits				
Research and development tax credits	(1,079)	(1.88)%	(773)	(1.74)%
Orphan drug tax credits	(1,097)	(1.91)%	(776)	(1.74)%
Changes in valuation allowance	13,030	22.72%	10,107	22.73%
Nontaxable or nondeductible items	795	1.39%	103	0.23%
Changes in unrecognized tax benefits	—	—%	—	—%
Other	40	0.06%	142	0.32%
Effective tax rate	$ —	—%	$ —	—%

(a) State and local taxes in New York and New York City comprise the majority of the state taxes, net of the federal benefit.

(amounts in thousands, except share and per share data)

13. Income Taxes (cont.)

Income taxes paid (net of refunds received) consisted of the following:

	For the Year Ended December 31,	
	2025	2024
Federal	$ —	$ —
State	—	—
Foreign	—	—
Effective tax rate	$ —	$ —

For the years ended December 31, 2025 and 2024, the Company's effective tax rate was 0%, which consisted principally of a federal rate of 21%, the Company's estimate of state income taxes, primarily driven by changes in tax rate and apportionment changes net of the federal benefit, research and development related tax credits, and the change in the valuation allowance recorded against its deferred tax assets.

As of December 31, 2025 and 2024 for U.S. federal and state income tax reporting purposes, the Company has approximately $300,069 and $244,842, respectively, of unused net operating losses, or NOLs, available for carry forward to future years. As a result of the Tax Cuts and Jobs Act of 2017, or TCJA, for U.S. income tax purposes, NOLs generated in tax years beginning before January 1, 2018 can be carried forward for up to 20 years, but NOLs generated for tax years beginning after December 31, 2017 may be carried forward indefinitely and can be used to offset 80% of taxable income. Of the total federal NOLs carried forward, $600 can be carried forward until 2037; and $177,416 can be carried forward indefinitely. The New York state and city NOLs may be carried forward through the year 2045 and may be applied against future taxable income, while Massachusetts NOLs may be carried forward through the year 2038 to apply against future taxable income. Further, the benefit from utilization of NOL carry forwards could be subject to limitations due to material ownership changes that may have occurred or could occur in the future as the Company continues to issue additional shares of common stock pursuant to its capital raising plans. Based on such limitations, the Company has significant NOLs for which realization of tax benefits is uncertain. The Company has not performed a study to determine whether or not there is such a limitation.

The Company remains subject to examination by tax authorities for all tax years.

Based on a history of cumulative losses at the Company and the results of operations for the years ended December 31, 2025 and 2024, the Company determined that it is more likely than not that it will not realize benefits from the net deferred tax assets. The Company will not record income tax benefits in the financial statements until it is determined that it is more likely than not that the Company will generate sufficient taxable income to realize the deferred income tax assets. As a result of the analysis, the Company determined that a full valuation allowance against the deferred tax assets, net, was required. As of December 31, 2025 and 2024, the Company has recorded a valuation allowance of $83.6 million and $72.5 million, respectively.

In July 2025, U.S. tax legislation known as the "One Big Beautiful Bill Act", or OBBBA, was signed into law which makes permanent many of the tax provisions enacted in 2017 as part of the TCJA that were set to expire at the end of 2025. In addition, the OBBBA makes changes to certain U.S. corporate tax provisions, many of which are generally not effective until January 1, 2026. The OBBBA did not have a material effect on the Company's consolidated financial statements for the year ended December 31, 2025.

As of December 31, 2025 and 2024, management does not believe that the Company has any material uncertain tax positions that would require it to measure and reflect the potential lack of sustainability of a position on audit in its consolidated financial statements. The Company will continue to evaluate its uncertain tax positions in future periods to determine if measurement and recognition in its consolidated financial statements is necessary. The Company does not believe there will be any material changes in its unrecognized tax positions over the next year.

(amounts in thousands, except share and per share data)

14. Employee Benefit Plan

The Company maintains a defined contribution benefit plan under section 401(k) of the Internal Revenue Code of 1986, as amended, covering substantially all qualified employees of the Company, or the 401(k) Plan. Under the 401(k) Plan, the Company matches 100% of employee contributions up to 4% of employee compensation. For the years ended December 31, 2025 and 2024, the Company recorded expenses of $342 and $251, respectively, representing employer contributions under the 401(k) Plan.

15. Net Income (Loss) per Common Share

The following table sets forth the computation of the net income (loss) per share attributable to common stockholders, basic and diluted:

	For the Year Ended December 31,	
	2025	2024
Numerator:		
Net income (loss) attributable to common stockholders	$ (57,439)	$ (44,596)
Denominator:		
Weighted-average shares of common stock outstanding, basic and diluted	42,836,129	20,592,847
Net income (loss) per share attributable to common stockholders, basic and diluted	$ (1.34)	$ (2.17)

Since the Company was in a net loss position for all periods presented, net income (loss) per share attributable to common stockholders was the same, on a basic and diluted basis, as the inclusion of all potential common equivalent shares outstanding would have been anti-dilutive. The Company excluded the following potential shares of common stock, presented based on amounts outstanding at each period end, from the computation of diluted net income (loss) per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of December 31,	
	2025	2024
April 2024 Common Warrants	10,118,380	10,118,380
Series 1 Convertible Preferred Stock	5,616,973	7,993,217
Stock options	5,693,891	3,855,478
2024 Underwriters' Option	—	438,738
Restricted stock units	571,145	295,914
Total potentially dilutive shares	22,000,389	22,701,727

Subject to the terms of the 2024 Underwriting Agreement, the 2024 Underwriters' Option allowed for the purchase of an additional 2,402,305 shares of common stock. On January 8, 2025, the 2024 Underwriters notified the Company of their determination to exercise the 2024 Underwriters' Option in part, and purchased an additional 438,738 shares of common stock, see Note 11 for further discussion.

16. Segment Information

The Company's Chief Executive Officer is the CODM. The CODM allocates resources and assesses performance of the Company's single reportable segment by regularly reviewing the segment net income (loss) that also is reported on the consolidated statements of operations and comprehensive loss as consolidated net income (loss). The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

(amounts in thousands, except share and per share data)

16. Segment Information (cont.)

The following table sets forth information about the Company's single reportable segment and the significant expenses reviewed by the CODM, including a reconciliation to consolidated net income (loss):

	For the Year Ended December 31,	
	2025	**2024**
Research and development expenses:		
TARA-002 in NMIBC	$ 18,377	$ 12,306
TARA-002 in LMs	2,606	2,558
IV Choline Chloride	8,501	4,555
Other research and development	12,216	11,220
General and administrative expenses	19,023	14,390
Stock-based compensation expense	3,826	4,125
Income (loss) from operations	(64,549)	(49,154)
Other income (expense), net	7,110	4,558
Segment net income (loss)	(57,439)	(44,596)
Adjustments and reconciling items	—	—
Net income (loss)	$ (57,439)	$ (44,596)

Other research and development expenses consist of personnel-related expenses as well as other external research and development expenses that are not directly attributable to a specific program.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not Applicable.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2025, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2025, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control-Integrated Framework (2013). Based on this assessment, management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2025, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control Over Financial Reporting

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting, as such term is defined in Rules 13a-15 and 15(d)-15 promulgated under the Exchange Act, that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) There is no information that was required to be disclosed in a report on Form 8-K during the fourth quarter of 2025 but was not reported.

(b) Insider trading arrangements

The following table provides information concerning Rule 10b5-1 trading arrangements (as defined in Item 408 of Regulation S-K under the Securities Exchange Act of 1934) adopted in the fourth quarter of 2025 by any director or any executive officer who is subject to the filing requirements of Section 16 of the Securities Exchange Act of 1934. These trading arrangements are intended to satisfy the affirmative defense of Rule 10b5-1(c). These trading arrangements permit transactions through and including the earlier to occur of (a) the completion of all purchases or sales or (b) the date listed in the table below. These trading arrangements, identified as "Rule 10b5-1 Trading Arrangements", only permit transactions upon expiration of the applicable mandatory cooling-off period under Rule 10b5-1.

Name	Title	Adoption Date	Duration	Aggregate number of shares of common stock to be purchased or sold pursuant to the trading arrangement
Jesse Shefferman.	President, Chief Executive Officer and Director	December 25, 2025	March 25, 2026 – September 24, 2026	69,448
Jacqueline Zummo . . .	Chief R&D Officer	December 31, 2025	April 1, 2026 – December 31, 2026	23,732

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item and not set forth below will be set forth in the sections headed "*— Election of Directors*," "*Information Regarding Director Nominees and Current Directors*," "*Information Regarding the Board of Directors and Corporate Governance*" and "*Executive Officers*" in our definitive Proxy Statement for our 2026 Annual Meeting of Stockholders to be filed with the SEC on or before April 30, 2026, or our Proxy Statement, and is incorporated in this report by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at *http://www.protaratx.com* under the Corporate Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Stockholders may request a free copy of the Code of Business Conduct and Ethics by emailing info@protaratx.com.

We have also adopted an Insider Trading Policy that governs the purchase, sale and/or other dispositions of our securities by us and by our directors, officers and employees, and that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations and applicable exchange listing standards. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this Item will be set forth in the sections headed "*Executive Compensation*" and "*Non-Employee Director Compensation*" in our Proxy Statement and is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item will be set forth in the section headed "*Security Ownership of Certain Beneficial Owners and Management*" in our Proxy Statement and is incorporated in this report by reference.

Information regarding our equity compensation plans will be set forth in the section headed "*Executive Compensation*" in our Proxy Statement and is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item will be set forth in the section headed "*Transactions with Related Persons*" in our Proxy Statement and is incorporated in this report by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item will be set forth in the section headed "*— Ratification of Selection of Independent Registered Public Accounting Firm*" in our Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Documents filed as part of this report.

1. The following financial statements of Protara Therapeutics, Inc. and Report of Ernst & Young LLP, Independent Registered Public Accounting Firm, are included in this report:

	Page Number
Report of Independent Registered Public Accounting Firm (PCAOB ID:42)	83
Consolidated Balance Sheets	85
Consolidated Statements of Operations and Comprehensive Loss	86
Consolidated Statements of Changes in Stockholders' Equity	87
Consolidated Statements of Cash Flows	89
Notes to Consolidated Financial Statements	90

2. List of financial statement schedules:

All schedules have been omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits.

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated September 23, 2019, by and among the Registrant, ArTara Therapeutics, Inc. and REM 1 Acquisition, Inc. (filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K as filed on September 24, 2019, and incorporated herein by reference).
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated November 19, 2019, by and among the Registrant, ArTara Therapeutics, Inc. and REM 1 Acquisition, Inc. (filed as Exhibit 2.2 to the Registrant's Registration Statement on Amendment No. 2 to Form S-4 as filed on December 4, 2019, and incorporated herein by reference).
3.1	Sixth Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 27, 2014).
3.2	Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
3.3	Second Certificate of Amendment to the Sixth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 13, 2020).
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
3.5	Certificate of Amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Convertible Non-Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 23, 2020).
3.6	Composite Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.6 to the Company's Annual Report on Form 10-K, filed with the SEC on March 8, 2023).
3.7	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on August 3, 2017).
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).

Exhibit No.	Description
4.2	Description of securities registered under Section 12 of the Exchange Act of 1934 (incorporated by reference to Exhibit 4.2 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 11, 2021).
4.3	Registration Rights Agreement, dated as of September 23, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2019).
10.1†	2014 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.25 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on October 7, 2014).
10.2+	Subscription Agreement, dated September 23, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 24, 2019).
10.3+	First Amendment to Subscription Agreement, dated November 19, 2019, by and among the Registrant and the institutional investors named therein (incorporated by reference to Exhibit 99.12 to the Registrant's Registration Statement on Form S-4 as filed on December 5, 2019).
10.4*	Second Amendment to Subscription Agreement, dated December 17, 2025, by and among the Registrant and the institutional investors named therein.
10.5†	Amended and Restated 2014 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 10, 2020).
10.6†	Forms of Stock Option Agreement, Option Exercise, Restricted Stock Unit Grant and Restricted Stock Unit Agreement under the Amended and Restated 2014 Equity Incentive Plan of the Registrant, as amended (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 20, 2020).
10.7†	2017 Equity Incentive Plan of ArTara Subsidiary, Inc. (incorporated by reference to Exhibit 10.11 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.8†	Inducement Plan of the Registrant (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 30, 2020).
10.9†	Form of Stock Option Grant Notice and Stock Option Agreement under the Inducement Plan of the Registrant (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 30, 2020).
10.10†	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under the Inducement Plan of the Registrant (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 30, 2020).
10.11†	Executive Employment Agreement, dated as of November 5, 2019, as amended on December 4, 2019, by and between ArTara Subsidiary, Inc. and Jesse Shefferman (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.12†	Executive Employment Agreement, dated as of December 17, 2019, by and between ArTara Subsidiary, Inc. and Jacqueline Zummo, Ph.D., MPH, MBA (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.13†	Amended and Restated Executive Employment Agreement, entered into as of June 1, 2023, by and between the Registrant and Patrick Fabbio (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 10-Q, filed with the SEC on August 3, 2023).
10.14††	Choline License Agreement, by and between ArTara Subsidiary, Inc. and Alan L. Buchman, M.D. dated as of September 27, 2017 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.15††	Sponsored Research and License Agreement, by and between ArTara Subsidiary, Inc. and The University of Iowa dated as of November 28, 2018 (incorporated by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.16††	License Agreement, by and between ArTara Subsidiary, Inc. and The Feinstein Institute for Medical Research dated as of December 22, 2017 (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.17††	Agreement, by and between ArTara Subsidiary, Inc. and Chugai Pharmaceutical Co., Ltd. dated as of June 17, 2019 (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).

Exhibit No.	Description
10.18††	Amendment to Agreement, by and between Chugai Pharmaceutical Co., Ltd. and the Registrant, dated as of July 14, 2020 and effective as of June 30, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 12, 2020).
10.19†	Form of Indemnity Agreement between the Registrant and each of its directors and officers (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K, filed with the SEC on January 10, 2020).
10.20†	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2025).
10.21††+	Lease by and between 345 PAS HOLDING LLC, and the Registrant, dated as of December 7, 2020 (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 11, 2021).
10.22+	Subscription Agreement, dated April 5, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
10.23	Form of Pre-Funded Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
10.24	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
10.25	Registration Rights Agreement, dated April 5, 2024 (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 5, 2024).
10.26†	2024 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 99.1 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 6, 2024).
10.27†	2024 Equity Incentive Plan, as Amended (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2025).
10.28†	2024 Employee Stock Purchase Plan of the Registrant (incorporated by reference to Exhibit 99.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 6, 2024).
10.29†	Forms of Stock Option Agreement, Stock Option Grant Notice, Restricted Stock Unit Agreement and Restricted Stock Unit Grant Notice under the 2024 Equity Incentive Plan of the Registrant (incorporated by reference to Exhibit 99.3 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 6, 2024).
10.30†	Separation and Consulting Agreement and Release, dated as of March 18, 2024, by and between the Company and Jathin Bandari, M.D. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on March 18, 2024).
10.31†	Retention Bonus, effective as of January 25, 2024, by and between Registrant and Jacqueline Zummo, Ph.D, MPH, MBA (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 2, 2024).
10.32	Form of Pre-Funded Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on December 11, 2024).
10.33	First Certificate of Amendment to Inducement Plan of the Registrant dated March 3, 2025 (incorporated by reference to Exhibit 10.36 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 5, 2025).
10.34†	Executive Employment Agreement, effective as of April 15, 2025, by and between the Registrant and Leonardo Nicacio, M.D. (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on May 8, 2025).
10.35†	Executive Employment Agreement, effective as of June 2, 2025, by and between the Registrant and William Conkling (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on August 11, 2025).
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 5, 2025).
21.1*	List of Subsidiaries.
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.
24.1*	Power of Attorney (Included in signature pages).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit No.	Description
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Principal Executive Officer Certification and Principal Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Executive Compensation Clawback Policy (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K, filed with the SEC on March 13, 2024).
101*	Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Consolidated Balance Sheets as of December 31, 2025 and 2024; (ii) the Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2025 and 2024; (iii) the Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2025 and 2024; (iv) the Consolidated Statements of Cash Flows for the years ended December 31, 2025 and 2024; and (v) the notes to the Consolidated Financial Statements.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

\+ Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedules will be furnished to the SEC upon request.

† Indicates management contract or compensatory plan or arrangement.

†† Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information is of the type the Registrant customarily and actually treats as private or confidential.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Protara Therapeutics, Inc.

Date: March 10, 2026

/s/ JESSE SHEFFERMAN
Jesse Shefferman
President and Chief Executive Officer
(on behalf of the registrant and as the registrant's Principal Executive Officer)

Date: March 10, 2026

/s/ PATRICK FABBIO
Patrick Fabbio
Chief Financial Officer
(on behalf of the registrant and as the registrant's Principal Financial Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each individual whose signature appears below constitutes and appoints Jesse Shefferman and Patrick Fabbio his or her true and lawful attorney-in-fact and agent with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities and Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JESSE SHEFFERMAN Jesse Shefferman	President and Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2026
/s/ PATRICK FABBIO Patrick Fabbio	Chief Financial Officer (Principal Financial Officer)	March 10, 2026
/s/ HANNAH FRY Hannah Fry	Vice President, Controller (Principal Accounting Officer)	March 10, 2026
/s/ LUKE BESHAR Luke Beshar	Chairman of the Board of Directors	March 10, 2026
/s/ BARRY FLANNELLY, PHARM.D. Barry Flannelly, Pharm.D.	Director	March 10, 2026
/s/ ROGER GARCEAU, M.D. Roger Garceau, M.D.	Director	March 10, 2026
/s/ JANE HUANG, M.D. Jane Huang, M.D.	Director	March 10, 2026
/s/ RICHARD LEVY, M.D. Richard Levy, M.D.	Director	March 10, 2026
/s/ GREGORY P. SARGEN Gregory P. Sargen	Director	March 10, 2026
/s/ CYNTHIA SMITH Cynthia Smith	Director	March 10, 2026
/s/ MICHAEL SOLOMON, PH.D. Michael Solomon, Ph.D.	Director	March 10, 2026